

K061248

AUG 31 2006

**Summary of Safety and Effectiveness
AxiEM™ Imageless Hip Module for the StealthStation® System**

I. Manufacturer

Medtronic Navigation, Inc.
826 Coal Creek Circle
Louisville, Colorado 80027 USA
Telephone Number: (720) 890-3217
Fax Number: (720) 890-3517

II. Contact

Tina Dreiling
Associate Regulatory Affairs Specialist
Medtronic Navigation, Inc.

III. Product Name / Classification

Common Name: Stereotaxic instrument
Classification Name: Instrument, Stereotaxic
Trade Name: Imageless Hip Module for the StealthStation® System
Stereotaxic instrument - Class II as described in 21 CFR § 882 4560
Product Code: HAW

IV. Date Summary Submitted

April 28, 2006

V. Description of Device Modification

The AxiEM™ Imageless Hip Module for the StealthStation® System provides a mechanism for the establishment of stereotactic coordinates without the use of a pre-operative or intra-operative image using electromagnetic navigation

VI. Substantial Equivalence

The primary difference between the Imageless Hip Module for the StealthStation® System and the AxiEM™ Imageless Hip Module for the StealthStation® System is that the AxiEM™ Imageless Hip Module utilizes electromagnetic navigation technology rather than optical tracking.

The primary difference between the AxiEM™ Imageless Knee Module for the StealthStation® System and the AxiEM™ Imageless Hip Module for the StealthStation® System is that the subject device navigates instruments for use in hip procedures and the AxiEM™ Imageless Knee application navigates instruments for use in knee procedures.

As required by risk analysis, all verification and validation activities will be performed by designated individuals and will demonstrate the safety and effectiveness of the device.

The information provided in this 510(k) application supports that the AxiEM™ Imageless Hip Module for the StealthStation® System is substantially equivalent to the Imageless Hip Module for the StealthStation® System (K052623).

VII. Indications for Use

The StealthStation System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The StealthStation System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

The AxiEM™ Imageless Hip Module for the StealthStation® is intended to precisely position instruments and implants in example procedures such as but not limited to:

Orthopedic Procedures:
Minimally Invasive Orthopedic Procedures
Total Hip Replacement (Primary and Revision)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 31 2006

Medtronic Navigation, Inc.
% Ms. Tina Dreiling
Associate RA Specialist
826 Coal Creek Circle
Louisville, Colorado 80027

Re: K061248

Trade/Device Name: AxiEM™ Imageless Hip Module for the StealthStation® System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: August 9, 2006
Received: August 10, 2006

Dear Ms. Dreiling:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

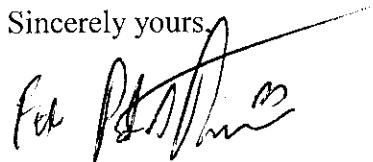
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Tina Dreiling

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061248

Device Name: AxiEM™ Imageless Hip Module for the StealthStation® System

Indications for Use:

The StealthStation System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The StealthStation System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

The AxiEM™ Imageless Hip Module for the StealthStation® is intended to precisely position instruments and implants in example procedures such as but not limited to:

Orthopedic Procedures:

Minimally Invasive Orthopedic Procedures

Total Hip Replacement (Primary and Revision)

Prescription Use (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**Division of General, Restorative,
and Neurological Devices**

Page 1 of 1

510(k) Number K061248

CONFIDENTIAL

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Page 20 of



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 31 2006

Medtronic Navigation, Inc.
% Ms. Tina Dreiling
Associate RA Specialist
826 Coal Creek Circle
Louisville, Colorado 80027

Re: K061248

Trade/Device Name: AxiEM™ Imageless Hip Module for the StealthStation® System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: August 9, 2006
Received: August 10, 2006

Dear Ms. Dreiling:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Tina Dreiling

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2

Indications for Use

510(k) Number (if known): K061248

Device Name: AxiEM™ Imageless Hip Module for the StealthStation® System

Indications for Use:

The StealthStation System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The StealthStation System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

The AxiEM™ Imageless Hip Module for the StealthStation® is intended to precisely position instruments and implants in example procedures such as but not limited to:

Orthopedic Procedures:

Minimally Invasive Orthopedic Procedures

Total Hip Replacement (Primary and Revision)

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**Division of General, Restorative,
and Neurological Devices**

Page 1 of 1

Medtronic Navigation, Inc.

510(k) Number K061248

CONFIDENTIAL

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

June 30, 2006

MEDTRONIC NAVIGATION, INC.
826 COAL CREEK CIR.
LOUISVILLE, CO 80027
ATTN: TINA DREILING

510(k) Number: K061248
Product: AXIEM IMAGELESS
HIP MODULE FOR
THE
STEALTHSTATION

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>.

416

If after 30 days the requested information, or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system. Please note our guidance document entitled, "Guidance for Industry and FDA Staff FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission. Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisor Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

417

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

May 04, 2006

MEDTRONIC NAVIGATION, INC.
826 COAL CREEK CIR.
LOUISVILLE, CO 80027
ATTN: TINA DREILING

510(k) Number: K061248
Received: 03-MAY-2006
Product: AXIEM IMAGELESS HIP
MODULE FOR THE
STEALTHSTATION
SYSTEM

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On May 21, 2004, FDA issued a Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. Please review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1567.html>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

421

You should be familiar with the regulatory requirements for medical device available at Device Advice <http://www.fda.gov/cdrh/devadvice/>. If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301)594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

422

K061248

Form Approved: OMB No. 0910-511 Expiration Date: August 31, 2015. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.
<p>A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:</p> <ol style="list-style-type: none"> 1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent. 2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check. 3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (Note: In no case should payment be submitted with the application.) 4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.) 5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfer. 6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center. 		
-> 1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) MEDTRONIC SURGICAL NAVIGATION TECHNOLOGIES 826 COAL CREEK CIRCLE LOUISVILLE CO 80027 US		2. CONTACT NAME Tina Dreiling 2.1 E-MAIL ADDRESS tina.dreiling@medtronic.com 2.2 TELEPHONE NUMBER (include Area code) 720-890-3217 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 720-890-3517
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/dc/mdufma)		
<u>Select an application type:</u> <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR)		<u>3.1 Select one of the types below</u> <input checked="" type="checkbox"/> Original Application <u>Supplement Types:</u> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business		
4.1 If Yes, please enter your Small Business Decision Number:		
5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially		
6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).) <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO		
7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005) (b)(4)		21-Nov-2005

Form FDA 8601 (08/2003)

 Close Window Print Cover sheetWE
IT

423



Medtronic

Medtronic Navigation
826 Coal Creek Circle
Louisville, CO 80027 USA
www.medtronicnavigation.com

tel 720.890.3200
fax 720.890.3500

April 28, 2006

Document Control Clerk
Food and Drug Administration
Center for Devices and Radiological Health Office of Device Evaluation
Document Mailing Center (HFZ-401)
9200 Corporate Blvd., Room 20
Rockville, Maryland 20850

Re: **Special 510(k) Notification:** **Device Modification**
Medical Specialty: **Neurology**
Legally Marketed Device: **AxiEM™ Imageless Hip Module for the StealthStation® System**

Dear Sir/Madam:

Enclosed please find an original and two copies of a 510(k) notification for the **AxiEM™ Imageless Hip Module for the StealthStation System**. The purpose of this submission is to add electromagnetic navigation to the existing Imageless Hip Module for the StealthStation® System.

Confidentiality of Information

The enclosed materials and descriptions contain information which is trade secret, privileged, or confidential information under 21 CFR 20.61 and is not disclosable to the public under the Freedom of Information Act (FOIA). Such information is stamped accordingly. If you are not able to assure us that the enclosed information will not be disclosed to the public, we request that this submission be handled by the FDA in accordance with 21 CFR 20.44 relating to pre-submission reviews.

If you have any questions regarding this submission, please contact me at (720) 890-3217 or via e-mail at tina.dreiling@medtronic.com

Sincerely,


Tina Dreiling
Associate Regulatory Affairs Specialist

K 25

510(k) Notification

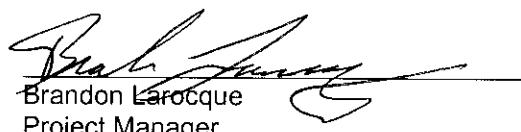
AxiEM™ Imageless Hip Module for the StealthStation® System

PRE-MARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Project Manager of Medtronic Navigation, Inc., I believe to the best of my knowledge, that all data and information submitted in the pre-market notification are truthful and accurate and that no material fact has been omitted.


Brandon Larocque
Project Manager

4/26/06
Date

Pre-market Notification 510(K) Number K061248

425

AxiEM™ Imageless Hip Module for the StealthStation® System

Table of Contents

I.	<i>Submitter Information</i>	3
II.	<i>Manufacturing Facility</i>	3
III.	<i>Device Name</i>	3
IV.	<i>Establishment Registration Number</i>	3
V.	<i>Classification</i>	3
VI.	<i>Performance Standards (FD&C Act 514)</i>	3
VII.	<i>Labeling</i>	3
VIII.	<i>Indications Summary</i>	3
IX.	<i>510(k) Summary</i>	3
X.	<i>Product Background and Module Description</i>	4
	A. Background of the StealthStation® System.....	4
	B. Description of the AxiEM™ Imageless Knee Module for the StealthStation® System....	4
	C. Description of the AxiEM™ Imageless Hip Module for the StealthStation® System	6
	D. Indications for Use	8
	E. Contraindications	9
	F. Product Manufacturing	9
	G. Biocompatibility.....	9
	H. Sterilization and Patient Contact	9
	I. Packaging.....	10
XI.	<i>Software Documentation</i>	11
	J. Level of Concern	11
	K. Software Description.....	11
	L. Operational Environment.....	11
	M. Device Hazards Analysis	11
	N. Software Requirements Specification.....	11
	O. Architecture Design Chart.....	11
	P. Design Specification	12
	Q. Traceability Analysis	12
	R. Development.....	13
	S. Verification, Validation and Testing	13
	T. Release Version.....	14
	U. Unresolved Anomalies (bugs).....	14
XII.	<i>Hardware and Software Verification and Validation</i>	15
XIII.	<i>Specific Standards and Guidelines</i>	15
XIV.	<i>Substantial Equivalence</i>	16

426

AxiEM™ Imageless Hip Module for the StealthStation® System

List of Figures

Figure 1: TCA.....	7
Figure 2: Navigation Probe Interface	7
Figure 3: Coil Array Control.....	7
Figure 4: Instrument Tracker Assembly	8
Figure 5: Pelvic Reference Frame	8
Figure 6: Femoral Reference Frame.....	8

List of Tables

Table 1: V&V Summary Table	13
Table 2: Summary Comparison of Subject and Predicate Devices	17

List of Attachments

- Attachment A** Indications Statement
- Attachment B** Safety and Effectiveness Summary
- Attachment C** Labeling
- Attachment D** Software Screen Images
- Attachment E** Architecture Diagrams
- Attachment F** Design Control Documents
- Attachment G** Product Requirements
- Attachment H** Verification and Validation Documents
- Attachment I** Hazard Analysis Documents
- Attachment J** Predicate Information
- Attachment K** Clinical Literature

AxiEM™ Imageless Hip Module for the StealthStation® System

510(K) NOTIFICATION

Submitted April 28, 2006

I. Submitter Information

Medtronic Navigation, Inc.
826 Coal Creek Circle
Louisville, Colorado 80027 USA
Telephone Number: (720) 890-3217
Fax Number: (720) 890-3517
Contact: Tina Dreiling, Associate Regulatory Affairs Specialist

II. Manufacturing Facility

Medtronic Navigation, Inc.
826 Coal Creek Circle
Louisville, Colorado 80027 USA
Telephone Number: (720) 890-3217
Fax Number: (720) 890-3517
Contact: Tina Dreiling, Associate Regulatory Affairs Specialist

III. Device Name

Common Name: Stereotactic instrument
Classification Name: Instrument, Stereotactic
Trade Name: AxiEM™ Imageless Hip Module for the StealthStation® System

IV. Establishment Registration Number

Medtronic Navigation, Inc.: 1723170

V. Classification

Stereotactic instrument - Class II as described in 21 CFR § 882.4560
Product Code: HAW

VI. Performance Standards (FD&C Act 514)

Medtronic Navigation, Inc. is unaware of any special controls for this product.

VII. Labeling

Labeling for the AxiEM™ Imageless Hip Module for the StealthStation® System and draft instructions for use are provided in **Attachment C**.

VIII. Indications Summary

The required indication statement is provided in **Attachment A**.

IX. 510(k) Summary

A 510(k) safety and effectiveness summary is provided **Attachment B**.

428

AxiEM™ Imageless Hip Module for the StealthStation® System

X. Product Background and Module Description

A. Background of the StealthStation® System

The StealthStation® System (K954276, K972398, K990214, K00153, and K001284) provides precise stereotactic determination of surgical targets using a stereotactic methodology. The principle features include:

- **Computer calculation of Stereotactic coordinates**

Digitized anatomic landmarks are stored on the StealthStation® System computer. The StealthStation® Software calculates Stereotactic coordinates with respect to the landmarks.

- **Measurement of Stereotactic coordinates within the surgical field**

Surgical instruments, which have been modified by incorporating infrared LED (light emitting diodes) markers or passive reflective markers onto the instrument, are tracked in real time in the surgical field. The instruments are referred to as "active" (the infrared light emanates directly from the LED's) or "passive" (utilizes the reflection of infrared light off of reflective markers). Through calibration using fiducial and/or anatomical reference points, the StealthStation® System computer can measure the stereotactic coordinates of the tip of the instruments.

- **High-resolution display of the images with stereotactic coordinates indicated**

Using the stereotactic coordinates of the tip of the surgical instrument, the StealthStation® computer indicates the calculated position of the tip of the surgical instrument on computer displayed images.

B. Description of the AxiEM™ Imageless Knee Module for the StealthStation® System (K043088)

The AxiEM™ Imageless Knee Module uses EM (electromagnetic) based navigation to facilitate the accurate placement of commercially available instrumentation in knee procedures using digitized landmarks of the anatomy. The AxiEM™ Imageless Knee Module can interface with any orthopaedic or navigational instrumentation that has been modified for use with EM tracking. The IGS procedures are conducted in the same manner as described in the Imageless Knee Module 510(k) (K030552), but uses EM localization, as described in the GoldenEye MicroMagnetic Option 510(k) (K001284), instead of optical tracking. The AxiEM™ Imageless Knee Module is composed of the following components:

1. Transmitter Coil Array (TCA)
2. Navigation Probe Interface (NPI)
3. Coil Array Control (CAC)
4. Instruments and a reference frame fitted with receive coils
5. AxiEM™ Imageless Knee Module Software

The Imageless Knee Module for the StealthStation® System does not utilize diagnostic image datasets as the basis for calculation of stereotactic coordinates. Because of this, the stereotactic coordinates must be established in an alternate manner by setting diagnostic image datasets. Stereotactic coordinates are thus established in the following manner:

1. The user positions and prepares the patient's anatomy for an Imageless Knee Module procedure in the same manner as for a conventional knee. After the patient has been exposed, the user affixes an image guided reference frame to the patient's femur and another to the patient's tibia. The user verifies the image guided instruments and selects accuracy checkpoints.

AxiEM™ Imageless Hip Module for the StealthStation® System

2. The user digitizes the location of the hip center, thus establishing the mechanical femoral axis. The hip center is determined by moving the operative side femur through a large range of motion, collecting dynamic information about the leg as it is moved in space. When enough data samples are collected, and the Root Mean Square (RMS) value is at an acceptable value, the user is informed that the digitization was successful.
3. The user then digitizes the knee axis, thus establishing the functional knee axis. The knee axis is determined by flexing and extending the tibia over the full range of motion of the knee, thus collecting information about the leg as it is moved in space. When enough data samples are collected, and the RMS value is at an acceptable value, the user is informed that the digitization was successful.
4. After successful digitization, the user landmarks the femur, tibia, and the ankle in order to establish navigational and reference axes. Each axis requires a set of specific points that must be identified and landmarked with a commercially available image guided surgical instrument. The software guides the user through this task. The following landmarks should be established:

Femur

- Posterior Lateral Condyle
- Posterior Medial Condyle
- Lateral Epicondyle
- Medial Epicondyle
- Anterior Cortex
- Distal Lateral Condyle
- Distal Medial Condyle
- Femoral Center
- Femoral Anterior/Posterior Axis

Tibia

- Lateral Defect Point
- Medial Defect Point
- Tibial Center
- Tibial Tuberosity

Ankle

- Lateral Malleolus
- Medial Malleolus

5. The Imageless Knee Application allows the surgeon to gain baseline knowledge about the range of motion of the patient's leg before the actual procedure is performed. These base kinematics tasks are used for comparison purposes after the surgical procedure is completed.

6. Once the landmarking task is complete and the user has performed either the base kinematics tests or elected to pass this step, the software guides the user to the navigate task. In the context of the Imageless Knee Application, navigation is defined as gaining knowledge about the position of the surgical probe with respect to the anatomy. This is done by observing the position of the image guided surgical instrument's cutting plane that is projected onto a rendering of the leg anatomy on the StealthStation® computer screen. Precise cutting angles are displayed for securing the cutting guides (provided as part of a commercially available endoprosthesis system) accordingly. The surgeon visualizes the cutting angles on the StealthStation® System computer monitor.

7. After making all of the osteotomy cuts on the femur and tibia, the surgeon can determine soft tissue laxity in the V&V stress test and visualize the final alignment of the leg.

AxiEM™ Imageless Hip Module for the StealthStation® System

C. Description of the AxiEM™ Imageless Hip Module for the StealthStation® System

The AxiEM™ Imageless Hip Module for the StealthStation® System uses electromagnetic (EM) based navigation to facilitate the accurate placement of commercially available instrumentation in hip procedures using digitized landmarks of the anatomy. The AxiEM™ Imageless Hip Module for the StealthStation® System interfaces with commercially available hip implant systems and/or instrumentation that has been modified or tested for use with EM navigation, but for marketing purposes may also be branded for a subset of commercially available implants such as those from a specific implant manufacturer (e.g. Zimmer).

The StealthStation® System and the Imageless Hip Module for the StealthStation® System utilize digitized anatomical landmarks to calculate the stereotactic coordinates with respect to the patient. The AxiEM™ Imageless Hip Module for the StealthStation® System uses the same digitized landmarks as the basis for calculation of stereotactic coordinates.

The AxiEM™ Imageless Hip Module for the StealthStation® System has the same principle of operation as the AxiEM™ Imageless Knee Module cleared in K043088. The various implants are tracked and navigated within the patient's anatomy and the information is displayed on the StealthStation® computer monitor.

The StealthStation® touchscreen is connected to the system and draped. The user connects the footswitch to the system breakout box and starts the system.

The user attaches a reference frame to the patient. Typically, for cup replacement procedures, the reference frames are affixed to the patient's iliac crest. The user positions the localizer to ensure that the electro-magnetic tracking unit sees the tracked instrument coils ("coils").

The user then selects a navigated instrument. The user may affix a calibration tip to a hip surgical instrument, such as an acetabulum reamer or pelvic cup impactor. The user verifies or calibrates the reamer or pelvic cup impactor by digitizing the calibration tip with the tracked pointer.

The surgeon establishes a patient-specific coordinate system via digitized anatomic landmarks, then makes an incision on the outside of the patient's hip and continues to prepare the patient's hip and/or pelvic area in the same manner as a conventional hip replacement procedure.

The user establishes accuracy checkpoints, which may be anatomical landmarks or other points that are designated by the surgeon. The surgeon can evaluate the accuracy at any point during the procedure by placing the probe in the checkpoint. Errors are displayed to the user. If a large error is displayed, it may be indicative of errors such as reference frame movement.

The user selects the reamer, and positions it within the patient's anatomy. The position of the reamer with respect to the patient's anatomy is known because the instrument contains a tracked coil array. This position information is displayed to the user on the StealthStation® System computer monitor. The user selects the appropriate cup implant size in the AxiEM Imageless Hip Module software. The user then affixes the implant to the navigated pelvic cup impactor, which allows the user to track and navigate the implant within the patient's anatomy.

The navigation will be conducted in the same manner as described in the AxiEM™ Imageless Knee Module 510(k), but will navigate hip procedures rather than knee procedures. The AxiEM™ Imageless Hip Module for the StealthStation® System is composed of the following components:

1. Transmitter Coil Array (TCA)
2. Navigation Probe Interface (NPI)
3. Coil Array Control (CAC)
4. Electro-magnetic Instrumentation fitted with receive coils
5. AxiEM™ Imageless Hip Module Software

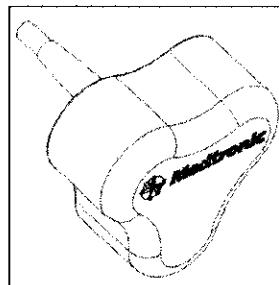
431

AxiEM™ Imageless Hip Module for the StealthStation® System

Transmitter Coil Array (TCA)

The "Transmitter Coil Array" (TCA) emits low energy, low frequency AC signals into the space surrounding a set of receiving coils. The signals emit precise field strengths over the field of view (FOV) of the system. The receive coils, located on the tracked instrument, detect these signals and measure their strength. The TCA used with the AxiEM™ Imageless Hip Module for the StealthStation® System is similar to the version of the TCA used for the GoldenEye System as described in K001284. The primary difference is that the localizer is designed to be placed where needed for navigation, rather than fixed under the patient's head. However, the technology or use of this version is the same as the previously cleared version.

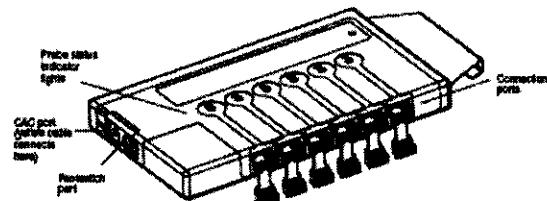
Figure 1: TCA



Navigation Probe Interface

The instruments plug into a "Navigation Probe Interface" (NPI) system. The NPI controls all of the data acquisition as well as processing some of the probe data. The NPI is identical to the NPI used for the GoldenEye System as described in K001284.

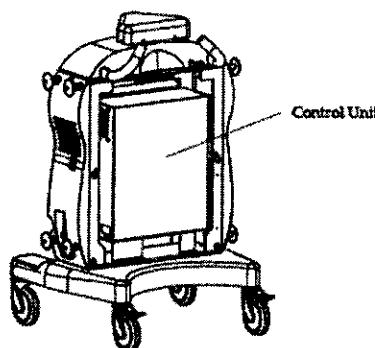
Figure 2: Navigation Probe Interface



Coil Array Control (CAC)

The "Coil Array Control" computer (CAC) applies a mathematical algorithm to find the point in space where the field strength of the receive coil is equivalent to the known fields transmitted from the TCA. This provides the information necessary to determine the x,y,z point and the angle and azimuth of the receive coil. The CAC is identical to the CAC used for the GoldenEye System as described in K001284.

Figure 3: Coil Array Control



AxiEM™ Imageless Hip Module for the StealthStation® System

EM Instrumentation

The AxiEM™ System interfaces with commercially available surgical instruments using receive coils for tracking the location of the instruments in the surgical field. In addition, the system tracks the location of the patient's boney anatomy via reference frames (trackers). These reference frames also contain receive coils and are rigidly fixed to the patient with bone screws. Both the modification of surgical instruments by the addition of receiving coils and the use of receive coils attached to the patient's anatomy for anatomical reference were included in the GoldenEye System cleared in K001284. (examples shown in **Figures 4, 5 and 6**).

Figure 4: Instrument Tracker Assembly

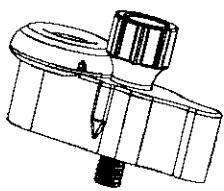


Figure 5: Pelvic Reference Frame

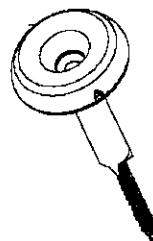
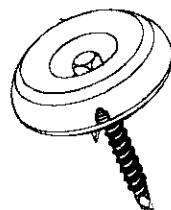


Figure 6: Femoral Reference Frame



AxiEM™ Imageless Hip Module Software

The AxiEM™ Imageless Hip Module Software navigates hip replacement/arthoplasty procedures without the use of images. The AxiEM™ Imageless Hip Module Software assists in the accurate placement of total hip replacement implants using EM localization.

A detailed description of the operation of the AxiEM™ Imageless Hip Module for the StealthStation® System is discussed in the DRAFT instructions for use, provided in **Attachment C**. Additionally, images of the software interface are provided in **Attachment D**.

D. Indications for Use

The StealthStation System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The StealthStation System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

The AxiEM™ Imageless Hip Module for the StealthStation® is intended to precisely position instruments and implants in example procedures such as but not limited to:

Orthopedic Procedures:

Minimally Invasive Orthopedic Procedures

Total Hip Replacement (Primary and Revision)

AxiEM™ Imageless Hip Module for the StealthStation® System**E. Contraindications**

The AxiEM™ Imageless Hip Module for the StealthStation® System is contraindicated for any medical condition for which surgery itself is contraindicated.

F. Product Manufacturing

Internal staff and various qualified subcontractors under the direction of Medtronic Navigation, Inc. manufacture the components of the AxiEM™ Imageless Hip Module for the StealthStation® System.

G. Biocompatibility

The patient contact components of the AxiEM™ Imageless Hip Module for the StealthStation® System are standard compliant materials used in surgical instruments such as titanium, medical grade stainless steel or plastic. Refer to **Table 1** for a list of specific patient contact components.

Table 1: Patient Contact Device Summary

Component	Material
Reference frames	Medical grade plastics, adhesive and titanium
Reference frame bone screws	Medical grade titanium
Instrument tracker	Medical grade plastics and adhesive
Pointer	Medical grade stainless steel and plastic
Calibration Tip	Medical grade titanium
Click and Point (Pointer holder)	Medical grade stainless steel
Screwdrivers	Medical grade stainless steel

H. Sterilization and Patient Contact

The following components are provided non-sterile and are not designed to be in the sterile field: The Transmitter Coil Array (TCA), the Navigation Probe Interface (NPI) and the Coil Array Computer (CAC).

The instruments to be used with AxiEM™ Imageless Hip Module for the StealthStation® System in the sterile field may be sent pre-sterilized or non-sterile. The pre-sterilized components will be sterilized using validated ethylene oxide (EtO) methods. Validation will be performed utilizing the overkill method as described in the AAMI Guidelines for Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization and/or EN 550 Sterilization of Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization. The Sterilization Assurance Level (SAL) will be 10^{-6} .

EtO (Ethylene Oxide) Gas Sterilization**Preconditioning Parameters**

- Temperature: 54° C (130° F) \pm 5° C
- Relative humidity: 70 \pm 5%
- Preconditioning time: 1 hour

Sterilization Parameters

- Cycle temperature: 54° C (130° F) \pm 5° C
- Relative humidity: 70 \pm 5%
- Ethylene oxide concentration: 725 \pm 25 mg/L
- Exposure time: 4 hours
- Aeration time and temperature: 11-12 hours at 51-59° C (124-138° F)

If provided non-sterile, the components will be sterilized prior to use using one of the three steam sterilization methods listed below:

434

AxiEM™ Imageless Hip Module for the StealthStation® System

Steam Sterilization (Autoclave)

Pre-vacuum

- Temperature: 270° F (132° C)
- Steam time: Five (5) minutes
- Minimum dry time: Two (2) minutes*
- Wrapped or Unwrapped (Flash) configuration**

Gravity (inside the United States)

- Temperature: 270° F (132° C)
- Steam time: Fifteen (15) minutes
- Minimum dry time: Two (2) minutes*
- Wrapped or Unwrapped (Flash) configuration**

Pre-vacuum (outside the United States)

- Temperature: 134° C (273° F)
- Steam time: Eighteen (18) minutes
- Minimum dry time: Two (2) minutes*
- Wrapped or Unwrapped (Flash) configuration**

Components will be provided as follows:

Component	Sterility
Reference frames	Provided sterile
Reference frame bone screws	Provided sterile
Instrument tracker	Provided sterile
Pointer	Provided sterile
Calibration Tip	Provided non-sterile
Click and Point (Pointer holder)	Provided non-sterile
Screwdrivers	Provided non-sterile

I. Packaging

All components are packaged in a secure manner to properly protect them during storage and delivery.

* Minimum dry time is required with wrapped configurations only

** Flash sterilization should only be performed following proper cleaning and decontamination

AxiEM™ Imageless Hip Module for the StealthStation® System

XI. Software Documentation

Based on "The Guidance for Pre-market Submissions of Software", the following software information is provided and substantiated by documentation (where appropriate) in the listed attachments.

J. Level of Concern

Medtronic Navigation, Inc. considers the AxiEM™ Imageless Hip Module for the StealthStation® System software to be of *Moderate Level of Concern*, based on the following criteria:

- It does not control a life supporting or sustaining device
- It does not control delivery of harmful energy
- It does not control treatment delivery
- It does not perform vital signs monitoring

It does provide diagnostic information as a basis for treatment or therapy, but software failure would not result in death, serious injury or non-serious injury.

K. Software Description

The AxiEM™ Imageless Hip Module software is based on the Imageless Hip Module for the StealthStation® System. A description of the AxiEM™ Imageless Hip Module for the StealthStation® System software is provided in the **Section X** of this document, as well as the draft instructions for use, provided in **Attachment C**.

L. Operational Environment

Software Documentation	Designation/ Location of Documentation
Programming Language	C++
Hardware Platform	Intel-based PC
Operating System	GemOS (Linux-based)
Use of Off the Shelf (OTS) software	None

M. Device Hazards Analysis

As part of the Medtronic Navigation, Inc. design control process (Refer to SP-C-01 and SOP-C-100, **Attachment F**) hazards are identified and resolved prior to commercial release. Included in this submission is a copy of the Hazards Analysis for the AxiEM™ Imageless Hip Module for the StealthStation® System. This document is provided in **Attachment I**.

N. Software Requirements Specification

As part of the Medtronic Navigation, Inc. design control process (Refer to SP-C-01 and SOP-C-100, **Attachment F**), software requirements are identified at the beginning of the development cycle. These requirements (also known as inputs) are verified to ensure that the inputs equal the outputs prior to commercial release. Included in this submission are the Software Requirements Test Protocols and results of the system accuracy verification. These documents are provided in **Attachment H**.

O. Architecture Design Chart

The architecture diagram of the AxiEM™ Imageless Hip Module for the StealthStation® System is provided as part of this submission. The diagram is found in **Attachment E**.

436

AxiEM™ Imageless Hip Module for the StealthStation® System

P. Design Specification

Provide a Software Requirements Specification, which includes predetermined criteria for acceptance of the program.	The functional requirements (Attachment G) are the predetermined criteria for acceptance of the program.
Provide/reference any and all development and programming standards used to develop the software.	Section 9.3.1 of SOP-C-100 StageGate Process outlines standards for software development and is provided in Attachment F .
Provide a Hazards Analysis for the software.	Refer to the Hazards Analysis Document, Attachment I .
Provide the parameters that are to be measured/recorded during verification and validation activities.	<p><u>Verification:</u> Verification testing ensures that all of the inputs match the outputs. This testing is provided in Attachments H.</p> <p><u>Performance Accuracy:</u> The accuracy of the Imageless Hip Module was determined to be substantially equivalent to existing StealthStation® parameters. The results are found in Attachment H.</p> <p><u>Validation:</u> Validation testing ensures that the user's needs are met. This testing is called "Simulated Use Testing" and is provided in Attachment H.</p>
Provide the Logical Structure, Control Logic, and Logic Processing Steps for the Software	Refer to the software architecture diagram, provided in Attachment E .
Provide Hardware Specifications that is to be used.	Intel-based PC
Provide the Data Structures and Data Flow Diagrams	Refer to the software architecture diagram, provided in Attachment E .
Define the variables (if any) regarding the control mechanism & data & provide a description of where variables are used.	Refer to the software architecture diagram, provided in Attachment E .

Q. Traceability Analysis

The traceability of the product design that links the requirements, design specifications, hazards, and validation is maintained using the process outlined in Medtronic Navigation, Inc. SOP-C-100 StageGate Process (**Attachment F**). This process includes establishing the product requirements in the functional test protocol (**Attachment H**). The design-input document (**Attachment G**) is revision controlled and each input is numbered for traceability. This document provides a pointer to the testing that was completed for each of the original inputs. The hazards are identified, numbered, and analyzed in a Hazard Analysis Report during the design phase (**Attachment I**). The resolution of each hazard is tested.

AxiEM™ Imageless Hip Module for the StealthStation® System

R. Development

The Software development life cycle plan is based on the work instruction titled *StageGate Process*. A copy of that work instruction (SOP-C-100) is provided in **Attachment F**. Briefly, the software development process includes the following steps:

- Creation of a Design and Development Plan that includes the team members, schedules, and the business plan.
- Design Input that identifies the project software requirements. This step is documented through an Input Document.
- Design Reviews are performed during the code development. These reviews are documented.
- Design Verification is performed to confirm that the design outputs meet the design inputs. All software design requirements must be tested and referenced in the output document.
- Design Validation is performed to ensure that the software meets the user needs and the intended uses. Design Validation can include simulated use testing, cadaver studies or clinical studies. Validation includes a final review of the Hazard Analysis Report and the testing of the hazard resolutions.
- Software is transferred to production using an Engineering Change Order (ECO) process. The software cannot be transferred until the appropriate reviews and signatures are completed. Once the software is approved for transfer, the software is transferred to a production hard drive that is revision controlled. Access to the production hard drive is limited to authorized personnel.
- The release of software changes is managed in a similar manner to new software releases. Software changes require a project plan, an input document, design reviews, verification and validation, and a release through the ECO process.

S. Verification, Validation and Testing

Included in this submission are copies of software test plan, pass/fail criteria and results for system accuracy. A summary of the test plan for the Imageless Hip Module is located in **Table 2**. Copies of the test documents are located in **Attachment H**.

Table 2: V&V Summary Table

V&V Activity	Description
Functional Test (VV1103)	Provides confirmation that the design and implementation of a product correctly fulfills all product requirements. (protocol only)
Labeling / User Manual Review (VV1232)	Confirms that all labeling and user documentation is accurate and appropriate.
Freeform Validation Test (VV1016)	This protocol is intended to serve as a "monkey test", where random scenarios take place, in the application parts that have been changed, or that were identified to be most sensitive.
Simulated Use Test (VV1105)	Confirms that the product appropriately satisfies the users needs and intended use. Involves using the product in an environment that simulates the real environment. (protocol only)
Accuracy Test (VV1102)	Provides confirmation that the product satisfies necessary accuracy requirements.

AxiEM™ Imageless Hip Module for the StealthStation® System

T. Release Version

The release version of the AxiEM™ Imageless Hip Module for the StealthStation® System is 1.01. A draft copy of the instructions for use that supports version 1.01 of the AxiEM™ Imageless Hip Module for the StealthStation® System is provided in **Attachment C**.

U. Unresolved Anomalies (bugs)

There are known software anomalies in the AxiEM™ Imageless Hip Module. Anomalies are listed on the Verification Report (provided in **Attachment H**). The software anomalies do not pose a safety risk. Unresolved anomalies are maintained on GNATS or another approved Medtronic Navigation, Inc. method. The GNATS system is an internet-based program which is password protected, but allows all members of the design team to keep track of ongoing anomalies. This program also maintains a "software wish-list"; a list of items to be considered in future releases. If the anomaly is marked "open" the software issues have not been resolved, and if marked "closed" the anomaly has been resolved. If the anomaly is marked "feedback" the design team is awaiting some type of response from other team members. This response is necessary to close the issue.

AxiEM™ Imageless Hip Module for the StealthStation® System

XII. Hardware and Software Verification and Validation

The product development process at Medtronic Navigation, Inc. includes assessing the quality of the software and hardware throughout the development process and qualification and verification/validation testing of the final product. The formal testing and validation assures the following:

- Test plans and protocols are derived from the Requirements Specification
- Evaluation of the software and hardware at the end of the development process to determine its compliance to the Requirements Specifications
- Testing under normal and limit conditions
- Identification, evaluation and resolution of potential hazards
- Algorithms, when used, are validated in a separate emulation environment

Software validation is performed under the direction of the Design Review Team. The verification and validation process for the AxiEM™ Imageless Hip Module for the StealthStation® System is as follows (test protocols/reports and hazards analysis reports are provided in **Attachments H and I** respectively):

- Verification and Validation testing which includes requirements test and performance accuracy.
- Hazards Analysis Report

Results of the verification and validation testing are analyzed, documented, and reviewed by the design team for the AxiEM™ Imageless Hip Module for the StealthStation® System to ensure the product meets the defined performance and safety requirements prior to commercial release. Reports of the workstation, software and component tests are filed and maintained at Medtronic Navigation, Inc.

XIII. Specific Standards and Guidelines

The software associated with the AxiEM™ Imageless Hip Module for the StealthStation® System was developed using the following standards and guidelines:

DHHS Document "Guidance for the Content of Pre-market Submissions for Software Contained in Medical Devices"

AxiEM™ Imageless Hip Module for the StealthStation® System

XIV. Substantial Equivalence

The AxiEM™ Imageless Hip Module for the StealthStation® System is substantially equivalent to the AxiEM™ Imageless Knee application (K043088) in that it utilizes digitized landmarks to setup a patient-specific coordinate system and EM tracking for surgical navigation of orthopaedic procedures.

The AxiEM™ Imageless Hip Module for the StealthStation® System is substantially equivalent to the Imageless Hip Module for the StealthStation® System (K052623) in that it utilizes the same patient landmarking to setup the navigation coordinate system and the same basic algorithms for generating navigation information during an orthopaedic hip procedure. Both modules perform navigation of hip procedures without diagnostic images or fluoroscopy.

The underlying technology of the AxiEM™ Imageless Hip Module for the StealthStation® System is all the same as that cleared for the AxiEM™ Imageless Knee application in K043088. Both systems use commercially available instrumentation and the same software libraries for the surgical procedure. The difference between these two systems is that the subject device navigates instruments for use in hip procedures and the AxiEM™ Imageless Knee application navigates instruments for use in knee procedures.

In addition, the indications for the AxiEM™ Imageless Hip Module for the StealthStation® System are a subset of those for the Imageless Hip Module for the StealthStation® System as cleared in K052623.

- Simulated use testing confirms that the product appropriately satisfies the users needs and intended use. This protocol involves using the product in an environment that simulates the real environment.
- All application-specific functionality is tested via functional requirements testing. This protocol also tests the system level integration of software, computer platform, and instrumentation (including the electro-magnetic localization system).
- Testing in a simulated surgical environment has been conducted to ensure that the application's measurement accuracy was within the performance claims listed herein.
- Free-form testing that exercises the system in a variety of randomly generated test cases has been conducted as a "monkey-test" to establish reliability of the software in uncontrolled scenarios.
- Hazard mitigation testing ensures that all labeling mitigations called out in the hazards analysis report were appropriately implemented in the draft user documentation.

The determination of substantial equivalence is based upon identifying currently marketed predicate devices and assessing equivalency (refer to **Table 3**) using the Federal Food and Drug Administration's Guidance Document entitled "Substantial Equivalence (SE) Decision Making Documentation" dated 01/01/1990.

AxiEM™ Imageless Hip Module for the StealthStation® System

Table 3: Summary Comparison of Subject and Predicate Devices

	AxiEM™ Imageless Hip Module for the StealthStation® System	AxiEM™ Imageless Knee Module for StealthStation® System	Imageless Hip Module for StealthStation® System
510k Number	Subject of this 510(k)	K043088	K052623
Tracking method	Electromagnetic	Electromagnetic	Optical (infrared)
Datasets used for patient registration and navigation	NA - digitized anatomical landmarks	NA - digitized anatomical landmarks	NA - digitized anatomical landmarks
Angular Accuracy (b)(4)	(b)(4)		
Tested Angular accuracy	AP Pelvic Tilt: (b)(4)	0mm Mean	Anteversion:
	(All intervals are for worst case test)		
Positioning accuracy Specification	95% confidence interval < (b)(4)	95% confidence interval < (b)(4)	NA
Tested Positioning accuracy **	Leg Length: 0.67 ± 0.67 mm (b)(4) (All intervals are for worst case test)	0.4mm +/- 1.1 (b)(4) 99% conf. interval of 3.4mm	(b)(4)
Image Display	2-D, not reconfigurable	2-D, not reconfigurable	2-D, not reconfigurable
Interference Warning Messages	YES	YES	NA
Instrument verification	GEOMETRY	GEOMETRY	GEOMETRY
Tracking	Receive Coils	Receive Coils	Active instruments or passive markers

** Limit of system accuracy (system alarm) was tested and reported separately from the standard (pristine) test case. Accuracy testing for the AxiEM Imageless Hip Module was conducted with all error sources included in the standard test setup (e.g. metal interference from surgical instruments, movement of the localizer, etc). The pristine case for hip was not tested.

AxiEM™ Imageless Hip Module for the StealthStation® System

	AxiEM™ Imageless Hip Module for the StealthStation® System	AxiEM™ Imageless Knee Module for StealthStation® System	Imageless Hip Module for StealthStation® System
Transmitter Coil Array (TCA)	(b)(4) [REDACTED]	(b)(4) [REDACTED]	(b)
Navigation Probe Interface (NPI)	(b)(4) [REDACTED]	(b)(4) [REDACTED]	(b)
Coil Array Control (CAC)	(b)(4) [REDACTED]	(b)(4) [REDACTED]	(b)
Indications for Use	<p>The StealthStation System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The StealthStation System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.</p> <p>The AxiEM™ Imageless Hip Module for the StealthStation® is intended to precisely position instruments and implants in example procedures such as but not limited to:</p> <p>Orthopedic Procedures: Minimally Invasive Orthopedic Procedures Total Hip Replacement (Primary and Revision)</p>	<p>The StealthStation® System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The StealthStation® System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy. Example procedures include, but are not limited to:</p> <p>Cranial Procedures: Cranial Biopsies Tumor Resections Craniotomies/ Craniectomies Skull Base procedures Thalamotomies/Pallidotomies Pituitary Tumor Removal CSF Leak Repair Pediatric Catheter Shunt Placement General Catheter Shunt Placement</p> <p>Spinal Procedures: Spinal Implant Procedures, such as Pedicle Screw Placement</p> <p>ENT Procedures: Transsphenoidal Procedures, Intranasal Procedures, Orbital Nerve Decompression Procedures Optic Nerve Decompression Procedures, Polypsis Procedures, Endoscopic Dacryocystorhinostomy Encephalocele Procedures Sinus procedures, such as Maxillary Antrostomies, Ethmoidectomies, Sphenoidotomies/Sphenoid Explorations, Turbinate Resections, and Frontal Sinusotomies</p> <p>Orthopaedic Procedures: Total Knee Arthroplasty (Primary and Revision) Unicompartmental Knee Arthroplasty Minimally Invasive Orthopaedic Knee Procedures</p>	<p>The StealthStation® System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The StealthStation® System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.</p> <p>The Imageless Hip Module for the StealthStation® is intended to precisely position instruments and implants in example procedures such as but not limited to:</p> <p>Orthopedic Procedures: Minimally Invasive Orthopedic Procedures Total Hip Replacement (Primary and Revision) Tumor Resection and Bone/Joint Reconstruction Placement of Iliosacral Screws Femoral Revision Stabilization and Repair of Pelvic Fractures (Including But Not Limited to Acetabular Fractures)</p>

ATTACHMENT A

AXIEM™ IMAGELESS HIP MODULE FOR THE STEALTHSTATION® SYSTEM
INDICATIONS STATEMENT

444

Indications for Use

510(k) Number (if known): K061248

Device Name: AxiEM™ Imageless Hip Module for the StealthStation® System

Indications for Use:

The StealthStation System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The StealthStation System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

The AxiEM™ Imageless Hip Module for the StealthStation® is intended to precisely position instruments and implants in example procedures such as but not limited to:

Orthopedic Procedures:

Minimally Invasive Orthopedic Procedures

Total Hip Replacement (Primary and Revision)

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

445

ATTACHMENT B

**AXIEM™ IMAGELESS HIP MODULE FOR THE STEALTHSTATION® SYSTEM
SUMMARY OF SAFETY AND EFFECTIVENESS**

446

K061248

**Summary of Safety and Effectiveness
AxiEM™ Imageless Hip Module for the StealthStation® System**

I. Manufacturer

Medtronic Navigation, Inc.
826 Coal Creek Circle
Louisville, Colorado 80027 USA
Telephone Number: (720) 890-3217
Fax Number: (720) 890-3517

II. Contact

Tina Dreiling
Associate Regulatory Affairs Specialist
Medtronic Navigation, Inc.

III. Product Name / Classification

Common Name: Stereotaxic instrument
Classification Name: Instrument, Stereotaxic
Trade Name: Imageless Hip Module for the StealthStation® System
Stereotaxic instrument - Class II as described in 21 CFR § 882.4560
Product Code: HAW

IV. Date Summary Submitted

April 28, 2006

V. Description of Device Modification

The AxiEM™ Imageless Hip Module for the StealthStation® System provides a mechanism for the establishment of stereotactic coordinates without the use of a pre-operative or intra-operative image using electromagnetic navigation.

VI. Substantial Equivalence

The primary difference between the Imageless Hip Module for the StealthStation® System and the AxiEM™ Imageless Hip Module for the StealthStation® System is that the AxiEM™ Imageless Hip Module utilizes electromagnetic navigation technology rather than optical tracking.

The primary difference between the AxiEM™ Imageless Knee Module for the StealthStation® System and the AxiEM™ Imageless Hip Module for the StealthStation® System is that the subject device navigates instruments for use in hip procedures and the AxiEM™ Imageless Knee application navigates instruments for use in knee procedures.

As required by risk analysis, all verification and validation activities will be performed by designated individuals and will demonstrate the safety and effectiveness of the device.

The information provided in this 510(k) application supports that the AxiEM™ Imageless Hip Module for the StealthStation® System is substantially equivalent to the Imageless Hip Module for the StealthStation® System (K052623).

VII. Indications for Use

The StealthStation System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The StealthStation System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

The AxiEM™ Imageless Hip Module for the StealthStation® is intended to precisely position instruments and implants in example procedures such as but not limited to:

Orthopedic Procedures:
Minimally Invasive Orthopedic Procedures
Total Hip Replacement (Primary and Revision)

447

Page 22 of 877

ATTACHMENT C

AXIEM™ IMAGELESS HIP MODULE FOR THE STEALTHSTATION® SYSTEM

LABELING

1. Application Label
2. AxiEM™ Imageless Hip Module for the StealthStation® System Pocket Guide
3. AxiEM™ System Manual

Click here to
select Overlay
Template

120mm

**Zimmer Imageless Hip for AxiEM
Version: [X.X]**

Medtronic Navigation

For installation assistance call **Medtronic Navigation at**
US: 1-800-595-9709 Outside US: 1-720-890-3200

Copyright 2005
Medtronic, Inc.
All rights reserved
Do Not Distribute.
Do Not Copy.
Form # K-03 Rev 2
Rx only



**Zimmer Imageless Hip for AxiEM
Version: [X.X]
P/N: 9732465
[Month of release] 2005
INAV**

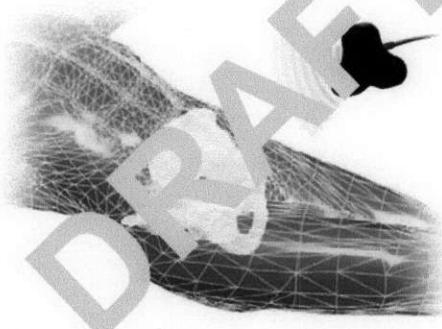
Move
Overlay
Template to
front

**StealthStation® iNAV
w/ AxiEM™ Technology**



Imageless Hip for AxiEM™ Application

POCKET GUIDE



©2005 MEDTRONIC NAVIGATION
9732770, REVISION 1

RX



Medtronic Navigation
826 Coal Creek Circle
Louisville, CO 80027
Main 720 890 3200
Fax 720 890 3500
Technical support 800 595 9709
www.stealthstation.com

CONTENTS

INTENDED USE.....	5
CONTRAINdicATIONS.....	5
WARNINGS.....	5
CAUTIONS	8
STANDARD EQUIPMENT	9
PROCEDURE.....	11
LOG IN.....	12
ENTER PATIENT NAME.....	14
SOFTWARE OVERVIEW	15
SELECT PROCEDURE.....	17
SELECT OPERATIVE SIDE.....	18
SELECT IMPLANT	19
RECOMMENDED SYSTEM AND CONNECTOR BOX PLACEMENT	20
CONNECT INSTRUMENTS	21
SWITCHING INSTRUMENTS DURING THE PROCEDURE....	23
CALIBRATE SHELL INSERTER	24
CALIBRATE ACETABULAR REAMER	26
ATTACH PELVIS TRACKER	28

4

LANDMARKS AND COORDINATE SYSTEM	29
DIGITIZE PELVIC LANDMARKS.....	32
CREATE PELVIS CHECKPOINT	37
VERIFY PELVIS CHECKPOINT	38
RECORD PRE-OP LEG LENGTH AND OFFSET.....	39
SELECT REAMER.....	40
NAVIGATE REAMER	42
SELECT SHELL SIZE.....	43
NAVIGATE SHELL	44
VERIFY SHELL	46
CAPTURE POST-OP LEG LENGTH & OFFSET	47
EXIT THE APPLICATION SOFTWARE	48
ARCHIVE	49
REMOVE EXAMS.....	50
EXIT.....	51
SYMBOLS	52

INTENDED USE

The Zimmer Imageless Hip for AxiEM is intended to precisely position instruments and implants in procedures including MIS Total Hip Replacement (Primary and Revision).

CONTRAINDICATIONS

The AxiEM™ Imageless Hip Module for the StealthStation® System is contraindicated for any medical condition for which surgery itself is contraindicated.

WARNINGs

- The system and its associated applications should be used only by qualified medical professionals who are trained on and familiar with the proper operation of Medtronic computer-assisted surgery systems.
- The system and its associated applications should be used only as an adjunct for surgical guidance. They do not replace the surgeon's knowledge, expertise, or judgement.
- If system navigation seems inaccurate and steps to restore accuracy are unsuccessful, abort use of the application.
- Discard before use any pre-sterilized component whose sterile packaging appears to be compromised.

6

- There is currently no effective sterilization method for components that are tainted with the virus that causes Creutzfeld-Jakob Disease (CJD). Therefore, you must discard immediately after surgery any components that come into contact with biologic material from patients who carry or are suspected to carry this virus. As a precaution, drape all non-disposable components that could otherwise come into contact with such material.
- Frequently confirm localization accuracy and system responsiveness during live navigation. Observe the correspondence between movement of instrument and movement of the virtual instrument on-screen.
- Do not operate the AxiEM™ Mobile Emitter (Localizer) in an ambient temperature of more than 86° F (30° C).
- Never use an AxiEM™ instrument as a lever or prying device.
- Physically examine all instruments and frames before use. Do not use a device that is bent or damaged.
- Do not connect multiple low isolation instruments.

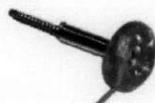
455

- AxiEM™ system technology has been tested for compatibility with the following Medtronic® implantable cardiac device families:
 - Marquis®
 - GEM III®
 - Kappa®
 - Sigma®
 - EnPulse®
 - EnRhythm®
 - EnTrust®
- Testing indicates that AxiEM™ systems do not adversely affect the function of these devices and do not constitute a patient hazard. However, the system may interfere with the programming or interrogating of these implantable devices and any other implantable device. Do not use an AxiEM™ system while programming or interrogating any implantable device.
- Do not change or edit configuration files. Only Medtronic Navigation service and field personnel, who have been trained to know which parameters and associated values can be changed, are authorized to modify application configurations. Any modification of the application software by the user is considered off-label use.

△ CAUTIONS

- Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.
- The system and its associated applications contain no user-repairable parts. For repair or replacement of any part of the system or application, contact a technical support representative.
- The patient-specific coordinate system created by the software from user-identified landmarks assumes typical anatomy at the landmark sites. Significant deformity or irregularity at these sites may produce unexpected navigation angles.
- Verify that all relevant instrumentation has been properly sterilized before surgery. Refer to the Universal Cleaning and Sterilization Instructions (pn 9730713) for general cleaning and sterilization instructions.

STANDARD EQUIPMENT



AxiEM™ Pelvis Tracker (pn 9732724)

Use the Pelvis Tracker to track the position of the patient's pelvis during the procedure.



AxiEM™ Instrument Tracker (pn 9732726)

Use the Instrument Tracker to track the position of surgical instruments during the procedure.



AxiEM™ Pointer (pn 9660236)

Use the AxiEM™ Pointer for digitizing accuracy checkpoints and landmarks.



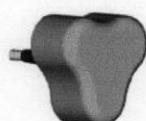
Click and Point Handle (pn 9660237)

Use the Click and Point Handle to hold the AxiEM™ Pointer.



Shell Inserter Calibration Tip (pn 9732727)

Use the Calibration Tip on the Shell Inserter to calibrate the instrument for accurate navigation.



AxiEM™ Mobile Emitter (pn 9660812)

The AxiEM™ Mobile Emitter produces the electromagnetic field used to track instruments.

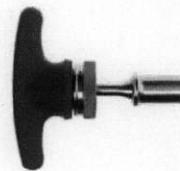
10

AxiEM Ortho Screwdriver (pn 9732133)



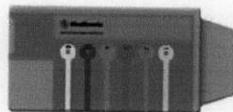
Use the AxiEM Screwdriver to drive the Tracker fixation screws into bone.

Ratcheting T-Handle (pn 9731974)



Use the Ratcheting T-Handle to hand tighten screws into bone.

Navigation Probe Interface (pn 9660700)



The Navigation Probe Interface or Connector Box is a junction box used to connect wired instruments to the system.

AxiEM™ Portable System (pn 9660560)



The AxiEM™ Portable system connects to the iNav™ Portable system. It is a junction box used to connect AxiEM™ instruments to the portable system.

System Footswitch (pn 960-135)



The system footswitch controls software functions.

PROCEDURE

11

LOG IN

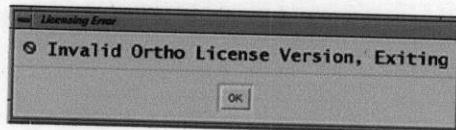
12

1. If necessary, scroll down until you can see the **Zimmer** icon.
2. Double-click the **Zimmer** icon on the login screen.
The group screen (below) displays.
3. Click the [**Zimmer Imageless Hip for AxiEM**] icon at the top of the group screen, or
4. Click the [**Zimmer Imageless Hip for AxiEM Portable**] icon (AxiEM™ Portable systems only).



LOG IN (CONT.)

For Treon® and Tria™ systems only: If you do not own an Orthopaedic OS license, you will not be able to start and run the Zimmer Imageless Hip for AxiEM™ application software. The following message displays if you do not own the license.



Please contact your local Medtronic Navigation representative or call Medtronic Navigation to obtain information on purchasing an Orthopaedic OS license.

ENTER PATIENT NAME

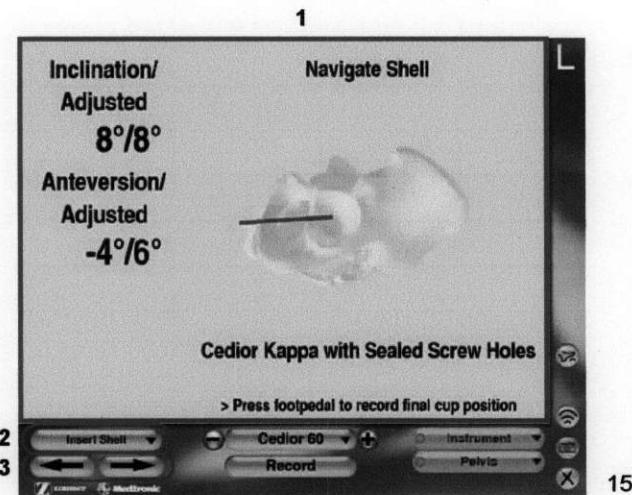
14

1. Enter the patient's name or an identification name for the exam using the virtual keyboard on-screen or the system keyboard.
If you are using the system keyboard, make sure that the mouse cursor is in the text box.
2. Click the **[OK]** button.



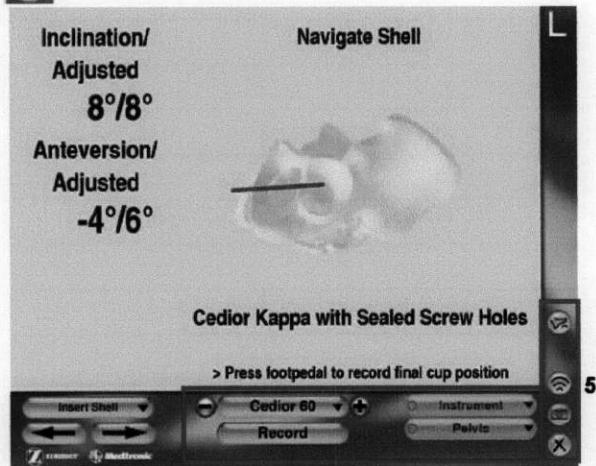
SOFTWARE OVERVIEW

1. Image Window: Interpretive images and measurement data for each task appear in this area.
2. Task Bar: Each active task for the procedure displays on the task bar. Click the bar to jump to any active task.
3. Next/Back Buttons: Click the right-pointing Arrow to go forward to the next task. Click the left-pointing Arrow to return to the previous task.



4. Task-Specific Area: Each task has its own specific set of buttons and other controls. The colors of the status indicators in the right side of the area correspond to instrument and reference frame visibility.
5. General Control Buttons: Use the general control buttons to access system-level features at any time during the procedure.

-  – Acts as a footpedal press
-  – Opens the emitter field viewer
-  – Takes a snapshot of the screen
-  – Exits the application

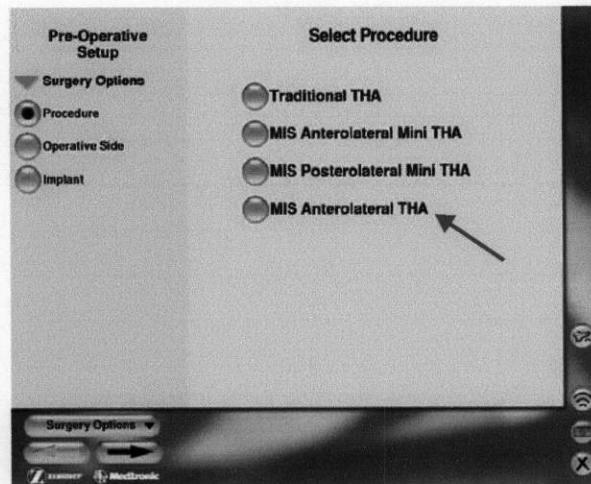


4

465

SELECT PROCEDURE

1. Select the type of procedure to be performed.



17

SELECT OPERATIVE SIDE

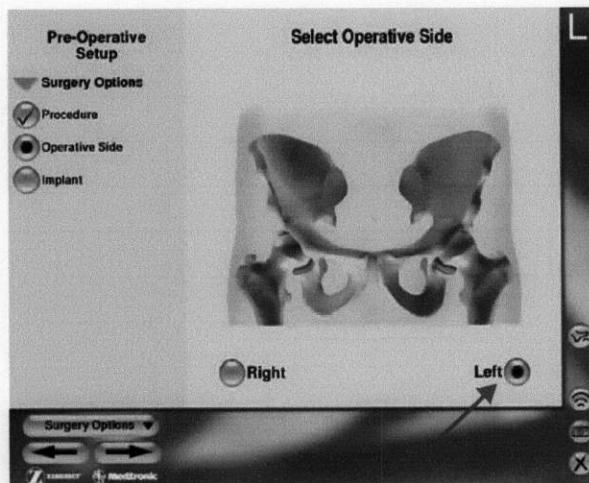
18

 Measurements in the inclination/anteverision of the acetabular cup and reamer will appear abnormal if the wrong hip side is selected.

Select the side of the patient on which the procedure will be performed.

1. Click [Right] or [Left].

The application software will automatically advance to the next screen after selecting the operative side.



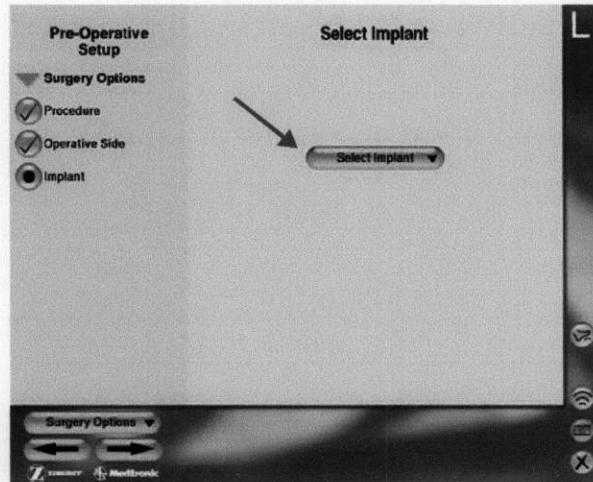
SELECT IMPLANT

1. Select the implant system to be used for the procedure.

This step ensures that the application software uses the correct implant data for all calculations.

The application software supports the following implant families.

- Trilogy
- Converge
- Converge Protrusio
- TM Modular
- Fitmore
- Allofit
- Cedior Kappa
- Cedior Kappa w/
sealed screw holes
- Cedior Alpha

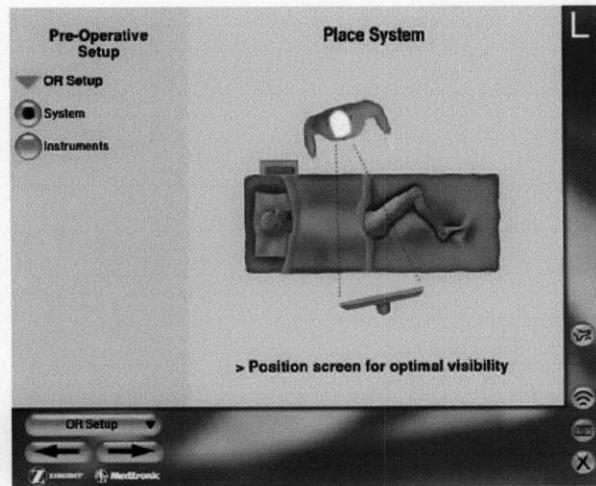


19

468

**RECOMMENDED SYSTEM AND CONNECTOR 20
BOXPLACEMENT**

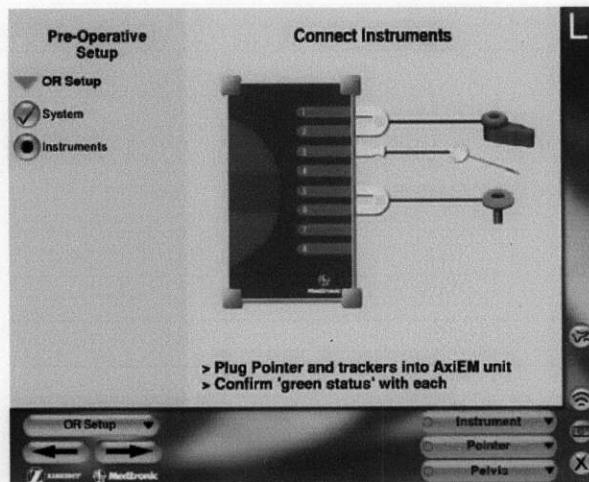
1. Place the AxiEM™ Unit to the side of the patient's head on the opposite side of the scrub nurse's table.
2. Move the touchscreen monitor into a position where both the surgeon and the assistant can see the screen.
3. Hang the Navigation Probe Interface (AxiEM™ Connector Box) on the operating table side rail.



CONNECT INSTRUMENTS

Plug the instruments into any open port on the Connector Box.

- ⚠ Inspect all probes and trackers for loose cabling or exposed wiring. Never use a device with wiring defects.
- ⚠ Do not simultaneously connect multiple low isolation instruments (for example, the Pointer). If the application software detects more than one low isolation instrument, a warning message displays instructing the user to disconnect one of the low-isolation instruments (not applicable to the portable AxiEM™ system).



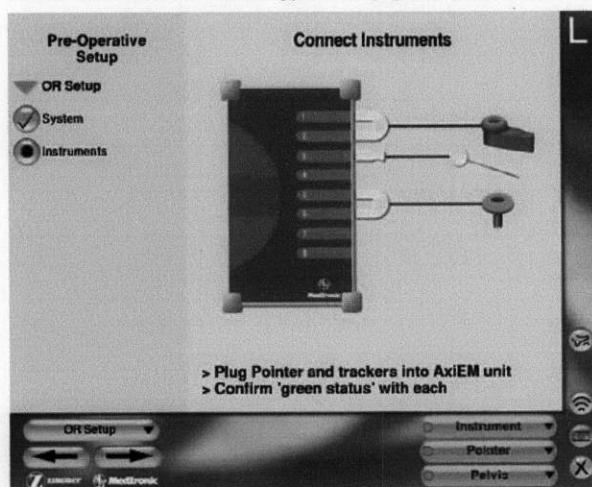
21

CONNECT INSTRUMENTS (CONT.)

22

1. Plug the AxiEM™ Pointer into an open port on the Connector Box.
2. Plug the AxiEM™ Pelvis Tracker's connector into two open ports on the Connector Box.
3. Plug the AxiEM™ Instrument Tracker's connector into two open ports on the Connector Box.
4. Make sure the indicator lights on the Connector Box change from orange to green indicating a successful connection for each instrument.

Note: The Zimmer Imageless Hip for AxiEM™ application only tracks one tracker of each type at any given moment in time.



**SWITCHING INSTRUMENTS DURING THE
PROCEDURE**

You may replace ("hot swap") an instrument at any time during the procedure.

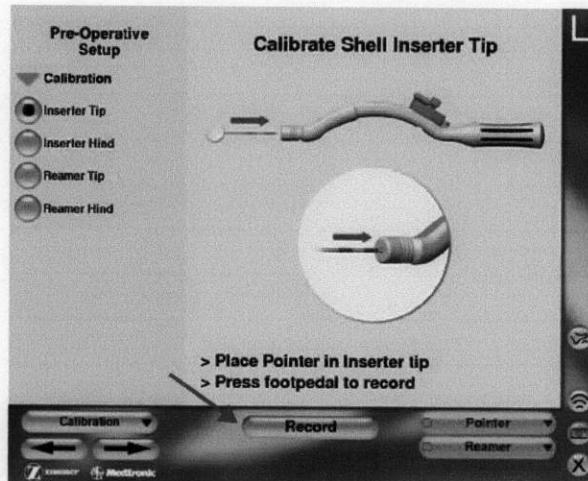
1. Unplug the instrument you wish to replace from the Connector Box.
2. Plug the new instrument into the open port on the connector box.
3. Make sure the indicator light on the Connector Box changes from orange to green indicating a successful connection.
*If you switch pelvis trackers after the **Digitize Pelvic Landmarks** task, the application software will prompt you to confirm switching trackers and that all landmarks saved with the tracker being replaced will be cleared.*
If you switch instrument trackers after calibration, the application software will prompt you to confirm switching trackers and that all instrument calibration data will be cleared.

23

CALIBRATE SHELL INSERTER

24

1. Attach the AxiEM™ Instrument Tracker to the Shell Inserter.
 - a. If necessary, wipe clean the handle attachment site.
 - b. Slide the AxiEM™ Instrument Tracker onto the pins located on the Inserter handle.
 - c. Tighten the AxiEM™ Instrument Tracker mounting screw.
2. Make sure that the AxiEM™ Instrument Tracker is plugged into the Connector Box and the status indicator is green.
3. Make sure the AxiEM™ Pointer is plugged into the Connector Box and the status indicator is green.
4. Attach the calibration tip to the Shell Inserter.

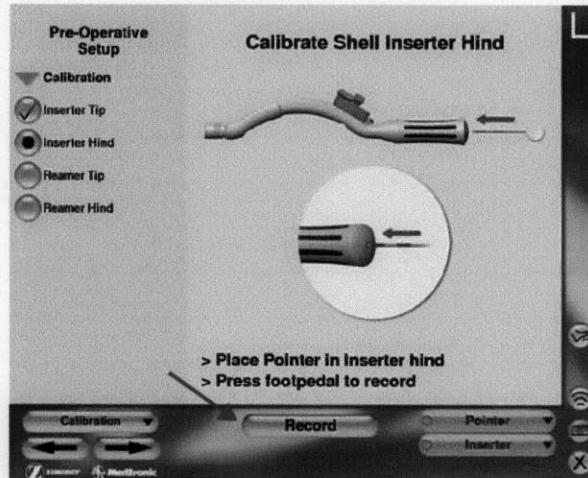


CALIBRATE SHELL INSERTER (CONT.)

5. **Insitzer Tip** - Place the tip of the AxiEM™ Pointer in the pivot located in the calibration tip, hold the pointer steady, and press the footswitch or click the [Record] button.
6. **Insitzer Hind** - Place the tip of the AxiEM™ Pointer in the pivot located in the hind of the Insitzer handle, hold the pointer steady, and press the footswitch or click the [Record] button.

The system emits a positive audio tone (bink) for the Tip and Hind steps when the calibration point is successfully recorded.

The application software displays an error message and the system emits a negative audio tone (bonk) if the attempted calibration point is more than 4mm from the nominal position.

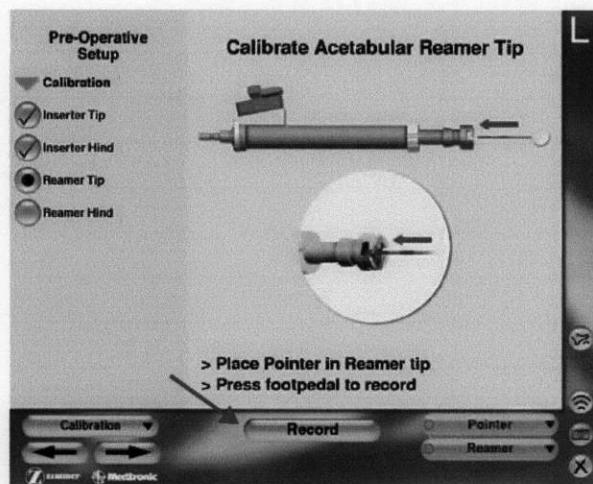


25

CALIBRATE ACETABULAR REAMER

26

1. Attach the AxiEM™ Instrument Tracker to the Reamer Handle.
 - a. If necessary, wipe clean the handle attachment site.
 - b. Slide the AxiEM™ Instrument Tracker onto the pins located on the Reamer Handle and Tighten the AxiEM™ Instrument Tracker mounting screw.
2. Make sure that the AxiEM™ Instrument Tracker is plugged into the Connector Box and the status indicator is green.
3. Make sure the AxiEM™ Pointer is plugged into the Connector Box and the status indicator is green.

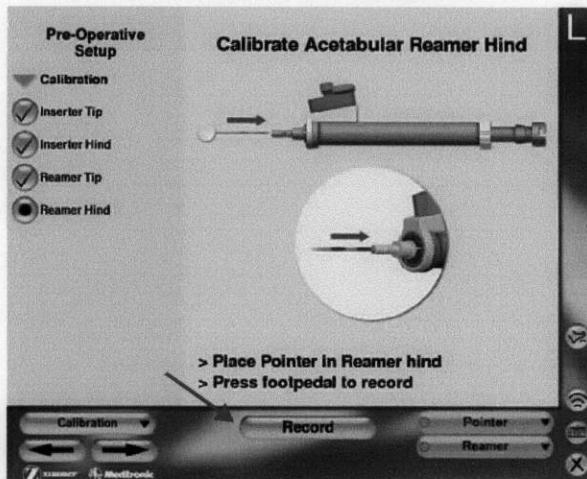


CALIBRATE ACETABULAR REAMER (CONT.)

4. **Reamer Tip** - Place the tip of the AxiEM™ Pointer in the divot located in the tip of the Reamer shaft, hold the pointer steady, and press the footswitch or click the [Record] button.
5. **Reamer Hind** - Place the tip of the AxiEM™ Pointer in the divot located in the hind of the Reamer shaft, hold the pointer steady, and press the footswitch or click the [Record] button.

The system emits a positive audio tone (bink) for the Tip and Hind steps when the calibration point is successfully recorded.

The application software displays an error message and the system emits a negative audio tone (bonk) if the attempted calibration point is more than 4mm from the nominal position.



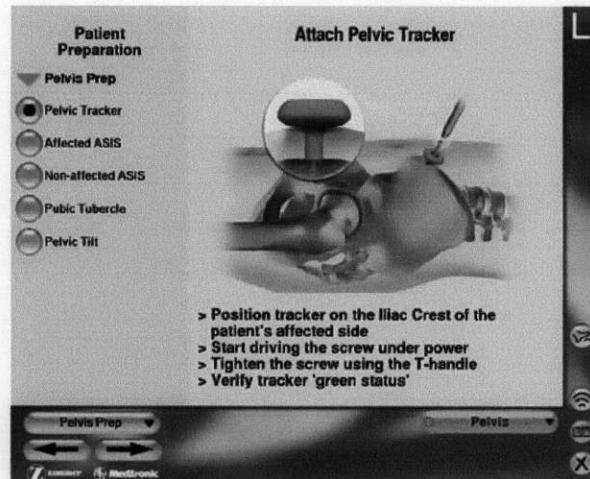
27

ATTACH PELVIS TRACKER

28

Attach the AxiEM™ Pelvis Tracker to the patient's iliac crest.

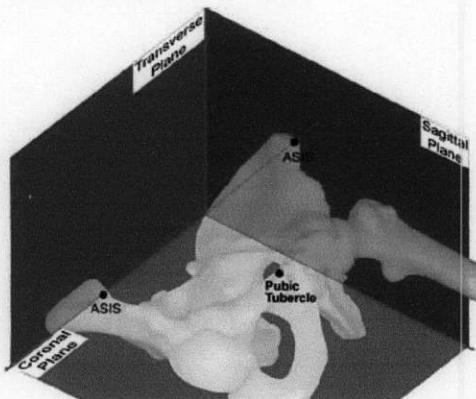
1. Make a small incision at the attachment location.
2. Place the tracker cannula through the incision onto the iliac crest so that the tracker's mounting teeth contact bone.
3. Drive the mounting screw into the bone under power.
4. Tighten the screw by hand with the ratcheting T-handle.
5. Make sure that the Pelvis Tracker status indicator is green.



LANDMARKS AND COORDINATE SYSTEM

△ The patient-specific coordinate system created by the software from user-identified landmarks assumes typical anatomy at the landmark sites. Significant deformity or irregularity at these sites may produce unexpected navigation angles.

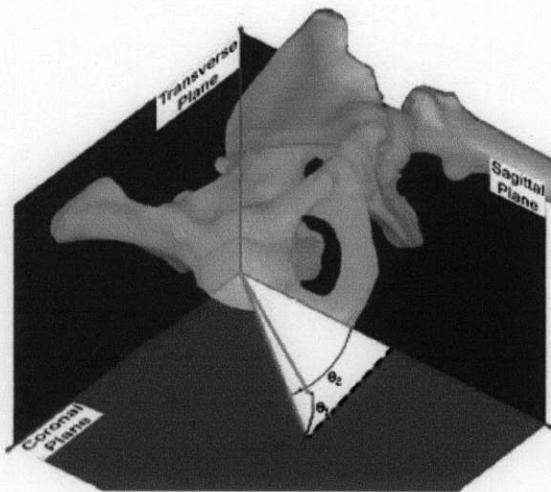
The Anterior Pelvic Plane (APP) can be described as the coronal plane passing through both Anterior-Superior Iliac Spine points and both Pubic Tubercles. The sagittal plane is perpendicular to the APP along the midline of the body. And the transverse plane is perpendicular to the APP and Sagittal planes. The anteversion and inclination values reported by the application software are directly related to the orientation of the surgical instrument with respect to these planes. The diagram below shows the anatomic planes constructed by the landmarks.



29

LANDMARKS AND COORDINATE SYSTEM (CONT.) 30

The angle θ_1 in the image below (known as radiographic anteversion) is the acetabular anteversion value reported by the application software. This is the angle between the axis of the shell implant (normal to the face of the shell) and the anterior coronal plane. The angle θ_2 (also known as radiographic inclination) is the acetabular inclination value reported by the application software. This is the angle between the projection of the surgical instrument onto the coronal plane and the SI axis of the pelvis.



LANDMARKS AND COORDINATE SYSTEM (CONT.)

Nominal accuracy of angle measurements displayed by the software is obtained if the anterior pelvic plane landmarks are recorded without soft tissue between the probe tip and the bone or with equal amounts of soft tissue covering each landmark. The accuracy of angle measurements will be affected by how accurately the landmarks are recorded. If the landmarks cannot be closely palpated on soft tissue and accurately recorded, percutaneous landmarking may be performed through a puncture or small incision. Proper sterile preparation of the landmark sites should be considered based on the landmarking method chosen.

Published data has indicated that landmarking on the skin could cause misinterpretation of measured angles by up to about 3° under normal conditions as compared to percutaneous landmarking¹. While the angle calculations in the software are less sensitive to variation in the location of the ASIS landmarks than to differences in the soft tissue depth over landmarks, care should be taken to record the ASIS points symmetrically on the patient.

¹Richolt JA, et al, "How Does Soft Tissue Distribution Affect Anteversion Accuracy of the Palpation Procedure in Image-Free Acetabular Cup Navigation? An Ultrasonic Assessment.", Computer Aided Surgery, March 2005; 10(2): 87-92.

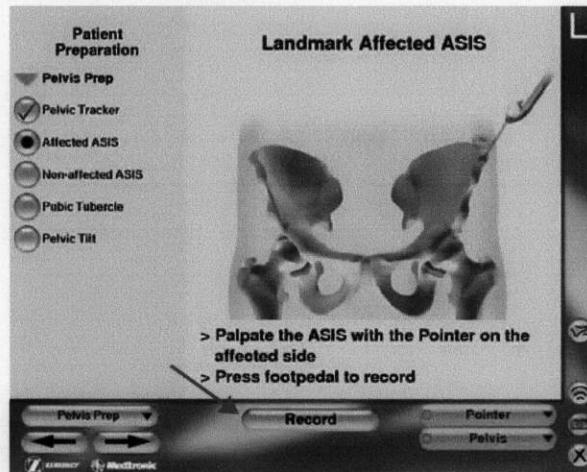
DIGITIZE PELVIC LANDMARKS

32

When digitizing landmarks, keep the Medtronic Logo on the emitter parallel to the floor. Do not rotate the AxiEM™ Mobile Emitter about its central axis. Make sure that the AxiEM™ Pointer and the Pelvic Tracker status indicators are green. If a tracker status indicator is red, the application software will not record landmarks.

1. Place the tip of the AxiEM™ Pointer on the affected anterior superior iliac spine (ASIS) and press the footswitch or click the [Record] button.

The system emits a positive audio tone (bink) when a landmark is successfully recorded and a negative audio tone (bonk) when a landmark is not recorded.

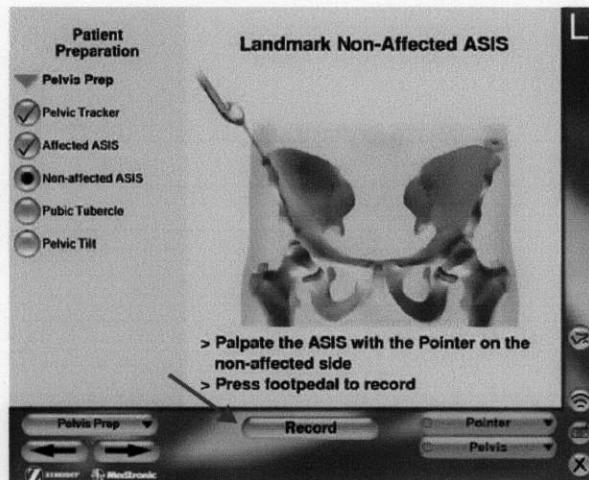


DIGITIZE PELVIC LANDMARKS (CONT.)

You may re-capture a landmark at any time during patient preparation by clicking the button to the left of the landmark and re-digitizing the landmark on the anatomy.

2. Place the tip of the Pointer on the non-affected ASIS and press the footswitch or click the [Record] button.

Note: The ASIS is actually a region of bone, not an exact point. The key to recording these two landmarks is to pick the same point within the ASIS region on both the affected and non-affected sides. Acetabular inclination will be most affected by the symmetry of these landmarks.



33

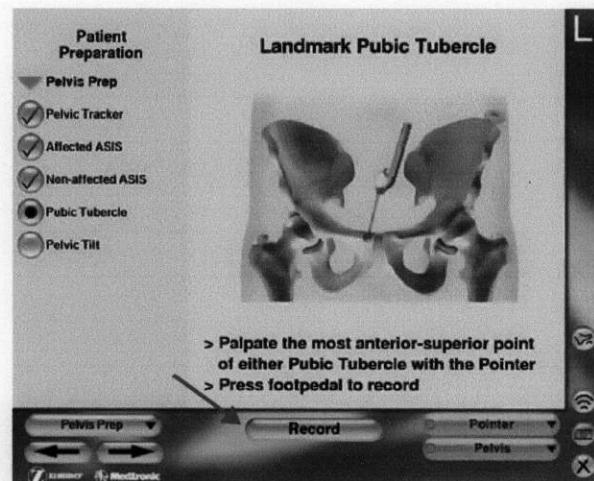
DIGITIZE PELVIC LANDMARKS (CONT.)

34

3. Place the tip of the Pointer on one of the pubic tubercles and press the footswitch or click the [Record] button.

Note: The pubic tubercles may be difficult to palpate so a point on the anterior-most aspect of the pubic bone may be used to establish the APP. Acetabular anteversion will be most affected by the depth of this landmark to the bone.

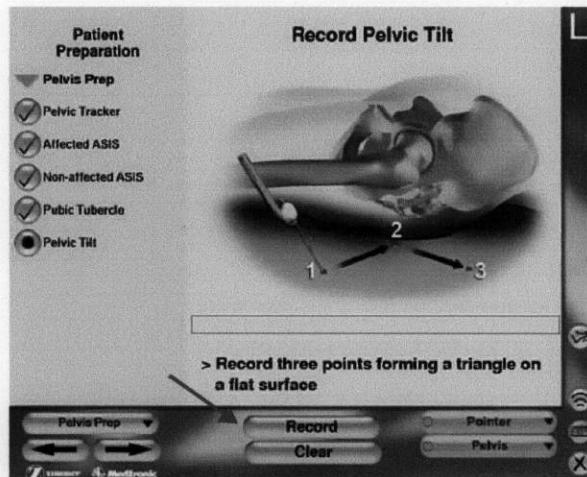
After successfully digitizing all pelvic landmarks, the application software automatically advances to the next task.



RECORD PELVIC TILT

The digitized points used to estimate Pelvic Tilt must be at a minimum distance of 100mm from each other and must form a near-triangular shape (they must not lie in a straight line). The software will report the angles between the patient's anterior pelvic plane and the plane digitized during this step to approximate the patient's natural pelvic tilt.

1. Hold the AxiEM™ Pointer on the table (supine) or back support (lateral) and press the footswitch or click the [Record] button.
2. Move the pointer to a second location (at least 100mm away) and press the footswitch or click the [Record] button.



35

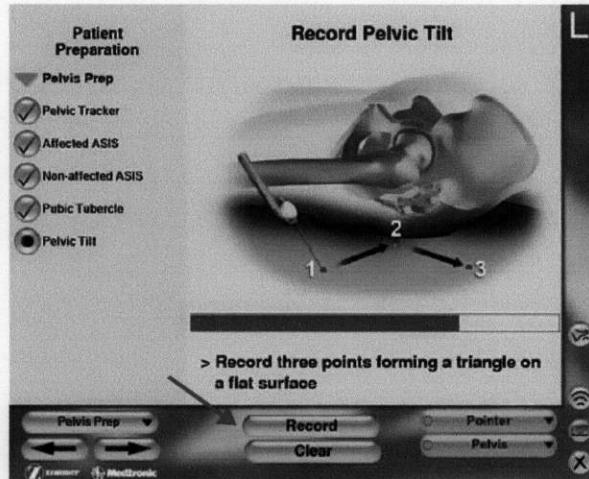
RECORD PELVIC TILT (CONT.)

36

3. Move the pointer to a third location to form a triangle and press the footswitch or click the [Record] button.

You may re-capture the previous checkpoint by clicking [Clear] and re-digitize the checkpoint on the anatomy.

The software application will calculate the tilt (flexion/extension) of the pelvis relative to the digitized plane. During navigation, acetabular angles adjusted for A/P pelvic tilt are displayed in addition to the standard radiographic angles.

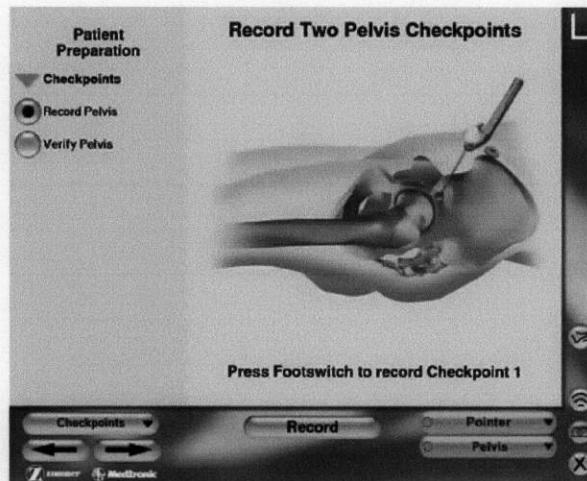


CREATE PELVIS CHECKPOINT

Digitize accuracy checkpoints to create a fixed reference used to determine if the AxiEM™ trackers have shifted with respect to the patient's anatomy at any time during the procedure.

1. Place the AxiEM™ Pointer on a recognizable anatomic point or user-created mark near the acetabulum
2. Hold the Pointer steady and press the footswitch or click the [Record] button. This records the pelvis checkpoint.

You may re-capture a checkpoint by clicking [Clear All Data] and re-digitizing the checkpoint on the anatomy.



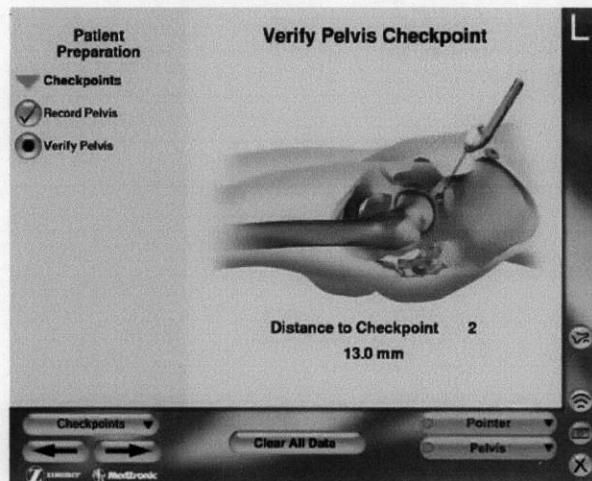
37

VERIFY PELVIS CHECKPOINT

38

1. Remove the Pointer from the navigation field and return it to the pelvis checkpoint
2. Observe the relationship between the position of the Pointer on-screen and its physical location on the anatomy. Observe the distance display and verify that the distance is less than 2mm.

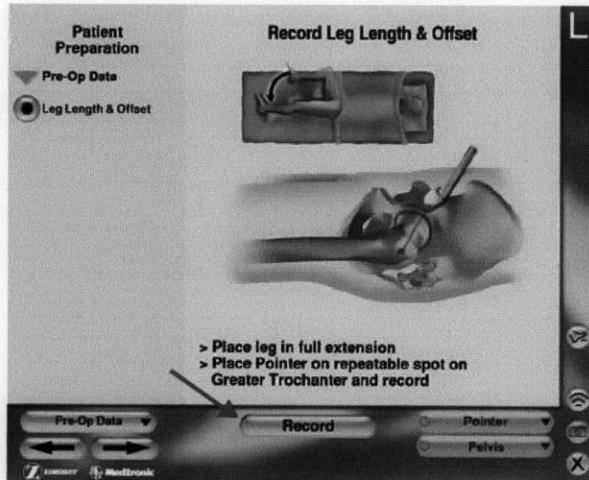
Note: if you suspect the Pelvis Tracker has moved or become dislodged during the procedure, return to the Checkpoint task and use the Pointer to verify that the checkpoint distance is still less than 2mm. If checkpoint verification fails, you may go back to the Pre-Operative Setup task and re-digitize landmarks.



RECORD PRE-OP LEG LENGTH AND OFFSET

1. Place the leg in full extension, parallel to the anterior pelvic plane. Make note of this leg position in order to return the leg to this position for post-op leg length and offset assessment.
2. Place the tip of the AxiEM™ Pointer on the apex of the greater trochanter.
3. Press the footswitch or click the [Record] button.

The system emits a positive audio tone (bink) when the pre-op data is successfully recorded and a negative audio tone (bonk) when the data is not recorded.



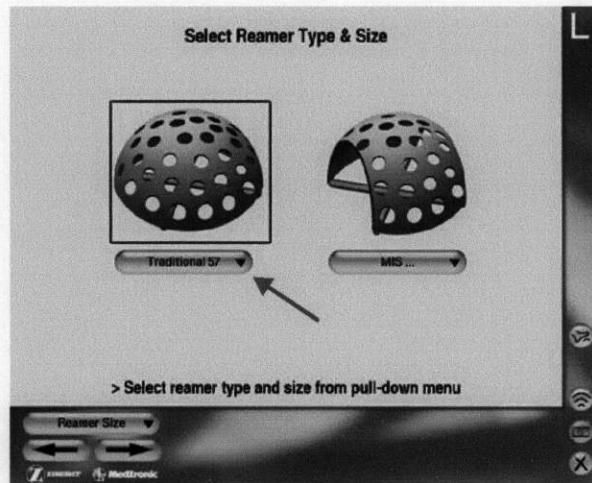
39

SELECT REAMER

40

Select the type and size of reamer to be used in the procedure.

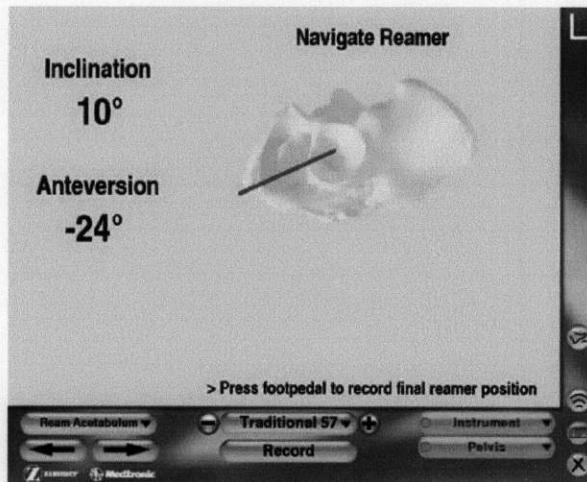
1. If you are using a traditional style (full dome) reamer, click [Traditional] to select the initial traditional reamer size.
2. If you are using the MIS style (truncated sides) reamer, click [MIS] to select the initial MIS reamer size.



NAVIGATE REAMER

When navigating, keep the Medtronic Logo on the AxiEM™ Mobile Emitter parallel to the floor. Do not rotate the emitter about its central axis. Make sure that the Pelvic Tracker status indicator is green, and that the acetabular reamer is selected and the status indicator is green.

1. Attach the correctly sized reamer dome to the reamer shaft.
Make sure that the dome is locked into the tip of the shaft.
2. Position the pelvic reamer in the anatomy.
Use the targeting values to orient the reamer to the target anteversion and inclination angles.



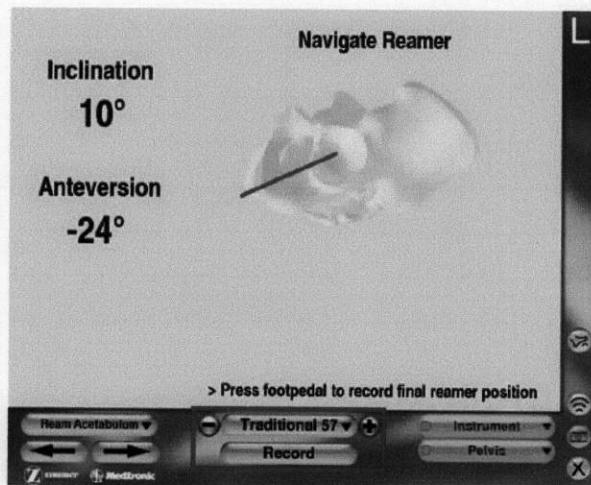
41

NAVIGATE REAMER (CONT.)

42

3. Ream the acetabulum according to standard surgical technique.
The software displays the real-time inclination and anteversion angles.
4. Make sure to increment the reamer size in the software using the pull-down menu or the [+] and [-] each time a new reamer shell size is used.
5. Click the **[Record]** button to record the final reamer position for the patient file.

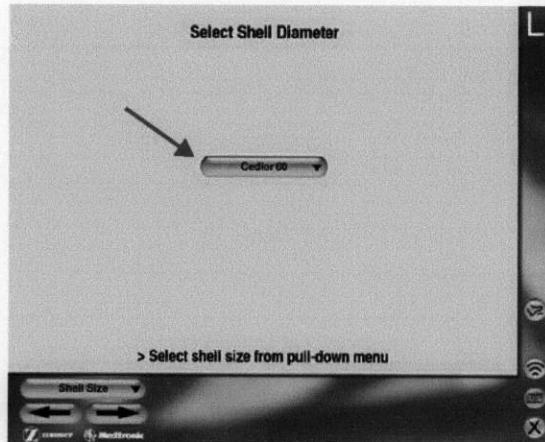
The final reamer position values are frozen on-screen.



SELECT SHELL SIZE

Select the size of the acetabular shell to be used in the procedure.

1. Select the shell size from the pull-down menu.



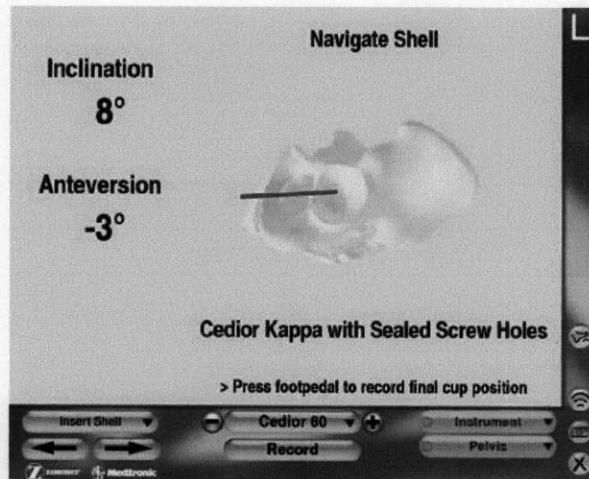
43

NAVIGATE SHELL

44

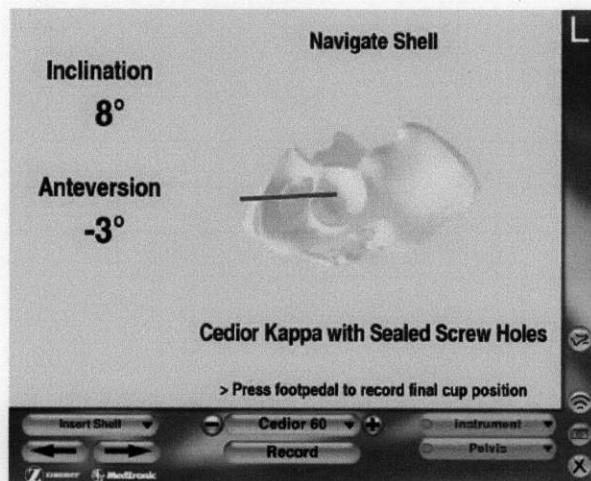
When navigating, keep the Medtronic Logo on the AxiEM™ Mobile Emitter parallel to the floor. Do not rotate the emitter about its central axis. Make sure that the Pelvic Tracker status indicator is green, and that the inserter is selected and its status indicator is green.

1. Make sure that the Pelvic Tracker status indicator is green.
2. Make sure the shell inserter is selected and the status indicator is green.
3. Attach the correctly sized acetabular shell to the inserter.



NAVIGATE SHELL (CONT.)

4. Insert the shell prosthesis into the anatomy.
Use the targeting views to orient the shell to the target anteverision and inclination angles.
5. Implant the prosthesis within the acetabulum using standard surgical technique.
6. Press and release the footswitch or click [Record] to freeze the final acetabular shell position in the software. Final position information displays on-screen.
7. Detach the implant from the inserter according to standard surgical technique, and remove the shell inserter.



45

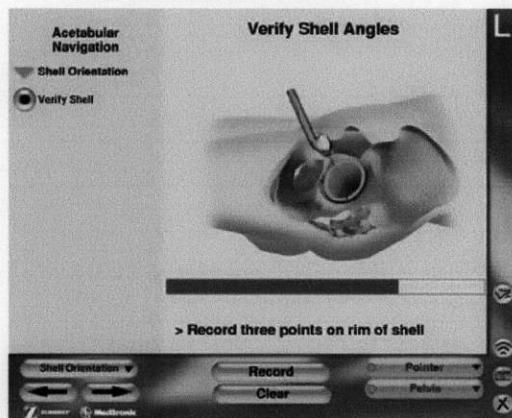
VERIFY SHELL

46

Verify that the acetabular prosthesis has not moved since insertion (for example, when inserting fixation screws) by digitizing three points in the face of the shell.

1. Place the AxiEM™ Pointer on a discreet point on the face of the implanted shell and press the footswitch or click [Record].
2. Place the AxiEM™ Pointer on another discreet point 20mm away from the first point on the face of the implanted shell. Press the footswitch or click [Record].
3. Place the AxiEM™ Pointer on a third discreet point 20mm away from the other points on the face of the implanted shell. Press the footswitch or click [Record].

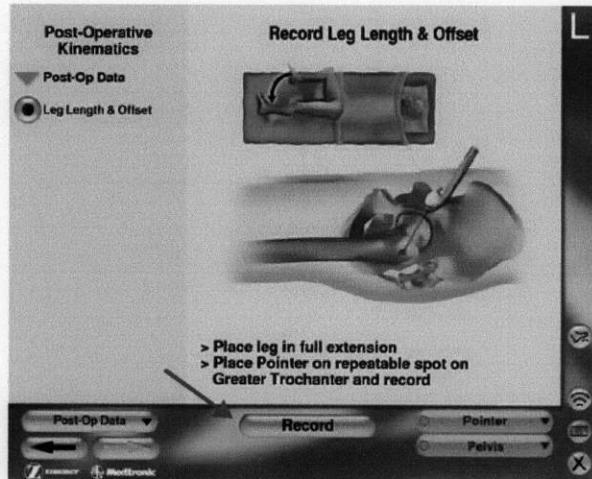
The application software displays the inclination and anteversion angles of the cup.



CAPTURE POST-OP LEG LENGTH & OFFSET

1. Place the leg in full extension, parallel to the anterior pelvic plane in the same manner and position that was used to record the pre-operative leg length and offset.
2. Place the tip of the AxiEM™ Pointer on the apex of the greater trochanter in the same spot used to record the pre-operative point.
3. Press the footswitch or click the [Record] button.

The application software displays the change in leg length and offset.



47

EXIT THE APPLICATION SOFTWARE

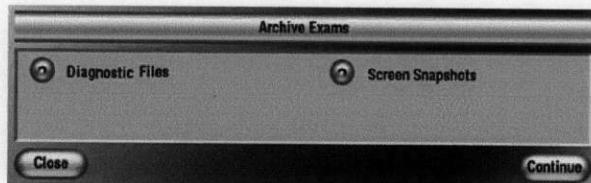
48

1. Click the **Exit** button in the main application window.
2. Click **[Yes]** to confirm that you want to exit.
The manage exams window displays.



ARCHIVE

1. Click **[Archive]** in the manage exams window.
2. Select each patient exam you wish to archive.
3. Choose which type of data you would like to archive.
 - a. Select **Screen Snapshots** to save the images you captured by clicking the snapshot button.
 - b. Select **Diagnostic Files** to save the software log and other diagnostic files created during the exam.
4. Insert an exam archive disk in the CD drive. Wait until the light on the drive stops blinking.
5. Click **[Continue]**. Wait while the OS software archives the selected images to the CD.
6. Click **[Close]** to close the archive exam window or click **[Back]** to return to the manage exams window.



49

REMOVE EXAMS

50

1. Click [Remove] in the manage exams window.
2. Select one or more patient exams. To deselect a patient exam, click it a second time.
3. Click [Remove] to permanently remove the selected exam(s) from the hard disk.



EXIT

1. Click [Exit] in the manage exams window and click [Yes] to confirm that you want to exit.
The log in screen displays.
2. From the log in screen, double-click the Shutdown icon. Wait until the system indicates it is okay to shut off the power.
3. Turn off the system power.



51

SYMBOLS

52



The device complies with European Directive MDD 93/42/EEC.



Classified by Underwriters Laboratories Inc. with respect to electric shock, fire, mechanical, and other specified hazards only in accordance with UL2601-1/CAN/CSA C22.2 NO.601.1. Control number 87HJ



When found in this guide, this symbol means: "Warning! Failure to observe could result in injury or death." When found on equipment, this symbol means: "Attention: consult accompanying documentation."



Caution! Failure to observe could result in damaged equipment, forfeited time or effort, or the need to abort use of the system.



Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.



Do not use in ambient (room) temperature greater than 30°C.



Use by date specified



Single use only. Do not reuse.



Quantity



STERILE EO Sterilized using ethylene oxide.



STERILE R Sterilized using irradiation.



Protective Earth (Ground)



Medtronic

AxiEM™ System Manual

Part Number 9660950, revision 5

***A Guide to Understanding the
AxiEM™ System***

***Read this manual completely prior to
using this device.***

R
X

502



MEDTRONIC NAVIGATION
826 COAL CREEK CIRCLE
LOUISVILLE, CO 80027
MAIN 720 890 3200
FAX 720 890 3500
TECHNICAL SUPPORT 800 595 9709
WWW.STEALTHSTATION.COM

[ECREP]

MEDTRONIC B.V.
EARL BAKKENSTRAAT 10
6422 PJ HEERLEN
NETHERLANDS
TEL 31 45 566 80 00

©2005 Medtronic.
All rights reserved.

503

Explanation Of Symbols On Package Labeling

The following symbols may appear on system equipment, system packaging, or in this reference guide.



The device complies with European Directive MDD 93/42/EEC.



Classified by Underwriters Laboratories Inc. with respect to electric shock, fire, mechanical, and other specified hazards only in accordance with UL2601-1/CAN/CSA C22.2 NO.601.1. Control number 87HJ.



Federal law (U.S.) restricts this device to sale by or on the order of a physician.



When found in this reference guide, this symbol means: "Warning! Failure to observe could result in injury or death." When found on equipment, this symbol means: "Attention: consult accompanying documentation."



Caution! Failure to observe could result in damaged equipment, forfeited time or effort, or the need to abort use of the system.



Type BF applied part, in compliance with IEC60601-1.



Type B applied part, in compliance with IEC60601-1.



Fragile contents



Keep upright



Keep dry



Power on. Connect to main power.



Power off. Disconnect from main power.



Power on for part of the system (typically energizes the Isolation Transformer and UPS).

504



Power off for part of the system.



Freeze caster



Lock caster angle



Use by date specified



Single use only. Do not reuse.



Quantity



Sterilized by ethylene oxide



Non-sterile



Protective Earth (Ground)



Connect system footswitch here.



Do not allow contact with patient. Temperature may exceed limits.



Localizer must not be used in ambient temperatures greater than 35°C (95°F).



Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations. See <http://recycling.medtronic.com> for instructions on proper disposal of this product.

505

Table of contents

Table of contents

1. Introduction

- Description of the AxiEM™ System 1-2
- Content of This Manual 1-2
- Related Documents 1-2
- Conventions 1-2
- Intended Use 1-3
- Contraindications 1-3
- Warnings and Precautions 1-3
- Contact Information 1-6
- Patents 1-7

2. System Overview

- How the System Works 2-2
 - Electromagnetic (EM) Localization System 2-2
 - System Carts 2-3
 - Input/Output Panel 2-5
 - Touchscreen Monitor 2-7
 - Keyboard and Mouse 2-7
 - Instruments 2-7
- System Specifications 2-7
- System Classifications 2-8
- System Electromagnetic Emissions and Immunity Declarations 2-9
- System Set Up 2-14

3. Inside the Cart

- Component Locations 3-2
- Opening the Viewing Cart 3-4
- Opening the Nav Cart 3-5
- Docking and Separating the Carts 3-5
- Component Connections 3-6
 - System Computer 3-6
 - Device Connectivity Diagrams 3-8

A. Index

Table of contents

List of figures

- Figure 2-1.** Viewing Cart 2-4
- Figure 2-2.** Nav Cart 2-5
- Figure 2-3.** Navigation Probe Interface 2-5
- Figure 2-4.** System I/O panel 2-6
- Figure 3-1.** Interior of Viewing Cart (Front) 3-2
- Figure 3-2.** Interior of Viewing Cart (Back) 3-3
- Figure 3-3.** Interior of Nav Cart 3-4
- Figure 3-4.** Device ports (standard system) 3-7
- Figure 3-5.** Device ports (Plus system) 3-7
- Figure 3-6.** View Cart connectivity - standard model system 3-9
- Figure 3-7.** View Cart connectivity - plus model system 3-10
- Figure 3-8.** Nav Cart connectivity 3-11

Introduction

1

Description of the AxiEM™ System 1-2

Content of This Manual 1-2

Related Documents 1-2

Conventions 1-2

Intended Use 1-3

Contraindications 1-3

Warnings and Precautions 1-3

Contact Information 1-6

Patents 1-7

AxiEM™ System Manual

1-1

510

Page 86 of 877

Introduction

Description of the AxiEM™ System

The AxiEM™ system is the hardware platform that enables real-time surgical navigation using radiological patient images. The software application reformats patient-specific CT or MR images acquired before surgery and displays them on-screen from a variety of perspectives (axial, sagittal, coronal, oblique). Prior to operating, the surgeon may then create, store, and simulate progression along one or more surgical trajectories. As an aid to visualization, the surgeon may also create and manipulate one or more 3D models of the anatomy. During surgery, the system tracks the position of specialized surgical probes in or on the patient anatomy and continuously updates the probe position on these images.

If desired, the application can also show how the actual position and path during surgery relate to the pre-surgical plan, and can help guide the surgeon along the planned trajectory. While the surgeon's judgement remains the ultimate authority, real-time positional information obtained through the AxiEM™ system can serve to validate this judgement as well as guide.

Content of This Manual

This system manual is intended as a reference document for users who require familiarity with and details about the AxiEM™ system. This manual is not an application usage manual. For complete instructions on using a specific software application, refer to the specific application reference guide.

Related Documents

Consult the application-specific Reference Guide for application-specific instructions.

Refer to manufacturer's guides for information on peripheral devices. Additional documentation on parts designated as user-repairable may be made available to qualified technicians upon request.

Conventions

This document employs the following conventions:



- Warnings are indicated by the symbol at left. Failure to observe a warning may result in physical injury to the patient or operator. Pay special attention to these items.



- Cautions are indicated by the symbol at left. Failure to observe a caution could result in damaged equipment, forfeited time or effort, or the need to abort use of the system.

- ◆
 - Procedures are preceded by diamond symbol at left
 - References to buttons that appear on the system display are enclosed in square brackets. For example:
Click the [Edit...] button.
 - References to menu options that appear on the system display are printed in bold letters. For example:
Choose **Clear** from the list.
 - Instructions to click an object on the screen means to tap the object on the touchscreen with your finger or some other blunt object. Alternatively, it means to place the pointer over the object using the system mouse, and depress and release the left mouse button. Click, Select, and Highlight are used interchangeably.
 - Right-click means click with the right mouse button instead of the left button.
 - Double-click means click twice in rapid succession.

Intended Use

Your Medtronic computer-assisted surgery system and its associated applications are intended as an aid for locating anatomical structures and planning surgical trajectories in open and percutaneous procedures. Their use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure can be identified relative to diagnostic images of the anatomy.

Contraindications

Medical conditions which contraindicate the use of a Medtronic computer-assisted surgery system and its associated applications include any medical conditions which may contraindicate the medical procedure itself. This may include pregnancy, for example, since surgery itself poses grave risks to the developing fetus.

Warnings and Precautions



Warnings:

- The system and its associated applications should be used only by qualified medical professionals who are thoroughly trained and experienced in performing surgery with Medtronic computer-assisted surgery systems.

Introduction

Warnings and Precautions

- The system and its associated applications should be used only as an adjunct for surgical guidance. They are not a replacement for the surgeon's knowledge, expertise, or judgement.
- If system navigation seems inaccurate and recommended steps to restore accuracy are not successful, abort use of the system.
- Accessory equipment connected to the analog and digital interfaces of the Medtronic computer-assisted surgery system must be certified according to the respective IEC standards (e.g. IEC 60601-1 for medical equipment). Furthermore all configurations shall comply with the system standard IEC 60601-1-1. Any person who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible for ensuring that the system complies with the requirements of the system standard IEC 60601-1-1. If in doubt, contact technical support or your local representative.
- The system is not suitable for use in the presence of a flammable, anesthetic mixture with air or oxygen or nitrous oxide. Position the system at least 25cm from any source of flammable gas.
- Some system components may contain batteries. Batteries can explode if mishandled. Do not recharge or disassemble batteries. Do not dispose of batteries in fire. Observe local regulations concerning battery disposal.
- Discard before use any pre-sterilized component whose sterile packaging appears to be compromised.
- There is currently no effective sterilization method for components that are tainted with the virus that causes Creutzfeld-Jakob Disease (CJD). Therefore, you must discard immediately after surgery any components that come into contact with biologic material from patients who carry or are suspected to carry this virus. As a precaution, drape all non-disposable components that could otherwise come into contact with such material.
- The AxiEM™ system has been tested for compatibility with the following Medtronic® implantable cardiac device families:
 - Marquis™
 - Gem III™
 - Kappa™
 - Sigma™
 - EnPulse™
 - EnRhythm™

– EnTrust™

Testing indicates that the AxiEM™ system does not adversely affect the function of these devices and does not constitute a patient hazard.

However, the system may interfere with the programming or interrogating of these implantable devices and any other implantable device. Do not use the AxiEM™ system while programming or interrogating any implantable device.

- Before use, examine each disposable instrument for damage, deterioration, and abuse. Discard any defective instrument.



Cautions:

- Metallic objects in or near the navigation field can degrade navigational accuracy. If metallic distortion causes excessive error, navigation will be disabled. To restore navigation, remove metallic objects from the navigation field.
- Electrical noise in or near the navigation field can degrade navigational accuracy. If electrical noise introduces excessive error, the system will automatically disable navigation. To restore navigation, remove devices that produce electrical noise (such as electro-cautery equipment and electric drills) from the navigation field.
- The AxiEM™ system supports the use of two different classes of instrument: those with detector coils embedded in the instrument handle and those with detector coils located at or near the instrument tip. The EM Sylet (pn 9731133) is an example of a tip-tracked instrument. For reasons of electrical safety, you should connect only one tip-tracked instrument to the Navigation Probe Interface at a time. If two or more such instruments are connected, navigation will be disabled and you will be asked to disconnect one of the instruments.
- The system has been successfully tested against the requirements of IEC 60601-1-2. However, RF interference could hamper its operation or the operation of other nearby electrical devices. If you suspect either of these conditions, move the conflicting equipment farther apart, separate the equipment with an RF barrier, or discontinue use of the system.
- Do not exceed the recommended electrical ratings for the system. Exceeding the ratings could damage the system.
- The system and its associated applications contain no user-repairable parts. For repair or replacement of any part of the system or application, contact a technical support representative.
- Before moving the system cart(s), shut down all components, remove any loose items from the top of the cart(s), and dock the carts together (if applicable). To avoid contaminating the inside of the cart(s), clean the power cord(s) before retracting.
- The system mouse is not designed for sterilization, and may be damaged if sterilization is attempted.
- Cart storage drawers have a maximum load capacity of ten pounds each.

Introduction

Contact Information

- System components, including the Localizer, are fragile. Use care when handling system components.

Contact Information

Telephone technical support is available at no cost to customers covered under a system warranty or service contract.

Telephone

- Within the United States:
 - (800) 595-9709 (technical support)
 - (720) 890-3200 (general)
- Outside the United States, contact your local representative.

Medtronic E.C. Authorized Representative

Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
NETHERLANDS
Tel. 31 45 566 80 00

Fax

(720) 890-3500

World Wide Web

www.stealthstation.com

Regular Mail

Medtronic Navigation, Inc.
Attn: Customer Care
826 Coal Creek Circle
Louisville, CO, U.S.A.
80027

E-mail

E-mail product enhancement requests to: suggestions@stealthnavigator.com

Patents

One or more of the following patents may apply to your Medtronic computer-assisted surgery system and its associated applications. Patents are U.S. unless otherwise indicated.

4,722,056	5,186,174	5,251,127
5,305,203	5,383,454	5,389,101
5,494,034	5,592,939	5,603,318
5,748,767	5,772,594	5,836,954
5,851,183	5,868,675	5,871,445
5,891,034	5,913,820	6,021,343
6,076,008	6,118,845	6,146,390
6,165,181	6,167,145	6,190,395
6,226,548	6,235,038	6,236,875
6,340,363	6,347,240	6,348,058
6,370,224	6,374,134	6,374,135
6,379,302	6,381,485	6,402,762
6,434,415	6,434,507	6,463,319
6,470,207	6,474,341	6,477,400
6,491,699	0359773, 0469966, 0553246 (European)	
1,336,451 (Canadian)		

Other U.S. and Foreign Patents Pending.

Introduction

Patents

System Overview

2

How the System Works 2-2

System Specifications 2-7

System Classifications 2-8

**System Electromagnetic Emissions and
Immunity Declarations** 2-9

System Set Up 2-14

System Overview

How the System Works

How the System Works

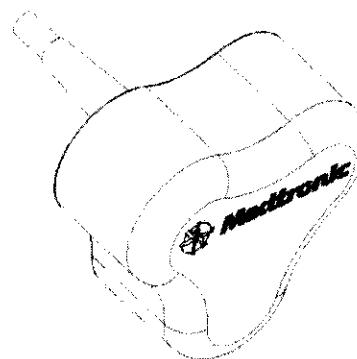
The AxiEM™ system creates a **translation map** between all points in the patient images and the corresponding points on the patient anatomy. After establishing this map, whenever the operator touches a point on the patient using a special tracked instrument or pointing device, the computer uses the map to identify the corresponding point on the images. This identification is called **navigation** or **localization**. A localized point is identified on the system display within multiple patient image planes and other anatomical renderings.

Electromagnetic (EM) Localization System

To enable navigation, the AxiEM™ system must be able to detect both the position of the anatomy and the position of the surgical instrument. Knowing the location of these two items allows the system to compute and display the position of the instrument *in relation* to the anatomy. The AxiEM™ system employs an electromagnetic localization system (**EM localization system**) to track the instrument and anatomy simultaneously.

The EM localization system works like this: a **Localizer** (also known as the **Transmitter Coil Array**, or **TCA**) is placed under the patient's head, encompassing the head in a cubical, low-energy magnetic field called the **navigation field**. Because every point in the navigation field has a unique field strength, the system can determine the position of a tracking device by measuring the field strength at that location. The **Dynamic Reference Frame (DRF)** you affix to the patient's skull identifies the location of the anatomy in the field. Similarly, a detector embedded in the pointer probe or other instrument measures the instrument's position and trajectory in the field.

The system continuously re-computes the relative spatial positions of the DRF and instrument in the navigation field, and relates this information to the **patient registration** data in order to identify the location of the probe on the preoperative images.



Dynamic Referencing

To maintain accuracy, the system must continuously track the position of the anatomy during registration and navigation. This is necessary because you may accidentally or unavoidably move the anatomy or Localizer after patient registration. If the system did not track the position of the anatomy via the dynamic reference frame, any movement of the patient or Localizer after registration or image acquisition would result in inaccurate navigation.

System Carts

The AxiEM™ system has two separate but complementary carts; the **Viewing Cart** and the **Nav Cart**. The carts may be docked together as a single unit, or separated for positional flexibility and convenience during surgery. The system carts are suitable for continuous operation.

The Viewing Cart contains the power supply, computer, touchscreen monitor, and all related peripheral devices. The Viewing Cart is the station from which the surgeon or qualified assistant controls the AxiEM™ system. Because it contains everything except the EM localization system, the Viewing Cart may be used as a stand-alone surgical planning station. See Figure 2-1.

The Nav Cart houses the houses the EM localization system components (see Figure 2-2), including the Localizer's Control Unit and the Navigation Probe Interface (see Figure 2-3). You will connect the DRF and any probes you will use for navigation to the Navigation Probe Interface.

System Overview

How the System Works

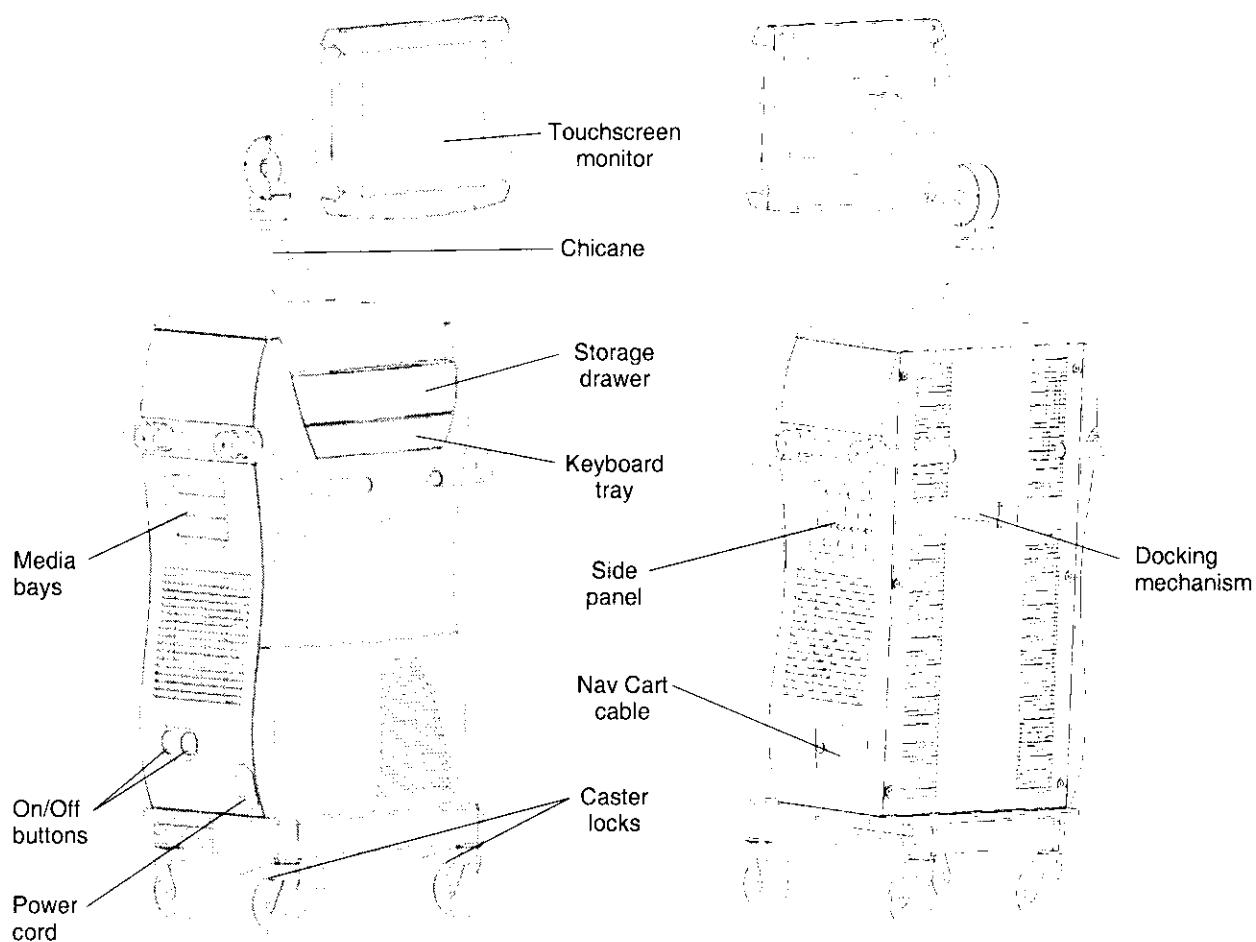


Figure 2-1. Viewing Cart

System Overview
How the System Works

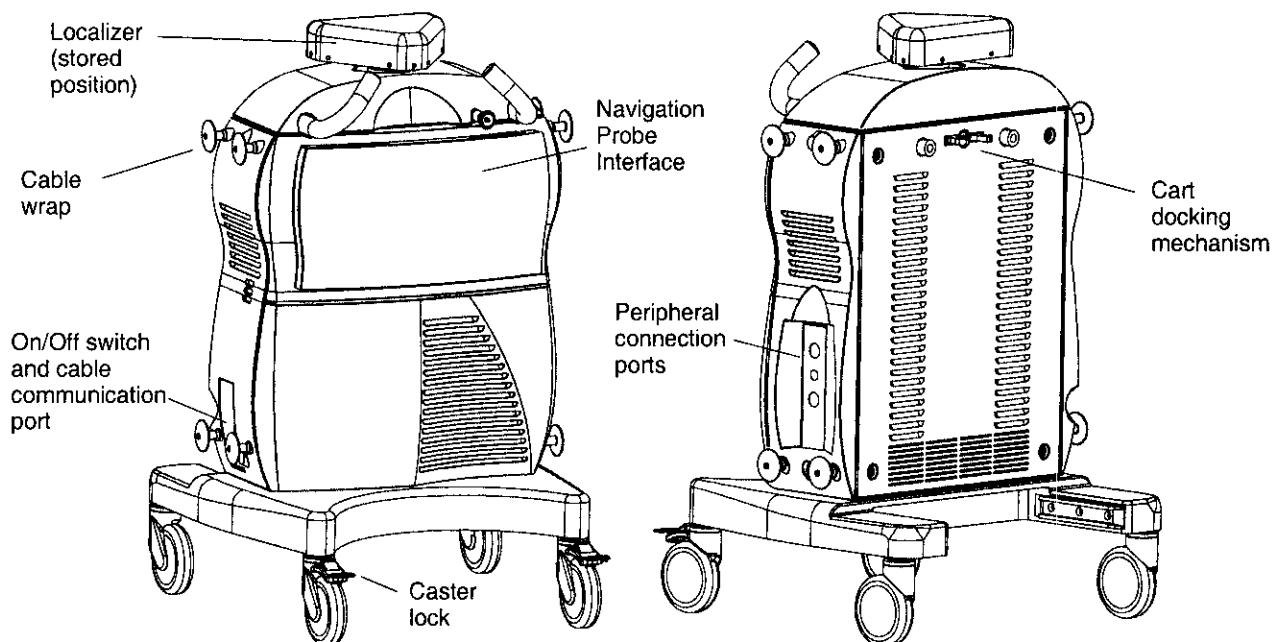


Figure 2-2. Nav Cart

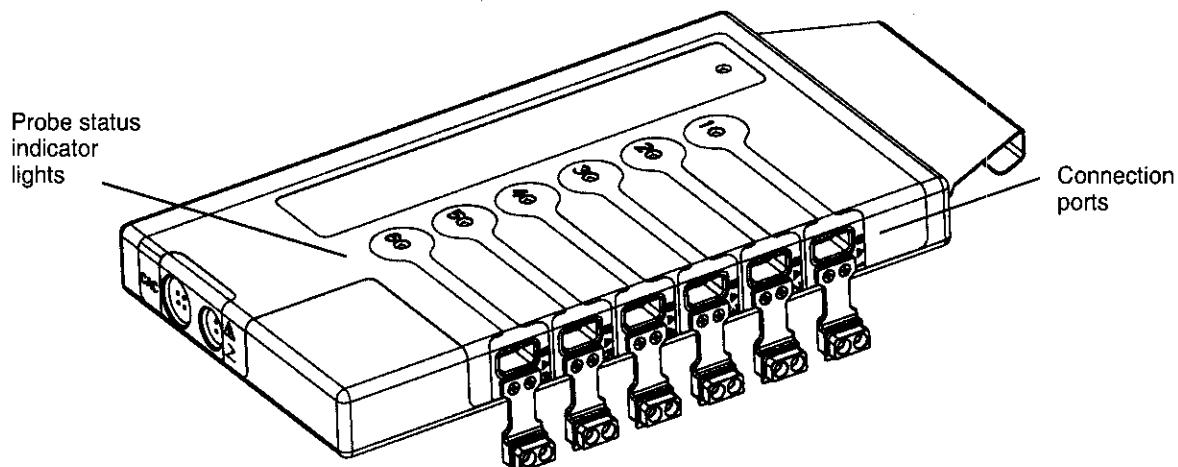


Figure 2-3. Navigation Probe Interface

Input/Output Panel

The right side of the cart contains a side panel with external connection ports for various input and output devices.

System Overview

How the System Works

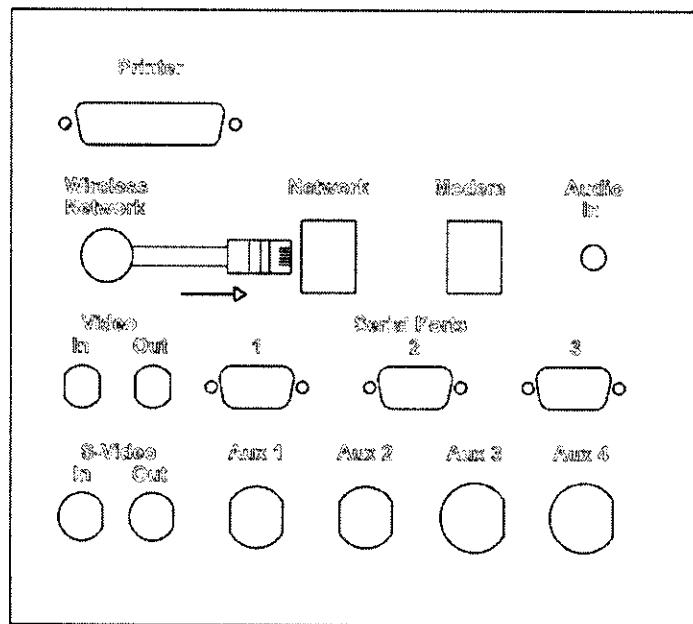


Figure 2-4. System I/O panel

Side panel connectors

Printer: Connects the system to a printer.

Network: Connects the system to the site Local Area Network (LAN).

Modem: Connects the system modem to an external telephone line.

Audio In: Connects the system to an audio input device such as a microphone.

Video In: Connects the system video input board to the composite video output of an external source.

Video Out: Connects the system video output to the composite video input of an external source.

S-Video In: Connects system video input to the S-VHS video output of an external source.

S-Video Out: Connects system video output to the S-VHS video input of an external source.

Serial Ports 1-3: Connects the system to external serial devices.

AUX 1-4: These ports are accessory ports for system expansion and are normally empty.

Wireless Network: Feature pending future development. When enabled, will connect the system to the site wireless network (where applicable). A network jack protruding from the Wireless Network Port connects to the Network connector. If the wireless network connection is interrupted, simply remove the Wireless Network jack and plug the Local Area Network into the Network connector.

Touchscreen Monitor

The touchscreen monitor is a high-resolution, flat panel computer display with built-in speakers. The display is visible at angles up to 80° from perpendicular. When placed in the surgical field, the touchscreen allows the physician to control the system without the need for an assistant, keyboard, or mouse. To select an item on the screen, tap the item with the sterilized stylus. For any software fields that require text entry, a virtual keyboard will appear on-screen with buttons that can be touched like a typewriter.

◆ **To dock the monitor:**

1. Adjust (push down) the articulating arm such that the arm button is in the lock position. There will be an audible click when the arm locks.
2. Adjust the monitor arm such that it is in the lock position. The lower elbow of the chicane will be at its closest point to the back of the system cart.
3. Rotate the monitor such that the face is pointing down.
4. Push the monitor down toward the back of the cart.

Keyboard and Mouse

Although the touchscreen eliminates the need for a keyboard and mouse, a keyboard and mouse are provided in the cart's lower storage drawer for use in certain circumstances. The drawer also features a built-in mouse tray.

Instruments

Instruments designed for use with the AxiEM™ system contain embedded field detectors that allow the system to determine their locations in the navigation field. All instruments are single-use only, and may not be re-used or re-sterilized. For instructions on the use of a specific instrument or accessory, refer to the package insert which accompanied the item or follow the instructions provided in the application reference guide.

System Specifications

The following tables outline the environmental and physical specifications of the AxiEM™ system.

System Overview

System Classifications

Table 2-1. Viewing Cart Specifications

	United States	International	Japan
Operating Temperature	64° to 92°F	18° to 33°C	18° to 33°C
Shipping and Storage Temperature	-40° to 150°F	-40° to 65°C	-40° to 65°C
Humidity	10% to 80% non-condensing		
Input Voltage	100 to 120 VAC 50 Hz to 60 Hz	220 to 240 VAC 50 Hz to 60 Hz	100 VAC 50 Hz to 60 Hz
Maximum Current Allowed	5.0 A	5.0 A	5.0 A
Nominal Power Dissipation	500 V-A		
Cart Dimensions	23 x 23 x variable height (in)	58.5 x 58.5 x variable height (cm)	58.5 x 58.5 x variable height (cm)
Cart Weight	330 lbs	150 kg	150 kg
Touchscreen	Screen pitch = 0.26 mm, resolution = 1280 x 1024 dpi, 60 Hz		
UPS	5 minutes autonomy		

Table 2-2. Nav Cart Specifications

	United States	International	Japan
Operating Temperature	64° to 92°F	18° to 33°C	18° to 33°C
Shipping and Storage	-20° to 140°F	-29° to 60°C	-40° to 65°C
Input Voltage	110 to 120 VAC 50 Hz to 60 Hz	220 to 240 VAC 50 Hz to 60 Hz	100 VAC 50 Hz to 60 Hz
Maximum Current Allowed	5.0 A	5.0 A	5.0 A
Nominal Power Dissipation	300 V-A		
Humidity	10% to 80% non-condensing		
Cart Dimensions	24 x 28 x 43 (in)	61 x 71 x 109 (cm)	61 x 71 x 109 (cm)
Cart Weight	150 lbs	68 kg	68 kg

System Classifications

Table 2-3. System classifications

Standard	Classification
European Medical Device Directive 93/42/EEC	Class IIa according to Rule 6, Annex IX
FDA Medical Device CFR part 21 882.4560	Class II
Electrical Safety Class EN60601-1/UL2601-V CAN/CSA-C22.2 No 601.1-M90	Class I, continuous operation with BF applied parts
Electromagnetic compatibility emissions EN60601-2	Class A, Group 1

System Overview
System Electromagnetic Emissions and Immunity Declarations

Table 2-4. Water ingress classifications

Component	Water Ingress Classification
View Cart	IPX0 (not protected)
Nav Cart	IPX0 (not protected)
Navigation Probe Interface	IPX0 (not protected)
Localizer	IPX2 (drip-proof)
Footswitch	IPX8 (water tight)
Instruments	IPX0 (not protected)

Warnings:

- Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (e.g. IEC 601-1 for medical equipment). Furthermore all configurations shall comply with the system standard IEC 601-1-1. Any person who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible for ensuring that the system complies with the requirements of the system standard IEC 601-1-1. If in doubt, contact your technical support representative.
- The AxiEM™ system is unsuitable for use in the presence of a flammable, anesthetic mixture with air or with oxygen or nitrous oxide. Position the AxiEM™ system at least 25cm from any source of flammable gas.



Caution: The AxiEM™ system has been successfully tested against the requirements of IEC 601-1-2 but the possibility remains that RF interference could hamper its operation, or that RF interference from the AxiEM™ system could hamper the operation of other nearby electrical devices. If you suspect either of these conditions, try moving the conflicting equipment farther apart, try separating the equipment with an RF barrier, or discontinue use of the AxiEM™ system.

System Electromagnetic Emissions and Immunity Declarations

Table 2-5. Guidance and Manufacturer's Declaration - Cables, Transducers, and Accessories

Medtronic Part Number	Description	Max. Possible Length (m)	Shielded (Y/N)
System Equipment			
9680159	Camera, Position Sensor Unit (PSU)	NA	NA
9731117, 9732610, 9732611, or 9731118	Monitor, 19"	NA	NA
1130700120	Monitor and Camera Ferrite	NA	NA
9680129	Keyboard	NA	NA

System Overview*System Electromagnetic Emissions and Immunity Declarations***Table 2-5. Guidance and Manufacturer's Declaration - Cables, Transducers, and Accessories**

The listed cables, transducers, and accessories have been determined by Medtronic to be compliant with the emissions and immunity requirements of IEC 60601-1-2: 2001.			
Medtronic Part Number	Description	Max. Possible Length (m)	Shielded (Y/N)
The listed cables, transducers, and accessories have been determined by Medtronic to be compliant with the emissions and immunity requirements of IEC 60601-1-2: 2001.			
Medtronic Part Number	Description	Max. Possible Length (m)	Shielded (Y/N)
System Equipment			
9680159	Camera, Position Sensor Unit (PSU)	NA	NA
9731117	Monitor, 19" HiBrite	NA	NA
1130700120	Monitor and Camera Ferrite	NA	NA
9680129	Keyboard	NA	NA
9680144	Mouse	NA	NA
9731332 or 9680162	Laser Pointer	NA	NA
9660700	EM NPI	NA	NA
Cables			
9680280	Power Cable	15 ft	No
9680177	Break-out Box with Cable	25 ft	No
9731736	Footswitch with Cable	10 ft	No
9680165	Power and Communication Cable	25 ft	Yes
9680141	Modem Cable	25 ft	No
9680142	Ethernet Cable	10 ft	No
9730750	Printer Cable	15 ft	No
Generic	Audio Cable	12 ft	No
963-809	BNC Video Cable (2x)	25 ft	No
Generic	S-Video Cable (2x)	12 ft	No
9731516	Calibration Target Cable	15 ft	No
9680232	Touchsite External Monitor Cable	18 ft	Yes
9660811	EM NPI Cable	25 ft	No
9660812, 9660501, or similar ***	EM TCA with Cable	20 ft	No
9660204 or similar **	EM Instrument	10 ft	No
963-719 or similar *	Optical Instrument	12 ft	No
9731086	Orthosoft Footswitch	17 ft	No
9731085	Orthosoft Keypad	15 ft	No
960-730, 960-486, 961-415, 960-442, 960-418, or similar****	Microscope Cables	25 ft	Yes
Accessories			

System Overview
System Electromagnetic Emissions and Immunity Declarations

Table 2-5. Guidance and Manufacturer's Declaration - Cables, Transducers, and Accessories

The listed cables, transducers, and accessories have been determined by Medtronic to be compliant with the emissions and immunity requirements of IEC 60601-1-2: 2001.

Medtronic Part Number	Description	Max. Possible Length (m)	Shielded (Y/N)
963-750, 963-781, 963-741, 963-745, or 9730259	Calibration Target	NA	NA
9732316	Wireless Surgeon Mouse	NA	NA
9732313	USB Wireless Antenna	NA	NA
* Any active or wireless active optical instrument has been qualified to IEC 60601-1-2: 2001			
** Any EM instrument has been qualified to IEC 60601-1-2: 2001			
*** Any EM TCA has been qualified to IEC 60601-1-2: 2001			
**** For use with Zeiss, Leica, Moller or Olympus microscopes			

Table 2-6. Guidance and Manufacturer's Declaration - Electromagnetic Emissions IEC 60601-1-2: 2001, Table 201

The AxiEM™ system is intended for use in the electromagnetic environment specified below. The customer or the user of the AxiEM™ system should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The AxiEM™ system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The AxiEM™ system is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations / Flicker Emissions IEC 61000-3-3	Complies	

Table 2-7. Guidance and Manufacturer's Declaration - Electromagnetic Immunity IEC 60601-1-2: 2001, Table 202

The AxiEM™ system is intended for use in the electromagnetic environment specified below. The customer or the user of the AxiEM™ system should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV Air	± 6 kV contact ± 8 kV Air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV Differential Mode ± 2 kV Common Mode	± 1 kV Differential Mode ± 2 kV Common Mode	Mains power quality should be that of a typical commercial or hospital environment.

System Overview*System Electromagnetic Emissions and Immunity Declarations***Table 2-7. Guidance and Manufacturer's Declaration - Electromagnetic Immunity IEC 60601-1-2: 2001, Table 202**

The AxiEM™ system is intended for use in the electromagnetic environment specified below. The customer or the user of the AxiEM™ system should assure that it is used in such an environment.				
Immunity Test	IEC 60601 Level	Test	Compliance Level	Electromagnetic Environment - Guidance
Voltage Dips, Short Interruptions, and Voltage Variations on Power Supply Input Lines IEC 61000-4-11	< 5% UT (> 95% dip in UT) for 0.5 cycle	< 5% UT (> 95% dip in UT) for 0.5 cycle	< 5% UT (> 95% dip in UT) for 0.5 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the AxiEM™ system requires continued operation during power mains interruptions, it is recommended that the AxiEM™ system be powered from an uninterruptible power supply or a battery.
	40% UT (60% Dip in UT) for 5 cycles	40% UT (60% Dip in UT) for 5 cycles	40% UT (60% Dip in UT) for 5 cycles	
	70% UT (30% dip in UT) for 25 cycles	70% UT (30% dip in UT) for 25 cycles	70% UT (30% dip in UT) for 25 cycles	
	<5% UT (> 95% Dip in UT) for 5 sec	<5% UT (> 95% Dip in UT) for 5 sec	<5% UT (> 95% Dip in UT) for 5 sec	
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	3 A/m	3 A/m	3 A/m	Power Frequency Magnetic Fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: UT is the a.c. mains voltage prior to application of the test level.				

Table 2-8. Guidance and Manufacturer's Declaration - Electromagnetic Immunity IEC 60601-1-2: 2001, Table 204

The AxiEM™ system is intended for use in the electromagnetic environment specified below. The customer or the user of the AxiEM™ system should assure that it is used in such an environment.				
Immunity Test	IEC 60601 Level	Test	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V		Portable and mobile RF communications equipment should be used no closer to any part of the AxiEM™ system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
				Recommended Separation Distance $d=1.2^* \sqrt{P}$ $d=1.2^* \sqrt{P}$ 80 MHz to 800 MHz
Radiated RF IEC 61000-4-3	3V/m 80 MHz to 2.5 GHz	3 V/m		$d=2.3^* \sqrt{P}$ 800 MHz to 2.5 GHz
				where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m)
				Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey*, should be less than the compliance level in each frequency range.**

System Overview
System Electromagnetic Emissions and Immunity Declarations

Table 2-8. Guidance and Manufacturer's Declaration - Electromagnetic Immunity IEC 60601-1-2: 2001, Table 204

The AxiEM™ system is intended for use in the electromagnetic environment specified below. The customer or the user of the AxiEM™ system should assure that it is used in such an environment.

Immunity Test	IEC 60601 Level	Test	Compliance Level	Electromagnetic Environment - Guidance			
				Interference may occur in the vicinity of equipment marked with the following symbol: 			
* Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the AxiEM™ system is used exceeds the applicable RF compliance level above, the AxiEM™ system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the AxiEM™ system.							
** Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m							
Notes: <ul style="list-style-type: none"> ■ At 80 MHz and 800 MHz, the higher frequency range applies. ■ These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people. 							

Table 2-9. Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the AxiEM™ system IEC 60601-1-2: 2001, Table 206

The AxiEM™ system is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the AxiEM™ system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the AxiEM™ system as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = 1.2 * \sqrt{P}$	$d = 1.2 * \sqrt{P}$	$d = 2.3 * \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Notes:			
<ul style="list-style-type: none"> ■ At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. ■ These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people. 			

System Overview

System Set Up



Cautions:

- The AxiEM™ system medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the EMC tables.
- Portable and mobile RF communications equipment can affect medical electrical equipment, such as the AxiEM™ system.
- The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by Medtronic as replacement parts for internal components, may result in increased emissions or decreased immunity of the AxiEM™ system.

System Set Up



Warnings:

- For electrical safety reasons, disconnect any local area network (LAN) cables from the AxiEM™ system before proceeding with system set up.
- Prevent fluid from entering any part of the AxiEM™ system. If you suspect fluid has entered any part of the unit, allow adequate dry time before connecting the system to power.



To set up and start the system:

1. Plug the Viewing Cart power cord into an electrical outlet.
2. Connect the communication cable from the Nav Cart to the Viewing Cart.
3. Connect the Localizer to the Nav Cart peripheral port labeled **TCA 1**.
4. Connect the Navigation Probe Interface to the Nav Cart peripheral port labeled **NPI** and secure it to the side rail of the operating table.
5. Connect the footswitch to the Navigation Probe Interface.
6. Plug the Nav Cart power cord into the power outlet.
7. Turn on the Nav Cart. (The switch is located next to the power cord.)
8. Press and briefly hold down the green power on button on the left side of the Viewing Cart.

The system will power-up and the login screen will appear when all boot-up diagnostics are complete.

9. Double-click the application icon to launch the software.



Inside the Cart

3

Component Locations 3-2

Opening the Viewing Cart 3-4

Opening the Nav Cart 3-5

Docking and Separating the Carts 3-5

Component Connections 3-6

Inside the Cart

Component Locations

Component Locations

Because the AxiEM™ system contains no user-repairable parts, the interior of the system is normally inaccessible. However, it may occasionally be necessary for a qualified service person to remove system panel(s) and access interior components. For example, it is necessary to remove cart panels in order to troubleshoot a connection problem or perform routine cleaning and maintenance.

Remove the lower front panel of the Viewing Cart to access the Isolation Transformer, Power Strip, and the Retractable Cord Assembly. Remove the upper front panel to access power supply ports for system accessories. Remove the back panel to access the A/V ports of the computer, modem, Uninterruptible Power Supply (UPS), and system cooling fan. Remove the right side panel to access the rear panel of the computer.

Figures 3-1 and 3-2 identify the principal components inside the Viewing Cart.

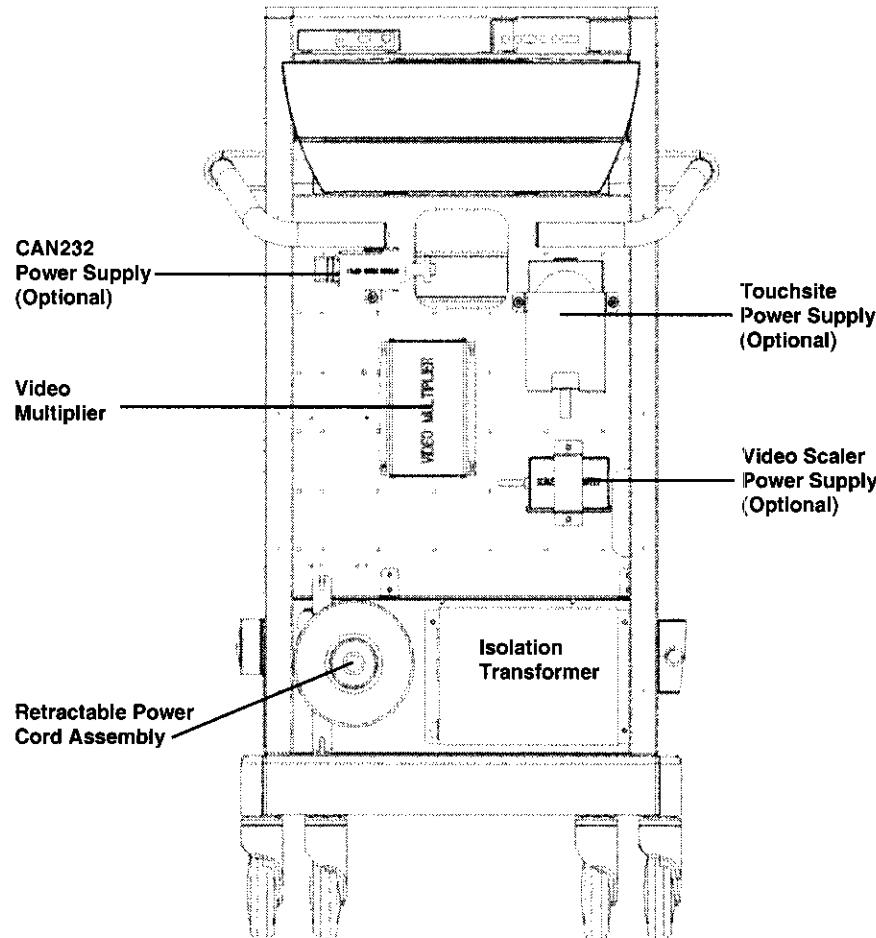


Figure 3-1. Interior of Viewing Cart (Front)

Inside the Cart
Component Locations

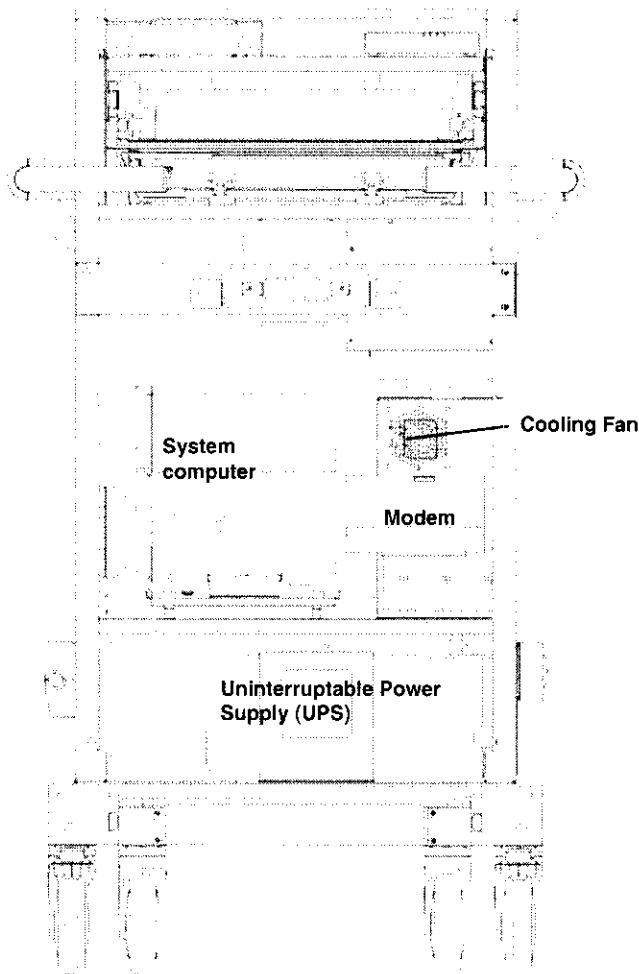


Figure 3-2. Interior of Viewing Cart (Back)

Remove the front panel on the Nav Cart to access the Control Unit connections. (The Control Unit is also sometimes called the CAC). The Control Unit uses the information gathered and processed by the Probe Interface Box to compute the point in space where the field strength of the receiver coil is equivalent to the known fields transmitted by the Localizer. Figure 3-3 identifies the location of the Control Unit.

Inside the Cart

Opening the Viewing Cart

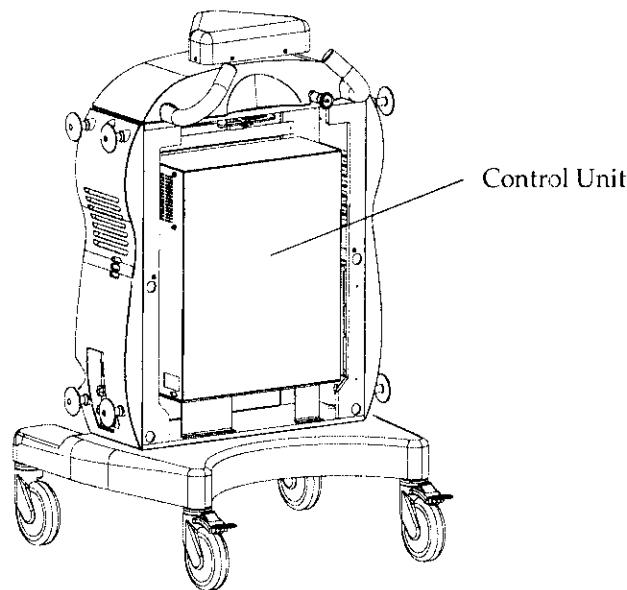


Figure 3-3. Interior of Nav Cart

Opening the Viewing Cart

To access the interior of the Viewing Cart, you must remove the appropriate cart panels. The front of the cart has a lower panel below the storage drawer and is held in place by ball stud connectors. The back of the cart has one single panel and is held in place by six Phillips head screws.

♦ **To remove the lower front panel:**

1. Place the flat end of standard screwdriver between the upper right corner of the panel and the cart frame. Use the tool as a lever to pop the panel corner off of the connecting ball stud.
2. Grasp the top of the panel and pop the upper left corner off of the connecting ball stud.
3. Pop the lower panel corners off of the connecting ball studs.
4. Lift the panel up and away from the cart.

♦ **To remove the back panel:**

1. Remove the two screws at the bottom of the panel using a Phillips head screwdriver.
2. Remove the two screws at the middle of the panel using a Phillips head screwdriver. Support the panel weight to prevent panel or screw damage.
3. Lift the panel up and away from the cart.

Opening the Nav Cart

◆ **To remove the lower front panel:**

1. Place the flat end of a screwdriver into the slot near the upper right corner.
2. Grasp the top of the panel and pop the upper left corner off of the connecting ball stud.
3. Pop the lower panel corners off of the connecting ball studs.
4. Lift the panel up and away from the cart.

◆ **To remove the upper front panel:**

Note: The drawer assembly is attached to the upper front panel. When you remove the upper front panel from the cart, the drawer assembly will slide out with the panel. Use care when removing the upper front panel, as the panel and drawer assembly weigh approximately 30 pounds.

△ **Caution:** Remove the NPI from the front of the cart before removing the upper front panel.

1. With the lower panel removed, grasp the top cover and pull firmly to pop it off of the four ball studs. It may be necessary to pry off one corner with a standard screwdriver.
2. Remove the two screws at the bottom of the upper front panel using a Phillips head screwdriver.
3. Remove the two screws at the top of the upper front panel using a Phillips head screwdriver.
4. Carefully lift the panel off the cart.

Docking and Separating the Carts

The AxiEM™ system carts can be docked together for transportation and storage.

◆ **To dock the carts:**

1. On a level surface, orient the Nav Cart and the Viewing Cart with their back panels facing each other.
2. Move the Nav Cart between the Viewing Cart feet.
3. Slowly push the two carts together until you hear the click from the latch mechanism.

Inside the Cart

Component Connections

◆ **To separate the carts:**

1. Disconnect and stow any loose cables.
2. Push the button on the head of the docking lever located on the Nav Cart, and simultaneously pull the docking lever straight out from the cart.
3. Separate the carts with a gentle tug.

Component Connections

System malfunctions are sometimes the result of loose or disconnected cables. This section shows the connection ports on the system computer and how the internal system components are connected. This information may be useful when you work with technical support to diagnose or fix a malfunction. Do not disconnect any cables unless instructed to do so by a Medtronic SNT technical support representative.

Note: Some of the hardware components used in the “Plus” system model are different from the components used in the standard model. Refer to the connectivity information for your particular system model.

System Computer

Device ports

Refer to the following diagrams for device connection locations on the system computer. The back of the system computer faces the right side of the View Cart.

Inside the Cart
Component Connections

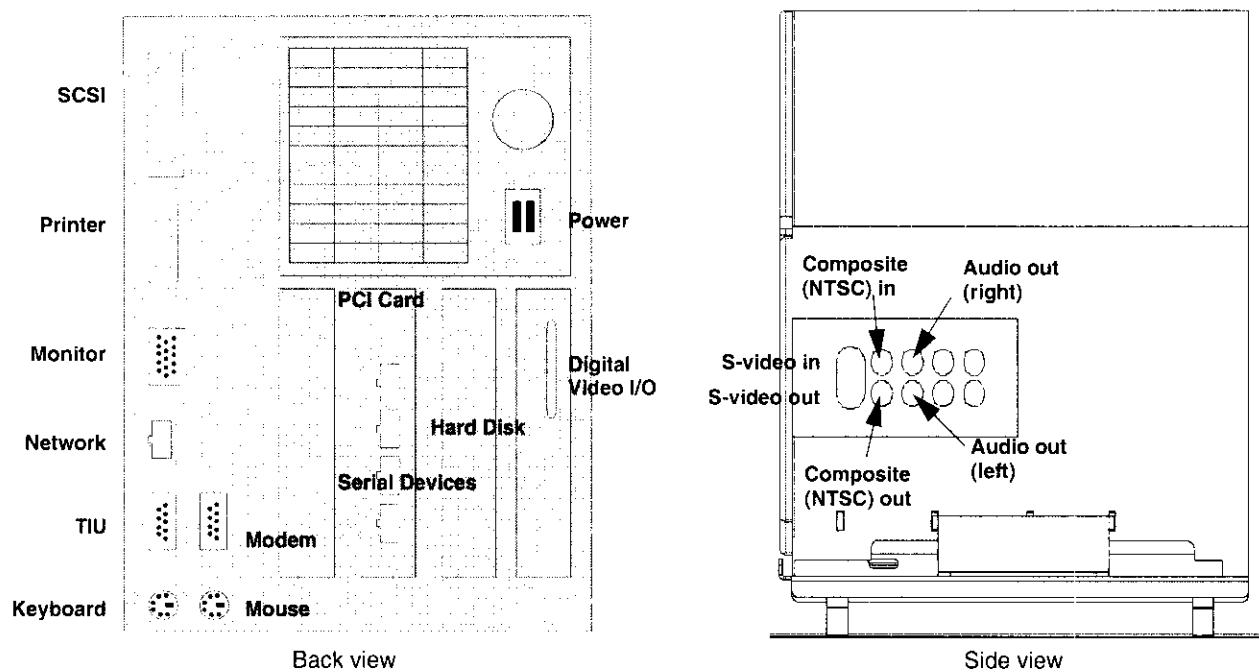


Figure 3-4. Device ports (standard system)

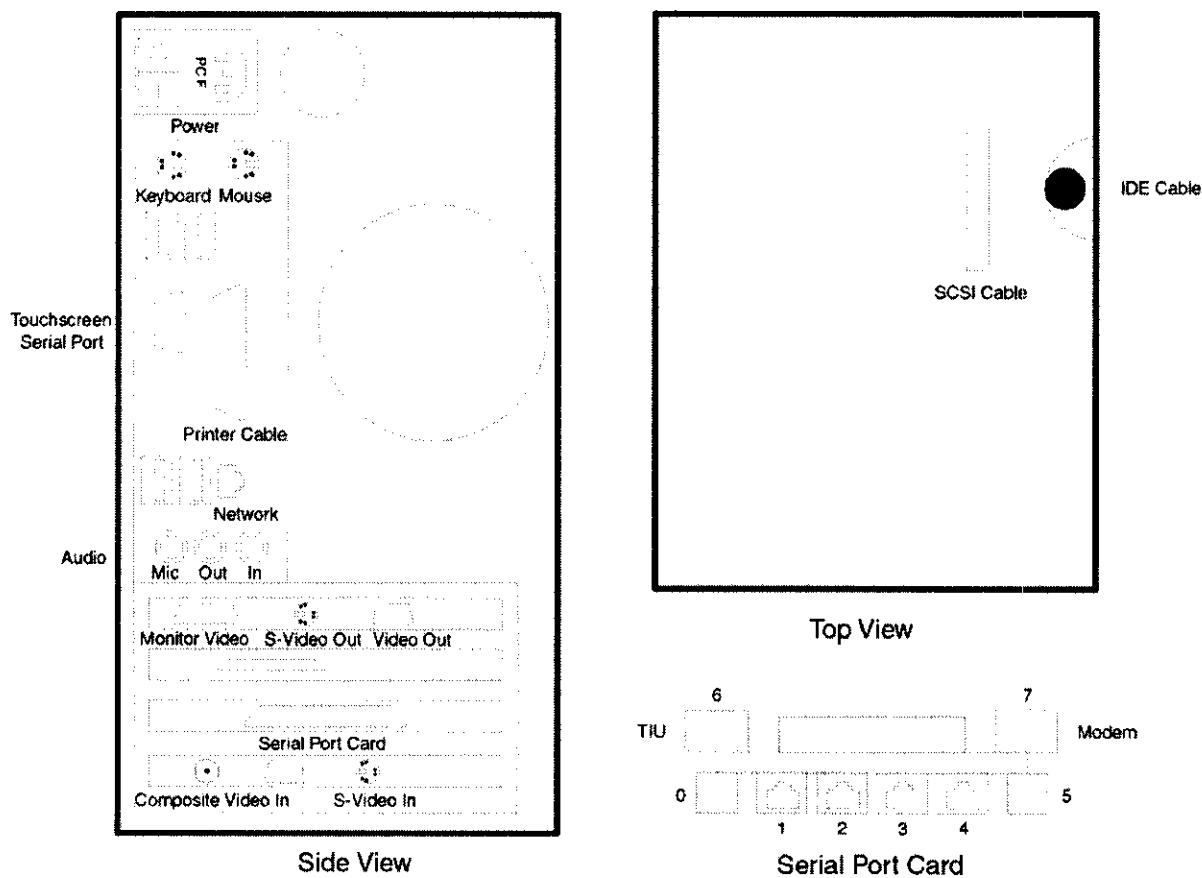
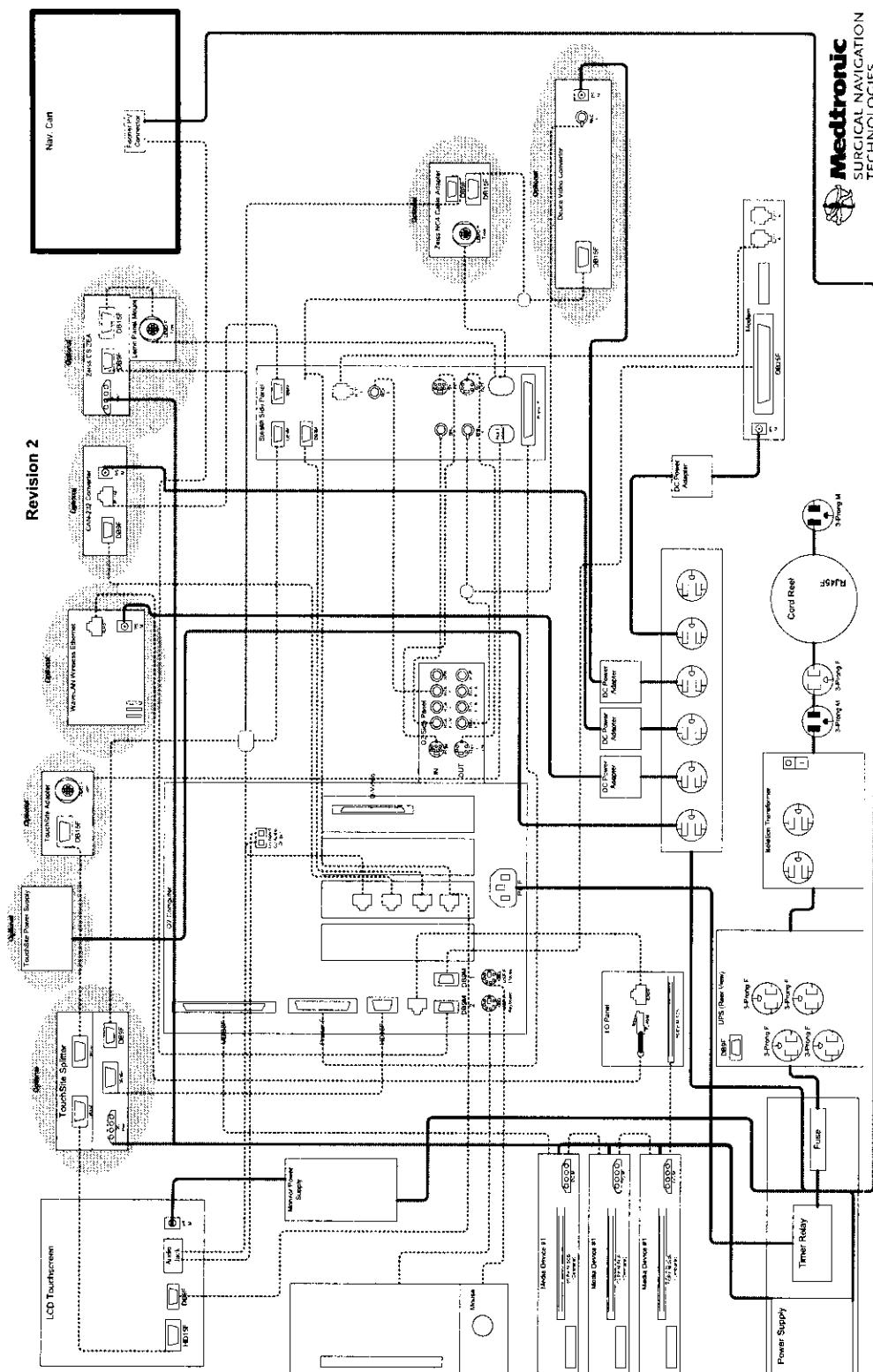


Figure 3-5. Device ports (Plus system)

Inside the Cart
Component Connections

Device Connectivity Diagrams

Complete device connectivity diagrams are provided on the following pages.



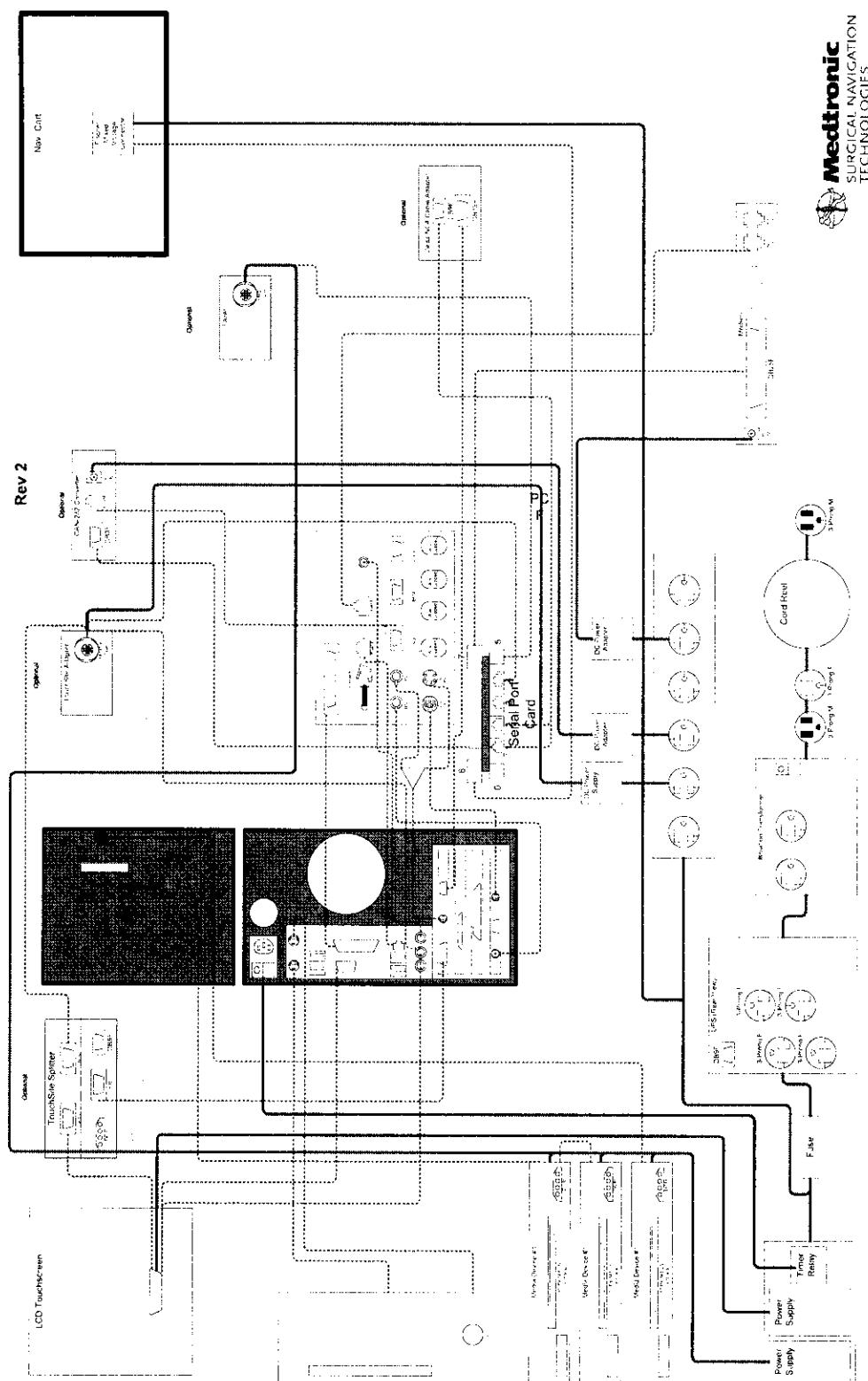


Figure 3-7. View Cart connectivity - plus model system

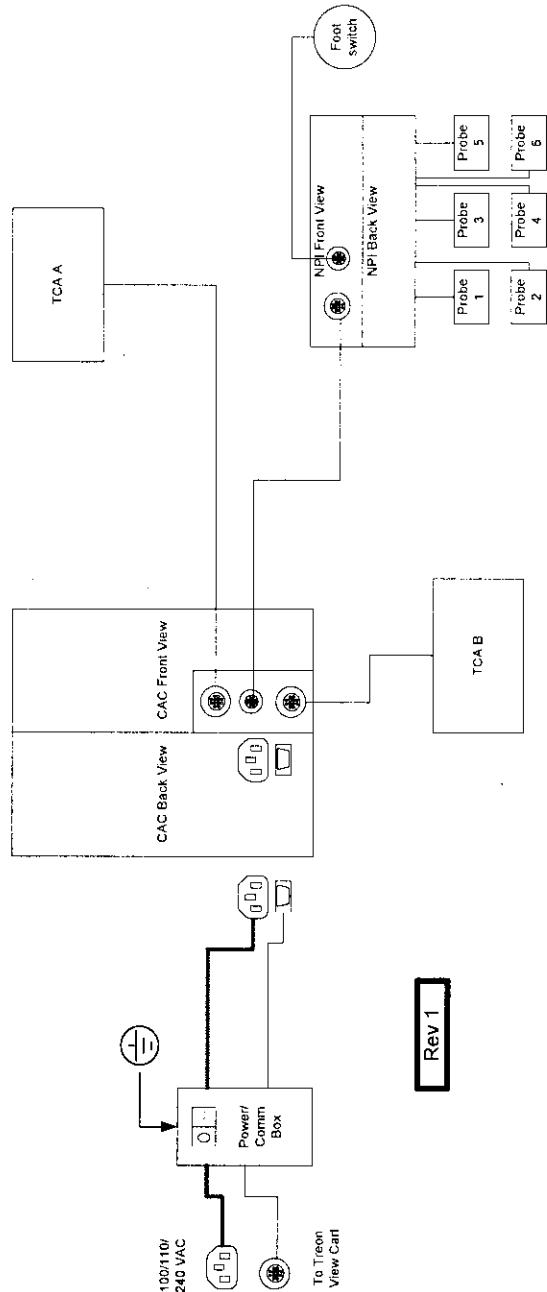


Figure 3-8. Nav Cart connectivity

Index

A

C

CAC 3-3
classifications 2-8
conventions 1-2

D

DRF 2-2

E

EM localization system 2-2

L

localization 2-2
focalizer 2-2

M

monitor 2-7

N

navigation 2-2

S

specifications 2-7

T

translation map 2-2

W

wireless 2-7

Index

A-2 *Axi-EM™ System Manual*

Medtronic Navigation, Inc.

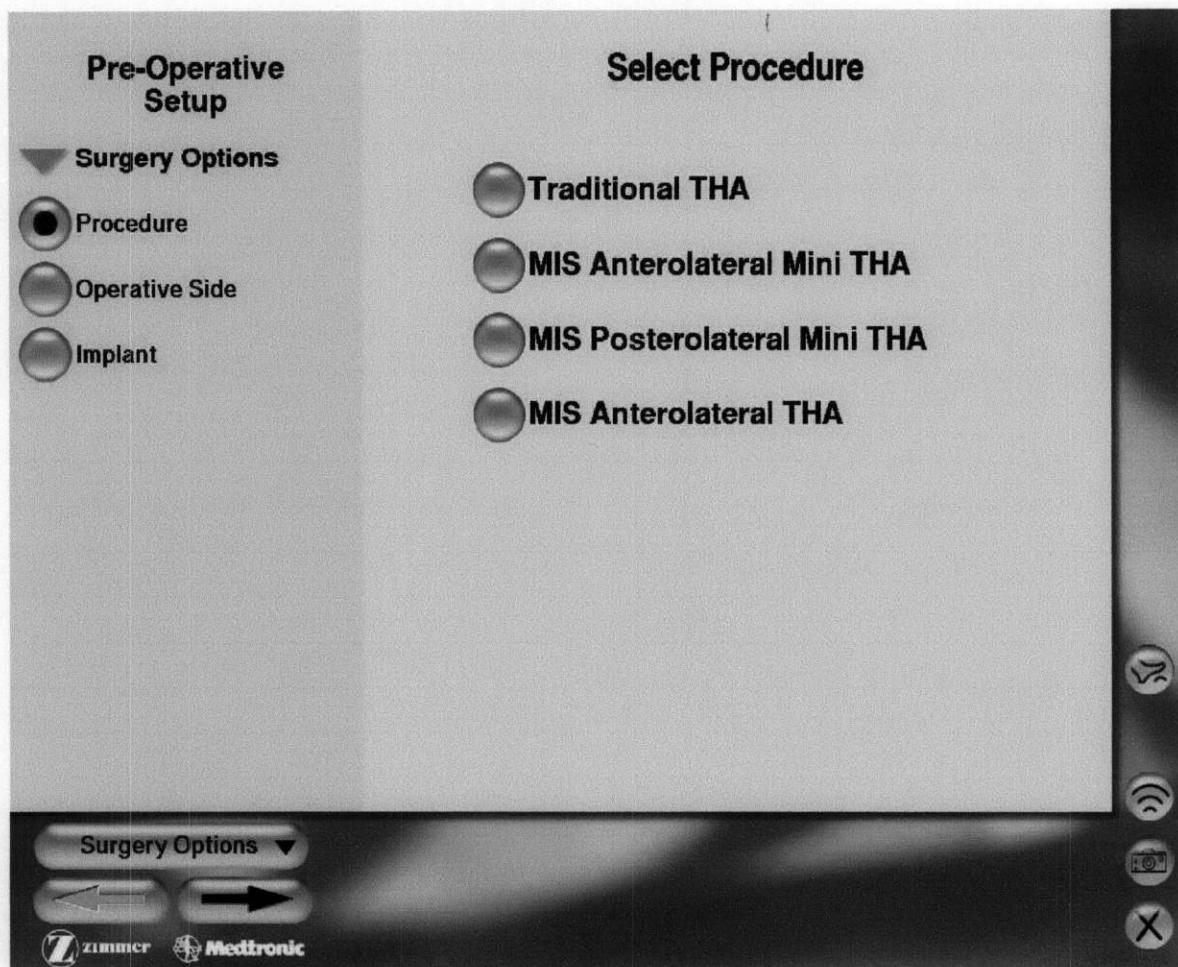
CONFIDENTIAL

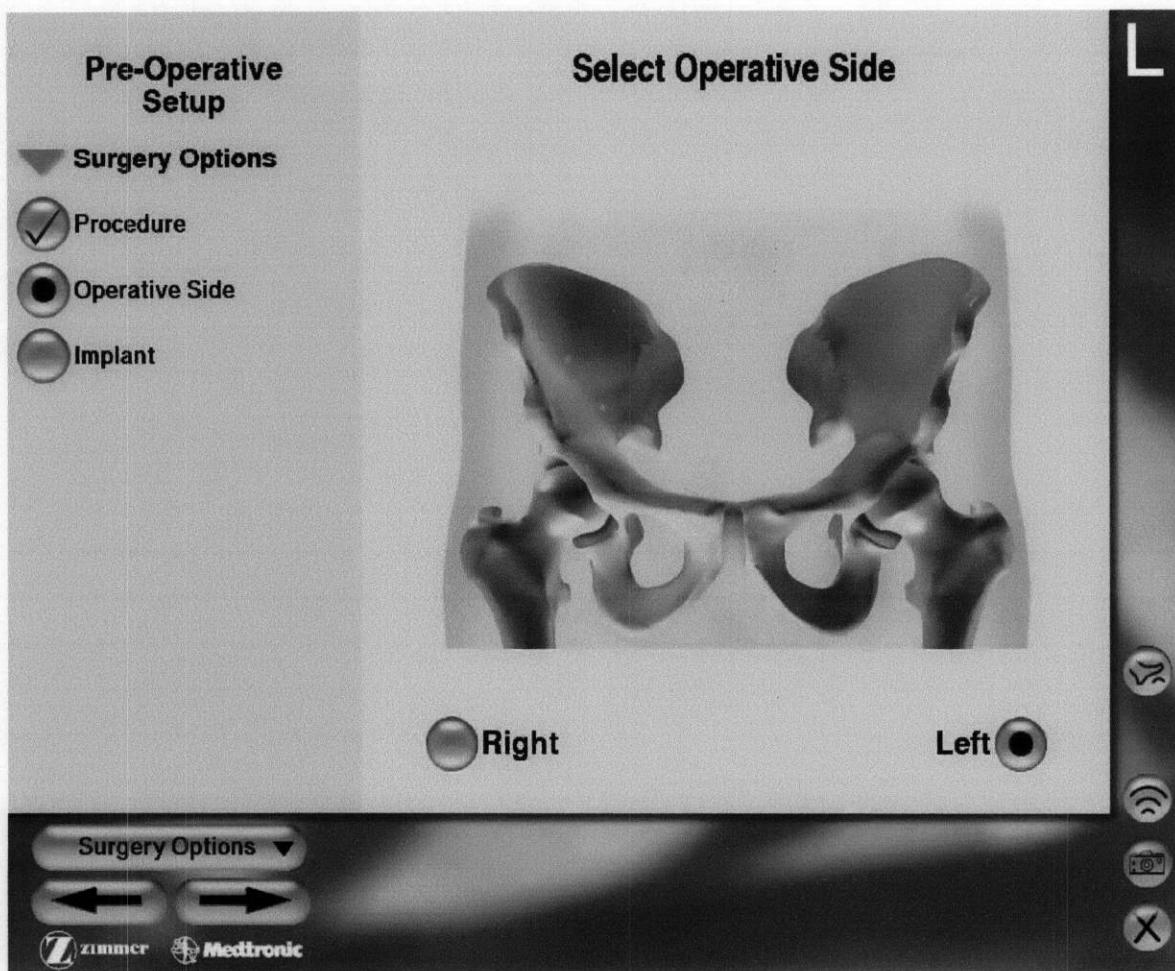
544
Page 120 of 877

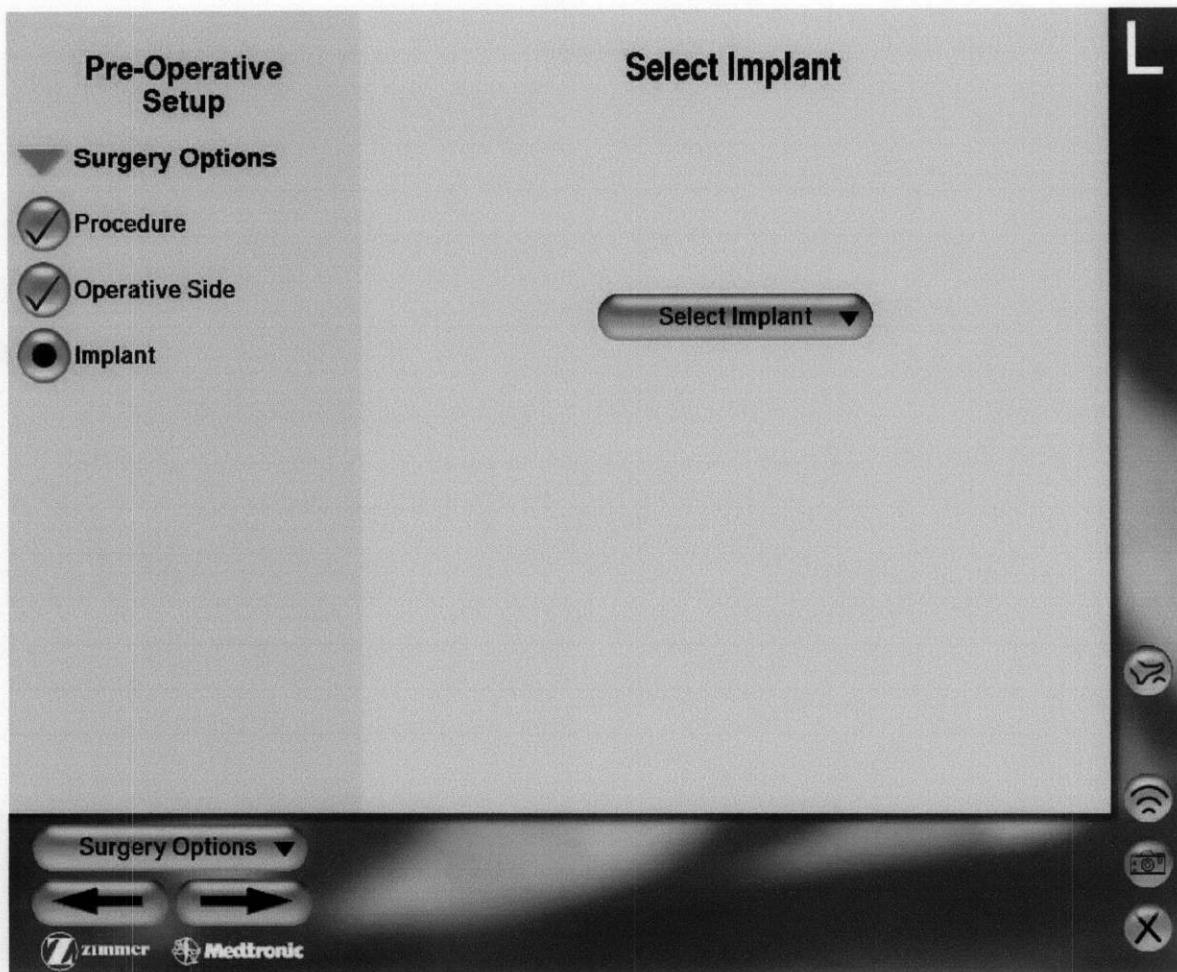
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

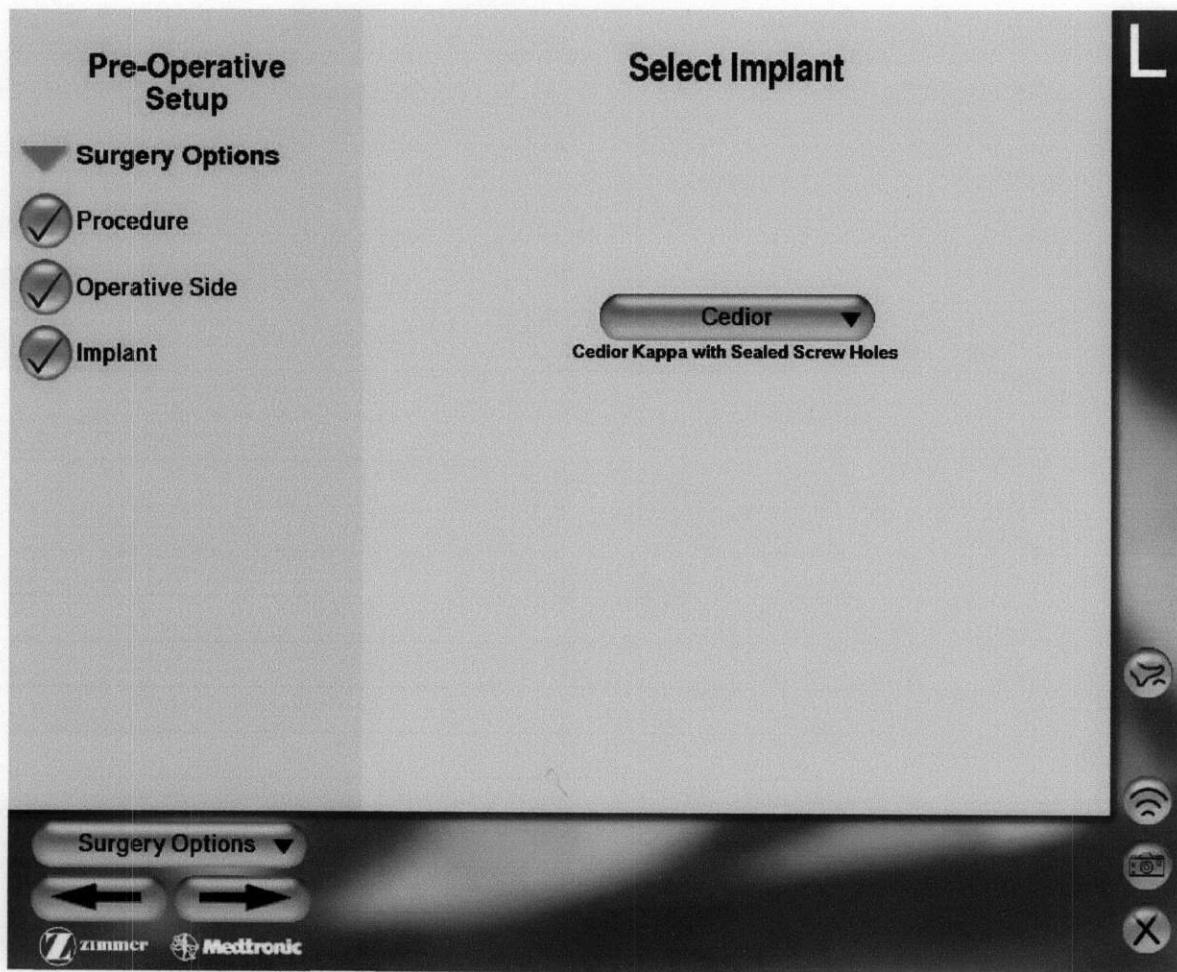
ATTACHMENT D

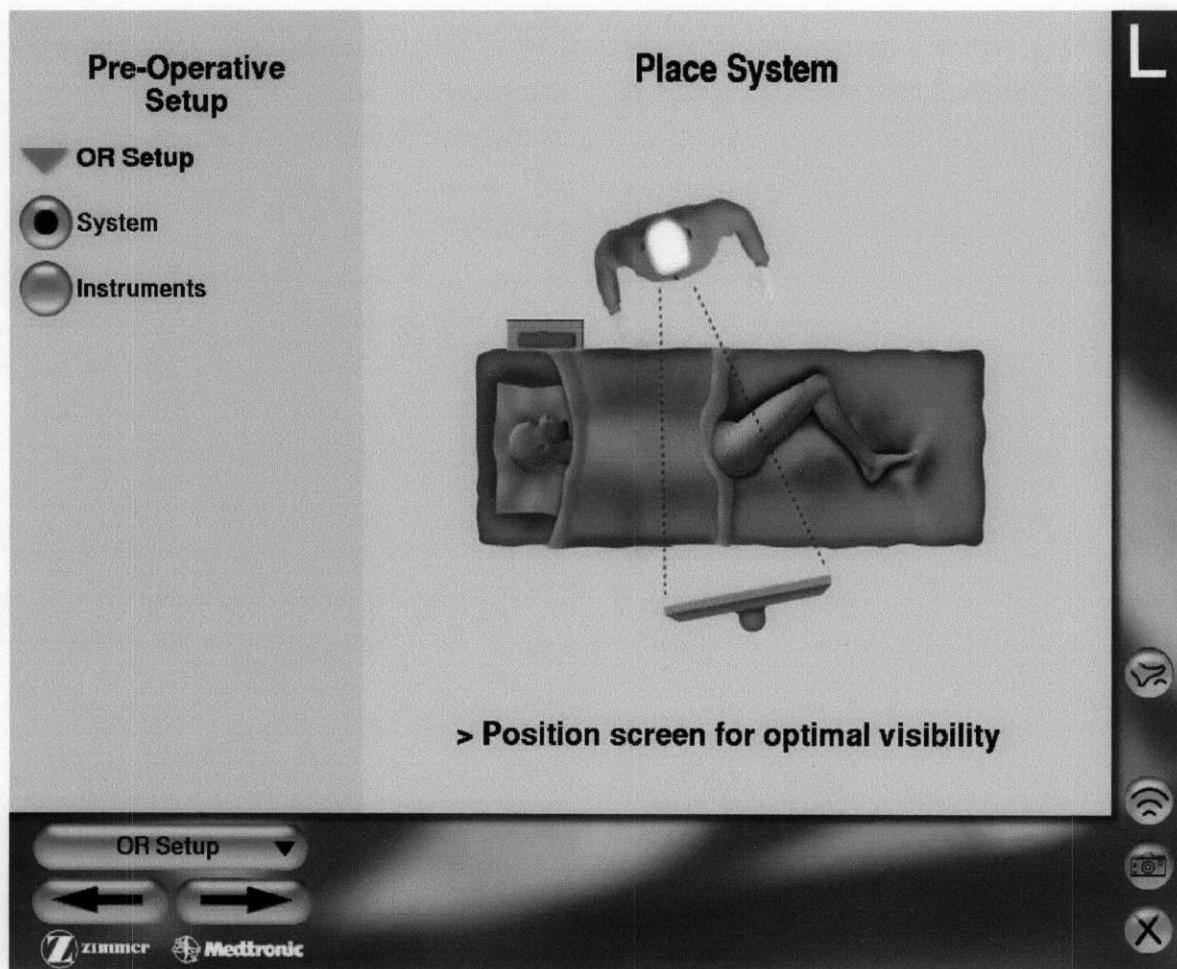
AXIEM™ IMAGELESS HIP MODULE FOR THE STEALTHSTATION® SYSTEM
SOFTWARE SCREENSHOTS

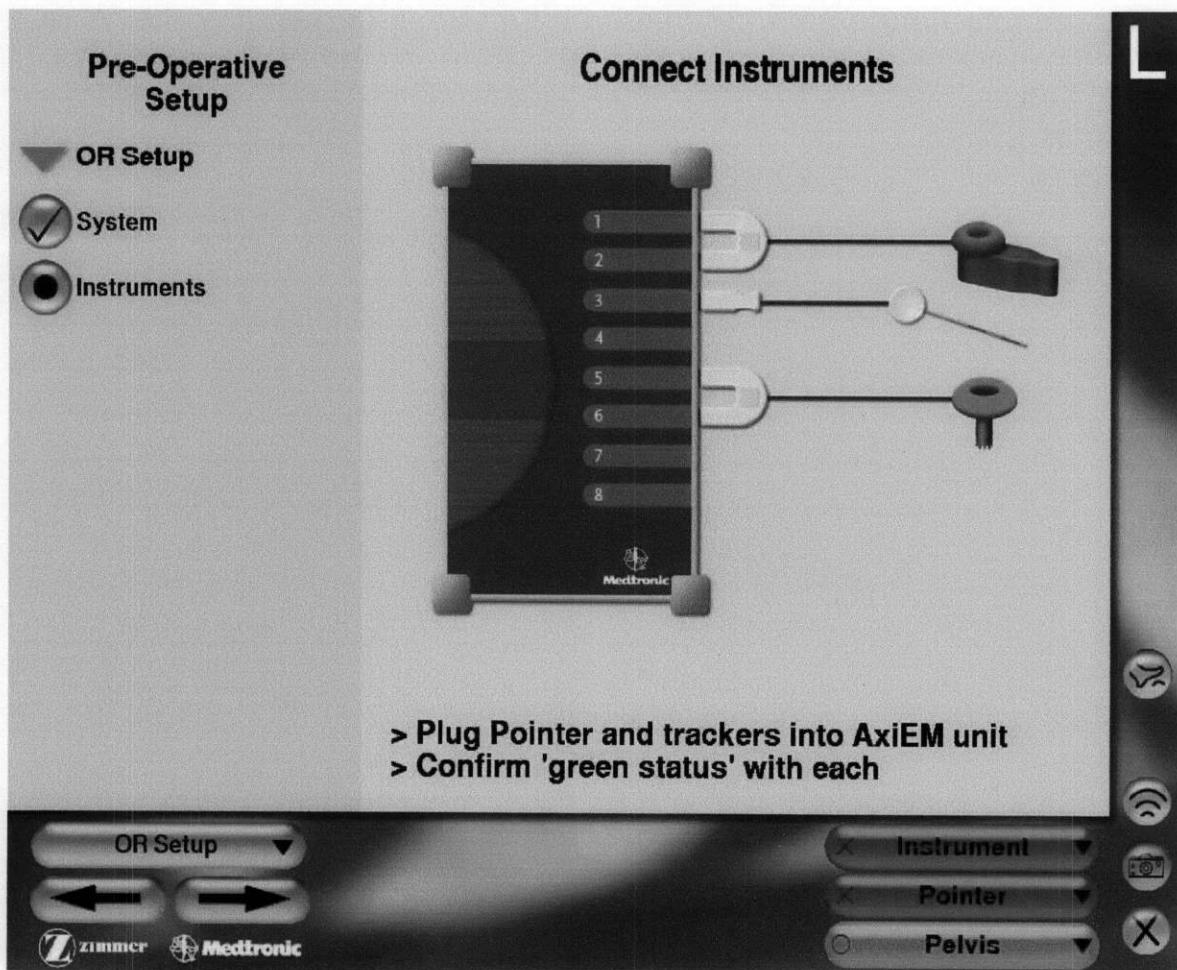


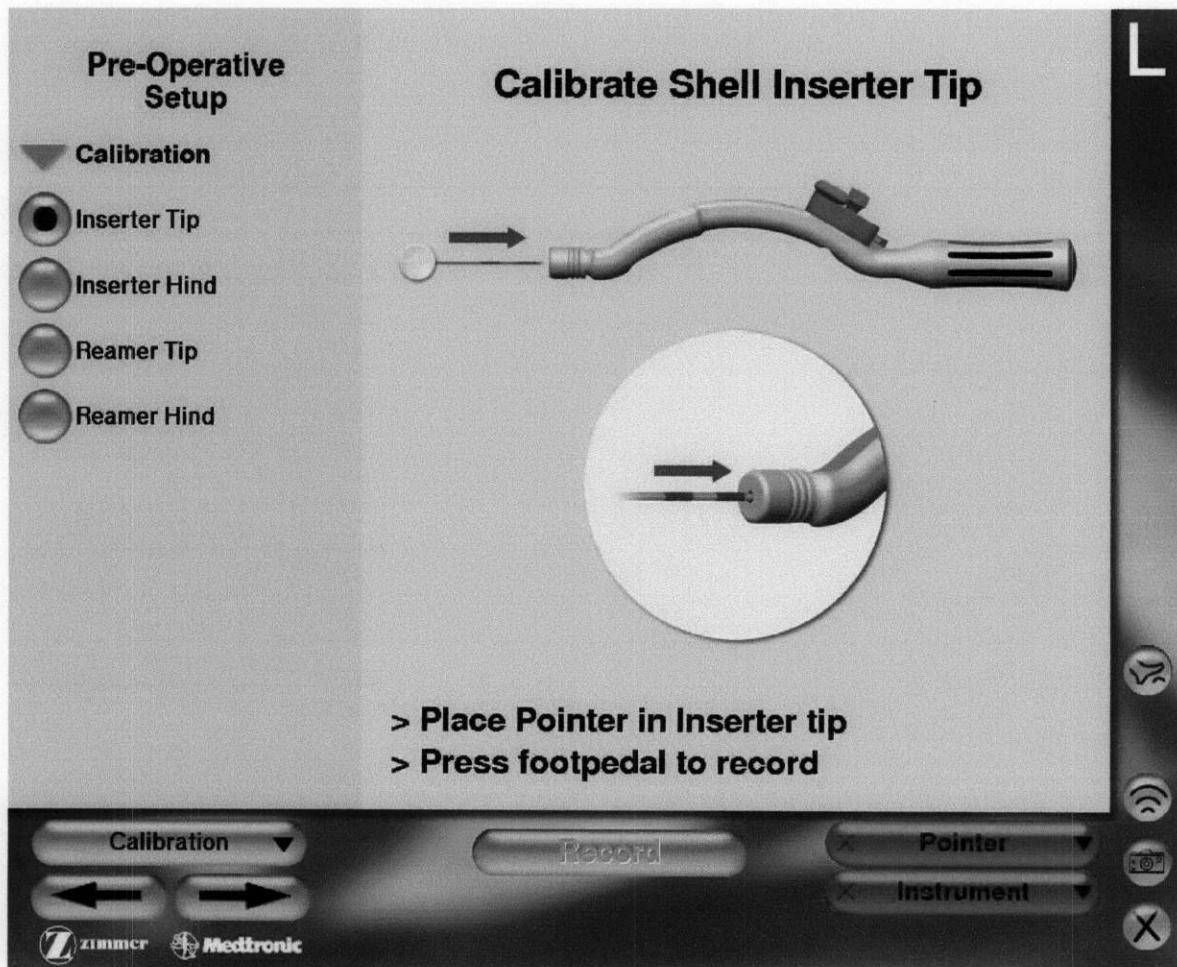


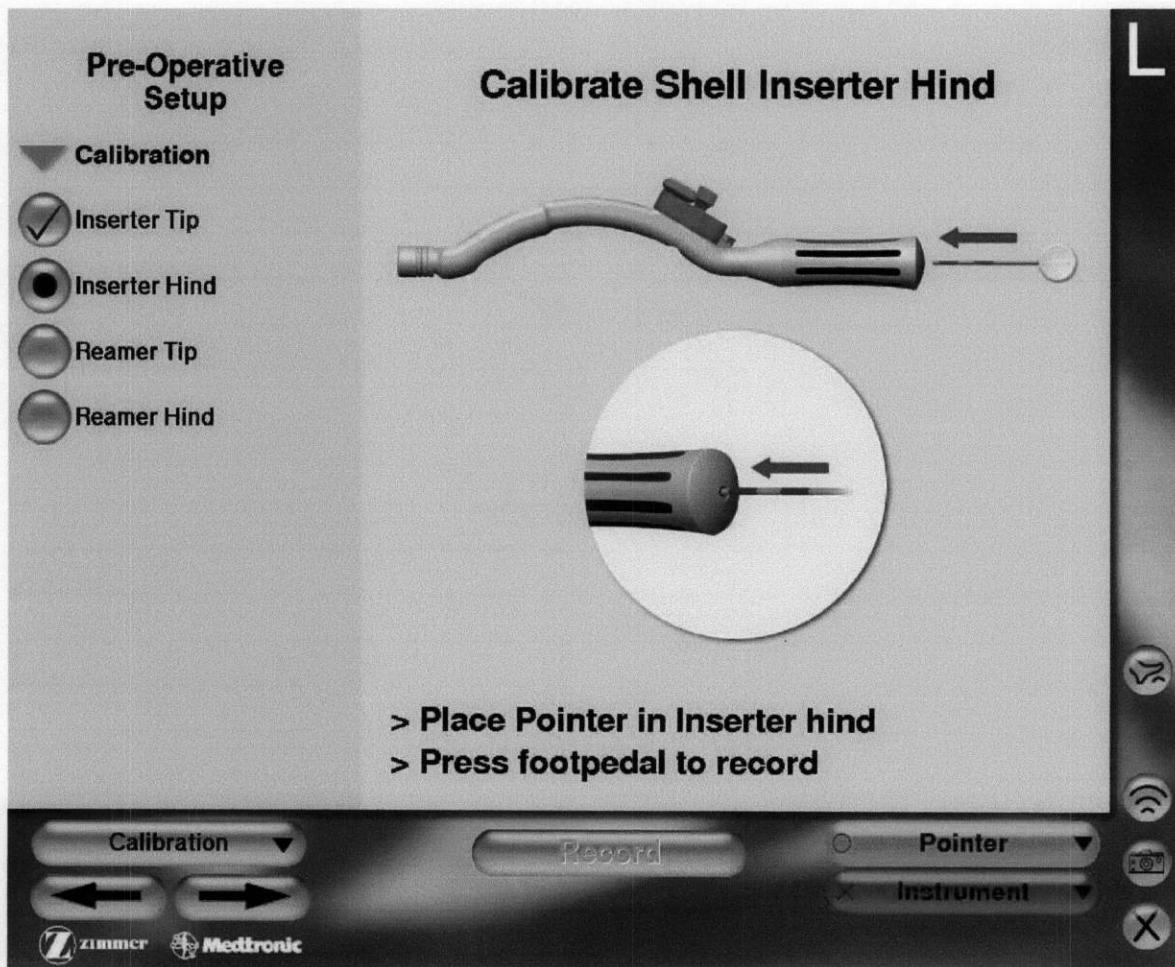


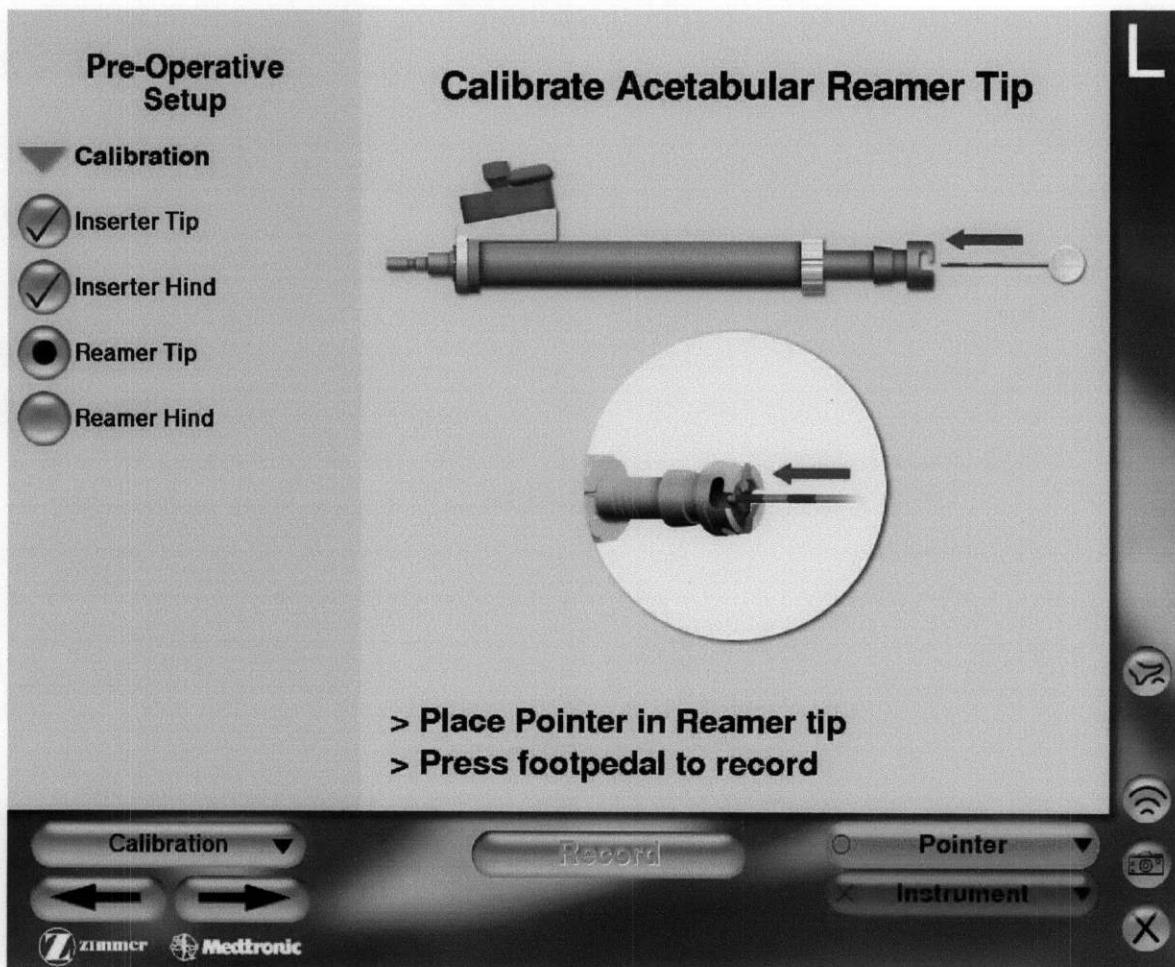


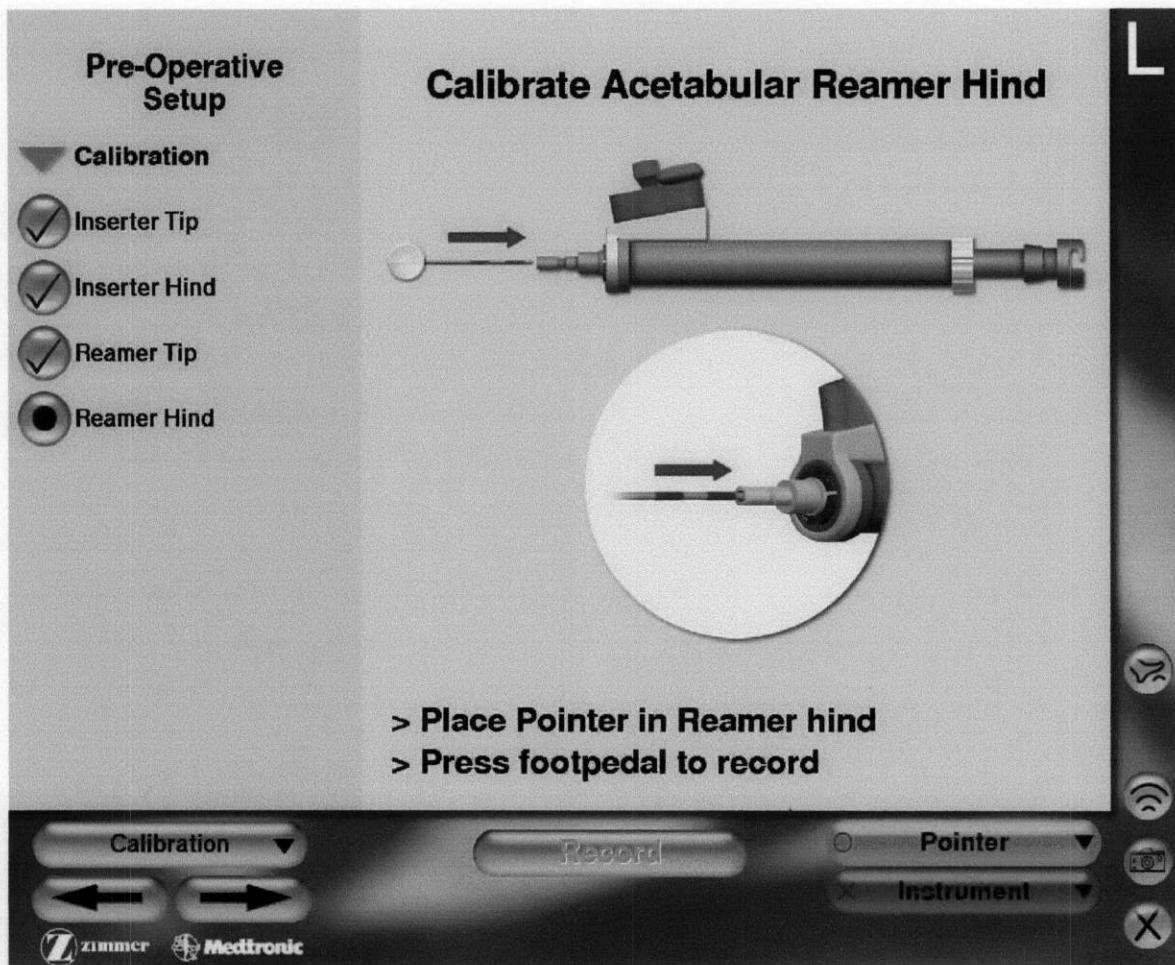


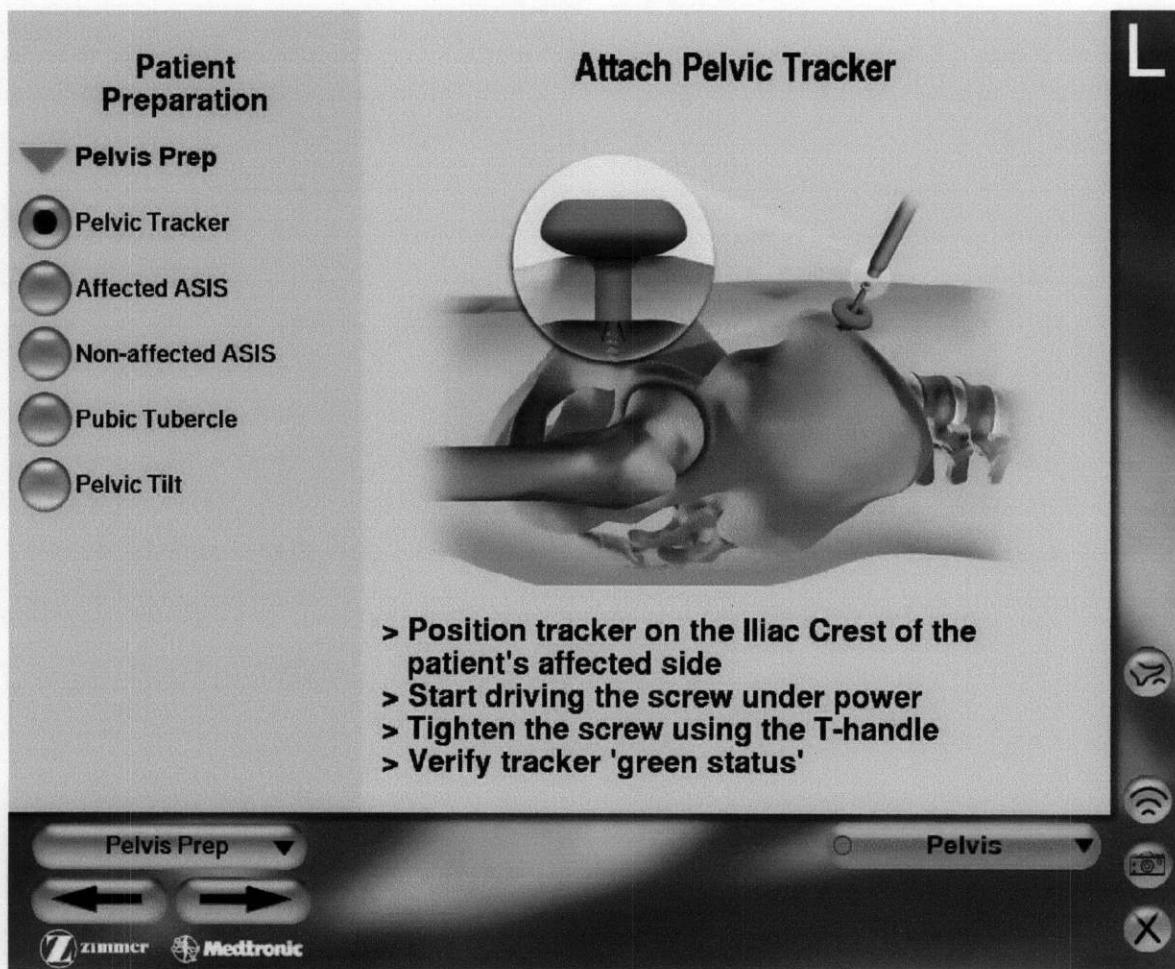


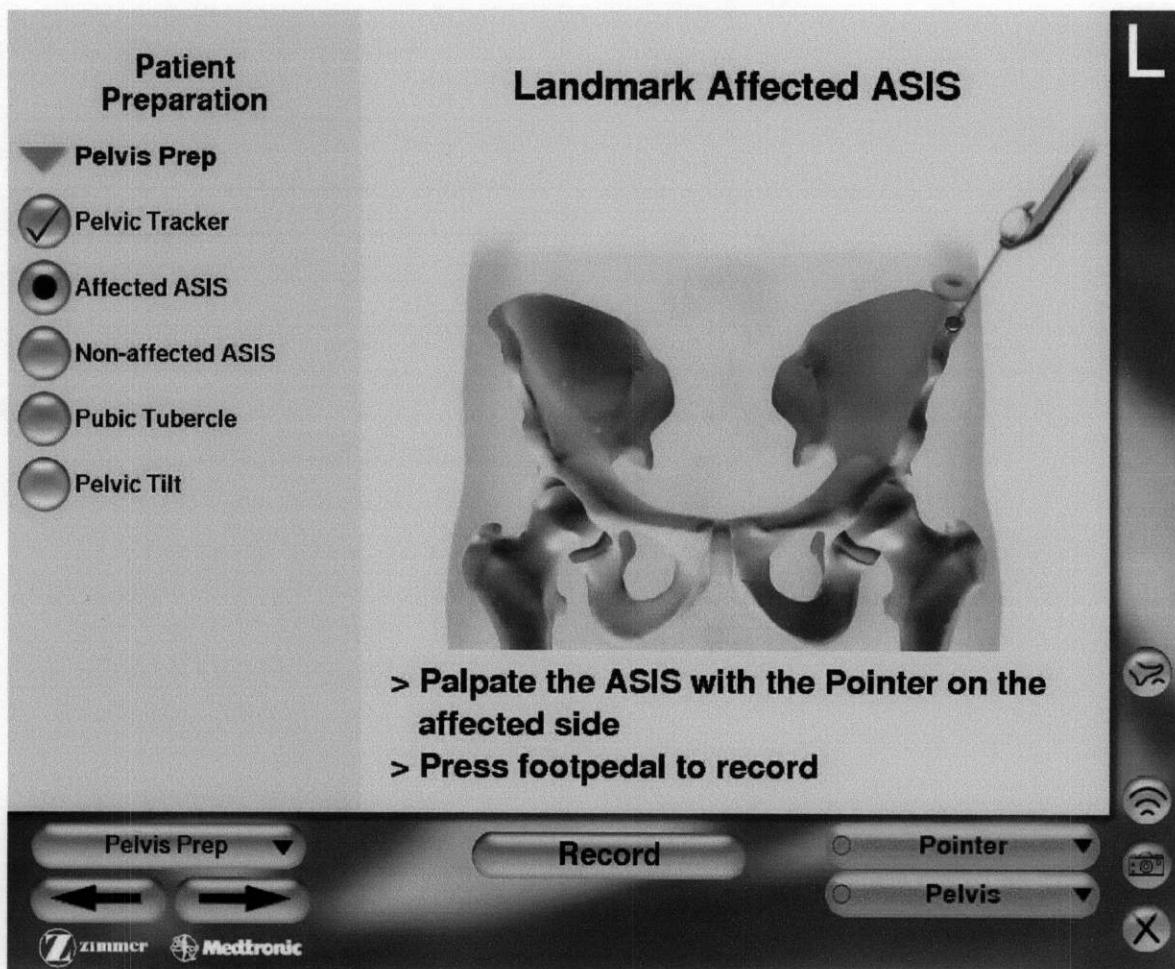


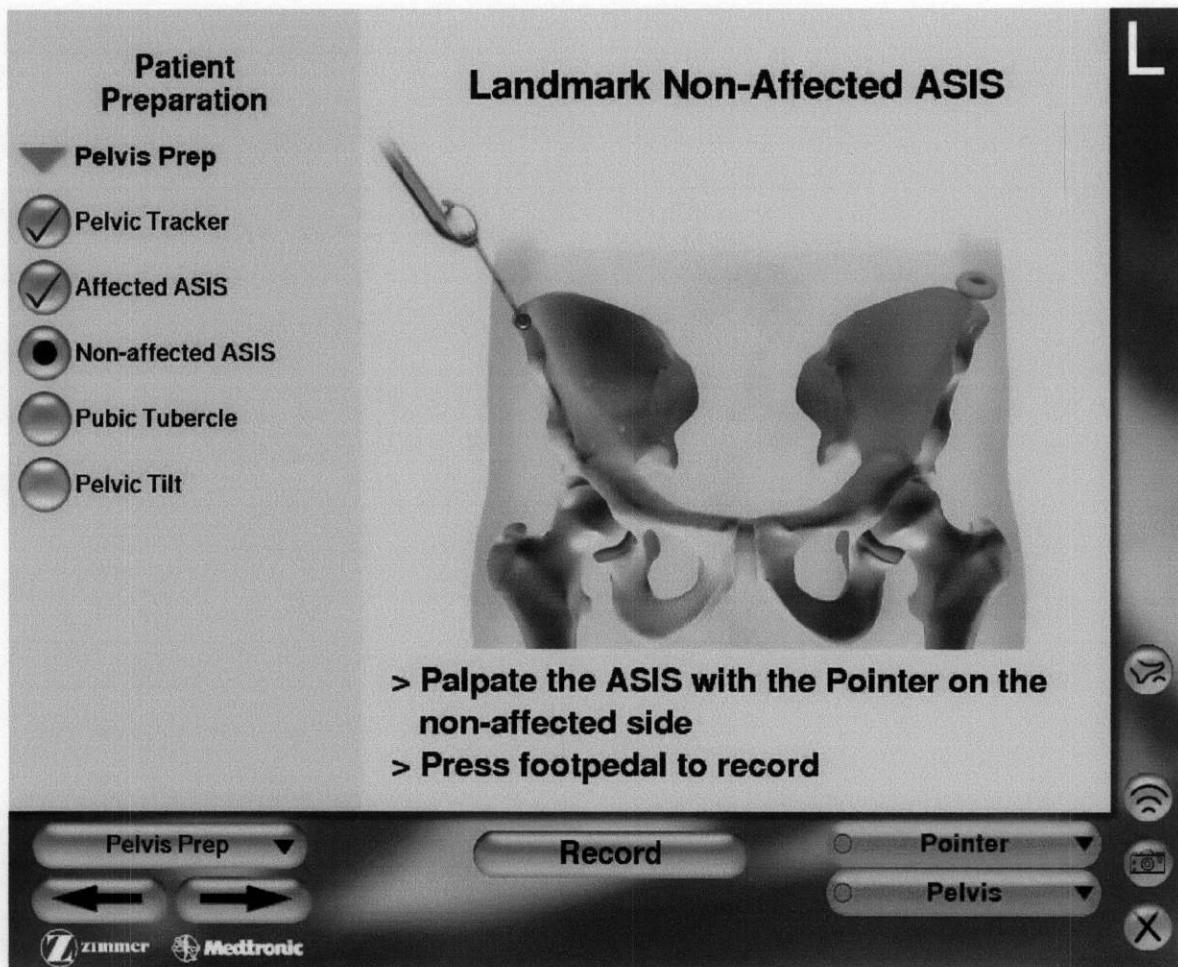










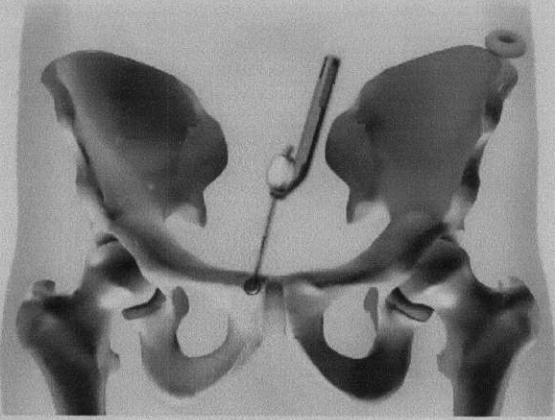


Patient Preparation

Pelvis Prep

- Pelvic Tracker
- Affected ASIS
- Non-affected ASIS
- Pubic Tubercl
- Pelvic Tilt

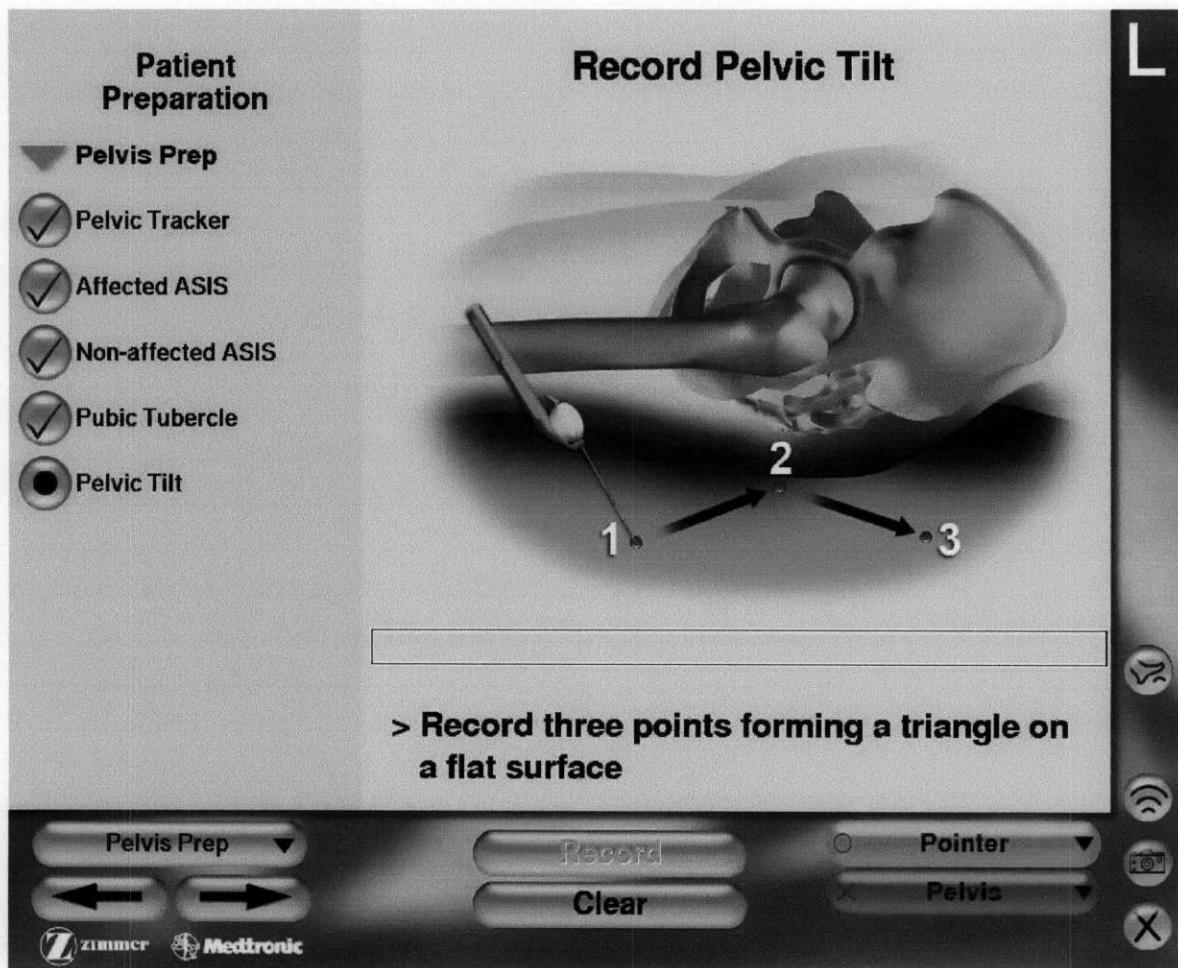
Landmark Public Tubercl

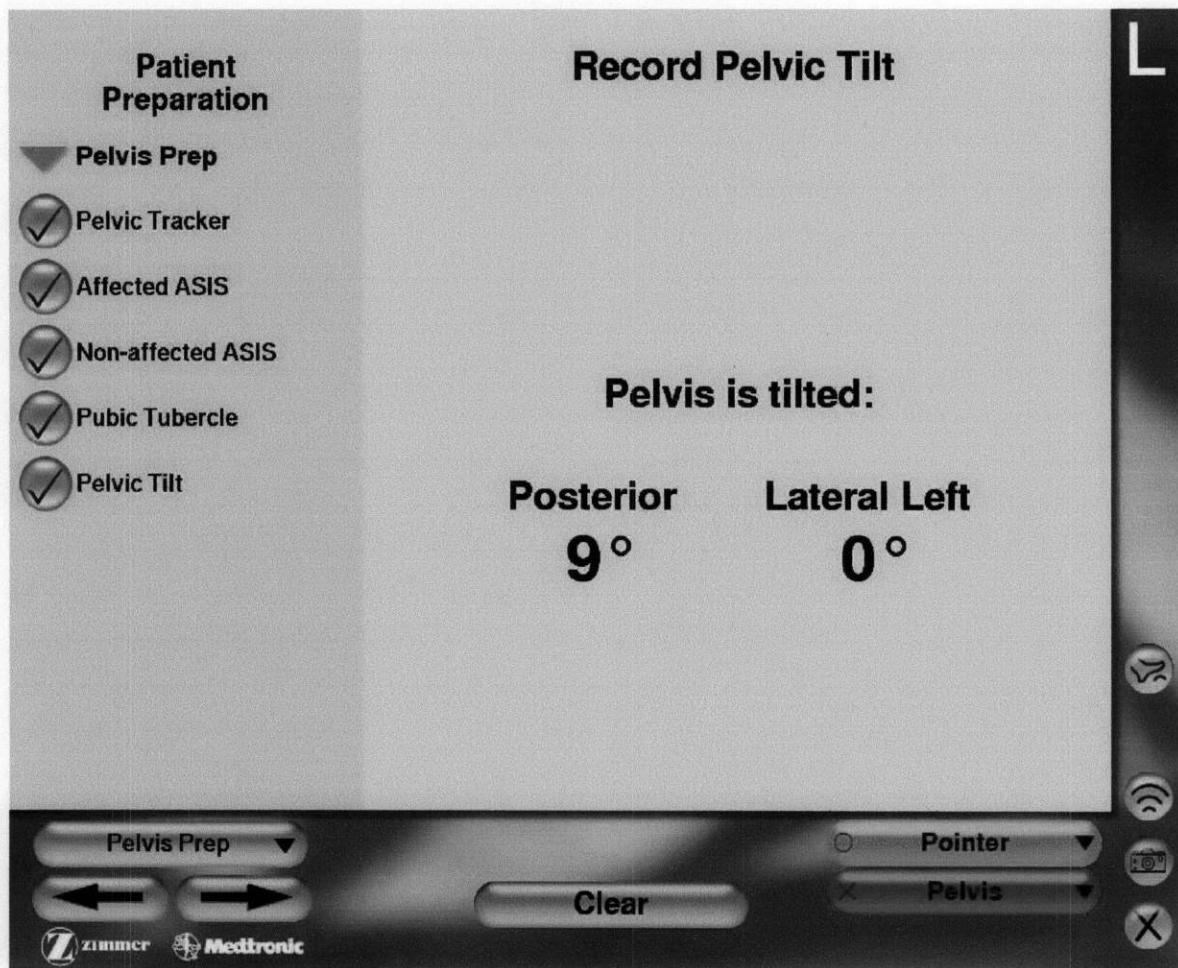


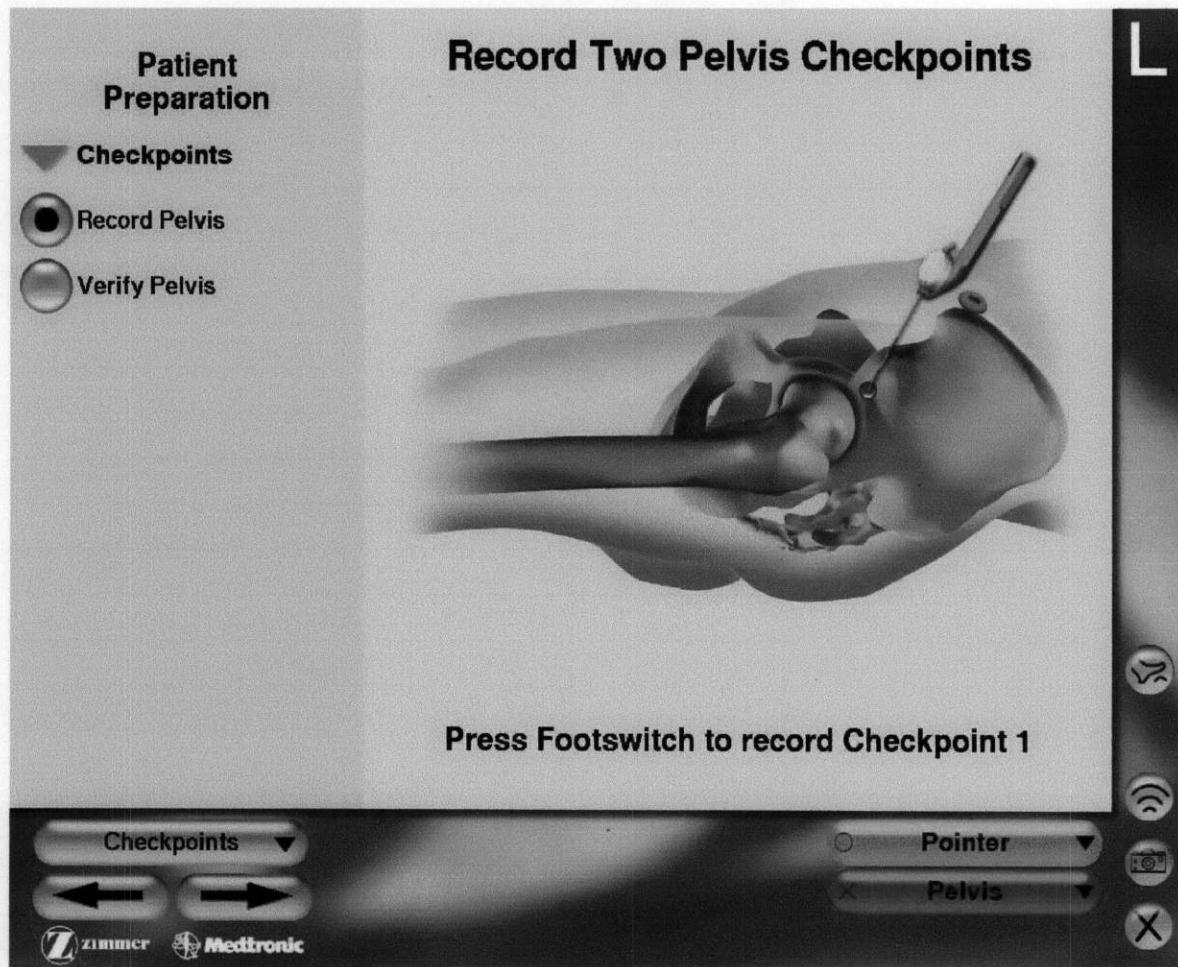
> Palpate the most anterior-superior point of either Pubic Tubercl with the Pointer
> Press footpedal to record

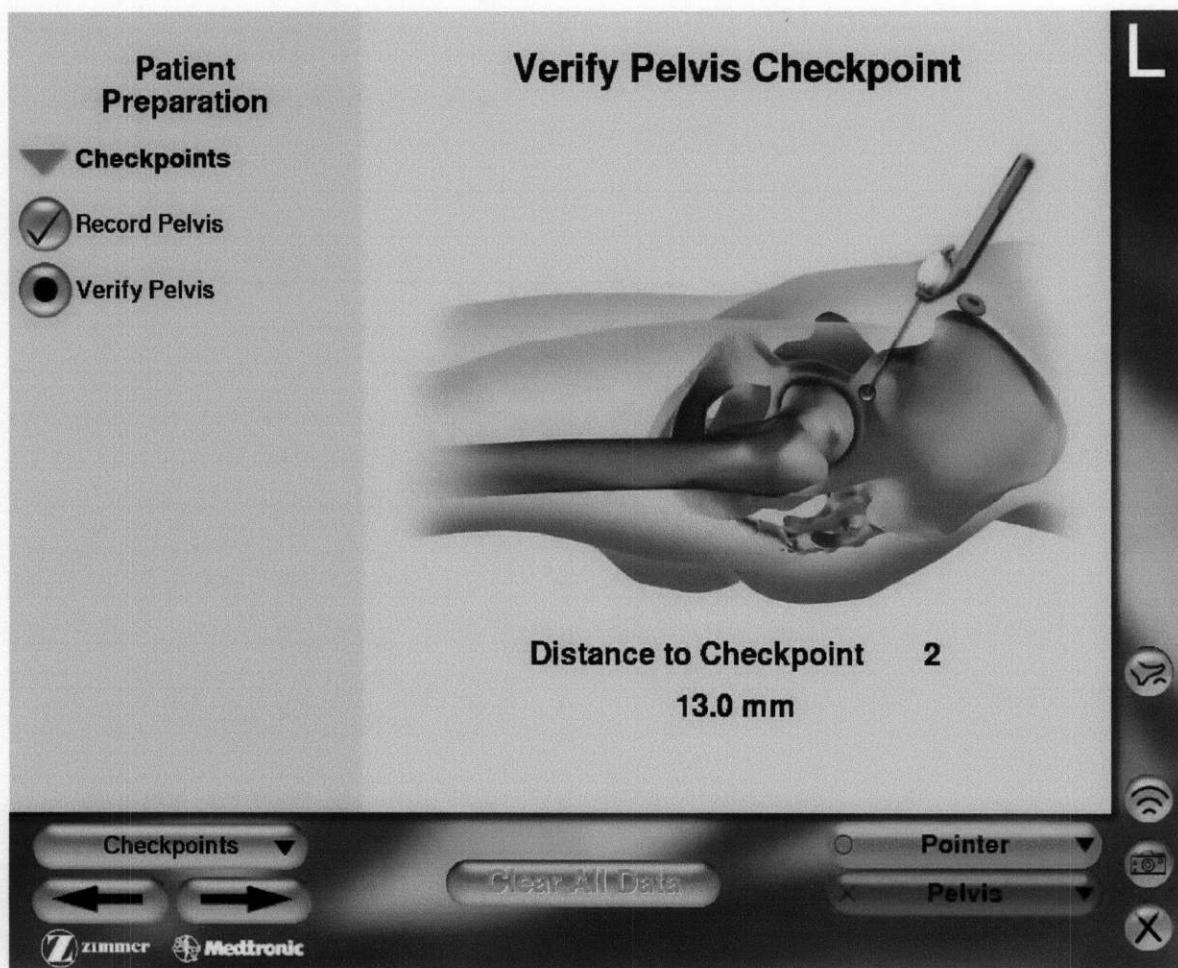
Pelvis Prep Record Pointer Pelvis X

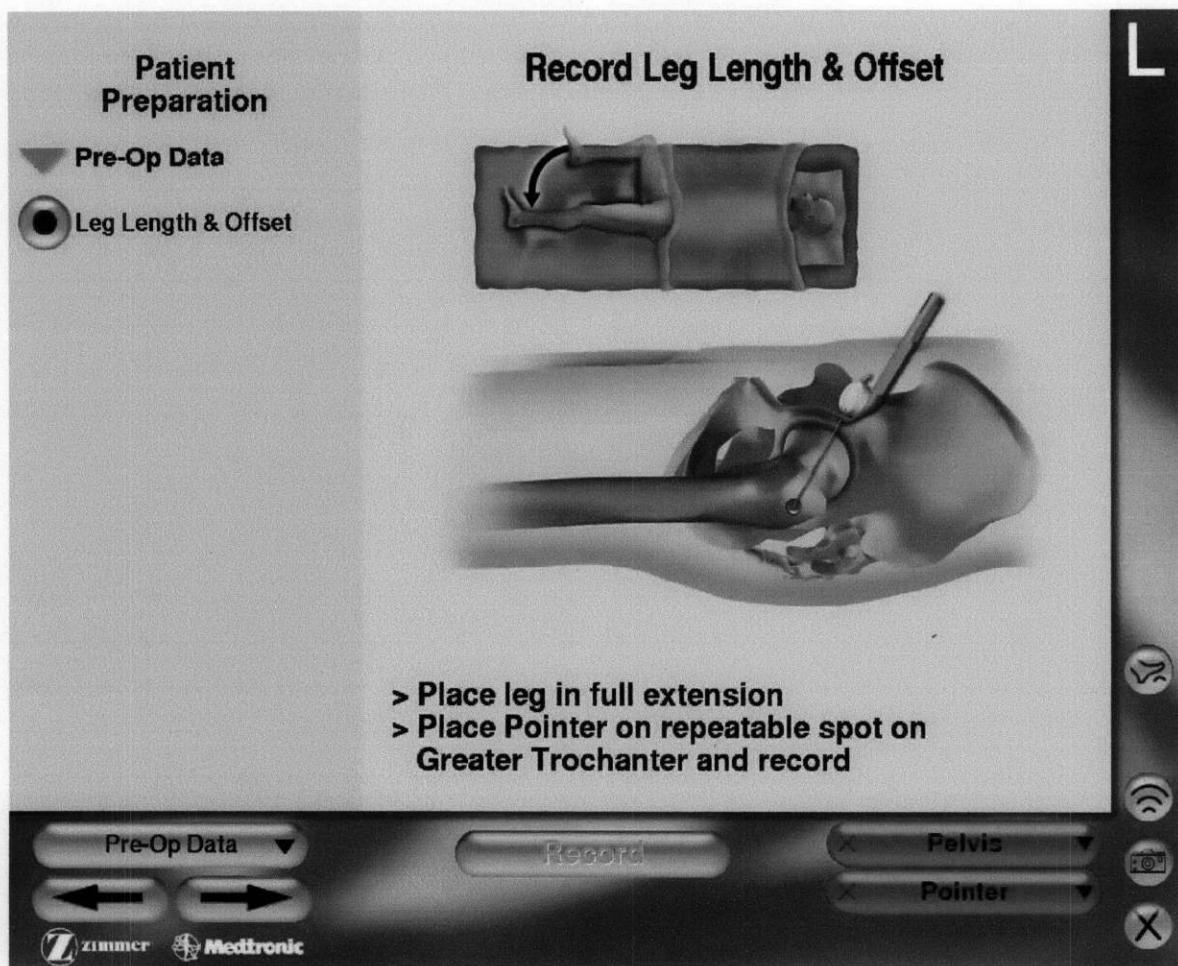
Zimmer Medtronic

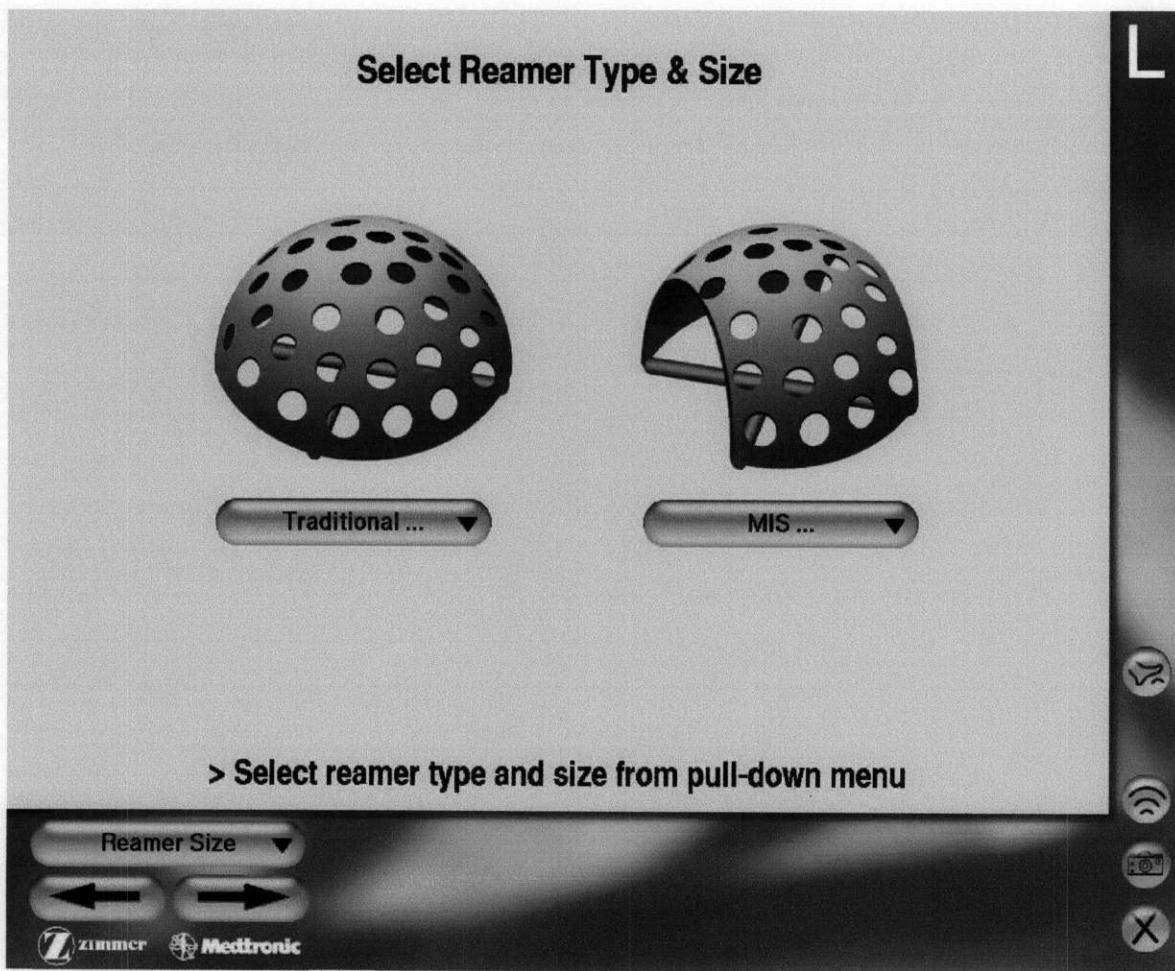


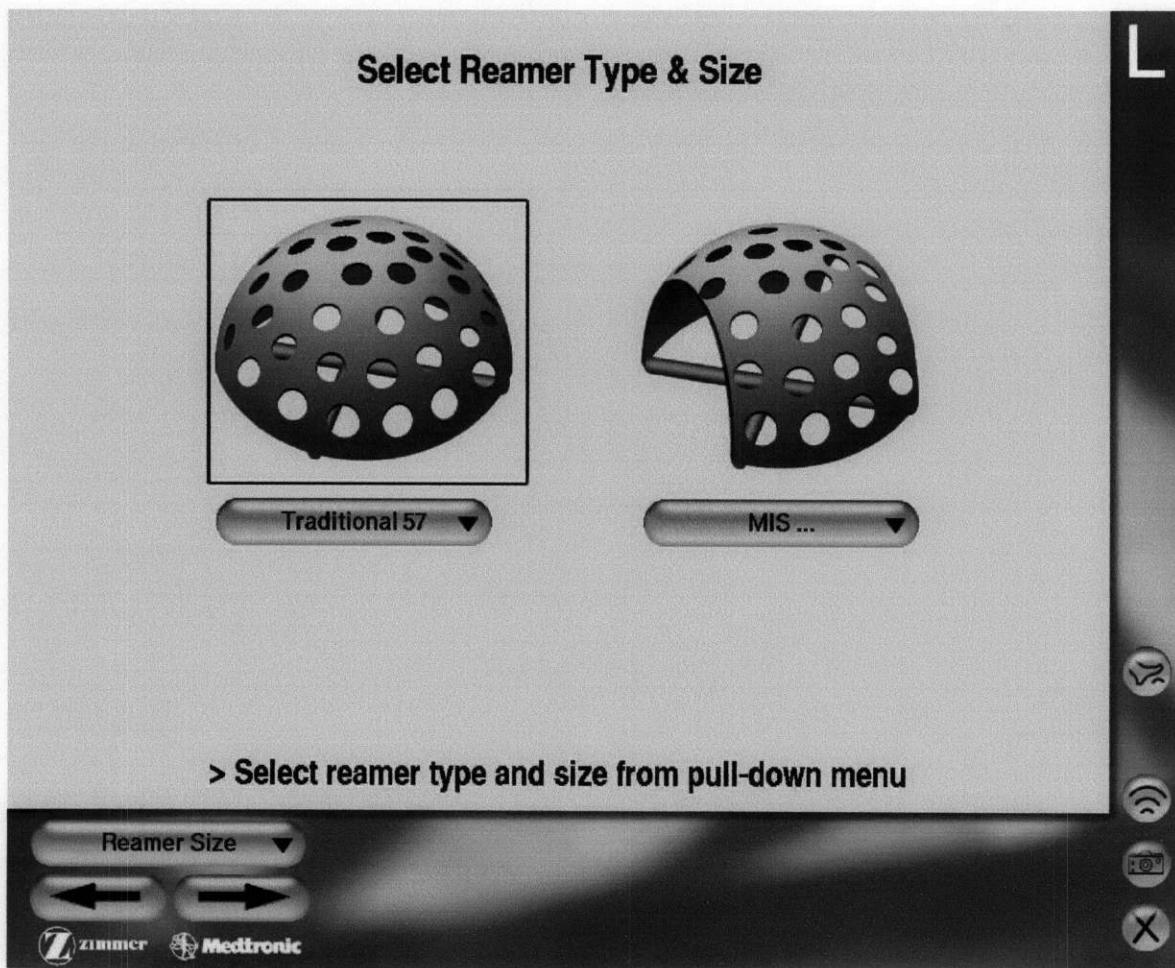


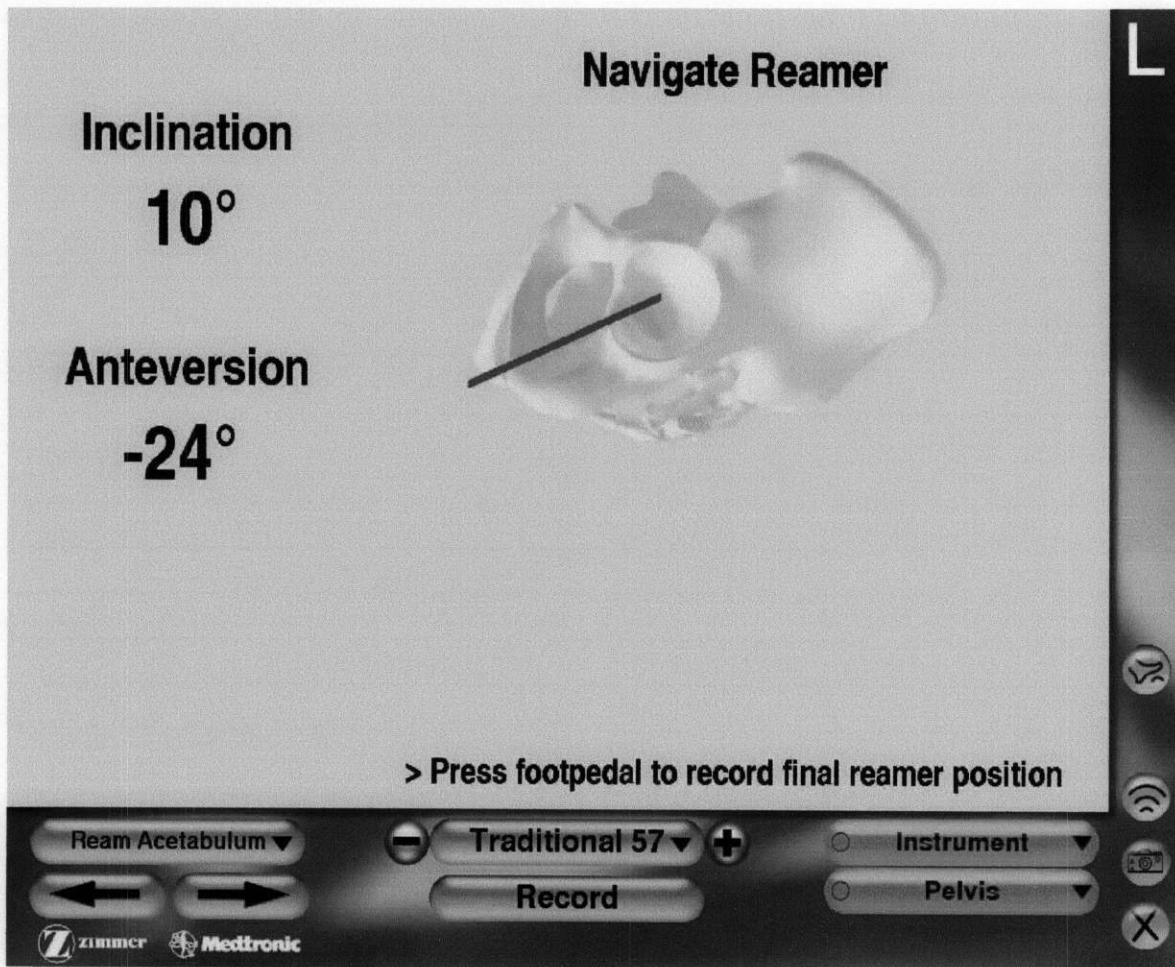


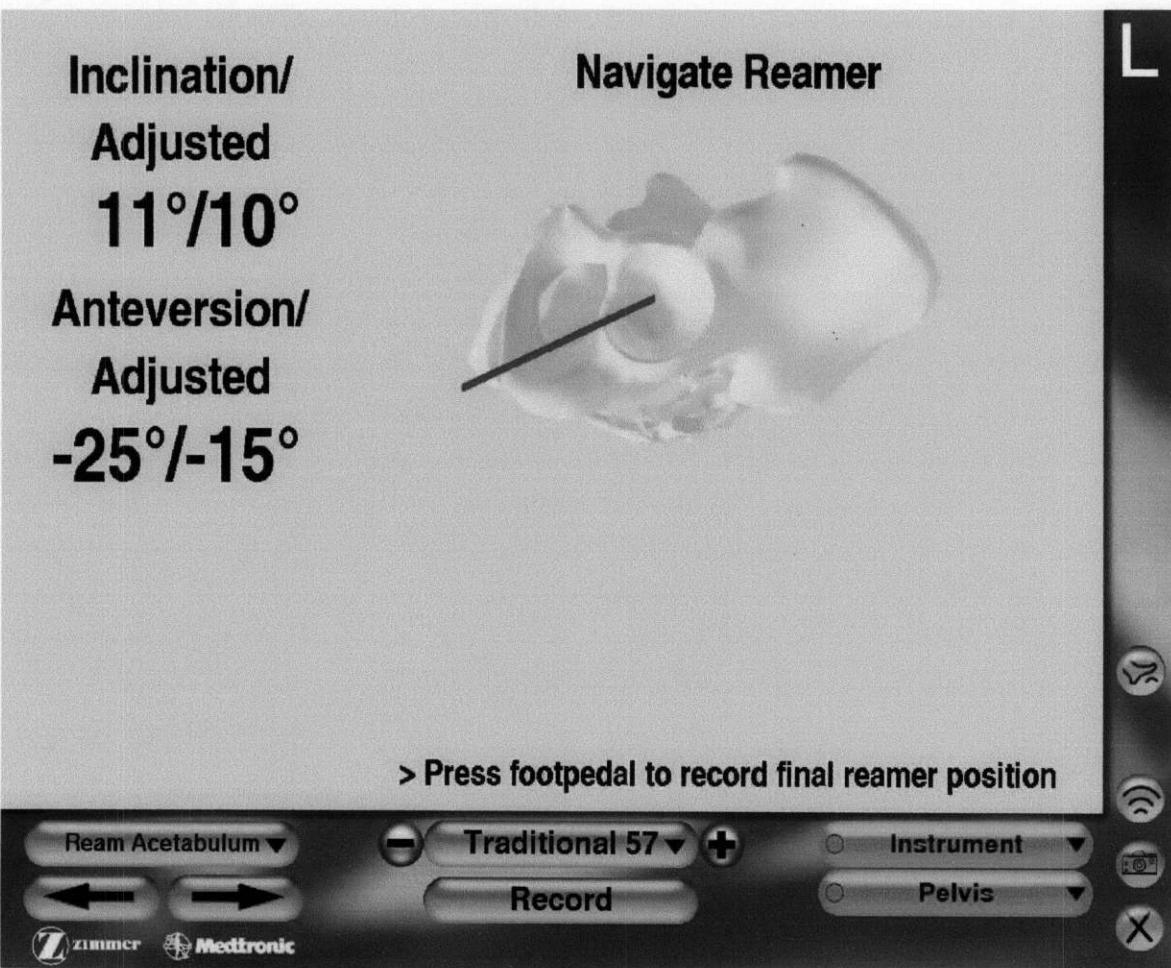


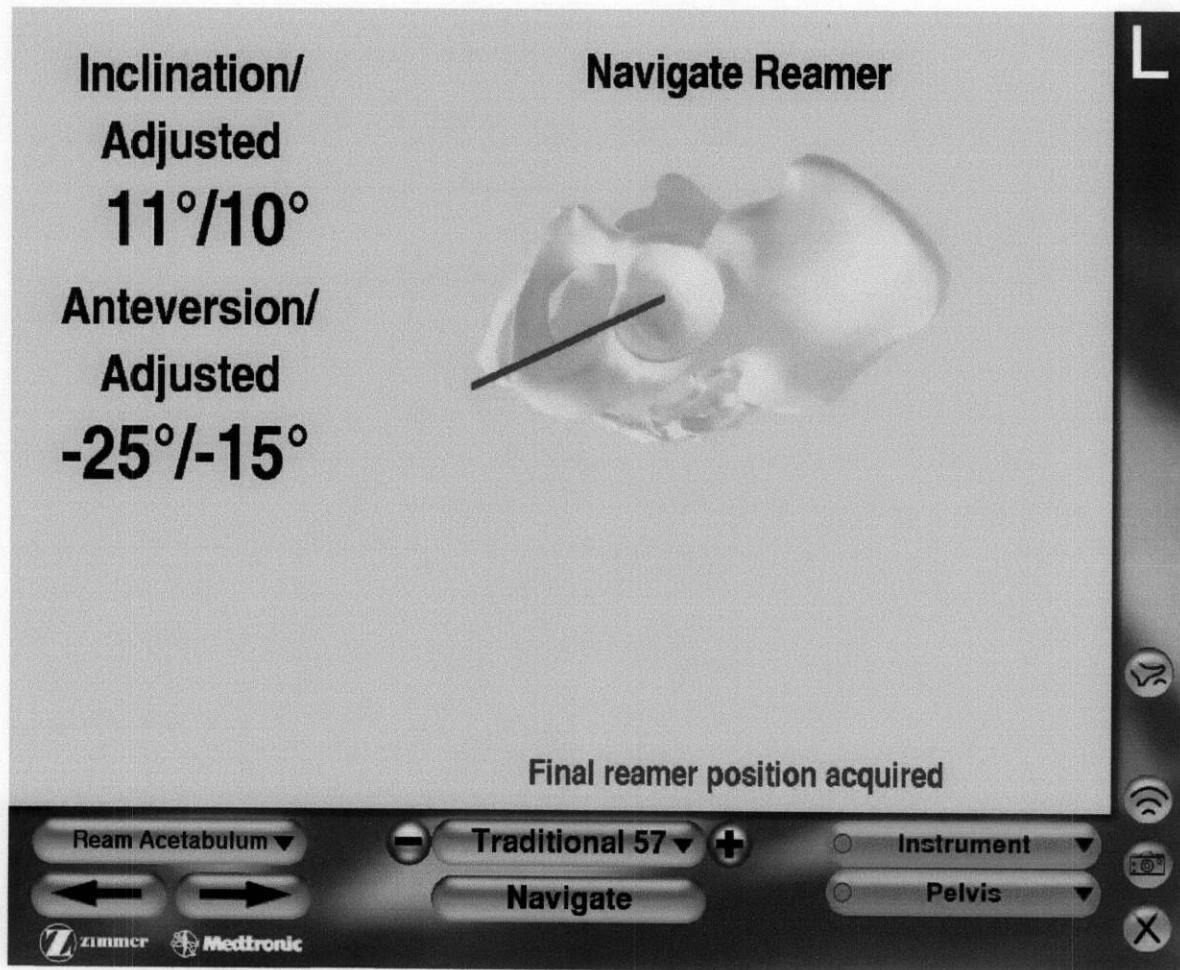






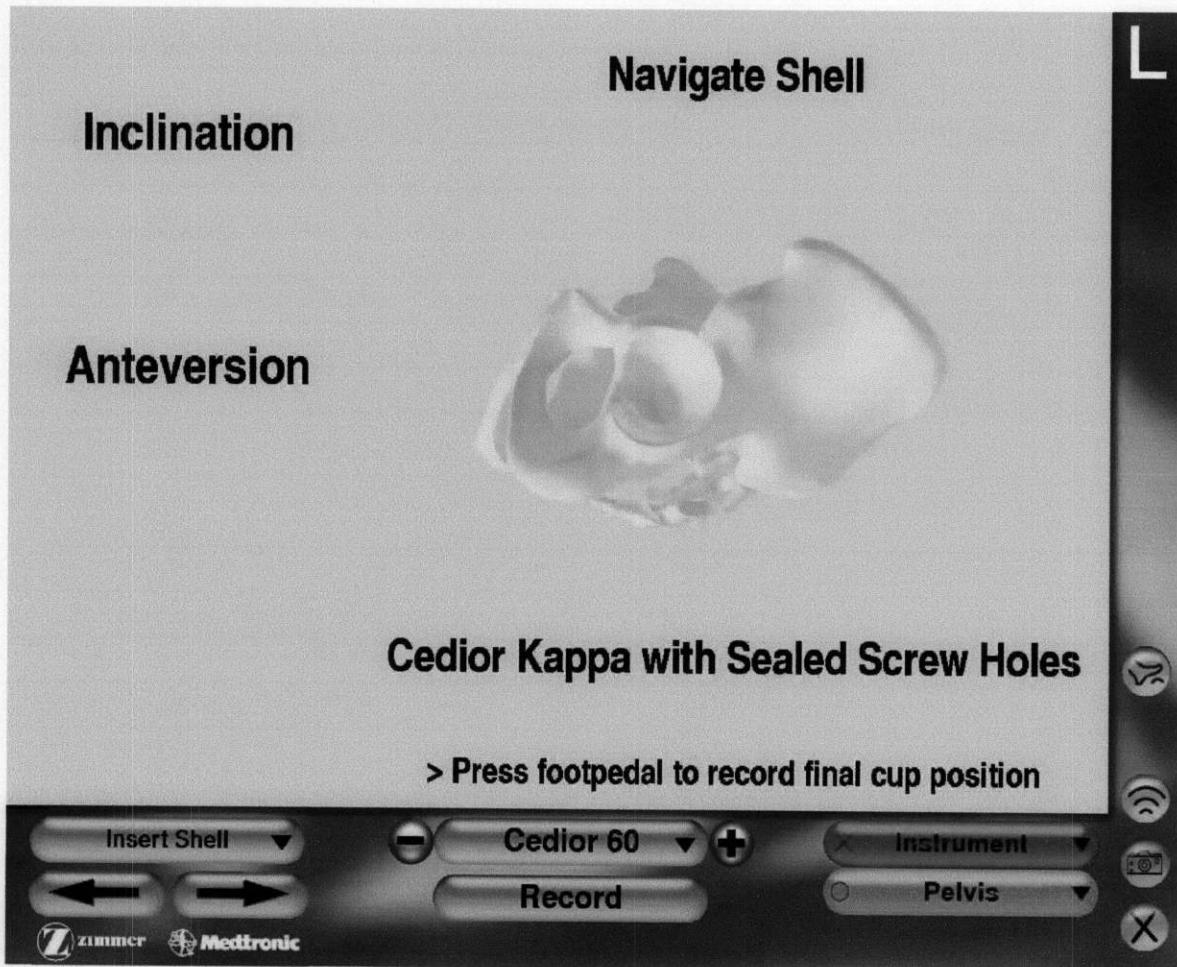


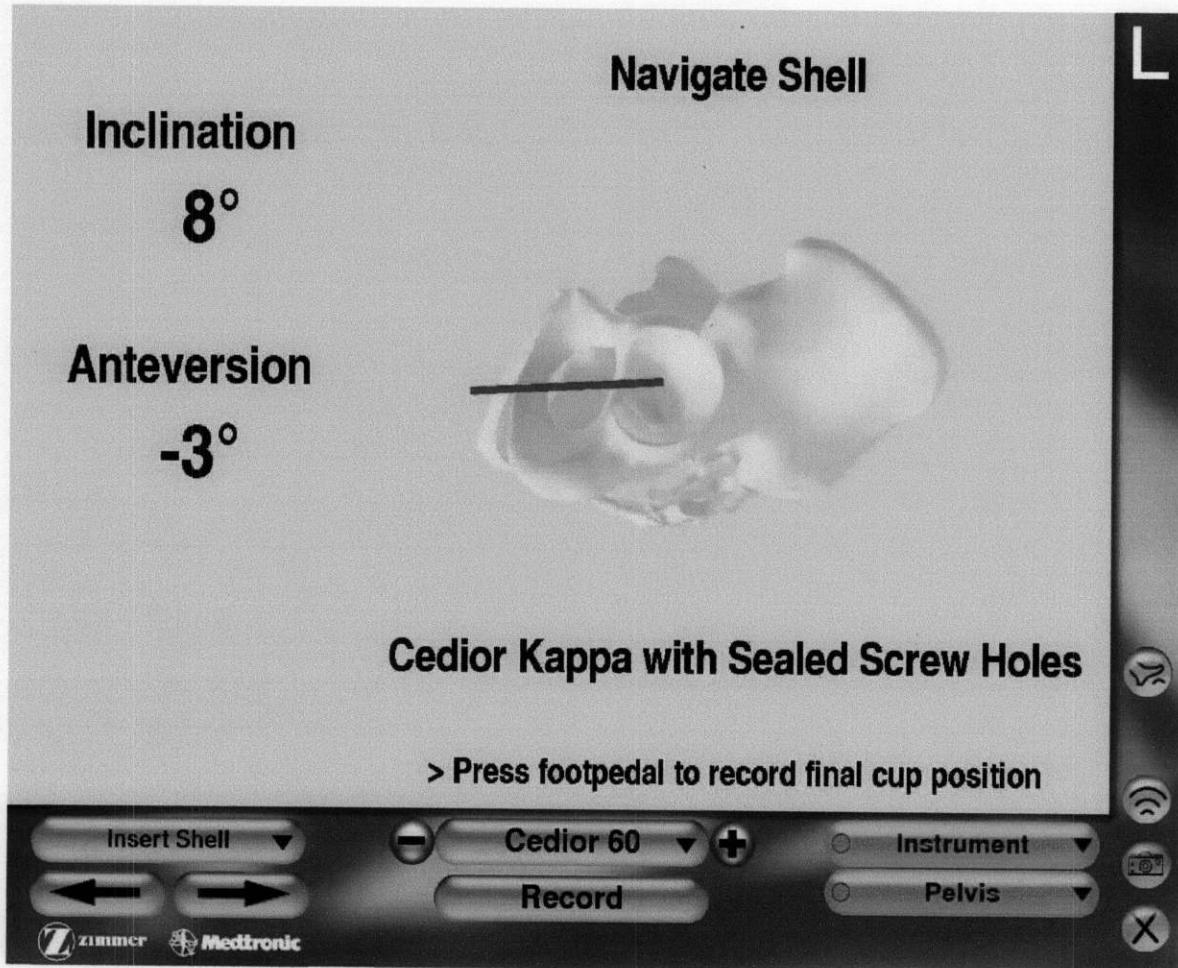












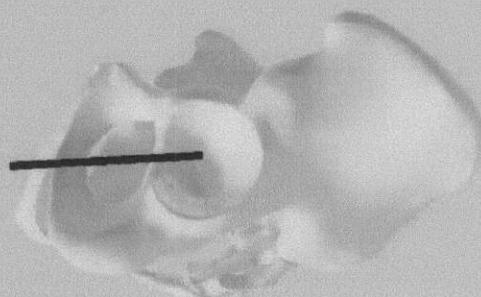
Inclination/
Adjusted

8°/8°

Anteversion/
Adjusted

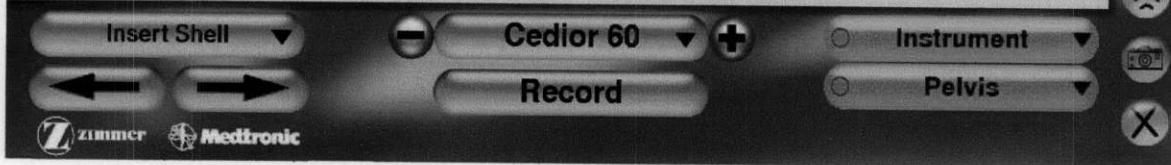
-4°/6°

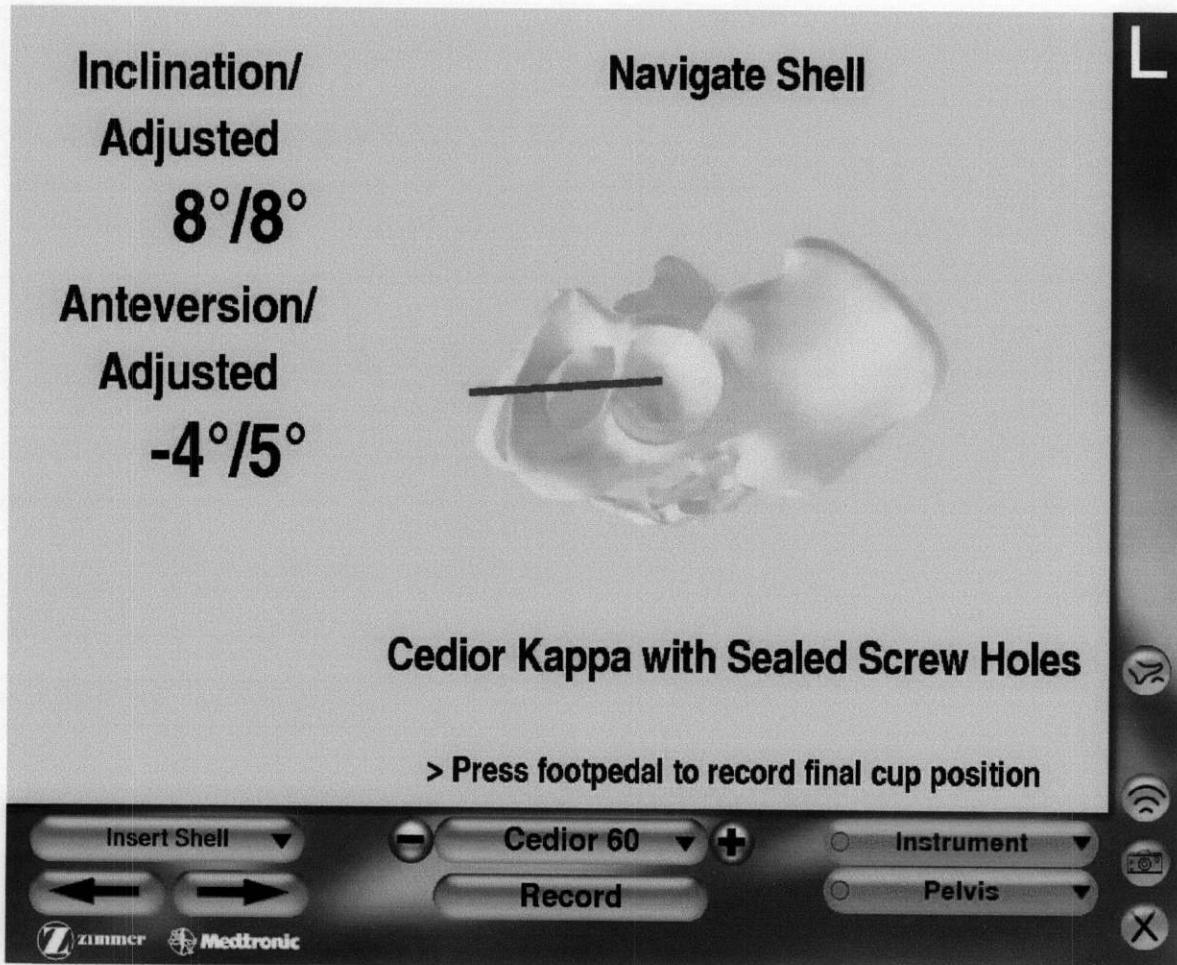
Navigate Shell

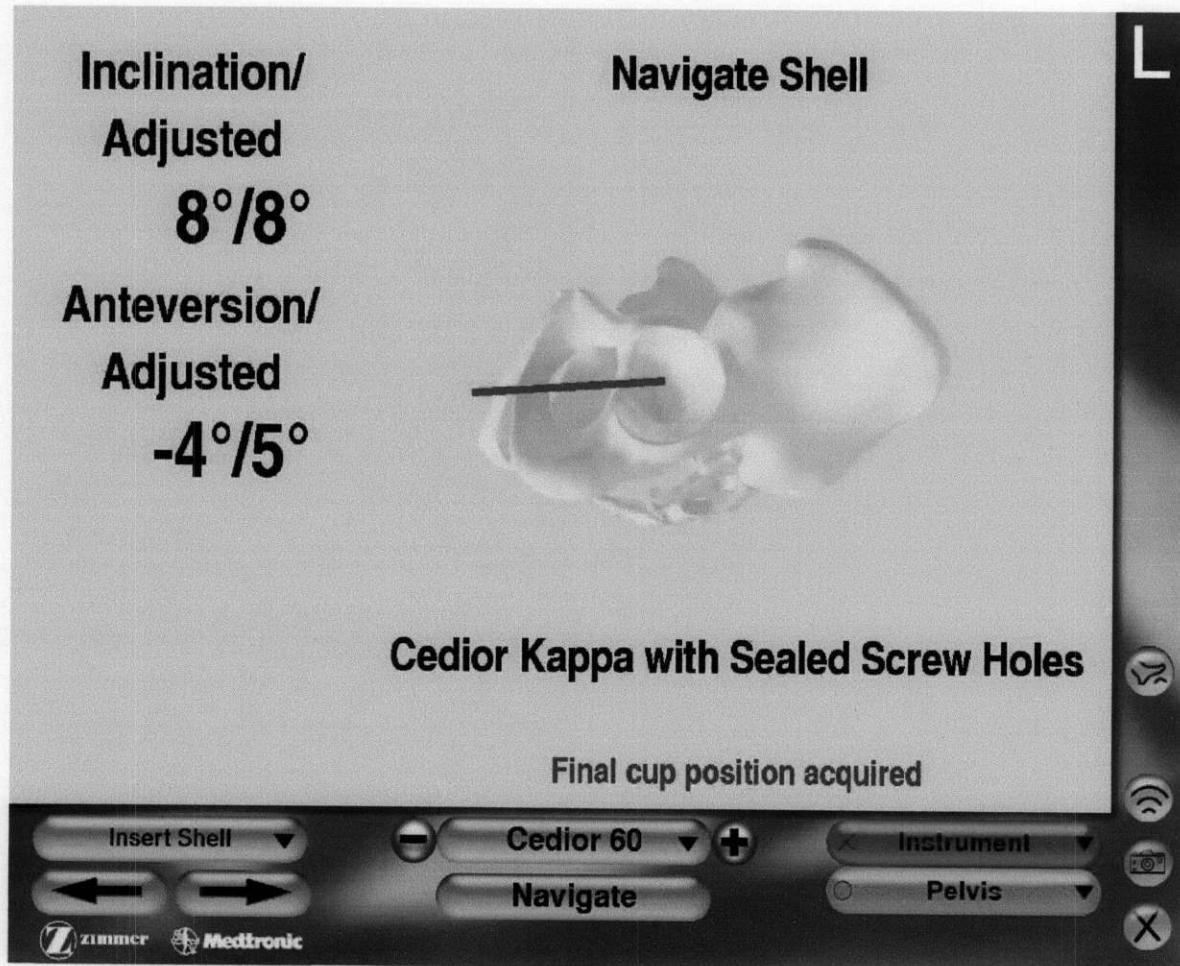


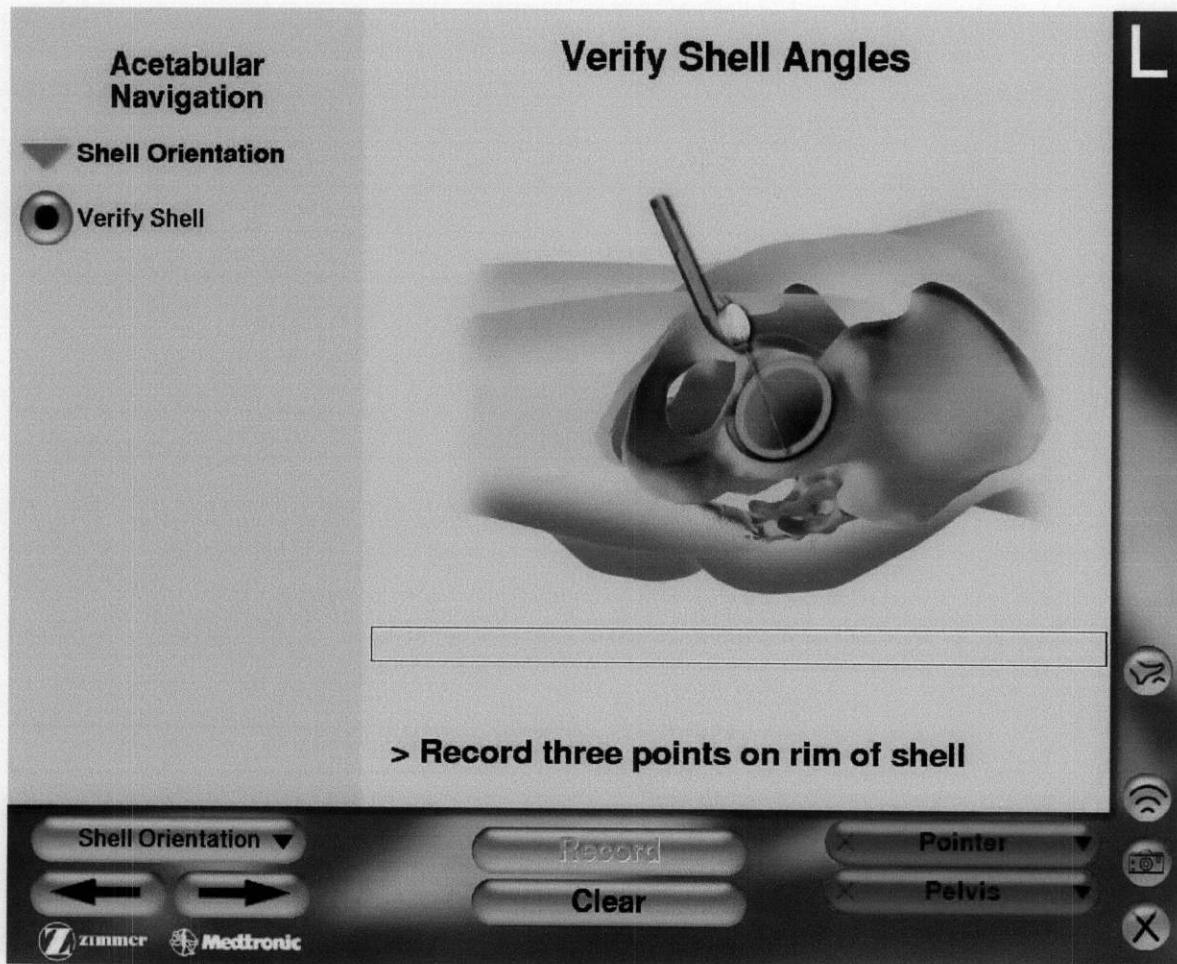
Cedior Kappa with Sealed Screw Holes

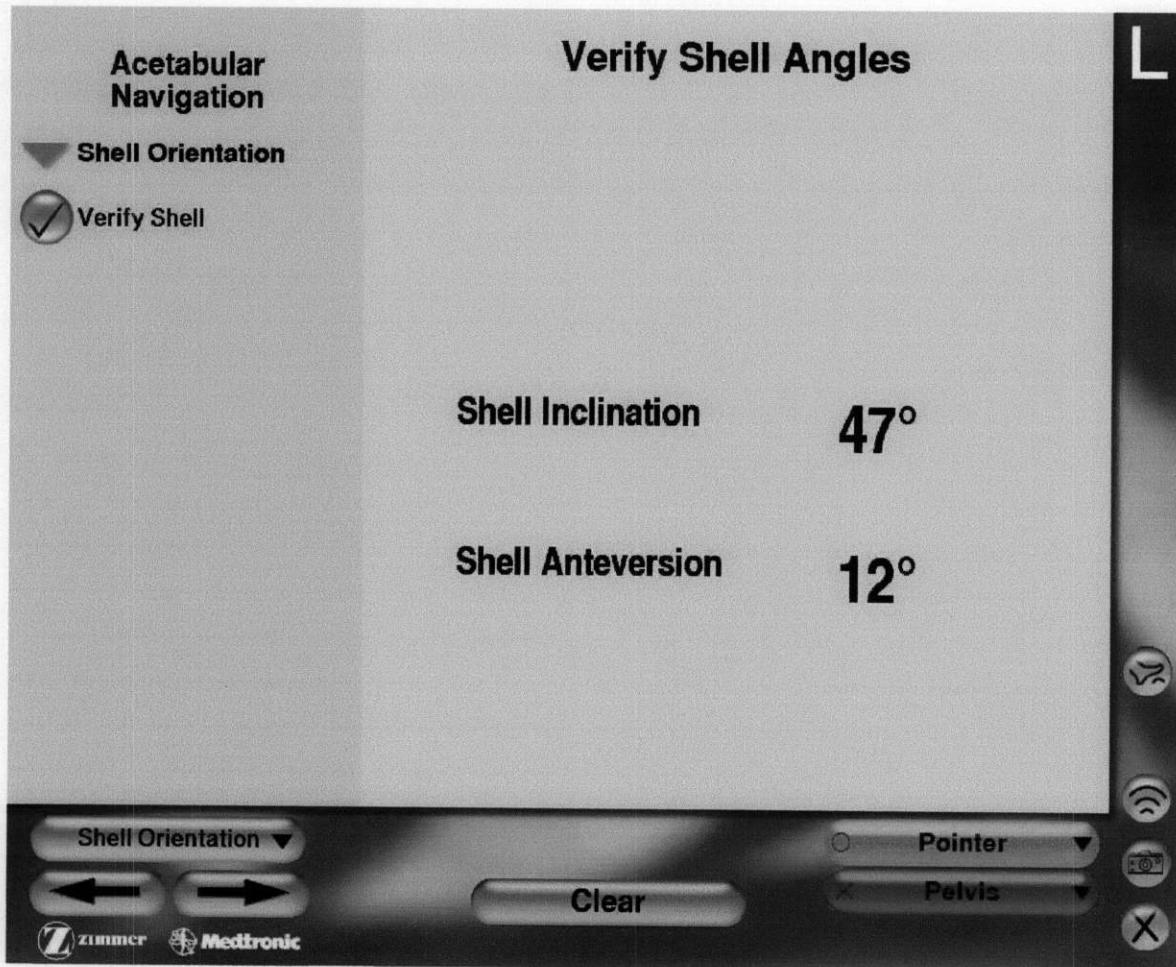
> Press footpedal to record final cup position

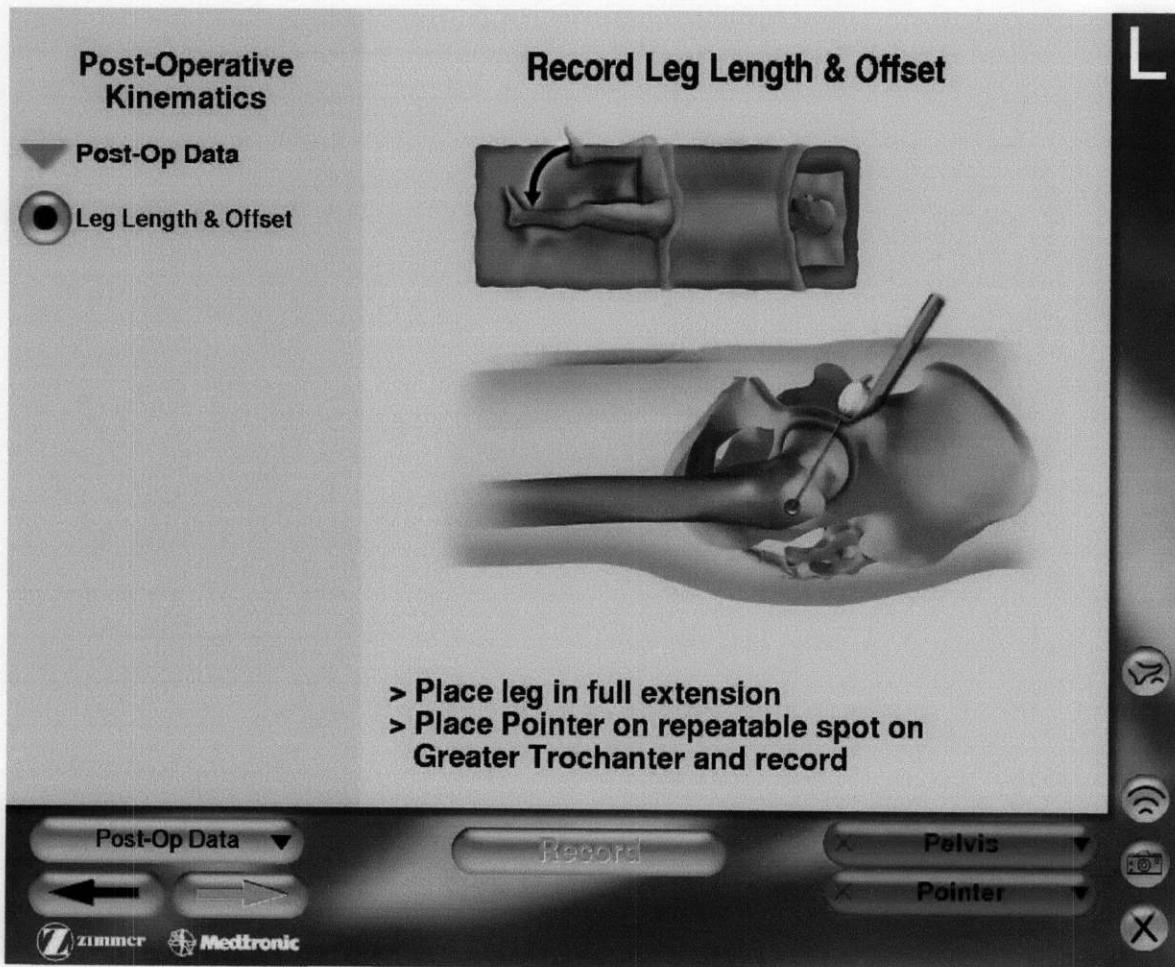


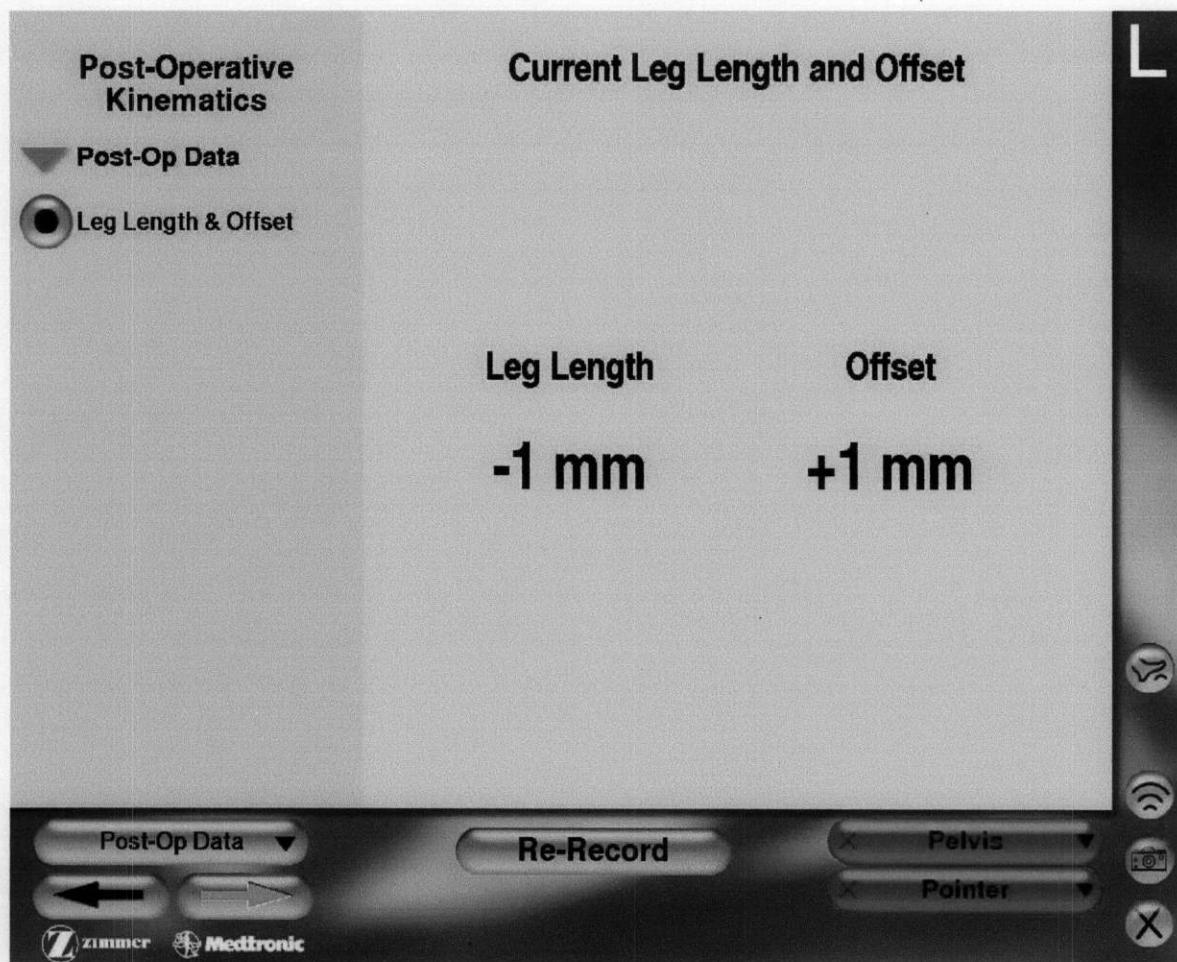












ATTACHMENT E

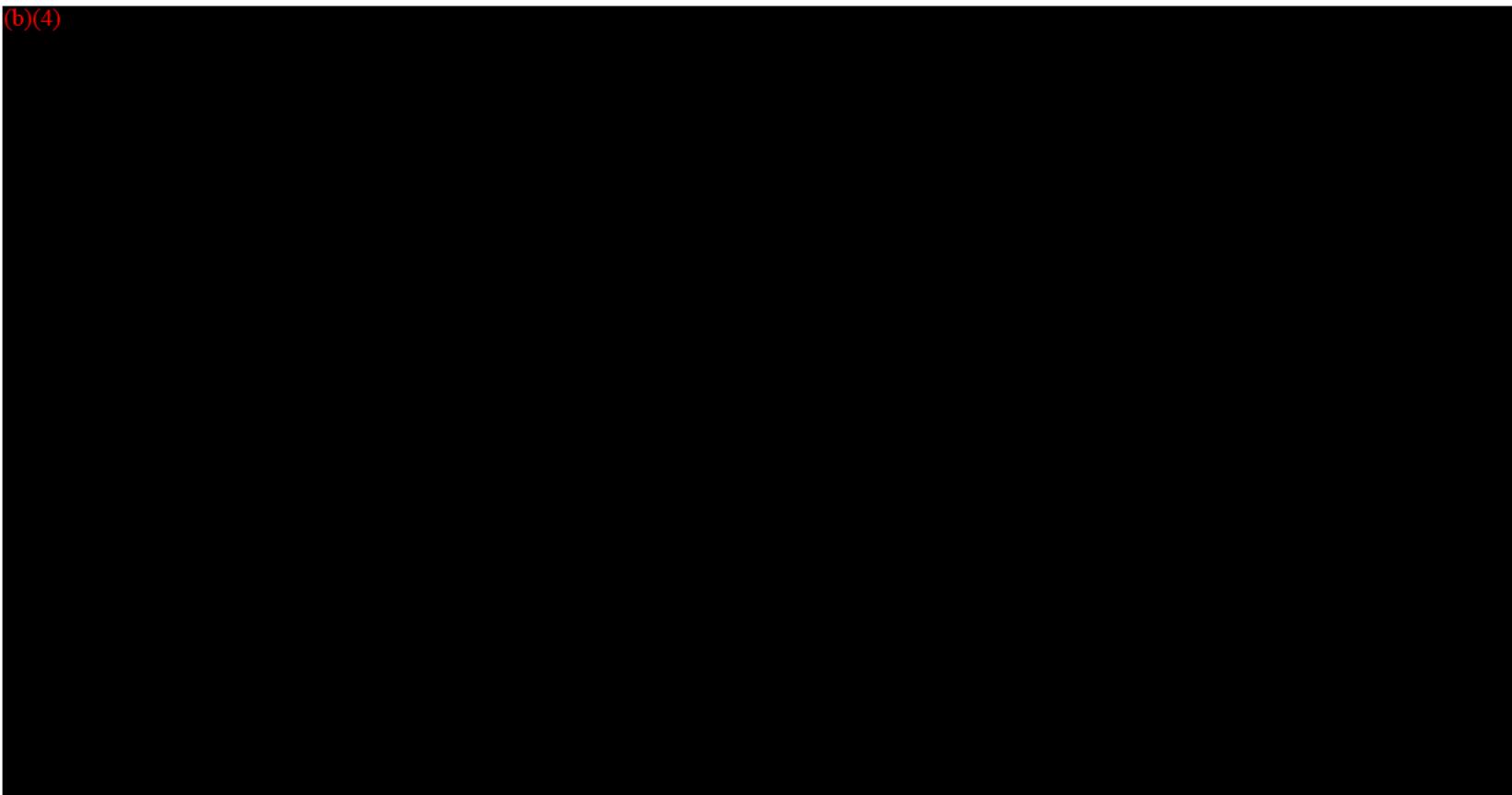
AXIEM™ IMAGELESS HIP MODULE FOR THE STEALTHSTATION® SYSTEM
SOFTWARE ARCHITECTURE DIAGRAM

S81



Zimmer Imageless Hip
DHF# 268
Software Architecture & Design
4/10/2006

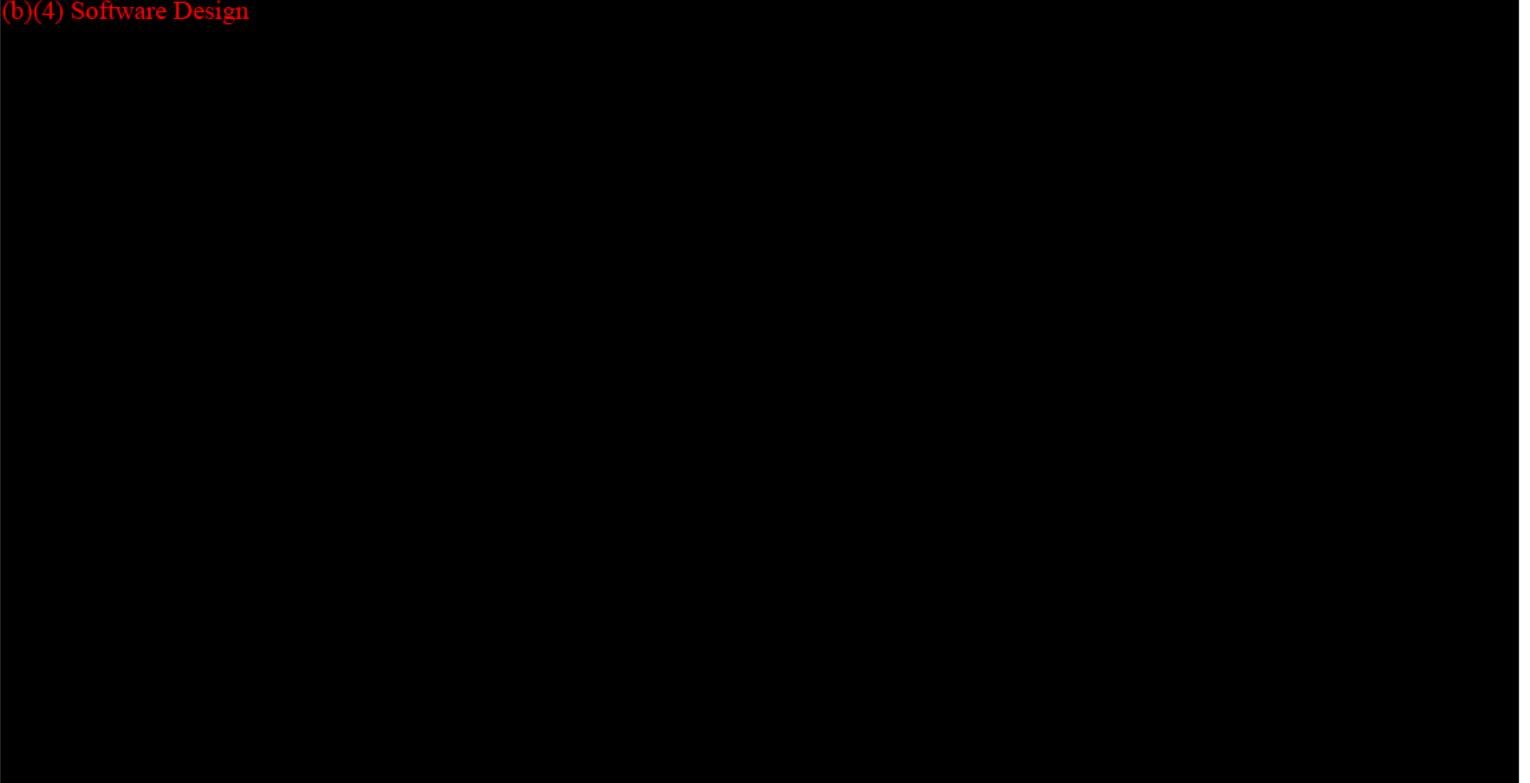
(b)(4)



582
Medtronic-SNT Confidential

CONFIDENTIAL

(b)(4) Software Design



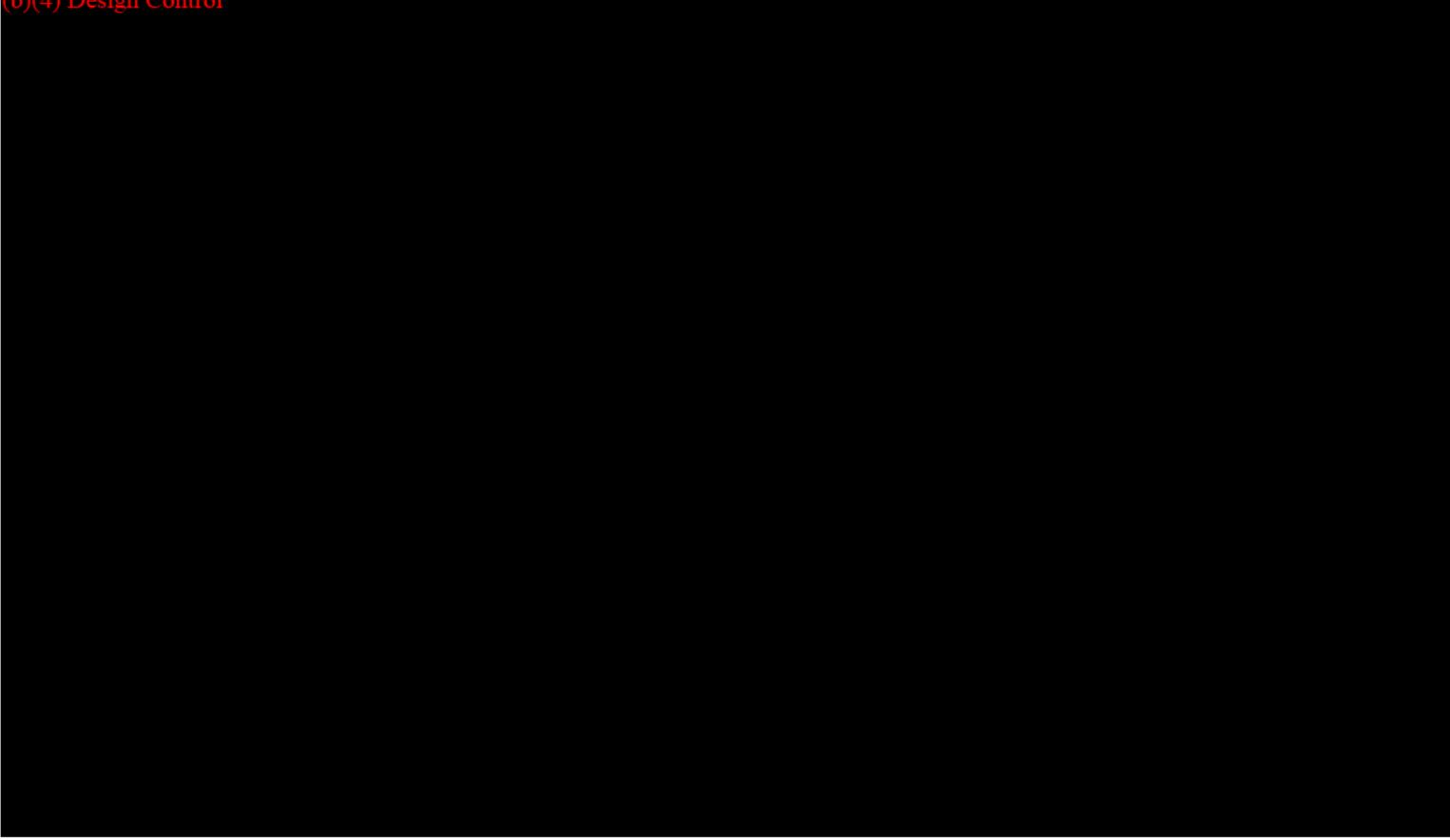
ATTACHMENT F

AXIEM™ IMAGELESS HIP MODULE FOR THE STEALTHSTATION® SYSTEM

DESIGN CONTROL DOCUMENTS

1. SP-C-01 Design Control System Procedure
2. SOP-C-100 StageGate Process
3. GUID C-1110 CCM Usage
4. GUID C-1200 Software Coding Standards

(b)(4) Design Control



591

MNav	Standard Operating Procedure # SOP C-100	Rev. 4
Title:	StageGate Product Development Process	Page 2 of 34

1 PURPOSE.....	5
2 SCOPE	5
3 DEFINITIONS	5
4 REFERENCES.....	7
4.1 STANDARD OPERATING PROCEDURES	7
4.2 STAGEGATE FORMS.....	7
4.3 STAGEGATE GUIDANCE MATERIALS.....	8
4.4 MEDTRONIC NAVIGATION	8
4.5 MDT CORPORATE POLICIES.....	8
5 RESPONSIBILITIES	8
5.1 PROJECT MANAGER	8
5.2 ENGINEERING	9
5.3 MARKETING.....	9
5.4 MANUFACTURING.....	9
5.5 REGULATORY AFFAIRS	9
5.6 QUALITY ASSURANCE.....	9
5.7 PURCHASING	10
5.8 MANAGEMENT.....	10
6 STAGEGATE	10
6.1 OVERVIEW	10
6.2 PROJECTS.....	10
6.2.1 Software Library	11
6.2.2 Research	11
6.3 DETAILS	12
6.4 STAGEGATE CUSTOMIZATION & PROJECT PLANNING (<i>DHF CHECKLIST</i>)	15
6.4.1 Built-In Modification.....	15
6.4.2 Manual Modification.....	15
6.5 STAGEGATE STAGE REVIEWS	15
7 BUSINESS ANALYSIS STAGE.....	16
7.1 INTENT	16
7.2 TYPICAL ACTIVITIES.....	16
7.2.1 Project Start-Up.....	16
7.2.1.1 Design History Files.....	16
7.2.1.2 Miscellaneous Setup	16
7.2.2 Business Planning.....	16
7.2.3 Project Planning	17
7.2.4 Project Risks And Mitigations.....	17
7.2.5 Stage Review.....	17
7.3 OPTIONS - VARIATIONS	17
7.3.1 User Site Testing Activities and Verifications	17

MNav	Standard Operating Procedure # SOP C-100	Rev. 4
	Title: StageGate Product Development Process	Page 3 of 34

8 COMMITMENT STAGE.....	18
8.1 INTENT	18
8.2 TYPICAL ACTIVITIES.....	18
8.2.1 <i>Project Planning</i>	18
8.2.1.1 Other Plans	18
8.2.2 <i>Design Input</i>	19
8.2.2.1 Internationalization.....	19
8.2.3 <i>Risk Management</i>	19
8.2.3.1 Hazards (Product Risks).....	19
8.2.3.2 Project Risks (Business Risks).....	20
8.2.4 <i>Design</i>	20
8.2.5 <i>Design Reviews</i>	20
8.2.6 <i>Stage Review</i>	20
8.3 OPTIONS - VARIATIONS	20
8.3.1 <i>User Site Testing Activities and Verifications</i>	20
9 DEVELOPMENT STAGE.....	21
9.1 INTENT	21
9.2 TYPICAL ACTIVITIES.....	21
9.2.1 <i>Design Inputs</i>	21
9.2.2 <i>Risk Management</i>	21
9.2.3 <i>Design Outputs</i>	21
9.2.3.1 Overview	21
9.2.3.2 Essential Outputs.....	22
9.2.4 <i>Design Reviews</i>	23
9.2.4.1 Overview	23
9.2.4.2 Scheduling	23
9.2.4.3 Design Review Details	24
9.2.4.4 Design Review Documentation	24
9.2.5 <i>Product Design Verification & Validation (V&V)</i>	24
9.2.5.1 Overview	24
9.2.5.2 Design Verification	25
9.2.5.3 Design Validation	25
9.2.5.4 Product Design V&V Plan-Summary	25
9.2.5.5 Acceptance Criteria	26
9.2.6 <i>Design Transfer</i>	26
9.2.6.1 Overview	26
9.2.6.2 Regulatory Clearance	26
9.2.6.3 Build/Test/Final Acceptance Procedure	26
9.2.6.4 Process Validation	27
9.2.6.5 Review	27
9.2.7 <i>Stage Review</i>	28
9.3 OPTIONS - VARIATIONS	28
9.3.1 <i>Software Development Activities and Verifications</i>	28
9.3.1.1 Software Architecture & Design Review	28
9.3.1.2 Software Code Reviews	28
9.3.1.3 Software Change Effect Analysis.....	28

MNav	Standard Operating Procedure # SOP C-100	Rev. 4
Title:	StageGate Product Development Process	Page 4 of 34

9.3.1.4 Software Language Translations.....	28
9.3.1.5 IQA Plan-Summary.....	28
9.3.2 <i>Hardware Development Activities and Verifications</i>	29
9.3.2.1 Concept Review	29
9.3.2.2 Drawing Review	29
9.3.3 <i>Internationalization</i>	29
9.3.4 <i>Biocompatibility</i>	29
9.3.5 <i>Electrical Power</i>	29
9.3.6 <i>User Site Testing Activities</i>	29
10 LIMITED MARKET RELEASE STAGE.....	29
10.1 INTENT	29
10.2 TRANSITION	29
10.3 STAGE REVIEW.....	30
11 FULL MARKET RELEASE STAGE.....	30
11.1 INTENT	30
12 POST LAUNCH PROJECT REVIEW.....	30
12.1 INTENT	30
12.2 TIMING	30
13 DESIGN CHANGES.....	31
14 DESIGN HISTORY FILE (DHF).....	31
14.1 OVERVIEW	31
14.2 CONTENTS.....	31
14.2.1 <i>Documents Based On Controlled Forms and Templates</i>	31
14.2.2 <i>Documents Based on Non-Controlled Forms or Templates</i>	31
14.2.3 <i>Documents Based on Previously Obsolete Forms or Templates</i>	31
14.2.3.1 <i>Revision History For Documents Based on Previously Obsolete Forms or Templates</i>	32
14.2.4 <i>Other Documents</i>	32
14.2.5 <i>Electronic Documents</i>	33
14.3 LIFECYCLE	33
14.3.1 <i>DHF Creation</i>	33
14.3.2 <i>DHF Management During A Project</i>	33
14.3.3 <i>DHF Completion</i>	34

594

ATTACHMENT G

AXIEM™ IMAGELESS HIP MODULE FOR THE STEALTHSTATION® SYSTEM
PRODUCT REQUIREMENTS



Imageless AxiEM Hip (software)

DHF# 0268

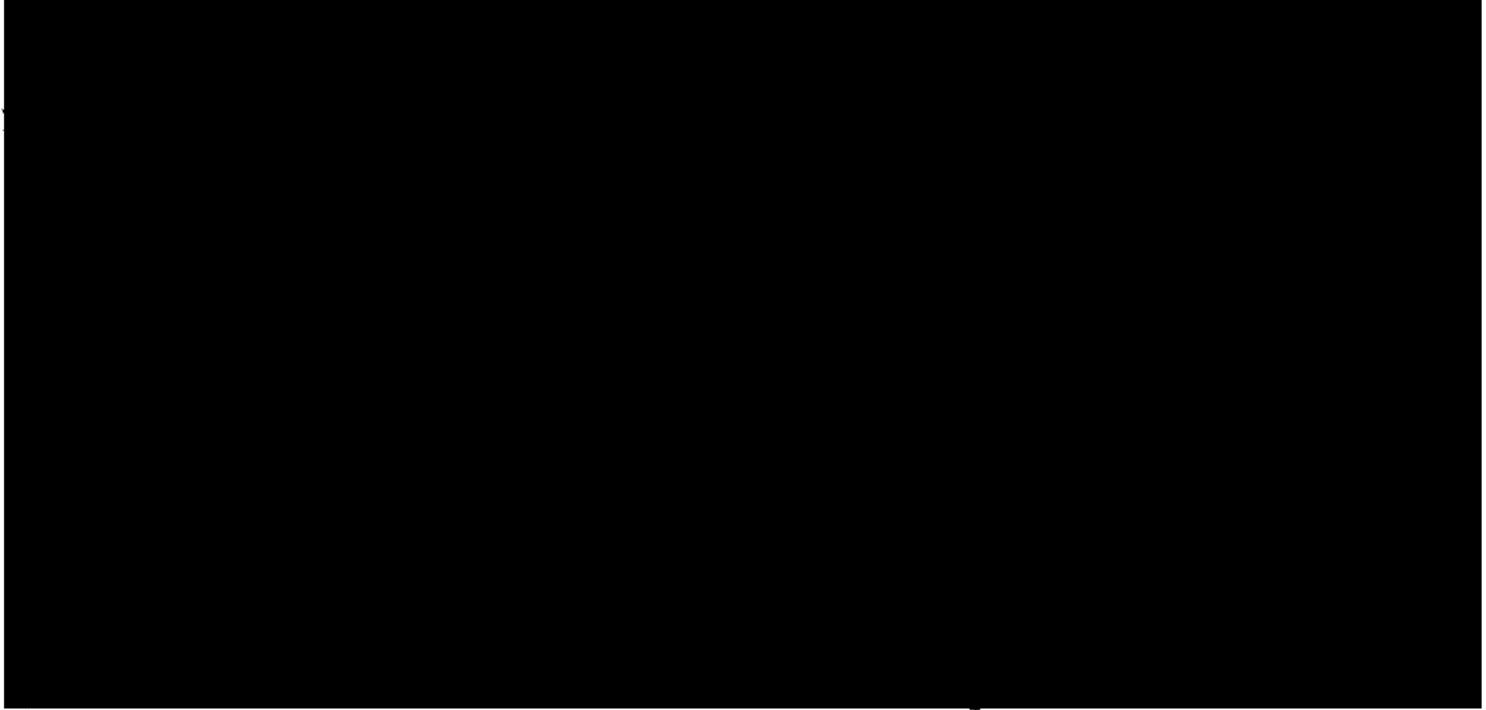
Product Definition & Requirements

3/14/2006

Check one or more of the following boxes to indicate which columns of this document are being reviewed and approved

- | | |
|-------------------------------------|----------------------|
| <input checked="" type="checkbox"/> | Product Definition |
| <input checked="" type="checkbox"/> | Requirements |
| <input checked="" type="checkbox"/> | Design Summary |
| <input type="checkbox"/> | Product Verification |
| <input type="checkbox"/> | Product Validation |
| <input checked="" type="checkbox"/> | IFU Requirement |
| <input type="checkbox"/> | IFU Verification |

(b)(4) Software requirements

A large rectangular area of the page is completely blacked out, indicating that the software requirements section has been redacted.

Revision History Record

Rev.	Areas affected	Author
1	Initial Release	JG
2	Update requirements for the ITKR code base.	JG
3	510K Release; updated PD&R based on Hazard Doc changes and review.	JG

¹ Signature required only if the IFU Requirement or IFU Verification columns are being reviewed and approved

² Signature required only if a software project

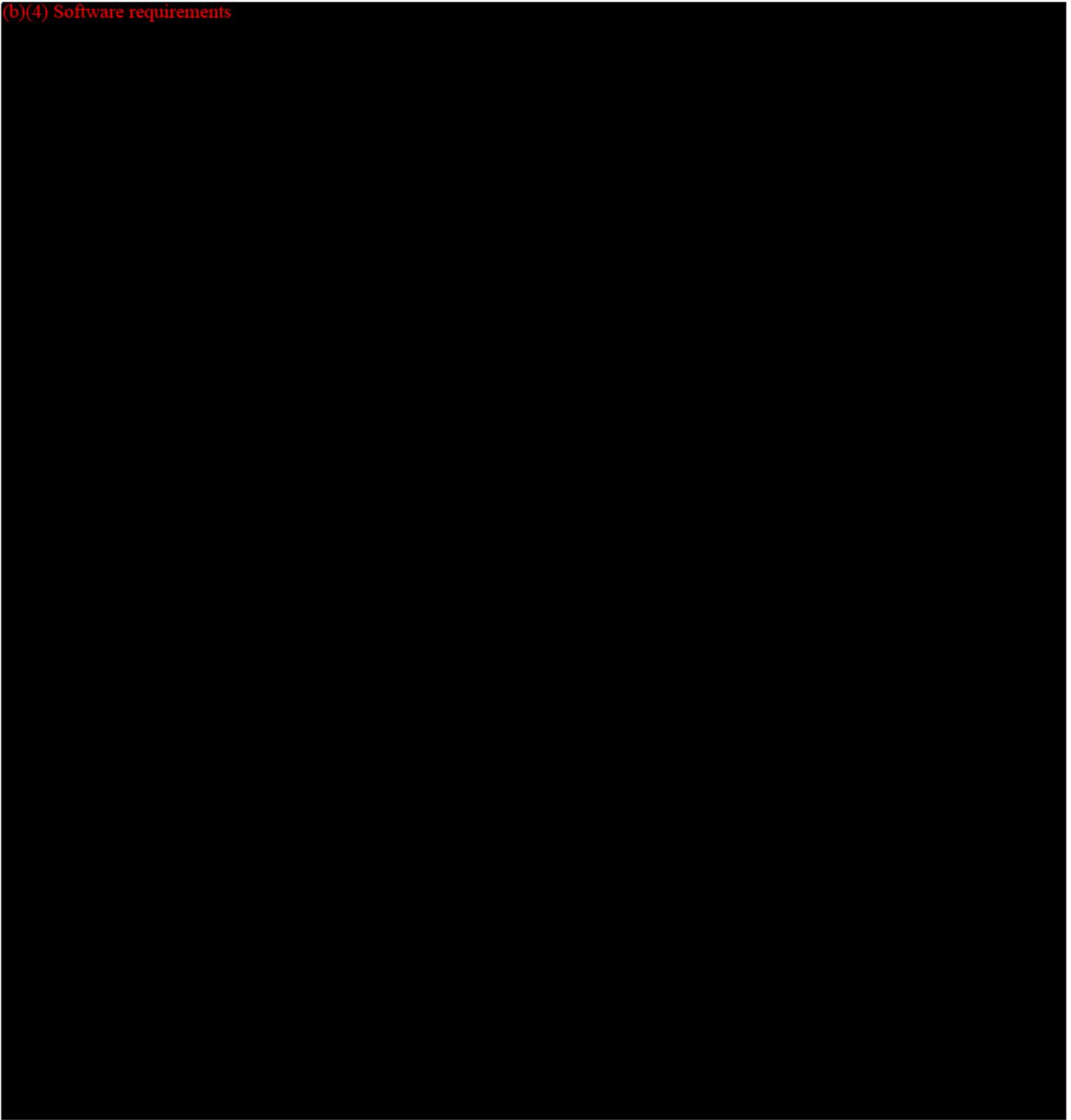
³ Signature required only if project involves usability requirements.

Medtronic-SNT Confidential

445

MSNT	Product Definition & Requirements	Rev./
	Title: Imageless AxiEM Hip (software)	Page 2 of 88

(b)(4) Software requirements



Medtronic-SNT Confidential

Medtronic Navigation, Inc.

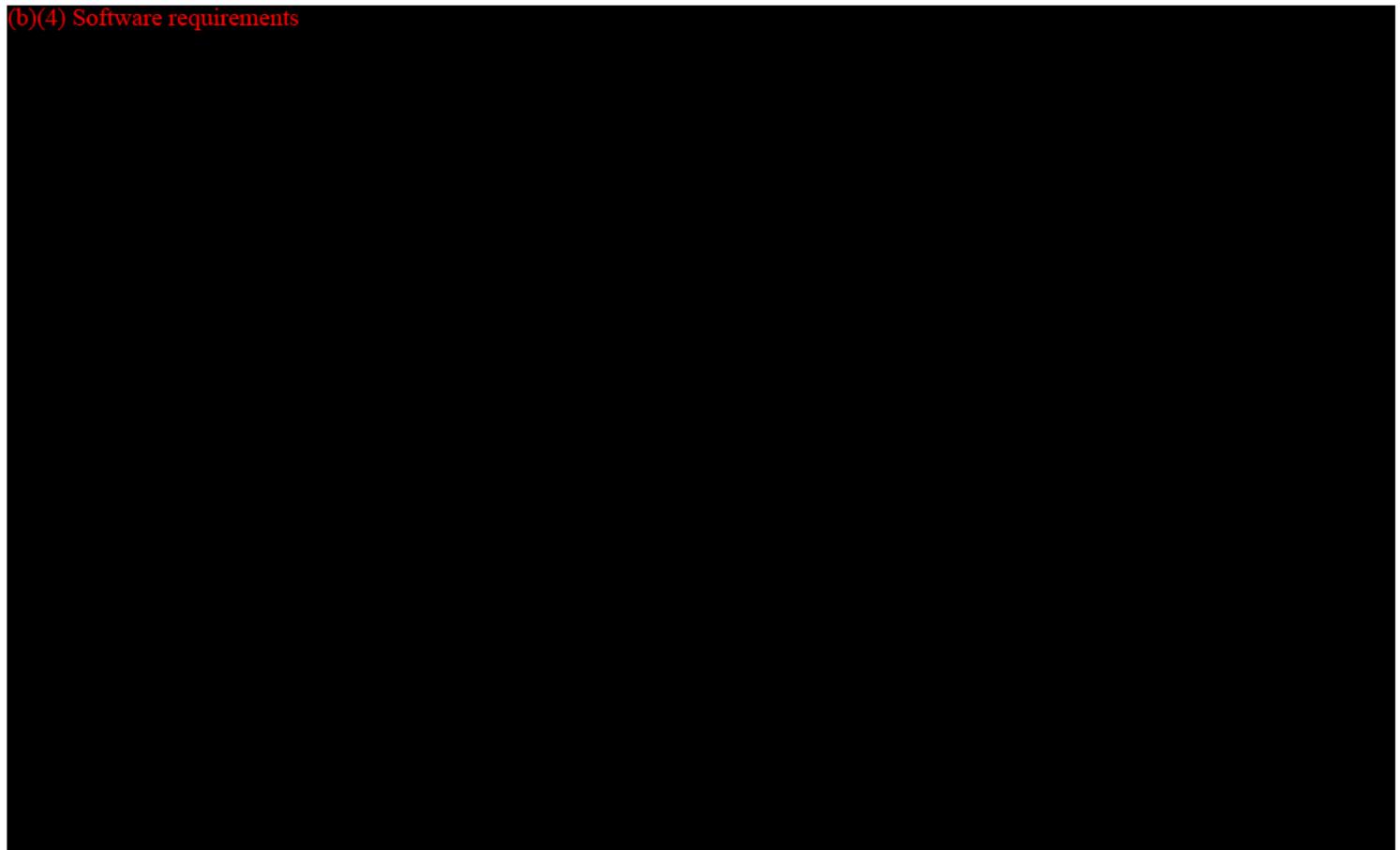
CONFIDENTIAL

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

646
Page 222 of 877

MSNT	Product Definition & Requirements	Rev.7
	Title: Imageless AxiEM Hip (software)	Page 3 of 88

(b)(4) Software requirements



Medtronic-SNT Confidential

Medtronic Navigation, Inc.

CONFIDENTIAL

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

647
Page 223 of 877

MSIN	Product Definition & Requirements	Rev.
	Title: Imageless AxiEM Hip (software)	Page 4 of 88

(b)(4) Software requirements

Medtronic-SNT Confidential

Medtronic Navigation, Inc.

CONFIDENTIAL

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

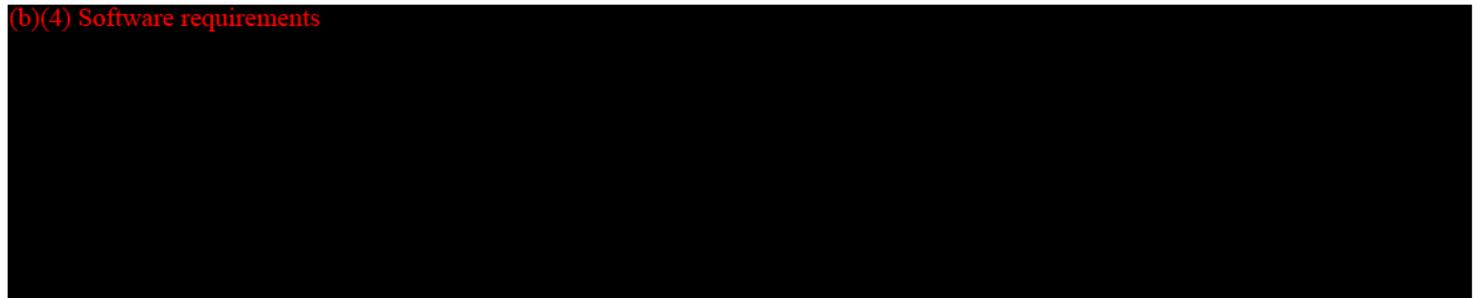
648
Page 224 of 877

MSNT	Product Definition & Requirements	Rev.7
	Title: Imageless AxiEM Hip (software)	Page 5 of 88

(b)(4) Software requirements

MISN#	Product Definition & Requirements	Rev.
	Title: Imageless AxiEM Hip (software)	Page 6 of 88

(b)(4) Software requirements



Medtronic-SNT Confidential

Medtronic Navigation, Inc.

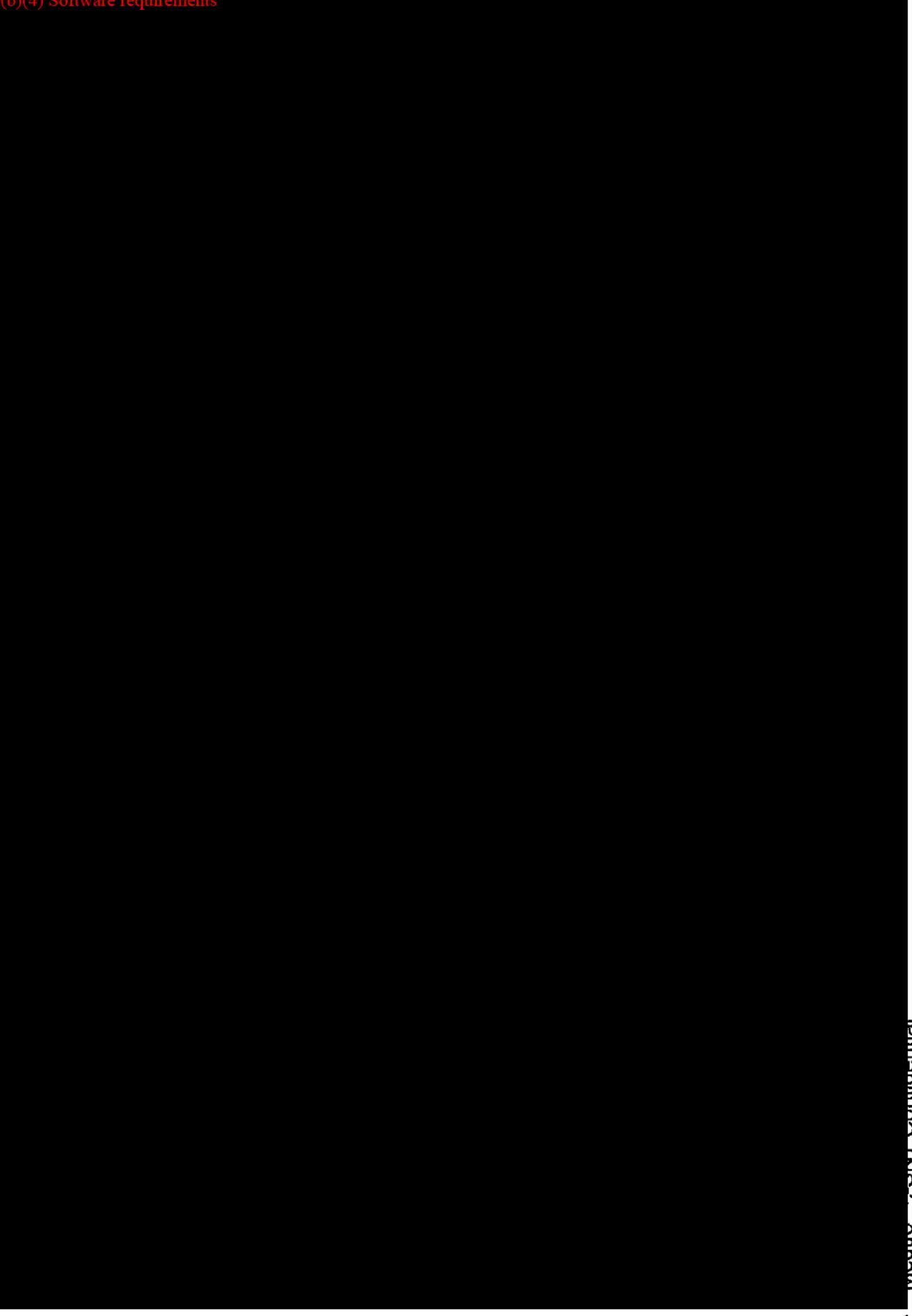
CONFIDENTIAL

650
Page 226 of 877

(b)(4) Software requirements

MSN	Product Definition & Requirements	Rev.7
Title: Imageless AxiEM Hip (software)		Date: 7/26/00

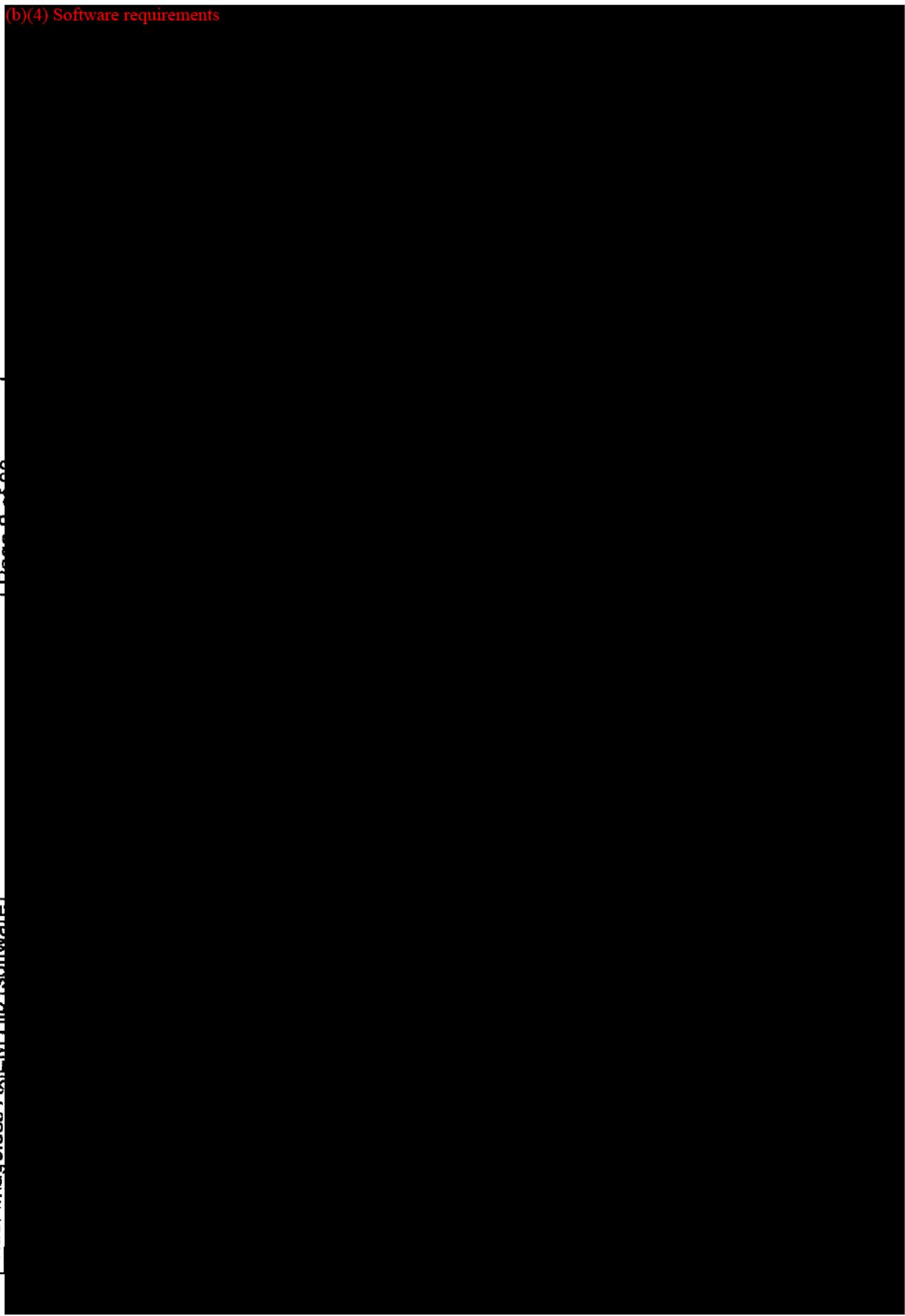
(b)(4) Software requirements



MSNT	Product Definition & Requirements	Rev.7
Title: Imageless AxilEM Hip (software)		Page 8 of 88

Medtronic Navigation Confidential
C-310, Product Definition & Requirements (Rev 3)

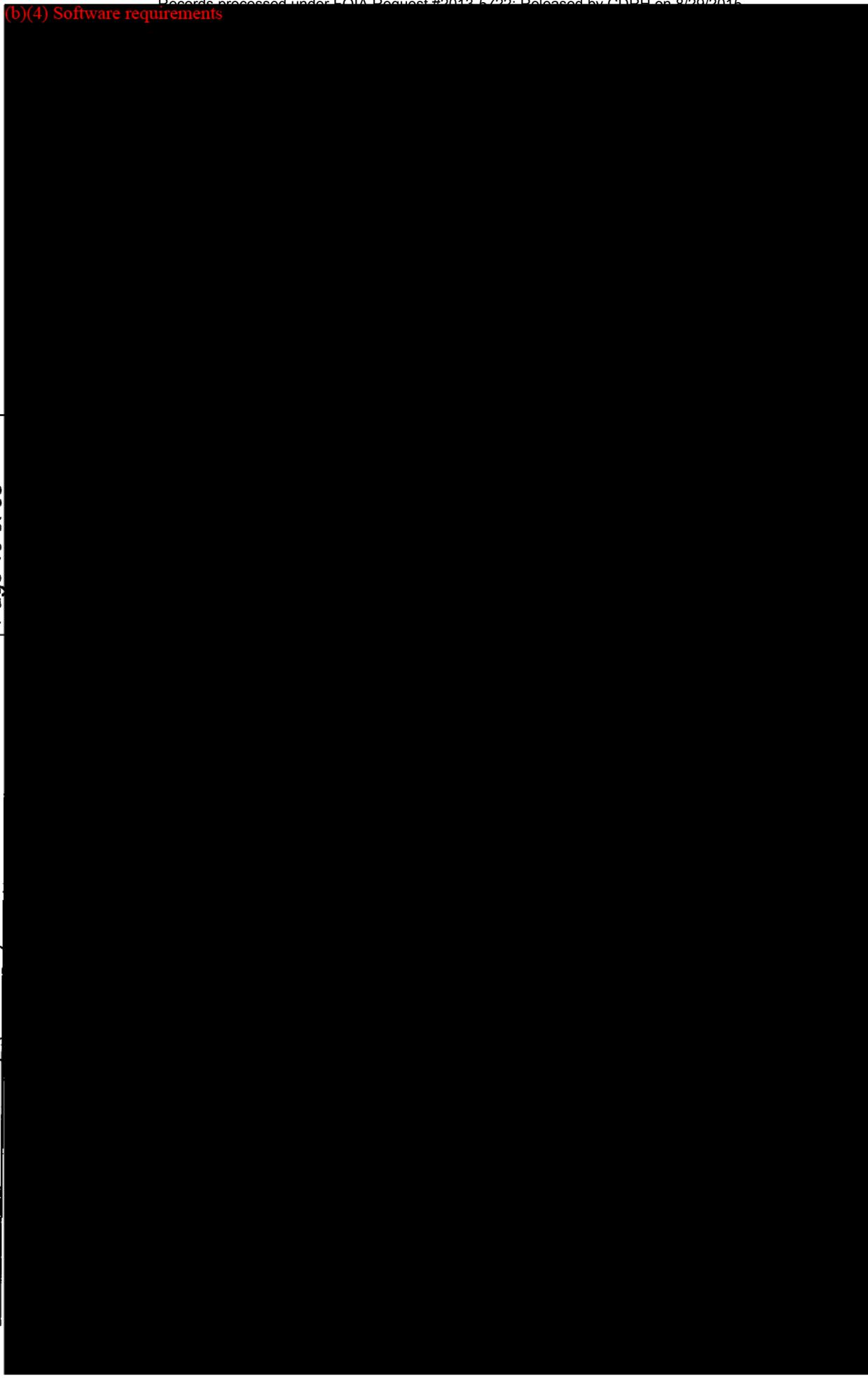
(b)(4) Software requirements



MSN	Product Definition & Requirements	Rev.7
Title: Imageless AxiEM Hip (software)		Date: 06/06/06

653
Medtronic-SNT Confidential
C-310, Product Definition & Requirements (Rev 3)

(b)(4) Software requirements



MSNT	Product Definition & Requirements	Rev.7
Title: Imageless AxiEM Hip (software)		Page 10 of 88

Medtronic-SNT Confidential
C-310, Product Definition & Requirements (Rev 3)

654



Imageless Hip- AxiEM Patient DRF
DHF# 0268
Product Definition & Requirements
02/10/06

Check one or more of the following boxes to indicate which columns of this document are being reviewed and approved

- | | |
|-------------------------------------|----------------------|
| <input checked="" type="checkbox"/> | Product Definition |
| <input checked="" type="checkbox"/> | Requirements |
| <input type="checkbox"/> | Design Summary |
| <input type="checkbox"/> | Product Verification |
| <input type="checkbox"/> | Product Validation |
| <input checked="" type="checkbox"/> | IFU Requirement |
| <input type="checkbox"/> | IFU Verification |

(b)(4) Software requirements

A large rectangular area of the page is completely blacked out, indicating that the software requirements section has been redacted.

¹ Signature required only if the IFU Requirement or IFU Verification columns are being reviewed and approved

² Signature required only if a software project

³ Signature required only if project requires usability requirements

K 061248
vol II

765



Medtronic

SURGICAL NAVIGATION TECHNOLOGIES

Imageless Hip (System Accuracy)

DHF# 0268

Product Design V&V Protocol

3/21/2006

Protocol Type

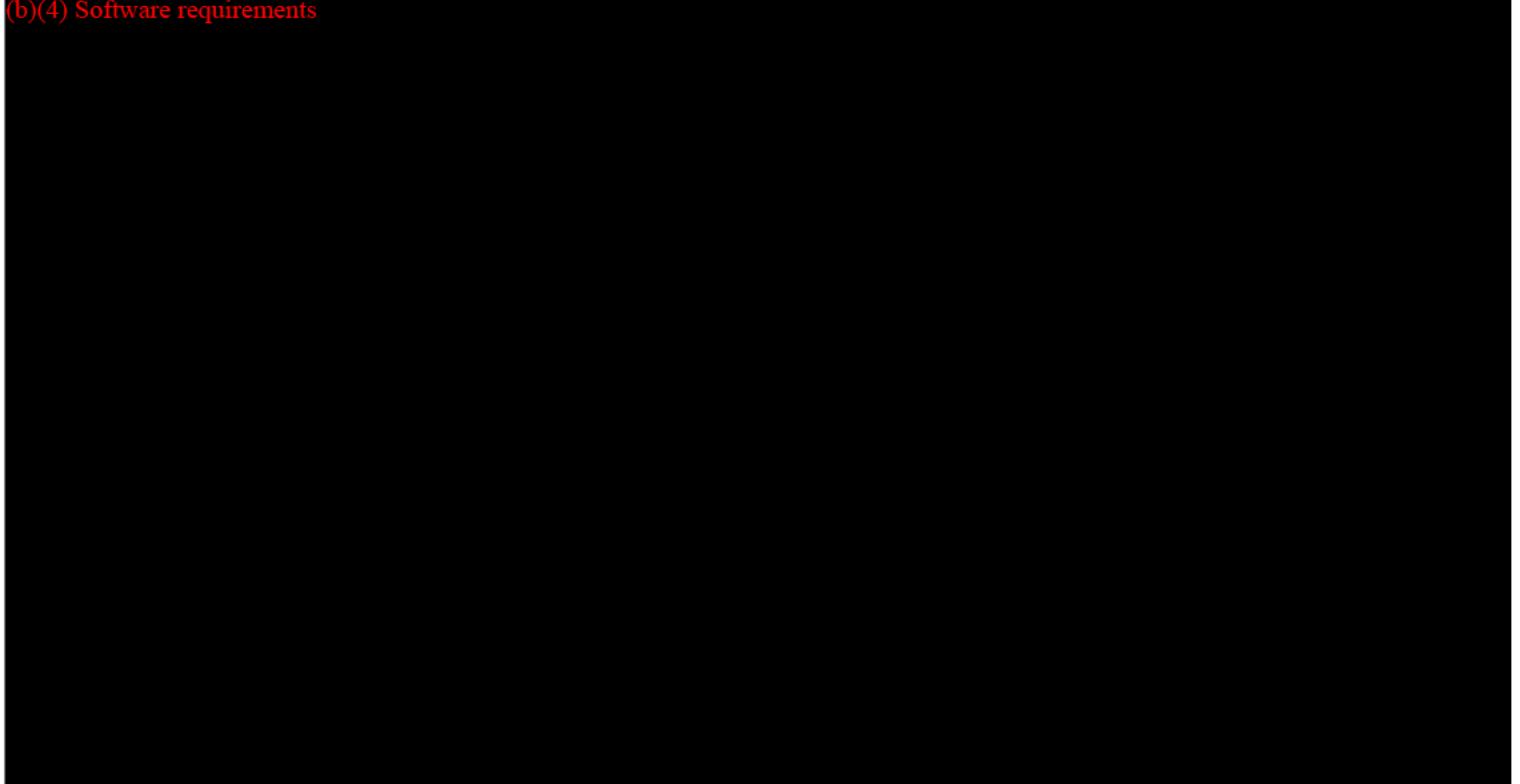
Validation

Verification

Protocol Document Retention #

VV 1102

(b)(4) Software requirements



¹ Signature required if software testing is involved.

Medtronic-SNT Confidential



Medtronic

SURGICAL NAVIGATION TECHNOLOGIES

Imageless AxiEM Hip (Functional)

DHF# 0268

Product Design V&V Protocol

03/14/2006

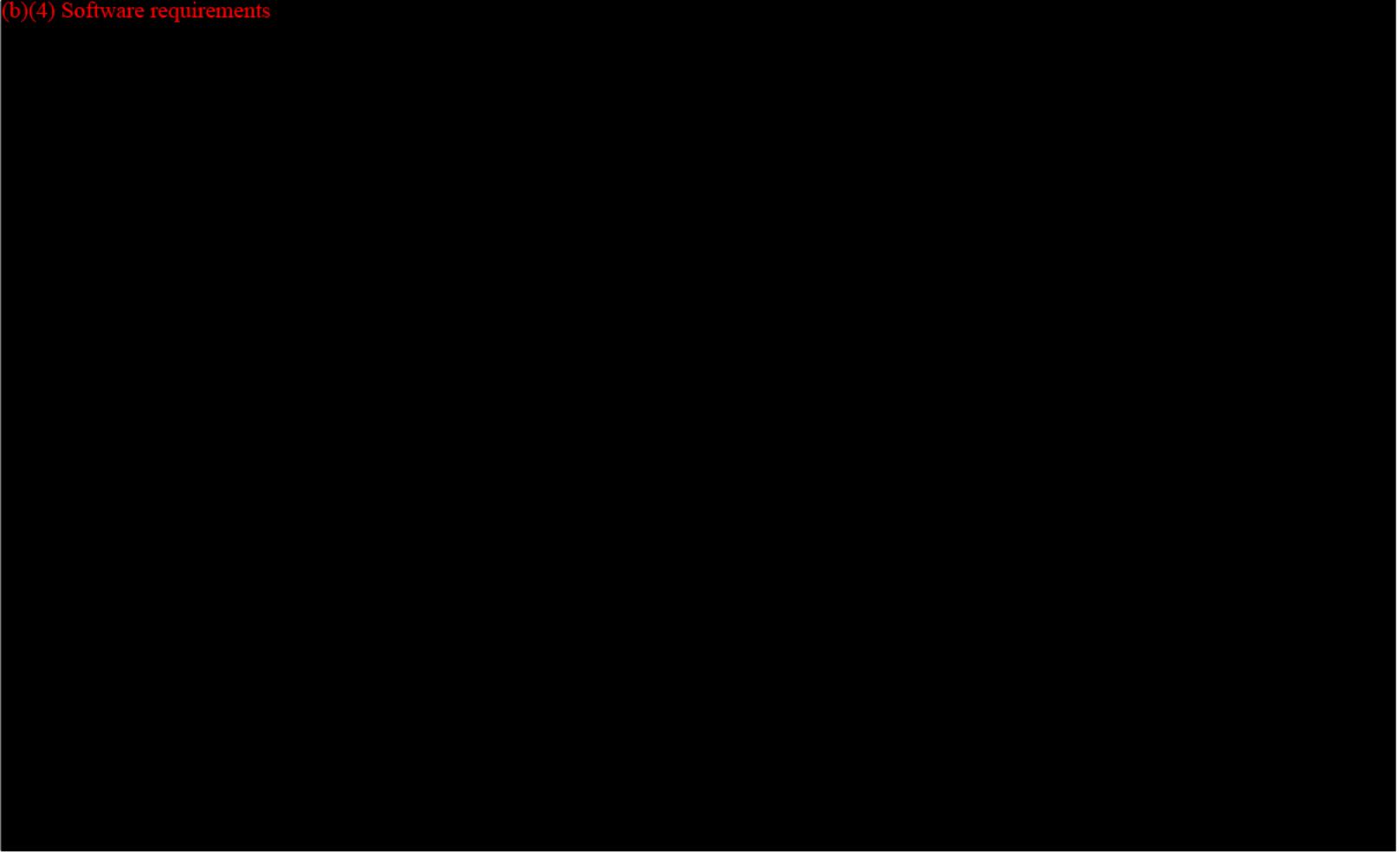
Protocol Type

Validation
 Verification

Protocol Document Retention #

VV1103

(b)(4) Software requirements



¹ Signature required if software testing is involved.



Medtronic

SURGICAL NAVIGATION TECHNOLOGIES

Imageless AxiEM Hip Functional Report

DHF# 0268

Product Design V&V Report

03/22/2006

Report Type

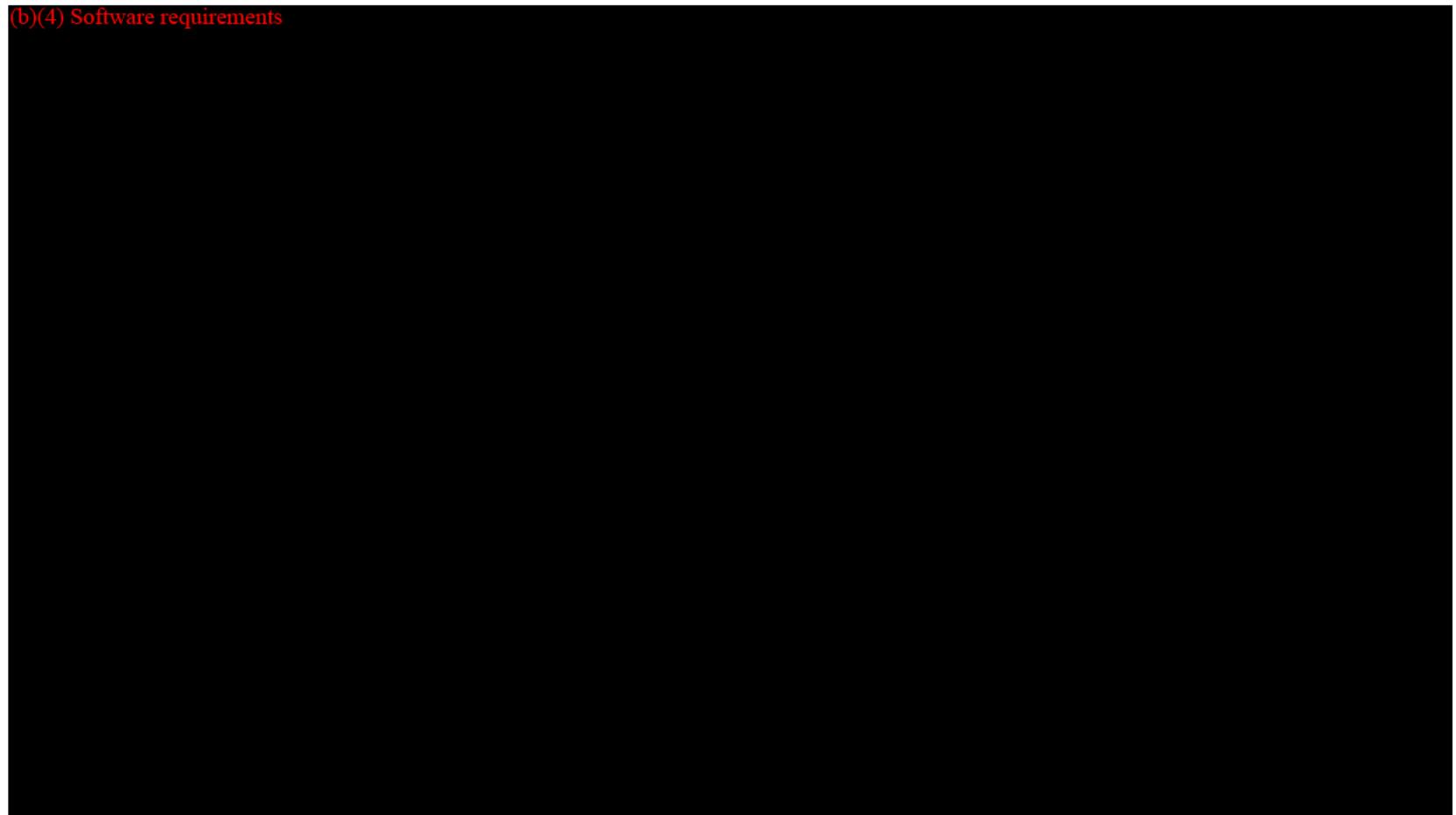
- Validation
 Verification

Protocol Document Retention # VV1103

Report Document Retention # VV1103

Protocol Revision Level # 4

(b)(4) Software requirements



¹ Signature required if software testing is involved.

892



Medtronic

SURGICAL NAVIGATION TECHNOLOGIES

Imageless AxiEM Hip (Simulated Use)

DHF# 0268

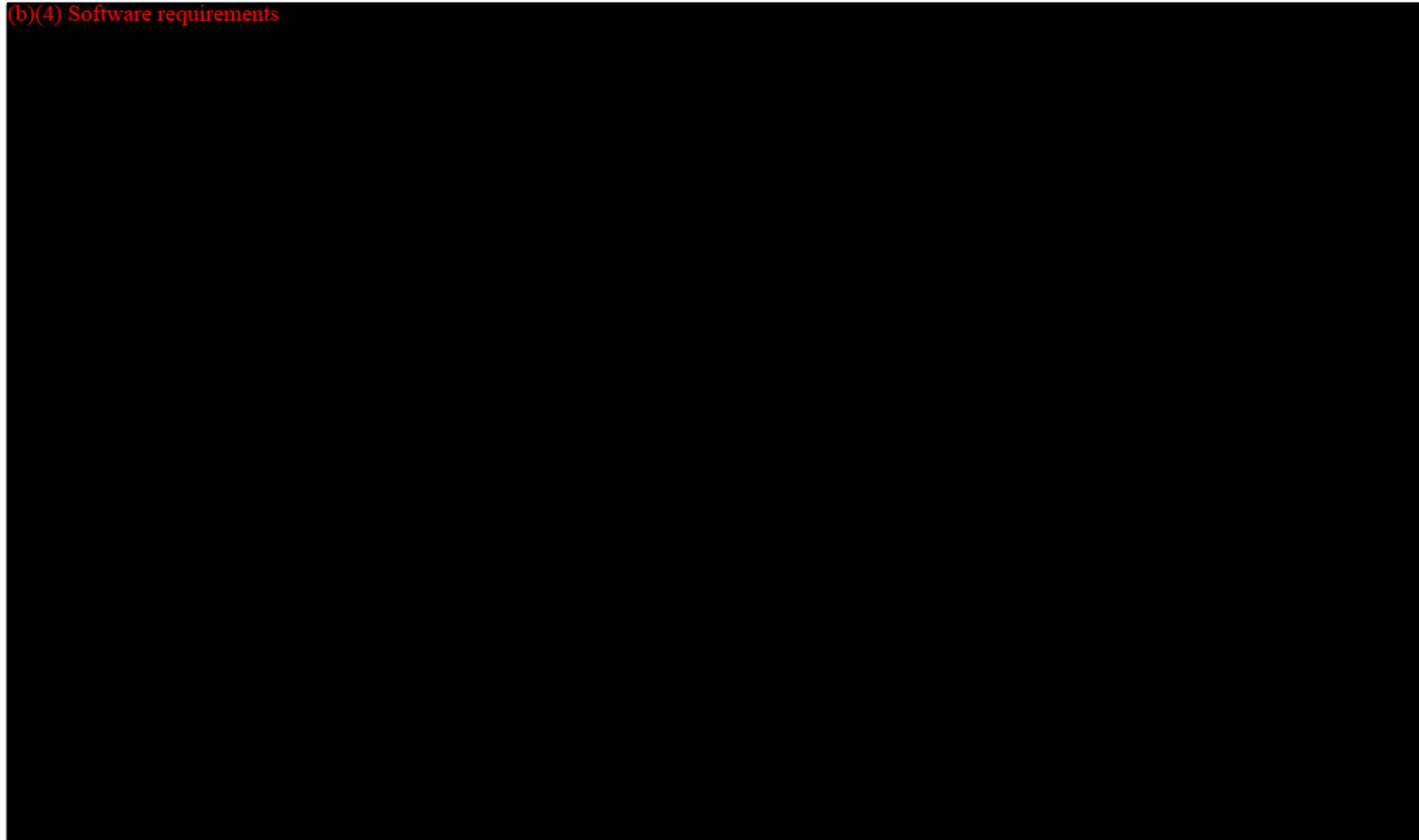
Product Design V&V Protocol

03/14/2006

Protocol Type Validation
 Verification

Protocol Document Retention # VV1105

(b)(4) Software requirements



¹ Signature required if software testing is involved.

Medtronic-SNT Confidential

Medtronic Navigation, Inc.

CONFIDENTIAL

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI STATUS@fda.hhs.gov or 301-796-8118

1059
Page 634 of 877



Medtronic

SURGICAL NAVIGATION TECHNOLOGIES

Imageless AxiEM Hip Simulated Use Report

DHF# 0268

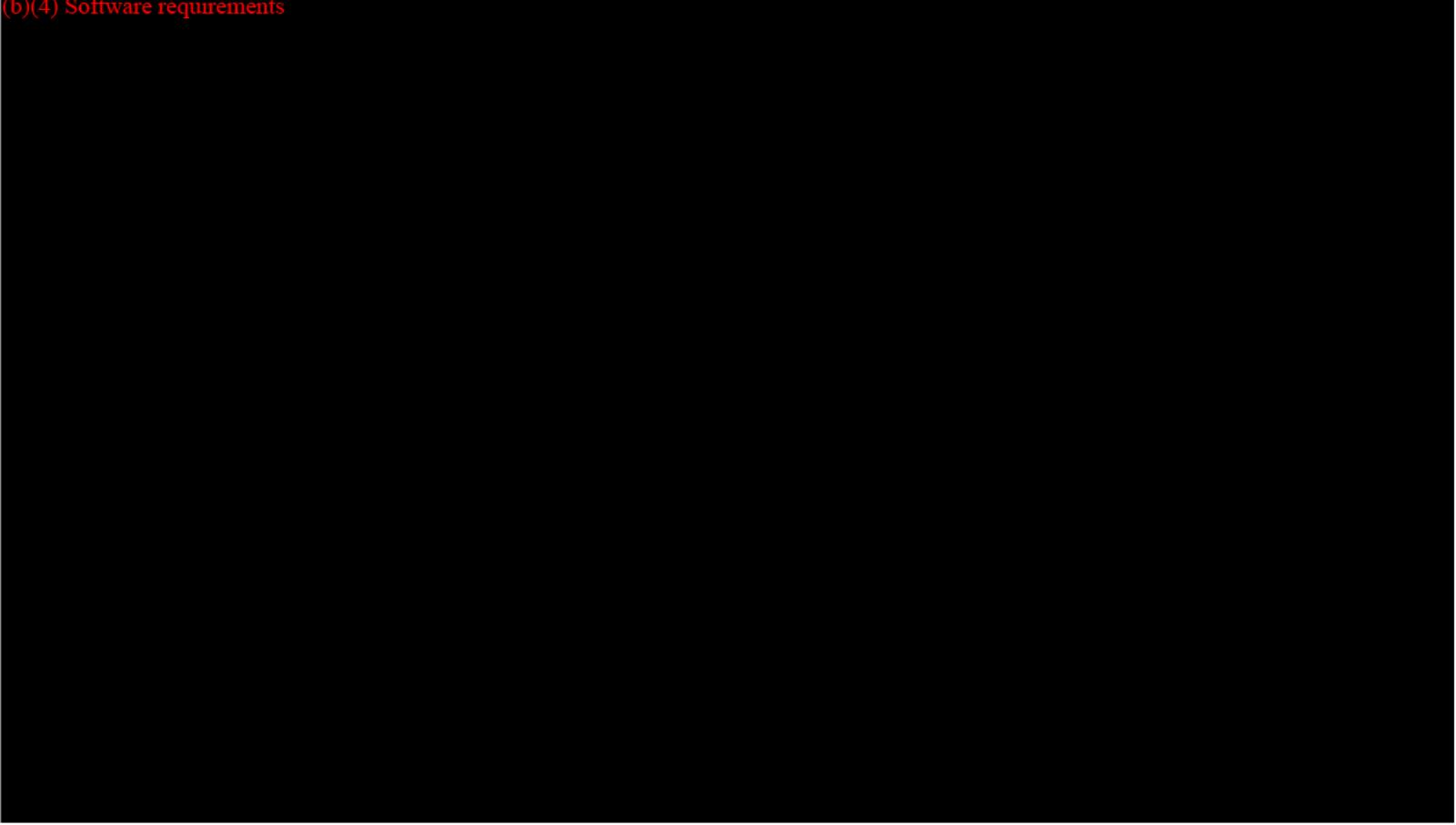
Product Design V&V Report

03/21/2006

Report Type Validation
 Verification

Protocol Document Retention # VV1105
Report Document Retention # VV1105
Protocol Revision Level # 4

(b)(4) Software requirements



¹ Signature required if software testing is involved.

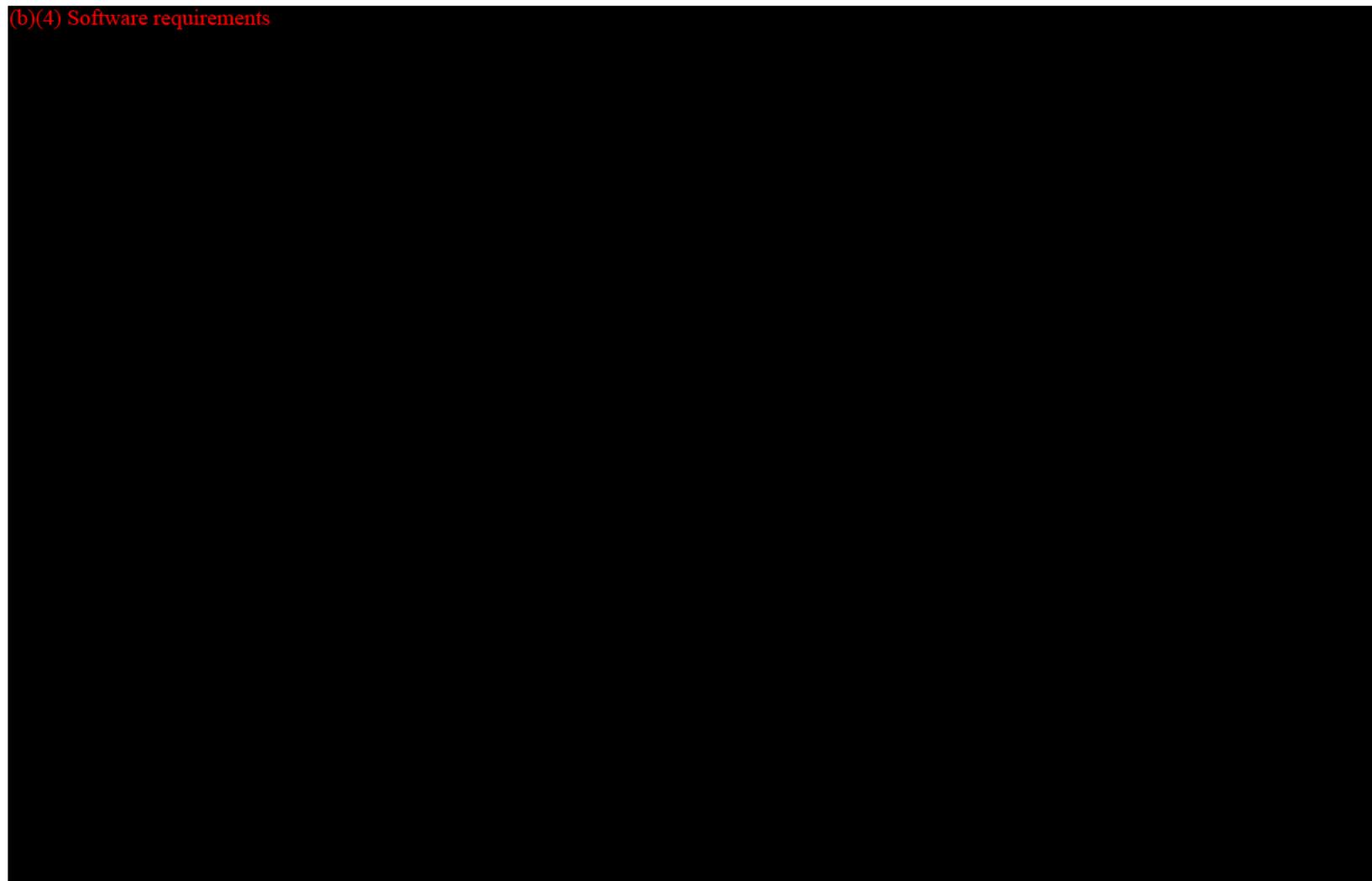


Freeform Test Execution
DHF#
Product Design V&V Protocol
05/12/05

Protocol Type Validation
 Verification

Protocol Document Retention # VV1016

(b)(4) Software requirements



¹ Signature required if software testing is involved.

Medtronic-Nav Confidential

C-502, Product Design V&V Protocol (Rev 3)

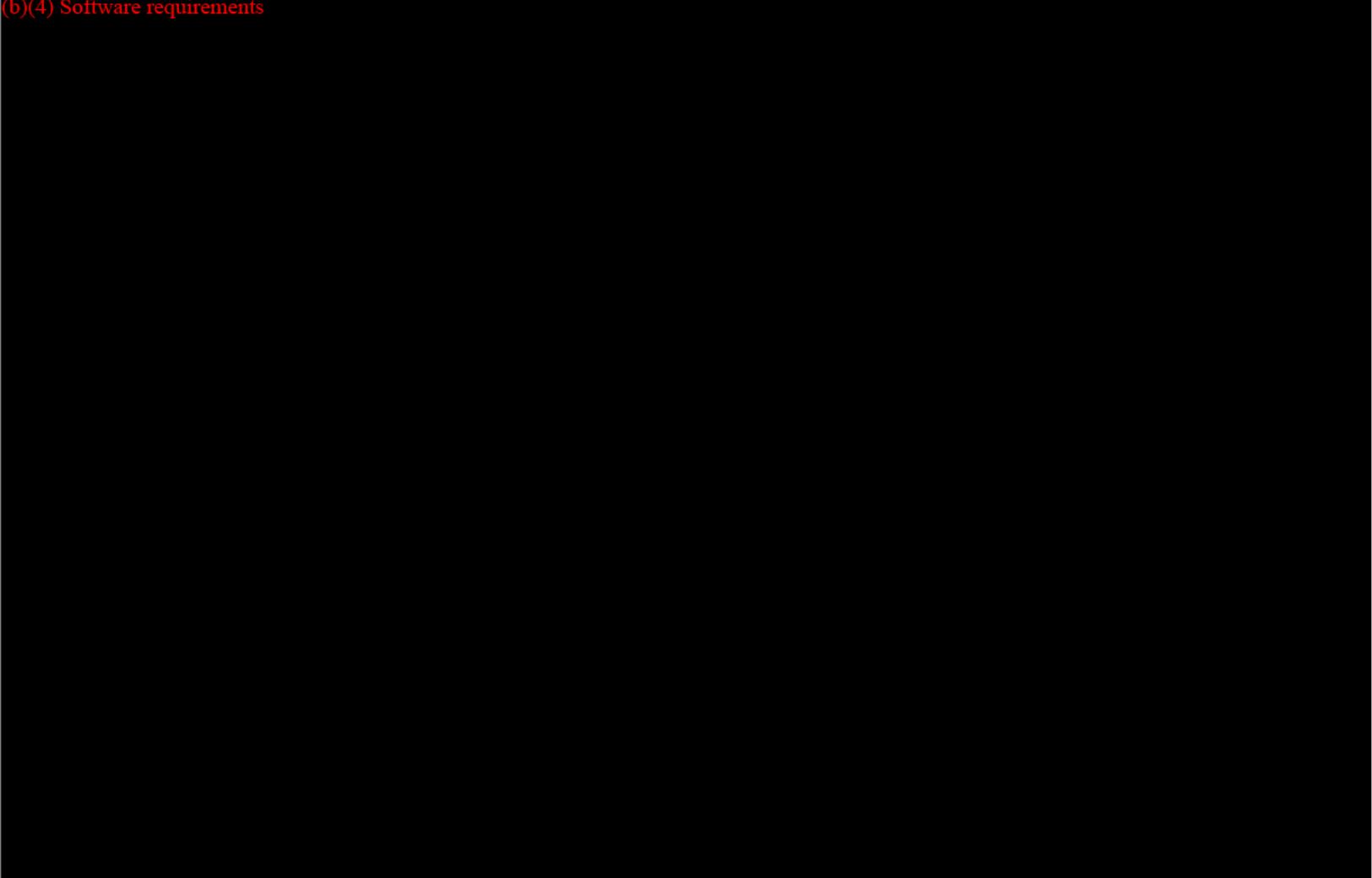
1090



FreeForm
DHF# 0145
Product Design V&V Report
3/22/06

Report Type	<input checked="" type="checkbox"/> Validation <input type="checkbox"/> Verification
Protocol Document Retention #	VV1016
Report Document Retention #	VV1016
Protocol Revision Level #	1

(b)(4) Software requirements



¹ Signature required if software testing is involved.

1096



Medtronic

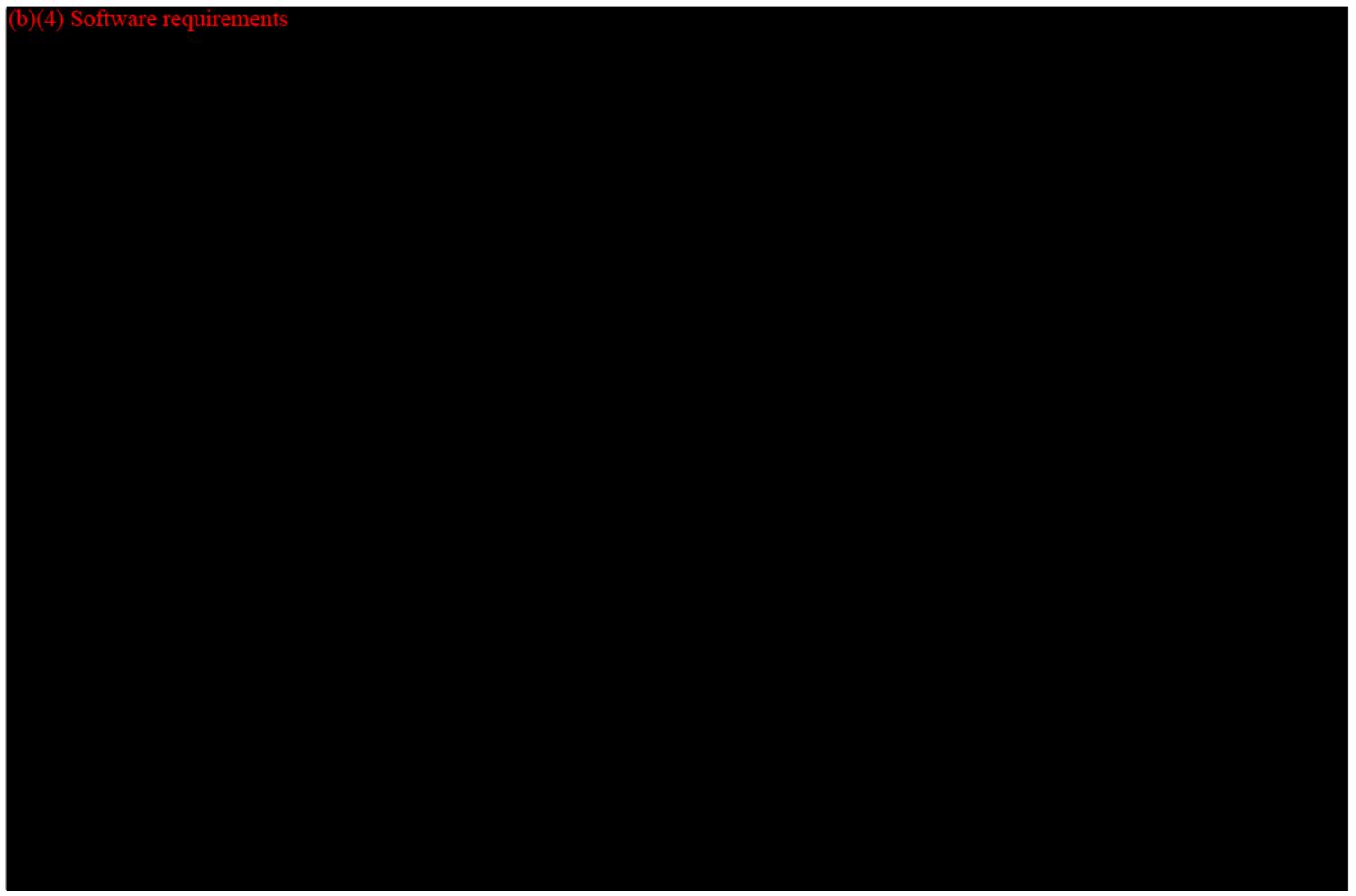
SURGICAL NAVIGATION TECHNOLOGIES

AxiEM™ Imageless Hip System Documentation Hazards Mitigation
DHF# 0268
Product Design V&V Protocol
04/21/06

Protocol Type Validation
 Verification

Protocol Document Retention # DR # VV1232

(b)(4) Software requirements



¹ Signature required if software testing is involved.

116



Medtronic

SURGICAL NAVIGATION TECHNOLOGIES

**AxiEM Imageless Hip System Documentation Hazards Mitigation
DHF# 0268
Product Design V&V Report
04/21/2006**

Report Type Validation
 Verification

Protocol Document Retention # VV1232
Report Document Retention # VV1232
Protocol Revision Level # 2

(b)(4) Software requirements



¹ Signature required if software testing is involved.

1114

ATTACHMENT I

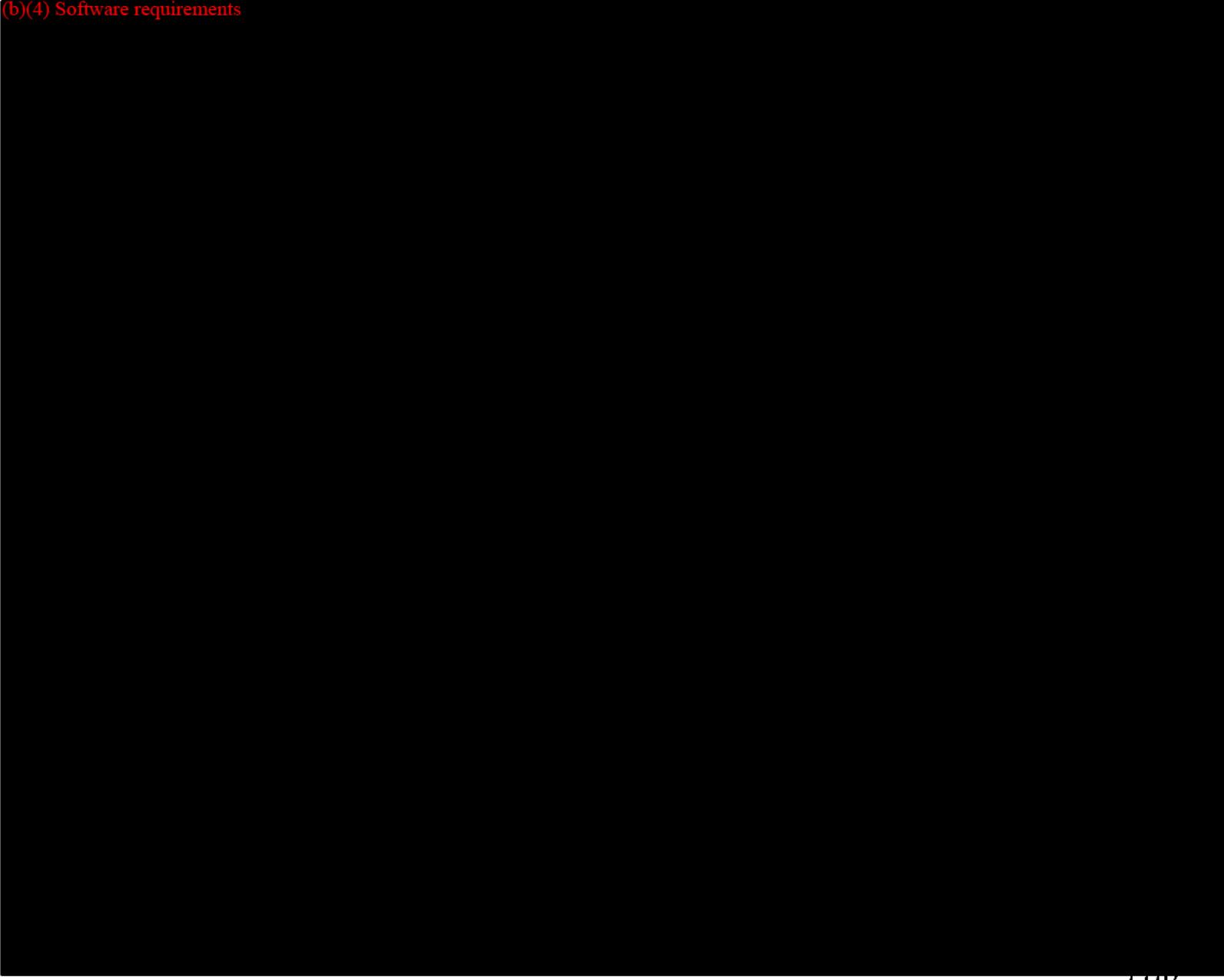
AXIEM™ IMAGELESS HIP MODULE FOR THE STEALTHSTATION® SYSTEM
HAZARDS ANALYSIS



Imageless Hip System
DHF# 0268
Hazards Analysis Report
3/14/2006

Document Retention # HZ-0076

(b)(4) Software requirements



Medtronic SAHT Confidential

1141

ATTACHMENT J

AXIEM™ IMAGELESS HIP MODULE FOR THE STEALTHSTATION® SYSTEM

PREDICATE INFORMATION

1. K052623– Imageless Hip Module for the StealthStation® System 510(k) Clearance Letter
2. Imageless Hip Module Pocket Guide
3. K030552 - AxiEM™ Imageless Knee Module for the StealthStation® System 510(k) Clearance Letter
2. AxiEM™ Imageless Knee Module Pocket Guide

1142



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 2006

Medtronic Navigation, Inc.
c/o Ms. Tina Dreiling
Associate Regulatory Affairs Specialist
826 Coal Creek Circle
Louisville, Colorado 80027

Re: K052623

Trade/Device Name: Imageless Hip Module for the StealthStation® System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: February 2, 2006
Received: February 3, 2006

Dear Ms. Dreiling:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

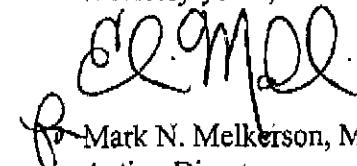
1143

Page 2 – Ms. Dreiling

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.htm>.

Sincerely yours,



Mark N. Melkerson, M.S.

Acting Director

Division of General, Restorative and

Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

1144

Indications for Use

510(k) Number (if known): K052623

Device Name: Imageless Hip Module for the StealthStation® System

Indications for Use:

The StealthStation® System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The StealthStation® System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

The Imageless Hip Module for the StealthStation is intended to precisely position instruments and implants in example procedures such as but not limited to:

Orthopedic Procedures:

Minimally Invasive Orthopedic Procedures

Total Hip Replacement (Primary and Revision)

Tumor Resection and Bone/Joint Reconstruction

Placement of Iliosacral Screws

Femoral Revision

Stabilization and Repair of Pelvic Fractures (Including But Not Limited To Acetabular Fractures)

Prescription Use (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

(Division Sign Off)
**Division of General, Restorative,
and Neurological Devices**

510(k) Number K052623



Imageless Hip Application

POCKET GUIDE

©2005 MEDTRONIC NAVIGATION
9732643, REVISION 1

RX



Medtronic Navigation
826 Coal Creek Circle
Louisville, CO 80027
Main 720 890 3200
Fax 720 890 3500
Technical support 800 595 9709
www.stealthstation.com

CONTENTS

INTENDED USE	5
CONTRAINdicATIONS	5
WARNINGS	5
CAUTIONS	7
STANDARD EQUIPMENT	8
PROCEDURE.....	11
LOG IN	12
ENTER PATIENT NAME	14
SOFTWARE OVERVIEW.....	15
SET UP OPERATING ROOM	17
AIM CAMERA	18
SELECT OPERATIVE SIDE	19
ATTACH TERATRACKERS TO INSTRUMENTS	20
CALIBRATE/VERIFY INSTRUMENTS	21
ATTACH WIRED REFERENCE TO PELVIS	25
RECORD ACCURACY CHECKPOINTS	28
LANDMARKS AND COORDINATE SYSTEM	29

3

CONTENTS

4

LANDMARK PELVIS	32
REAM ACETABULUM	34
NAVIGATE CUP	36
EXIT THE APPLICATION SOFTWARE.....	38
ARCHIVE	39
REMOVE EXAMS.....	40
EXIT.....	41
SYMBOLS	42

INTENDED USE

Your Medtronic computer-assisted surgery system and its associated applications are intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. Their use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT- or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy.

CONTRAINDICATIONS

Medical conditions which contraindicate the use of a Medtronic Navigation computer-assisted surgery (CAS) system and its associated applications include any medical conditions which may contraindicate the medical procedure itself. This may include pregnancy, for example, since surgery itself poses grave risks to the developing fetus.

⚠️ WARNINGS

- The system and its associated applications should be used only by qualified medical professionals who are trained on and familiar with the proper operation of Medtronic computer-assisted surgery systems.
- The system and its associated applications should be used only as an adjunct for surgical guidance. They do not replace the surgeon's knowledge, expertise, or judgement.

6

- If system navigation seems inaccurate and steps to restore accuracy are unsuccessful, abort use of the application.
- Discard before use any pre-sterilized component whose sterile packaging appears to be compromised.
- There is currently no effective sterilization method for components that are tainted with the virus that causes Creutzfeld-Jakob Disease (CJD). Therefore, you must discard immediately after surgery any components that come into contact with biologic material from patients who carry or are suspected to carry this virus. As a precaution, drape all non-disposable components that could otherwise come into contact with such material.
- Frequently confirm localization accuracy and system responsiveness during live navigation. Observe the correspondence between movement of instrument and movement of the virtual instrument on-screen, and periodically cover the optical markers on the instrument and confirm the transitions between green and red instrument statuses.
- Observe the geometry error associated with the use of each instrument. Use another instrument if the geometry error exceeds the maximum threshold for the device. If you change an instrument, always verify/calibrate the instrument before using it.

△ CAUTIONS

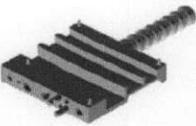
- Federal law restricts this device to sale by or on the order of a physician.
- The system and its associated applications contain no user-repairable parts. For repair or replacement of any part of the system or application, contact a technical support representative.
- The optical sensor (camera) lenses should be cleaned before each use.
- Always verify an instrument before using it.
- Always use single-use passive optical markers on all TeraTrackers, especially for the cup inserter.
- The patient-specific coordinate system created by the software from user-identified landmarks assumes typical anatomy at the landmark sites. Significant deformity or irregularity at these sites may produce unexpected navigation angles.

7

STANDARD EQUIPMENT

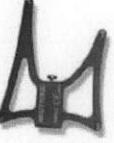
B

	Wired Orthopaedic Reference Frame (pn 963-863) Use the Wired Reference Frame to track the position of the patient's pelvis during the procedure.
	Passive Orthopaedic Reference Frame (pn 963-864) Use the Passive Reference Frame to track the position of the patient's femur during the procedure.
	2-Pin Fixator (pn 9730864), Pins (pn 9730476; 3" and pn 9730477; 5") Use the 2-pin Fixator to secure the Orthopaedic Reference Frame to the patient's anatomy. Caution: Fixator pins are single-use components. Do not resterilize or reuse.
	Blunt Tip Pointer (pn 960-556) Use the Blunt Tip Pointer for digitizing accuracy checkpoints and landmarks.

	<p>Calibration/Interface Block (pn 9730026) Use the Calibration/Interface block to verify and calibrate instruments.</p>
	<p>Sterile spheres (pn 9730950, single), (pn 9730951, 5-pack) Place sterile spheres on passive instruments so that the system can track these devices. Caution: Sterile spheres are presterilized, single-use components. Do not resterilize or reuse</p>
	<p>Reamer Set • Adapter (9730288) • Teflon Sleeve (9730422) • Verification Tip (9730478) Use the reamer for reaming the acetabulum.</p>
	<p>Green Passive TeraTracker (pn 9730490) Attach the Green Passive TeraTracker to the Acetabular Reamer so that the system can track the Reamer during the procedure.</p>

9

1 □

	<p>Purple Passive TeraTracker (pn 9730492) Attach the Purple Passive TeraTracker to the Cup Inserter so that the system can track the Inserter during the procedure.</p>
	<p>Breakout Box (pn 9680117) The Breakout Box is a junction box used to connect wired instruments to the system.</p>
	<p>System Footswitch (pn 960-135) The system footswitch controls software functions.</p>

PROCEDURE

11

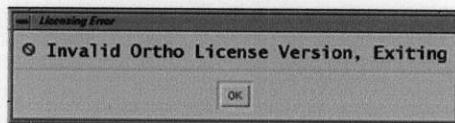
LOG IN

12

1. If necessary, scroll down until you can see the Orthopaedic icon.
2. Double-click the Orthopaedic icon on the login screen.
The group screen (left) displays.
3. Click the Imageless Hip icon at the top of the group screen.

LOG IN (CONT.)

If you do not own an Orthopaedic OS license, you will not be able to start and run the Imageless Hip application software (Treon™/Tria® systems only). The following message displays.



Please contact your local Medtronic Navigation representative or call Medtronic Navigation to obtain information on purchasing an Orthopaedic OS license.

13

ENTER PATIENT NAME

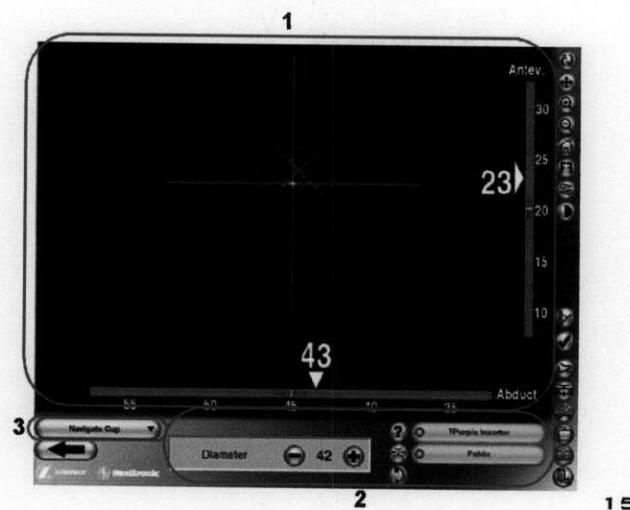
14

1. Enter the patient's name or an identification name for the exam using the virtual keyboard on-screen or the system keyboard.
If you are using the system keyboard, make sure that the mouse cursor is in the text box.
2. Click the [OK] button.



SOFTWARE OVERVIEW

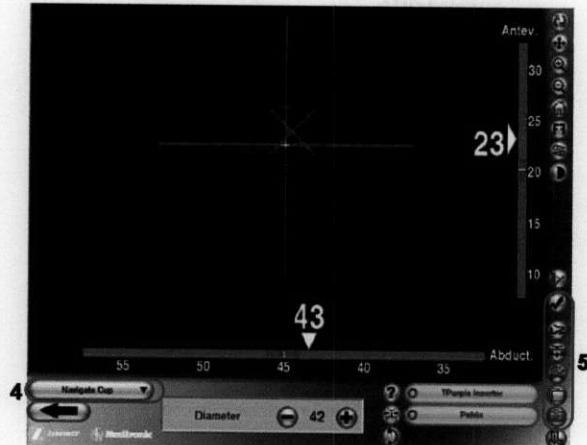
1. Display Window: Navigation information and instrument renderings appear in this area.
2. Task-Specific Area: Each task has its own specific set of buttons and other controls. The colors of the status indicators in the right side of the area correspond to instrument and reference frame visibility.
3. Task Bar: Each active task for the procedure displays on the task bar. Click the bar to display all tasks. Click a displayed task to enter that task.



SOFTWARE OVERVIEW (CONT.)

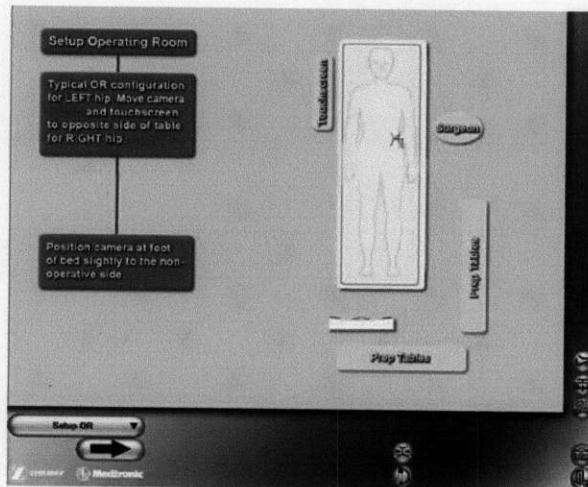
16

4. **Next/Back Buttons:** Click the right-pointing arrow to go forward to the next task. Click the left-pointing arrow to return to the previous task.
5. **General Control Buttons:** Use the general control buttons to access system-level features at any time during the procedure.



SET UP OPERATING ROOM

1. Place the patient in a supine position.
2. Position the camera at the foot of the table, slightly to the non-operative side. Adjust the camera boom so that the camera is 2 to 2.5m from the floor and angled so that it is pointing at the patient's mid thigh.
3. Position the touchscreen across from the surgeon with the articulating arm swung out to move the display as close to the surgeon as possible. The touchscreen can be draped sterile for fingertip control, or it can be left drapeless for use with a sterile stylus.



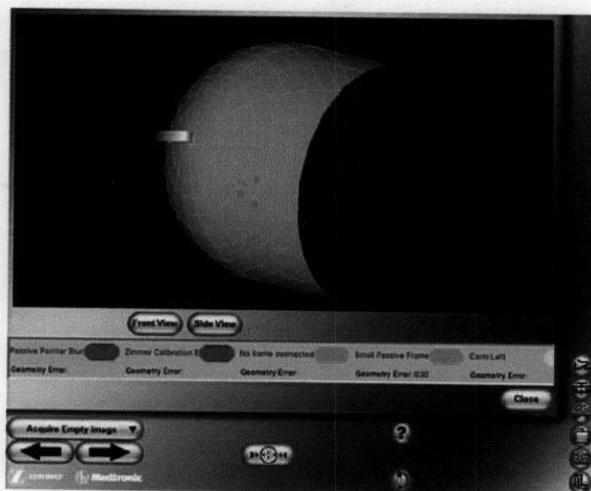
17

18

AIM CAMERA

Aim the camera toward the surgical area of interest.

1. Click the **Aim Camera** button.
The Aim Camera window opens.
2. Use the alignment target to determine optimum camera position.
3. Position the camera so that the tibial tracker, femoral tracker, and instruments are centered in the camera's field of view.
4. Observe the geometry error associated with the use of each



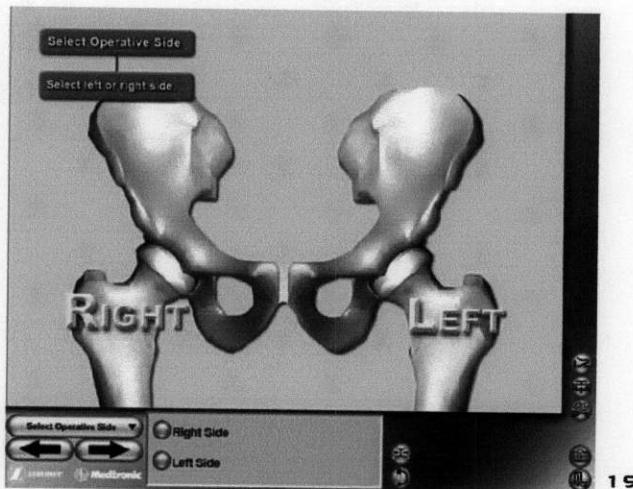
SELECT OPERATIVE SIDE

⚠Warning: Measurements in the abduction/anteverision of the acetabular cup and reamer will appear abnormal if the wrong hip side is selected.

Select the side of the patient on which the procedure will be performed.

Click the [Right Side] or [Left Side] button.

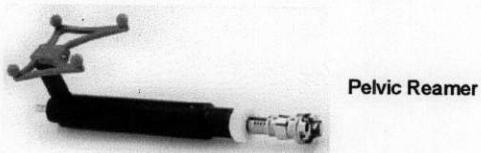
The application software will automatically advance to the next screen after selecting the operative side.



ATTACH TERATRACKERS TO INSTRUMENTS 20

Mount the green TeraTracker to the Pelvic Reamer and the purple TeraTracker to the Cup Inserter.

1. Remove the teflon sleeve from the Reamer Handle and replace with Medtronic Navigation teflon sleeve
2. Position the TeraTracker's female dovetail onto the instrument's male dovetail.
3. Slide the tracker firmly along the dovetail.
4. Insert the tracker's mounting screw into the instrument's dovetail flange and tighten firmly.
5. Repeat Steps 2 - 4 for the Cup Inserter and purple TeraTracker.



Pelvic Reamer

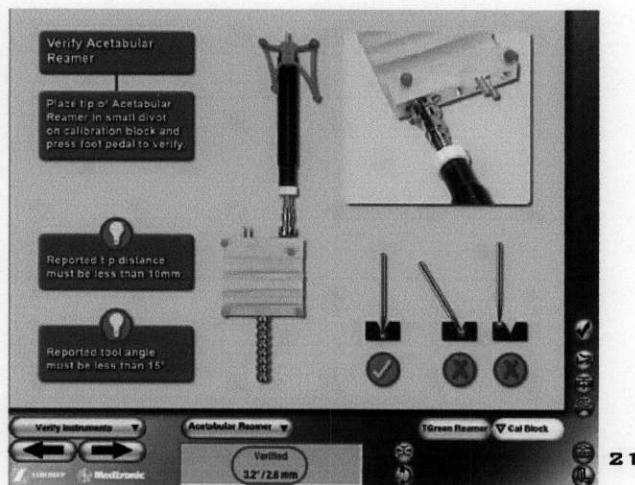


Cup Inserter

CALIBRATE/VERIFY INSTRUMENTS

Instrument calibration/verification is the process of holding each tracked instrument in a divot on the face of the Calibration/Interface Block. This process ensures that the navigation system knows where the tip of each instrument is and prevents the use of bent or damaged instruments.

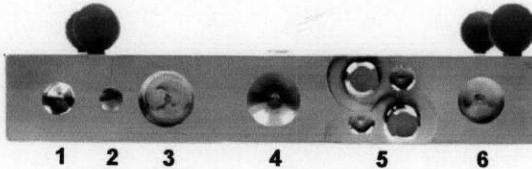
For each instrument, successful verification is indicated by a positive system sound (chime). Failed verification, usually due to bent or damaged instruments or spheres, is indicated by a negative system sound (bonk). A quantitative measure of instrument verification is given in the form of tip angle and distance for troubleshooting purposes



CALIBRATE/VERIFY INSTRUMENTS (CONT.)

22

1. Make sure the instrument/tracker color is selected from the tools list and that the name of the instrument is displayed on the tool status indicator.
2. Position the Calibration/Interface Block in the camera's field of view.
3. Insert the tip of the instrument into the bottom of the assigned divot on the block, keeping the instrument as perpendicular to the divot as possible.
4. Confirm that both the instrument and calibration/interface block status indicators are green.
5. Press and release the footswitch.



- 1 Not used
2 Standard divot
3 Not used
4 Large divot
5 Not used
6 Not used

CALIBRATE/VERIFY INSTRUMENTS (CONT.)

Status indicators give a visual representation of the visibility status of the selected instrument and reference frame.

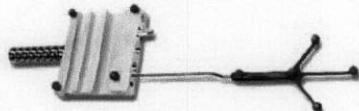
Color of Status Indicator	Symbol	Meaning
Green	O	The camera can currently detect optical markers on this device in excess of the minimum number required for navigation or acquisition.
Yellow	▽	The camera can currently detect the exact number of optical markers on this device required for navigation.
Orange	!	The geometry error of the device exceeds the maximum threshold. Navigation is not permitted.
Red	X	The camera can currently detect fewer optical markers on this device than are required for navigation or acquisition.
Black	X	The camera and the computer are not communicating.

CALIBRATE/VERIFY INSTRUMENTS (CONT.)

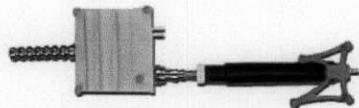
24

⚠ Warnings:

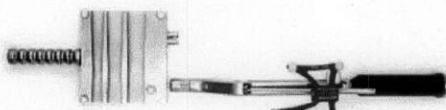
- Physically inspect instruments for any defects. Never attempt to use a bent or damaged instrument.
- Always verify an instrument before use.



1. Verify the Pointer in the standard pivot.



2. Attach a calibration tip to the Reamer Handle and verify in the standard pivot.

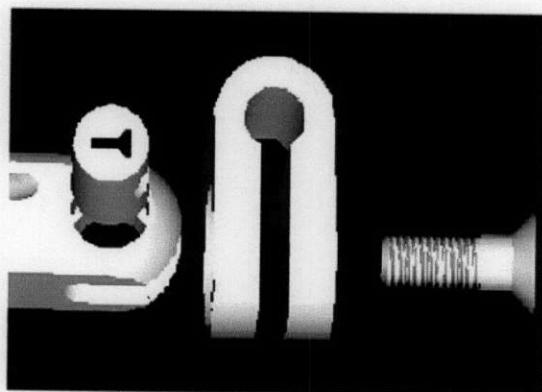


2. Attach a calibration tip to the Cup Inserter Handle and verify in the standard pivot.

ATTACH WIRED REFERENCE TO PELVIS

Assemble a 2-pin fixator before drilling the fixator pins into place.

1. Place the clamp ring onto the fixator hub.
2. Push the lock bushing into the fixator hub.
3. Align the lock bushing using the laser etching of the hex screw as a guide.
4. The etching should be pointed in the same direction as the hex screw.
5. Insert the hex screw through the clamp ring into the lock bushing and tighten with the hex driver. Remember to leave enough slack in the clamp to accept the tracker mounting post.



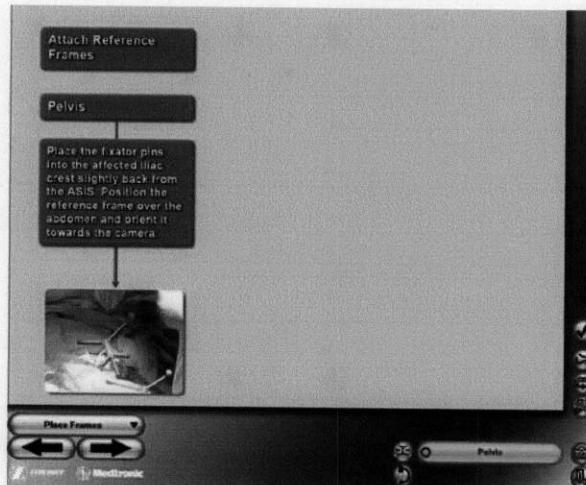
25

ATTACH REFERENCE TO PELVIS (CONT.)

26

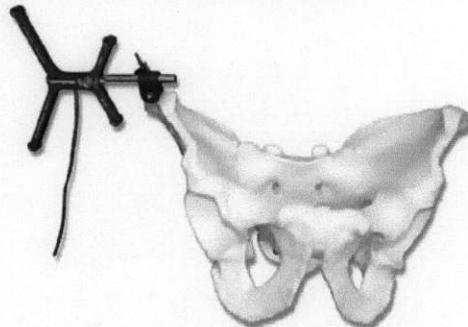
△Cautions:

- Physically examine the reference frame for damage before use.
Do not use a bent or damaged reference.
- Fixator pins are single-use components. Do not resterilize or reuse.
 1. Select either the 3" or the 5" pin set (use the shortest pin that reaches bone through the surrounding tissue).
 2. Position the fixator on the affected iliac crest, slightly posterior of the ASIS.
 3. Note a suitable location for the first pin and remove the fixator.



ATTACH WIRED REFERENCE TO PELVIS (CONT.)

4. Drill the pin into the bone to ensure rigid fixation.
5. Slip the fixator over the pin and position the fixator for the second pin location.
6. Drill the second pin through the fixator into the iliac crest.
7. Tighten the fixator set screw for each pin with the supplied hex wrench.
△**Caution:** Tighten the set screws onto the shaft of the pin, not the threads.
8. Secure the hex screw on the fixator but do not fully clamp the mounting post in place.
9. Position the reference over the abdomen and orient it so that it faces the system camera.
10. Securely tighten the clamp screw onto the mounting post with the supplied hex wrench.
11. If using the wired reference, plug the cord into the Reference Arc (Frame) port on the system breakout box.



27

RECORD ACCURACY CHECKPOINTS

28

△Caution: Do not select checkpoints on anatomy that will be removed during the procedure.

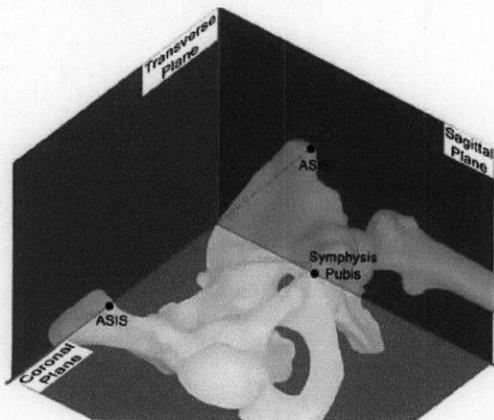
1. Click the [Checkpoint] button.
2. Click the [Pelvis] button.
3. Pick or create a readily identifiable point on the Pelvis.
4. Place the tip of the pointer on the point.
5. Press and release the footswitch.
6. Verify that the checkpoint was properly recorded by removing and replacing the pointer tip in the checkpoint. A reported error less than 2mm is considered normal.
7. Repeat for another checkpoint on the pelvis.



LANDMARKS AND COORDINATE SYSTEM

The Anterior Pelvic Plane can also be described as the coronal plane of the pelvis. The plane created by the SI and AP axes is the sagittal plane of the pelvis. And the plane created by the ML and AP axes is the transverse plane of the pelvis. The anteversion and abduction values reported by the application software are directly related to the orientation of the surgical instrument with respect to these planes. The diagram below shows the anatomic planes constructed by our landmarks.

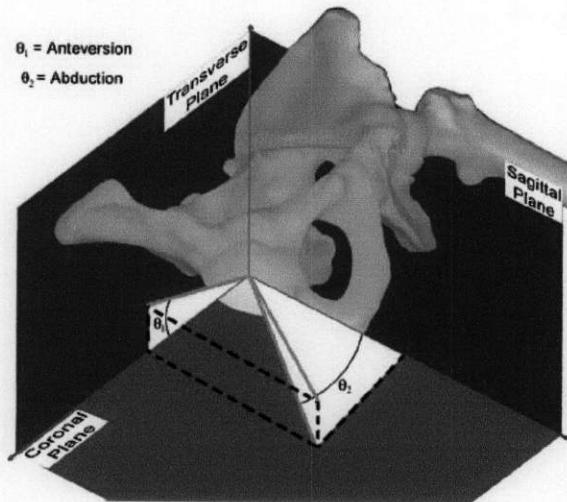
△ Caution: The patient-specific coordinate system created by the software from user-identified landmarks assumes typical anatomy at the landmark sites. Significant deformity or irregularity at these sites may produce unexpected navigation angles.



29

LANDMARKS AND COORDINATE SYSTEM (CONT.) 30

The angle θ_1 in the image below (known as anatomic anteversion) is the acetabular anteversion value reported by the application software. This is the angle between the projection of the surgical instrument onto the transverse plane and the ML axis of the pelvis. The angle θ_2 (also known as radiographic inclination) is the acetabular abduction value reported by the application software. This is the angle between the projection of the surgical instrument onto the coronal plane and the SI axis of the pelvis.



LANDMARKS AND COORDINATE SYSTEM (CONT.)

Nominal accuracy of angle measurements displayed by the software is obtained if the anterior pelvic plane landmarks are recorded without soft tissue between the probe tip and the bone or with equal amounts of soft tissue covering each landmark. The accuracy of angle measurements will be affected by how accurately the landmarks are recorded. If the landmarks cannot be closely palpated on soft tissue and accurately recorded, percutaneous landmarking may be performed through a puncture or small incision. Proper sterile preparation of the landmark sites should be considered based on the landmarking method chosen.

Published data has indicated that landmarking on the skin could cause misinterpretation of measured angles by up to about 3° under normal conditions as compared to percutaneous landmarking. While the angle calculations in the software are less sensitive to variation in the location of the ASIS landmarks than to differences in the soft tissue depth over landmarks, care should be taken to record the ASIS points symmetrically on the patient.

31

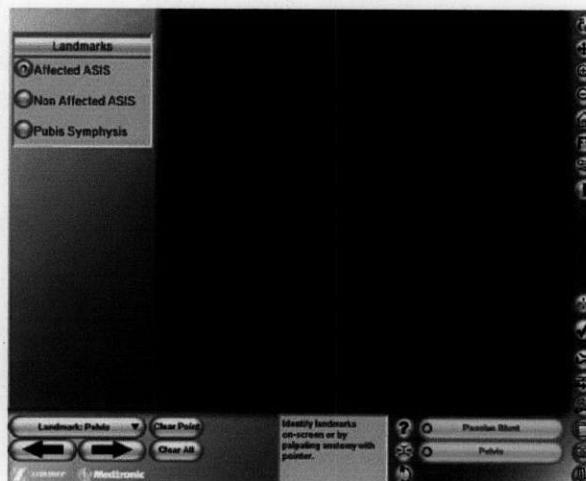
LANDMARK PELVIS

32

Record and save landmarks to construct a coordinate system defined by the patient's own anatomy.

1. Place the tip of the pointer at the landmark location on the patient's anatomy.
2. Verify that the pointer and related reference frame status indicators are green.
3. Press and release the footswitch to save the landmark.

The application software will automatically advance to the next landmark on the list.



LANDMARK PELVIS (CONT.)

Record all the landmarks on the Landmark Pelvis List.

1. Affected ASIS
2. Non-affected ASIS
3. Pubis Symphysis

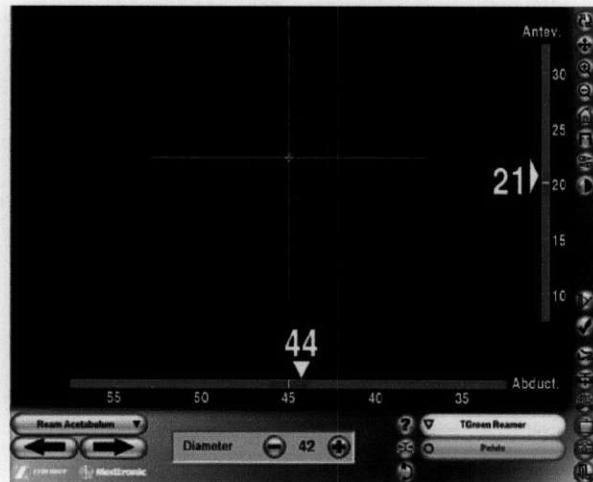
You can delete all of the saved landmarks by clicking the [Clear All] button. Clear a single landmark by clicking the [Clear Point] button after selecting the landmark from the landmark list.



REAM ACETABULUM

34

1. Make sure the acetabular reamer is selected and the status indicator is green.
2. Attach the correctly sized acetabular dome to the reamer shaft. Make sure that the dome is locked into the tip of the shaft.
3. Position the pelvic reamer in the anatomy.



REAM ACETABULUM (CONT.)

4. Use the targeting view to orient the reamer to the target anteversion and abduction angles.
You may adjust the target implant orientation by clicking the implant orientation button and adjusting the reamer and implant anteversion and abduction target values.
5. Begin reaming the acetabulum.
6. Increment the reamer size according to standard surgical technique and repeat steps 1 - 5 as needed.



NAVIGATE CUP

36

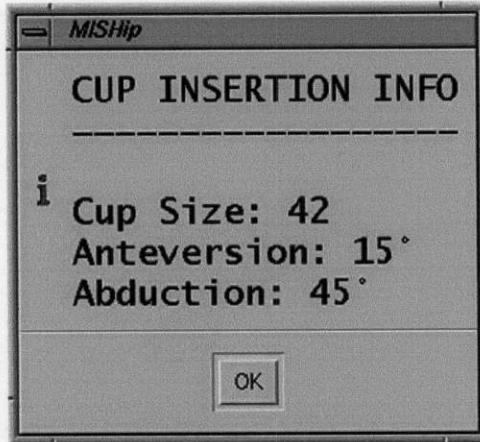
1. Make sure the cup inserter is selected and the status indicator is green.
2. Attach the correctly sized acetabular cup to the inserter shaft.
3. Insert the prosthesis into the anatomy.
4. Use the targeting view to orient the cup to the target anteversion and abduction angles.

You may adjust the target implant orientation by clicking the implant orientation button and adjusting the anteversion and abduction target values.



NAVIGATE CUP (CONT.)

5. Implant the prosthesis within the acetabulum using standard surgical technique.
 6. Press the footswitch to freeze the final acetabular cup position in the software.
 7. Detach the implant from the inserter according to standard surgical technique.
 8. Remove the cup inserter.
- The application software will display a yellow CAD image of the implant in position. The cup size, anteversion angle, and abduction angle will also display on-screen in a dialog shell.
9. Click [OK] to confirm that the implant information is correct.



37

EXIT THE APPLICATION SOFTWARE

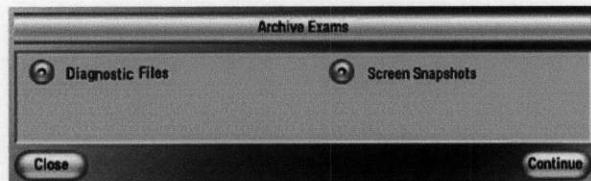
38

1. Click the **Exit** button in the main application window.
2. Click **[Yes]** to confirm that you want to exit.
The manage exams window displays.



ARCHIVE

1. Click the **[Archive]** button in the manage exams window.
2. Select each patient exam you wish to archive.
3. Choose which type of data you would like to archive.
 - a. Select **[Screen Snapshots]** to save the images you captured by clicking the snapshot button.
 - b. Select **[Diagnostic Files]** to save the software log and other diagnostic files created during the exam.
4. Insert an exam archive disk in the CD drive. Wait until the light on the drive stops blinking.
5. Click the **[Continue]** button. Wait while the OS software archives the selected images to the CD.
6. Click the **[Close]** button to close the archive exam window or click the **[Back]** button to return to the manage exams window.



39

40

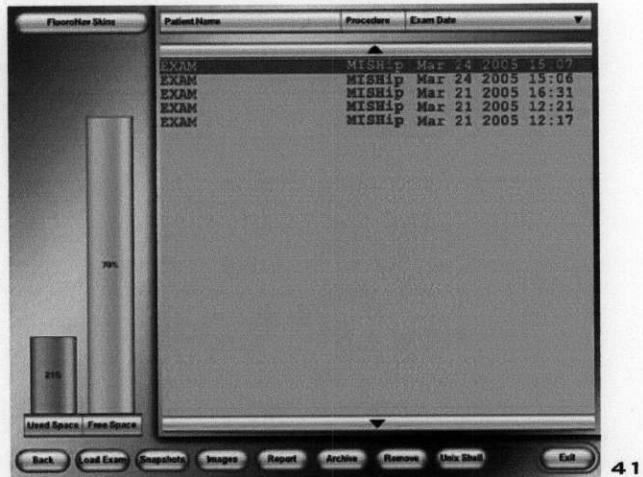
REMOVE EXAMS

1. Click the [Remove] button in the manage exams window.
2. Highlight one or more exam directories. To deselect a patient exam, click it a second time.
3. Choose which exam directories you wish to remove from the hard disk.
4. Click the [Remove] button to permanently remove the selected exam(s) from the hard disk.



EXIT

1. Click the **[Exit]** button in the manage exams window and click **[Yes]** to confirm that you want to exit.
The log in screen displays.
2. From the log in screen, double-click the **Shutdown** icon. Wait until the system indicates it is okay to shut off the power.
3. Turn off the system power.



SYMBOLS

42

-  The device complies with European Directive MDD 93/42/EEC.
-  Classified by Underwriters Laboratories Inc. with respect to electric shock, fire, mechanical, and other specified hazards only in accordance with UL2601-1/CAN/CSA C22.2 NO.601.1. Control number 87HJ
-  When found in this guide, this symbol means: "Warning! Failure to observe could result in injury or death." When found on equipment, this symbol means: "Attention: consult accompanying documentation."
-  Caution! Failure to observe could result in damaged equipment, forfeited time or effort, or the need to abort use of the system.
-  Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.
-  Use by date specified
-  Single use only. Do not reuse.
-  Quantity
-  **STERILE EO** Sterilized using ethylene oxide.
-  **STERILE R** Sterilized using irradiation.
-  Protective Earth (Ground)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 5 2005

Ms. Tina Dreiling
Associate Regulatory Affairs Specialist
Medtronic Surgical Navigation Technologies
826 Coal Creek Circle
Louisville, Colorado 80027

Re: K043088

Trade/Device Name: Medtronic (SNT) StealthStation AxiEM™ Imageless Knee Module
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: November 4, 2004
Received: November 8, 2004

Dear Ms. Dreiling:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Ms. Tina Dreiling

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

Miriam C. Provost
for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Medtronic (SNT) StealthStation AxiEM™ Imageless Knee Module

510(k) Number (if known): K043088

Device Name: Medtronic (SNT) StealthStation AxiEM™ Imageless Knee Module

Indications for Use:

The indications for use are as follows:

The StealthStation® System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The StealthStation® System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

Example procedures include, but are not limited to:

Cranial Procedures:

- Cranial Biopsies
- Tumor Resections
- Craniotomies/ Craniectomies
- Skull Base procedures
- Thalamotomies/Pallidotomies
- Pituitary Tumor Removal
- CSF Leak Repair
- Pediatric Catheter Shunt Placement
- General Catheter Shunt Placement

Spinal Procedures:

Spinal Implant Procedures, such as Pedicle Screw Placement

ENT Procedures:

- Transsphenoidal Procedures
- Intranasal Procedures
- Orbital Nerve Decompression Procedures
- Optic Nerve Decompression Procedures
- Polypsis Procedures
- Endoscopic Dacryocystorhinostomy
- Encephalocele Procedures
- Sinus procedures, such as Maxillary Antrostomies, Ethmoidectomies, Sphenoidotomies/Sphenoid Explorations, Turbinate Resections, and Frontal Sinusotomies

Orthopaedic Procedures:

- Total Knee Arthroplasty (Primary and Revision)
- Unicompartimental Knee Arthroplasty
- Minimally Invasive Orthopaedic Knee Procedures

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Brovost
(Division Sign-Off)
**Division of General, Restorative,
and Neurological Devices**

Page 1 of 1

510(k) Number K043088

Medtronic Surgical Navigation Technologies



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 5 2005

Ms. Tina Dreiling
Associate Regulatory Affairs Specialist
Medtronic Surgical Navigation Technologies
826 Coal Creek Circle
Louisville, Colorado 80027

Re: K043088

Trade/Device Name: Medtronic (SNT) StealthStation AxiEM™ Imageless Knee Module
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: November 4, 2004
Received: November 8, 2004

Dear Ms. Dreiling:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Ms. Tina Dreiling

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

Miriam C. Provost
for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Medtronic (SNT) StealthStation AxiEM™ Imageless Knee Module

510(k) Number (if known): K043088

Device Name: Medtronic (SNT) StealthStation AxiEM™ Imageless Knee Module

Indications for Use:

The indications for use are as follows:

The StealthStation® System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The StealthStation® System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

Example procedures include, but are not limited to:

Cranial Procedures:

Cranial Biopsies
Tumor Resections
Craniotomies/ Craniectomies
Skull Base procedures
Thalamotomies/Pallidotomies
Pituitary Tumor Removal
CSF Leak Repair
Pediatric Catheter Shunt Placement
General Catheter Shunt Placement

Spinal Procedures:

Spinal Implant Procedures, such as Pedicle Screw Placement

ENT Procedures:

Transsphenoidal Procedures
Intranasal Procedures
Orbital Nerve Decompression Procedures
Optic Nerve Decompression Procedures
Polypsis Procedures
Endoscopic Dacryocystorhinostomy
Encephalocele Procedures
Sinus procedures, such as Maxillary Antrostomies, Ethmoidectomies, Sphenoidotomies/Sphenoid Explorations, Turbinate Resections, and Frontal Sinusotomies

Orthopaedic Procedures:

Total Knee Arthroplasty (Primary and Revision)
Unicompartimental Knee Arthroplasty
Minimally Invasive Orthopaedic Knee Procedures

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
**Division of General, Restorative,
and Neurological Devices**

Page 1 of 1

510(k) Number K043088

Medtronic Surgical Navigation Technologies



**Zimmer®
AxiEM™ Knee
Application
POCKET GUIDE**



©2005 MEDTRONIC NAVIGATION
9732383, REVISION 4





MEDTRONIC NAVIGATION
826 COAL CREEK CIRCLE
LOUISVILLE, CO 80027
MAIN 720 890 3200
FAX 720 890 3500
TECHNICAL SUPPORT 800 595 9709
WWW.STEALTHSTATION.COM

[ECREP]

MEDTRONIC B.V
EARL BAKKENSTRAAT 10
6422 PJ HEERLEN
NETHERLANDS
TEL 31 45 566 80 00

CONTENTS

INTENDED USE	8
CONTRAINdications	8
WARNINGS	9
CAUTIONS.....	11
STANDARD EQUIPMENT.....	12
PROCEDURE.....	15
LOG IN	16
SOFTWARE OVERVIEW	19
CONNECT INSTRUMENTS.....	22
SWITCHING INSTRUMENTS DURING THE PROCEDURE.....	24
ATTACH TRACKER TO FEMUR	26
ATTACH TRACKER TO TIBIA.....	28
CONFIRM SETUP.....	30

4

FIELD VIEWER	31
RECORD FEMUR ACCURACY	
CHECKPOINTS.....	32
RECORD TIBIA ACCURACY	
CHECKPOINTS.....	33
VERIFY ACCURACY	34
DIGITIZE HIP CENTER	35
QUAD SPARING TECHNIQUE	37
RECORD FEMUR LANDMARKS	38
RECORD TIBIA LANDMARKS.....	39
RECORD ANKLE LANDMARKS.....	40
RECORD LEG IN EXTENSION	41
SELECT FEMUR AXIS	42
SELECT TIBIA AXIS.....	44
RECORD PRE-OPERATIVE ALIGNMENT	45

VERIFY FEMUR ACCURACY CHECKPOINT..	47
NAVIGATE DISTAL FEMUR CUT	48
VERIFY TIBIA ACCURACY	
CHECKPOINTS.....	50
NAVIGATE PROXIMAL TIBIA CUT.....	51
RECORD CONDYLES	53
RECORD DISTAL CUT.....	54
SIZE THE FEMUR	55
NAVIGATE POSTERIOR AND ANTERIOR	
FEMUR CUTS	56
PERFORM STRESS TEST	59
RECORD POST-OPERATIVE ALIGNMENT... 	61
MINI INCISION TECHNIQUE	62
RECORD FEMUR LANDMARKS	63
RECORD TIBIA LANDMARKS.....	65

RECORD ANKLE LANDMARKS.....	66
RECORD LEG IN EXTENSION	67
SELECT FEMUR AXIS	68
SELECT TIBIA AXIS.....	70
RECORD PRE-OPERATIVE ALIGNMENT.....	71
VERIFY FEMUR ACCURACY CHECKPOINT..	73
NAVIGATE DISTAL FEMUR CUT	74
RECORD DISTAL CUT.....	76
SIZE THE FEMUR	77
NAVIGATE PIN POSITIONER	78
NAVIGATE POSTERIOR AND ANTERIOR FEMUR CUTS	79
VERIFY TIBIA ACCURACY CHECKPOINTS ..	82
NAVIGATE PROXIMAL TIBIA CUT.....	83
PERFORM STRESS TEST	85

RECORD POST-OPERATIVE ALIGNMENT...	87
EXIT THE APPLICATION SOFTWARE	88
ARCHIVE (OPTIONAL).....	89
REMOVE EXAMS (OPTIONAL)	90
EXIT	91
SYMBOLS	92
NOTES.....	93

INTENDED USE

Your Medtronic computer-assisted surgery system and its associated applications are intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. Their use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT- or MR-based model, fluoroscopic images, or digitized landmarks of the anatomy.

CONTRAINDICATIONS

Medical conditions which contraindicate the use of a Medtronic Navigation computer-assisted surgery (CAS) system and its associated applications include any medical conditions which may contraindicate the medical procedure itself. This may include pregnancy, for example, since surgery itself poses grave risks to the developing fetus.

⚠️ WARNINGS

- The system and its associated applications should be used only as an adjunct for surgical guidance. They do not replace the surgeon's knowledge, expertise, or judgement.
- If system navigation seems inaccurate and steps to restore accuracy are unsuccessful, abort use of the application.
- Discard before use any pre-sterilized component whose sterile packaging appears to be compromised.
- There is currently no effective sterilization method for components that are tainted with the infectious agent that causes Creutzfeld-Jakob Disease (CJD). Therefore, you must discard immediately after surgery any components that come into contact with biologic material from patients who carry or are suspected to carry this infectious agent. As a precaution, drape all non-disposable components that could otherwise come into contact with such material.
- Frequently confirm localization accuracy and system responsiveness during live navigation. Observe the correspondence between movement of instrument and movement of the virtual instrument on-screen.
- Observe the geometry error associated with the use of each instrument. Use another instrument if the geometry error exceeds the maximum threshold for the device. If you change an instrument, always verify/calibrate the instrument before using it.

10

- AxiEM™ system technology has been tested for compatibility with the following Medtronic® implantable cardiac device families:
 - Marquis®
 - GEM III®
 - Kappa®
 - Sigma®
 - EnPulse®
 - EnRhythm®
 - EnTrust®

Testing indicates that AxiEM™ systems do not adversely affect the function of these devices and do not constitute a patient hazard. However, the system may interfere with the programming or interrogating of these implantable devices and any other implantable device. Do not use an AxiEM™ system while programming or interrogating any implantable device.

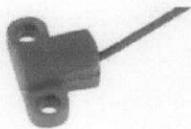
 - Do not operate the AxiEM™ Mobile Emitter in an ambient temperature of more than 86° F (30° C).
 - Never use the AxiEM™ Paddle as a lever or prying device.
 - Do not change or edit configuration files. Only Medtronic Navigation service and field personnel, who have been trained to know which parameters and associated values can be changed, are authorized to modify application configurations. Any modification of the application software by the user is considered off-label use.

△ CAUTIONS

- Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.
- The system and its associated applications contain no user-repairable parts. For repair or replacement of any part of the system or application, contact a technical support representative.
- Once the digitizing, landmarking, or navigating tasks have begun, take care so as not to bump, dislodge, move, or replace a tracker. Do not attempt to reattach a dislodged tracker. If a tracker is replaced, the application software will invalidate all landmarks and prompt the user to repeat the digitizing, landmarking, and base kinematics tasks.
- This procedure requires use of a surgical bed featuring a radiolucent table top and stainless steel side rails. Nonconforming surgical beds may introduce navigational inaccuracy.
- Verify that all necessary instrumentation has been properly sterilized before surgery. Refer to the Universal Cleaning and Sterilization Instructions (pn 9730713) for current cleaning and sterilization instructions.

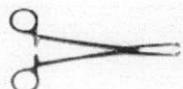
STANDARD EQUIPMENT

12



AxiEM™ Orthopaedic Trackers
(Femur pn 9731253, Tibia pn 9731254)

Use Trackers to track the position of the patient's anatomy during the procedure.



Tracker Holder (pn 9732175)

Use the Tracker Holder to position and hold the tracker while attaching it to bone.



AxiEM™ Ortho Screwdriver (pn 9732133)

Use the AxiEM™ Screwdriver to drive the Tracker fixation screws into bone.



AxiEM™ Pointer (pn 9660236)

Use the AxiEM™ Pointer for digitizing accuracy checkpoints and landmarks.



Click and Point Handle (pn 9660237)

Use the Click and Point Handle to hold the AxiEM™ Pointer.



AxiEM™ Paddle (pn 9731255)

Use the AxiEM™ Paddle to navigate cutting guides into position.



AxiEM™ Mobile Emitter (pn 9660812)

The AxiEM™ Mobile Emitter or Emitter produces the electromagnetic field used to track instruments.



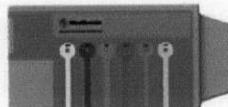
AxiEM™ Mobile Emitter Stand (pn 9732698)

The AxiEM™ Mobile Emitter Stand holds the Emitter in a steady position.



Ratcheting T-Handle (pn 9731974)

Use the Ratcheting T-Handle to hand tighten screws into bone during the procedure.



Navigation Probe Interface (pn 9660700)

The Navigation Probe Interface or Connector Box is a junction box used to connect AxiEM™ instruments to the system (Treon®/Tria™ only).



System Footswitch (pn 960-135)

Use the footswitch to control certain software functions.

14



AxiEM™ Portable System (pn 9660560 or
pn 9660561)

The **AxiEM™ Portable system** connects to the **iNav™ Portable system**. It is a junction box used to connect **AxiEM™ instruments** to the portable system.

PROCEDURE

15

LOG IN

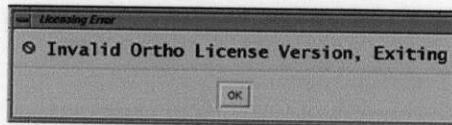
16

1. Click the **[QS AxiEM Knee]** icon if you are using the Quad Sparing incision approach with an AxiEM™ Cart.
2. Click the **[QS AxiEM Knee Portable]** icon if you are using the Quad Sparing incision approach with an AxiEM™ Portable system.
3. Click the **[Mini AxiEM Knee]** icon if you are using the Mini incision approach with an AxiEM™ Cart.
4. Click the **[Mini AxiEM Knee Portable]** icon if you are using the Mini incision approach with an AxiEM™ Portable system.



LOG IN (CONT.)

If you do not own an Orthopaedic OS license, you will not be able to start and run the Zimmer Imageless Knee for AxiEM application software (Treon®/Tria™ systems only). The following message displays.



Please contact your local Medtronic Navigation representative or call Medtronic Navigation to obtain information on purchasing an Orthopaedic OS license.

ENTER PATIENT NAME

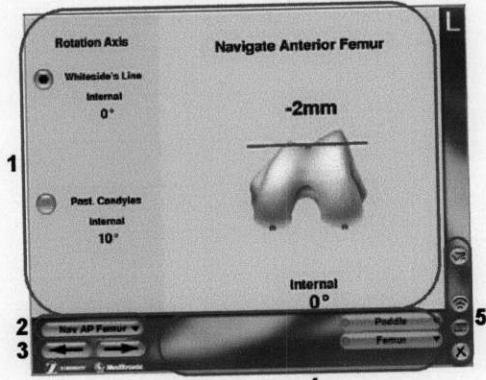
18

1. Enter the patient's name or an identification name for the exam using the virtual keyboard on-screen or the system keyboard.
If you are using the system keyboard, make sure that the mouse cursor is in the text box.
2. Click the [OK] button.



SOFTWARE OVERVIEW

1. Image Window: Interpretive images for each task appear in this area.
2. Task Bar: Each active task for the procedure displays on the task bar. Click the bar to display all tasks. Click a displayed task to enter that task.
3. Next/Back Buttons: Click the right-pointing Arrow to go forward to the next task. Click the left-pointing Arrow to return to the previous task.
4. Task-Specific Area: Each task has its own specific set of buttons and other controls. The colors of the status indicators in the right side of the area correspond to instrument and reference frame visibility.
5. General Control Buttons: Use the general control buttons to access system-level features at any time during the procedure.



CONFIDENTIAL

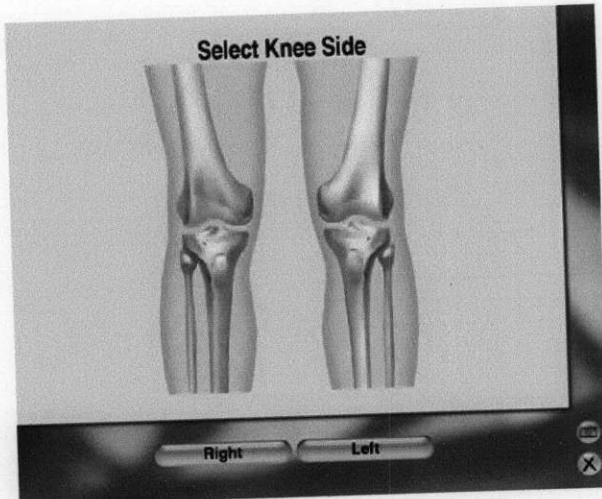
20

SELECT KNEE SIDE

Note the leg on which you will perform the procedure.

Click [Right] or [Left].

All calculations and anatomical representations are dependent upon choosing the correct knee side. Once the knee side is selected, it cannot be changed without starting over. If the wrong knee side is selected, all measurements and subsequent calculations (especially during knee alignment kinematics) will appear abnormal.



CONFIDENTIAL

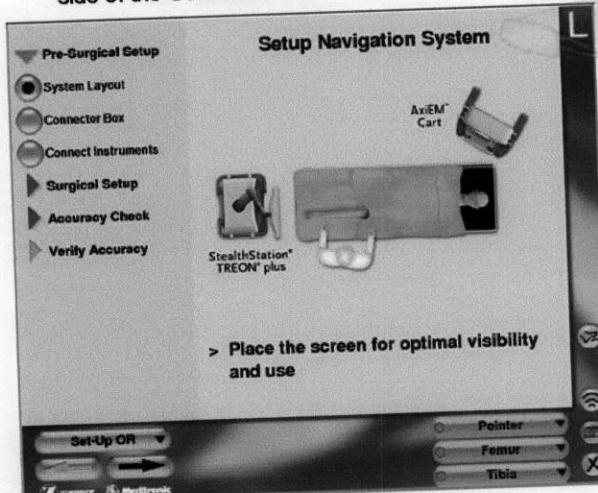
Medtronic Navigation, Inc.

Page 785 of 877

1213

SYSTEM LAYOUT AND CONNECTOR BOX

1. Place the AxiEM™ Cart to the side of the patient's head on the opposite side of the scrub nurse's table.
2. Move the touchscreen monitor into a position at the foot of the operating table where both the surgeon and the assistant can see the screen.
3. Plug the Emitter LEMO connector to LEMO port 1.
4. Hang the NPI (Connector Box) on the operating table side rail.
5. Connect the Connector Box cable to the AxiEM™ Cart peripheral port labelled NPI.
6. Plug the footswitch connector into the Footswitch port on the side of the Connector Box.

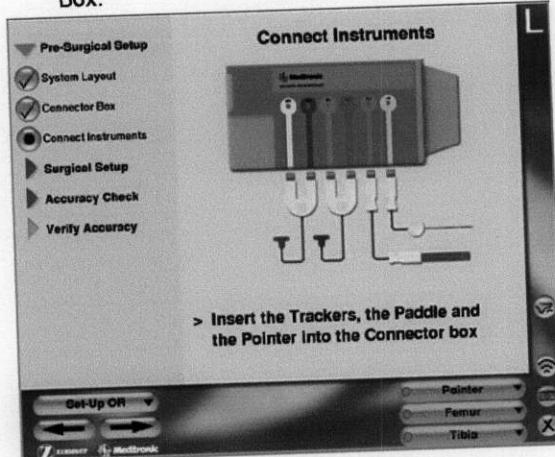


21

22

CONNECT INSTRUMENTS

- ⚠ Inspect all probes and trackers for loose cabling or exposed wiring. Never use a device with wiring defects.
 - ⚠ Do not connect multiple low isolation instruments (such as the Pointer).
1. Plug the footswitch connector into the Footswitch port on the side of the Connector Box.
 2. Plug the Femur Tracker's double ended connector into two adjacent instrument ports on the Connector Box.
 3. Plug the Tibia Tracker's double ended connector into two adjacent instrument ports on the Connector Box.
 4. Plug the AxiEM™ Paddle into an open port on the Connector Box.

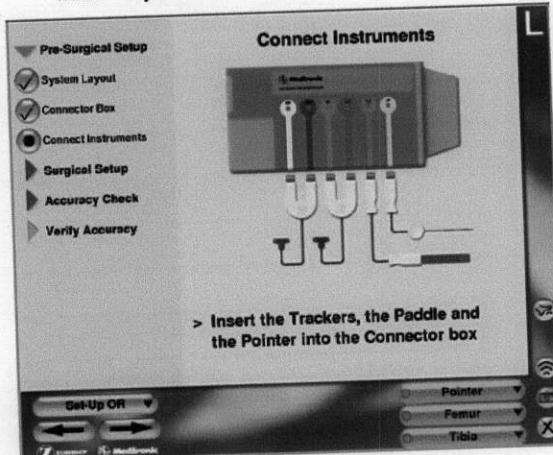


CONNECT INSTRUMENTS (CONT.)

5. Plug the AxiEM™ Pointer into an open port on the Connector Box.
6. Make sure the indicator lights on the connector box change from orange to green indicating a successful connection.

iNAV™ SYSTEM SETUP

7. Plug the Emitter LEMO connector into the **left** LEMO port on the back of the iNav™ Portable system.
8. Use cable (pn 9660865) to connect the AxiEM™ Portable system (9660560) to the **right** LEMO connector on the iNav™ Portable system.
9. Use cable (pn 9732448) to connect the Connector Box to the iNav™ system.



23

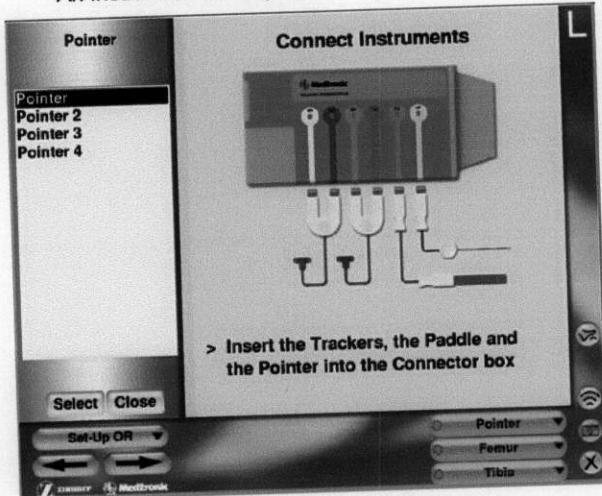
24

SWITCHING INSTRUMENTS DURING THE PROCEDURE

You may replace an instrument at any time during the procedure. However, you must select the instrument in the application software to activate it. The new instrument will have the label [Instrument N+1], where N=the current instrument, for example [Pointer 2].

1. Unplug the instrument you wish to replace from the connector box.
2. Plug the new instrument into the open port on the connector box.
3. Click the relevant status indicator.

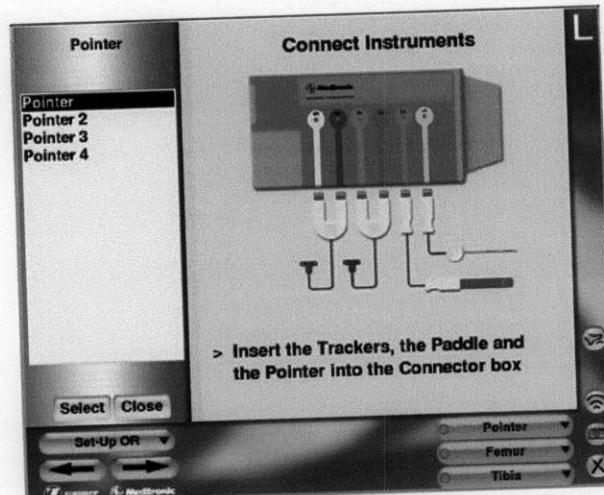
An instrument list displays.



SWITCHING INSTRUMENTS DURING THE PROCEDURE

(CONT.)

4. Select the new instrument from the list and click [Select].
5. Make sure the indicator light on the connector box changes from orange to green indicating a successful connection.



25

ATTACH TRACKER TO FEMUR

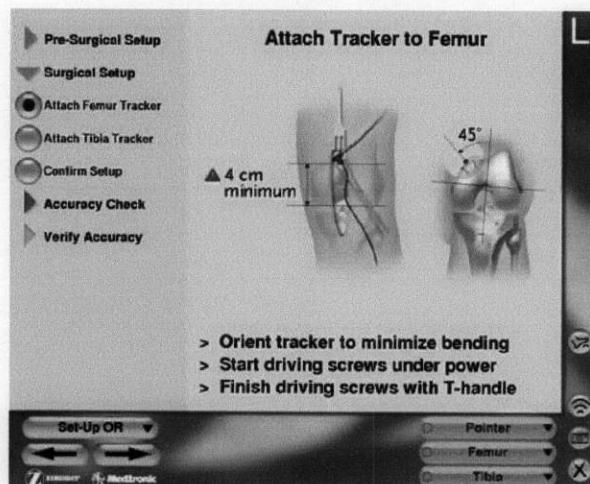
26

1. Select an attachment site on the femur at least 4 cm proximal to the joint line, and internally rotated approximately 45° from Whiteside's Line.

This site will ensure that the tracker is located far enough away from the anticipated standard surgical instrumentation.

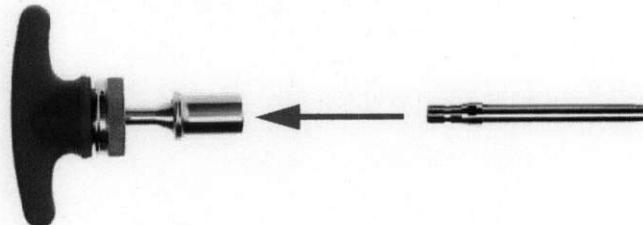
2. Open the Tracker Holder (pn 9732175) and clamp the tip around the body of the Femur Tracker (pn 9731253).
3. Orient the tracker so that the screws are inserted into the bone along the long axis of the femur.

This will minimize bending of the tracker around the circumferential curvature of the bone.



ATTACH TRACKER TO FEMUR (CONT.)

4. Place and hold the tracker on the bone attachment site using the Tracker Holder.
5. Insert a fixation screw through the screw hole making sure that the screw is at a perpendicular direction relative to the screw hole and drive the screw approximately half-way into the bone (trochar tip plus 1 - 2 threads).
If bone is hard, tap the end of the T-handle to get the trochar tip into bone and assist starting the screw.
6. Drive the second fixation screw as in Steps 5 - 6.
7. Attach the tracker screwdriver (pn 9732174) to the Ratcheting T-handle.



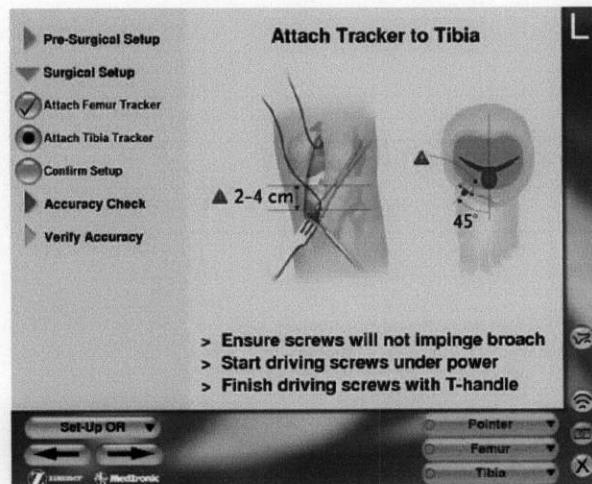
8. Finish tightening both screws with the hand-held T-handle and make sure that the tracker is stable.
Do not over-tighten the screws as this may strip the bone and compromise the tracker's rigid attachment to the bone.
Do not bump or detach and re-attach the trackers after digitizing the hip center or landmarks.

ATTACH TRACKER TO TIBIA

28

△ The tibial cutting guide may interfere with the tibial tracker. It is important to place the tracker far enough down the shaft of the tibia in order to prevent this type of interference.

1. Attach the tracker screwdriver (pn 9732174) to the Ratcheting T-handle.
2. Select an attachment site on the tibia that is 2 - 4 cm distal to the joint line, and rotated approximately 45° inward from the AP axis.
3. Open the Tracker Holder (pn 9732175) and clamp the tip around the body of the Tibia Tracker (pn 9731253).



ATTACH TRACKER TO TIBIA (CONT.)

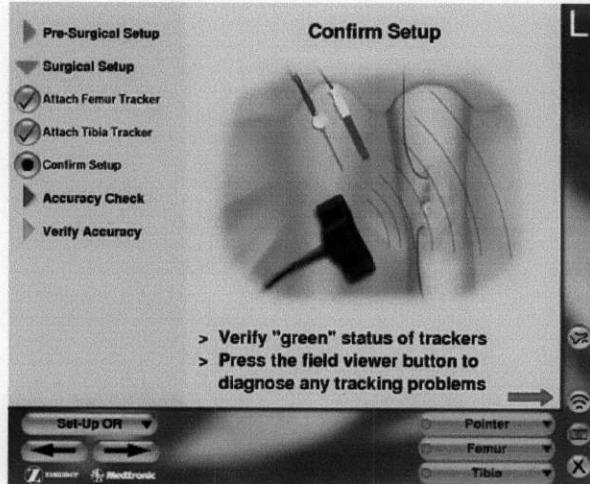
4. Orient the tracker so that the screws are inserted into the bone along the long axis of the tibia.
This will minimize bending of the tracker around the circumferential curvature of the bone.
5. Place and hold the tracker on the bone attachment site using the Tracker Holder.
6. Insert a fixation screw through the screw hole making sure that the screw is at a perpendicular direction relative to the screw hole and drive the screw approximately half-way into the bone (trochar tip plus 1 - 2 threads).
If bone is hard, tap the end of the T-handle to get the trochar tip into bone and assist starting the screw.
7. Drive the second fixation screw as in Steps 5 - 6.
8. Finish tightening both screws with the hand-held T-handle and make sure that the tracker is stable.

After setting up the Tibia Tracker, make sure that it will not interfere with the anticipated standard surgical instrumentation. Also make sure that the fixation screws (which can extend up to 11 mm into the tibia) will not interfere with any of the keel/punch instrumentation.

CONFIRM SETUP

30

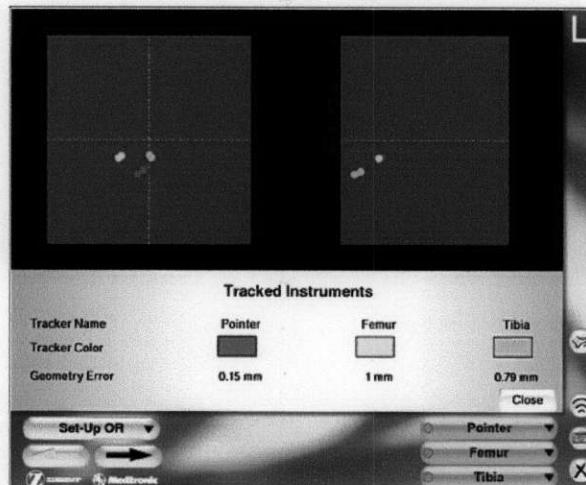
1. Confirm that the trackers and instruments are connected to the Connector Box and the indicator lights are green.
2. Bring the AxiEM™ Emitter about 20cm away from the surgical area of interest.
3. Verify that the on-screen instrument and reference status indicators are green.
4. Press the **Field Viewer** button and open the field viewer.



FIELD VIEWER

Tracked sensors in each device display as spheres. The sensors are displayed according to their color legend. The legend is displayed in the lower portion of the field viewer window. Click [Close] to close the field viewer window.

Below the label for each device in the field of view window is a number representing that device's geometry error. Geometry error can indicate the impact of influences such as metal in the navigation field, a localized instrument placed too close to the edge of the navigation field, damaged instruments, and excess motion of instruments or trackers while within the navigation field. These influences may cause a reduction in localization accuracy.



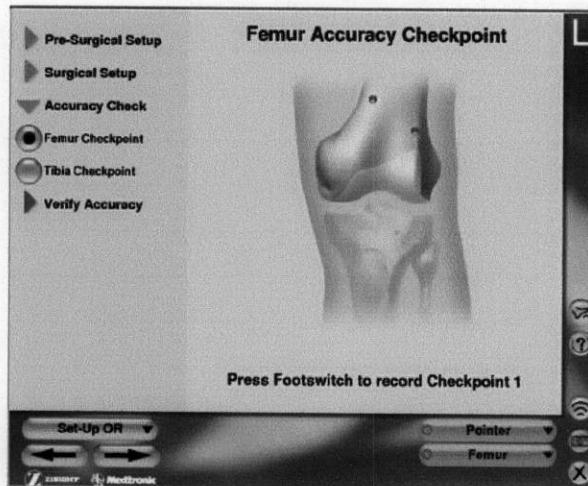
31

RECORD FEMUR ACCURACY CHECKPOINTS 32

△ Visually inspect the pointer before use. Do not use the pointer if it appears damaged.

1. Pick or create a readily identifiable point on the femur.
2. Place the tip of the pointer on the point.
3. Press and release the footswitch.
4. The application software will auto-advance to the next point
5. Repeat steps 1 - 3 for a second point

After you record the second point, the application software will automatically advance to the next screen.



RECORD TIBIA ACCURACY CHECKPOINTS

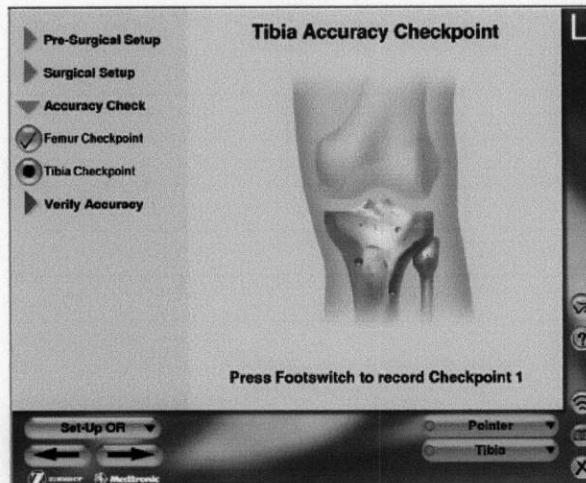
Pick or create a readily identifiable point on the tibia.

1. Place the tip of the pointer on the point.
2. Press and release the footswitch.

The application software will auto-advance to the next point.

3. Repeat steps 1 - 3 for a second point.

After you record the second point, the application software will automatically advance to the next screen.



33

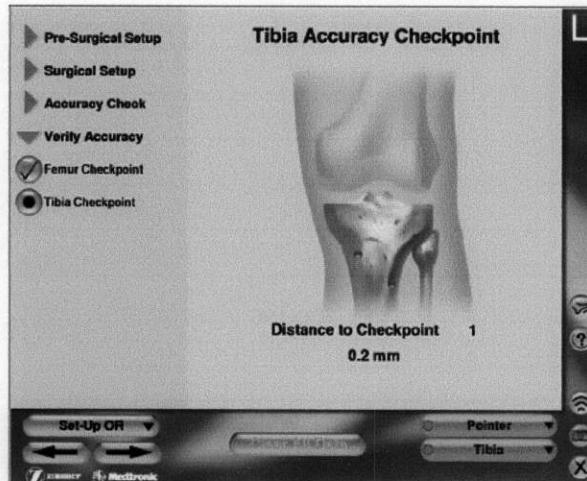
VERIFY ACCURACY

34

Verify a femur and tibia accuracy checkpoint.

1. Place the pointer on a saved femur accuracy checkpoint.
2. Press and release the footswitch.
3. Observe the distance display and verify that the distance is less than 2mm.
4. Repeat Steps 1 - 3 for a tibia accuracy checkpoint.

The application software requires an accuracy of 2mm or better to proceed.

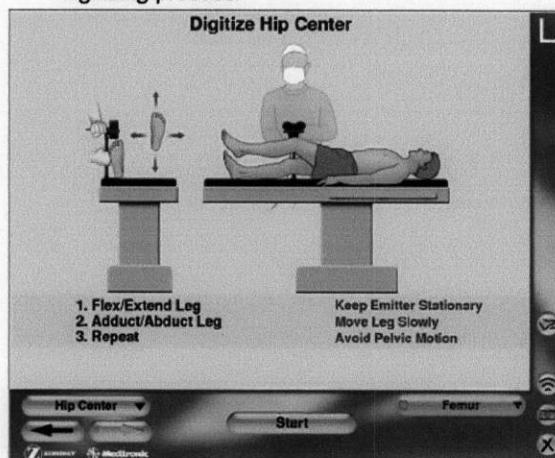


DIGITIZE HIP CENTER

△ The Emitter must be kept motionless during this task.

The location of the hip center is required to determine the mechanical femoral axis. The overall goal of hip digitization is to move the pelvis as little as possible while moving the femur through as large a range of motion as possible.

1. Place the base of the Emitter Stand under the patient's contralateral leg.
2. Set the Emitter in the stand and have the assistant hold the Emitter and stand motionless.
3. Verify that the femur status indicator is green.
4. Press and release the footswitch or click [Start] to begin the digitizing process.

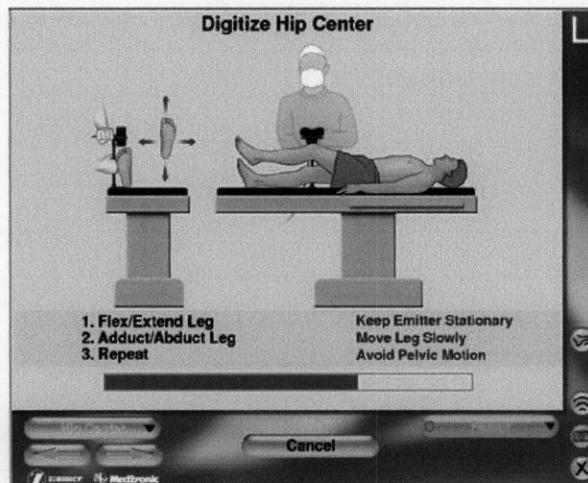


35

DIGITIZE HIP CENTER (CONT.)

36

5. Flex and extend the hip until the indicator bar is approximately half filled. Flex and extend the knee while flexing and extending the hip in order to obtain the necessary range of motion.
6. Abduct and adduct the leg until the indicator bar is completely full.
7. Press and release the footswitch or click [Cancel] at any time to stop the digitizing process and begin the process again.
8. If the Emitter or the patient's pelvis were not held completely motionless, it may be necessary to repeat Steps 3 and 4.



QUAD SPARING TECHNIQUE

Follow the instructions on the following pages if you are using the Quad Sparing technique.

If you are using the Mini Incision technique, please proceed to "Mini Incision Technique" on page 62.

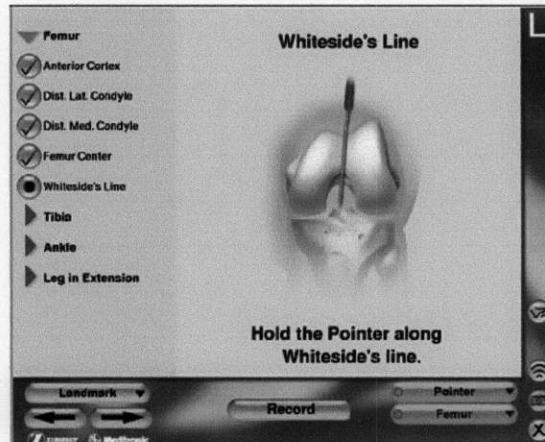
RECORD FEMUR LANDMARKS

38

△ Visually inspect the pointer before use. Do not use the pointer if it appears damaged.

Place the tip of the pointer on each point in the list and press and release the footswitch or click [Record] to record the point. The application software will automatically advance to the next point on the list after a point has been successfully recorded.

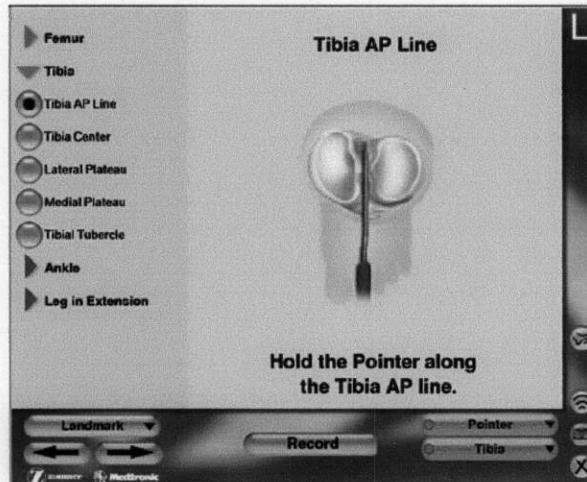
1. Record the anterior cortex.
2. Record the distal lateral condyle.
3. Record the distal medial condyle.
4. Record the distal femoral center.
5. Align the pointer along Whiteside's line to record the femoral AP axis.



RECORD TIBIA LANDMARKS

Place the tip of the pointer on each point in the list and press and release the footswitch or click [Record] to record each point. The application software will automatically advance to the next point on the list after a point has been successfully recorded.

1. Align the pointer along the tibial AP line to record the tibial AP axis.
2. Record the tibial center.
3. Record the deepest aspect of the lateral plateau.
4. Record the deepest aspect of the medial plateau.
5. Record the tibial tubercle.



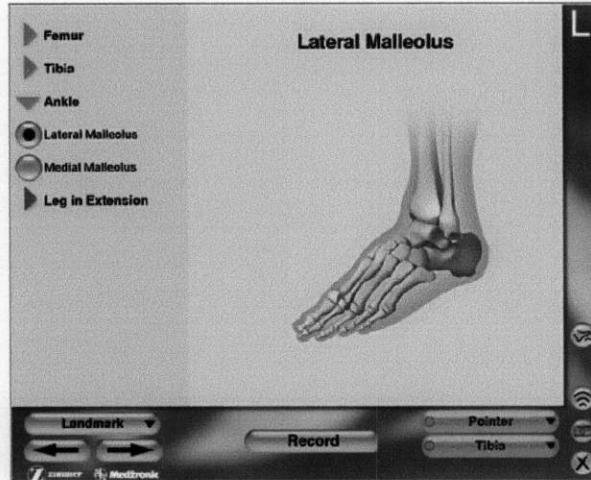
39

RECORD ANKLE LANDMARKS

40

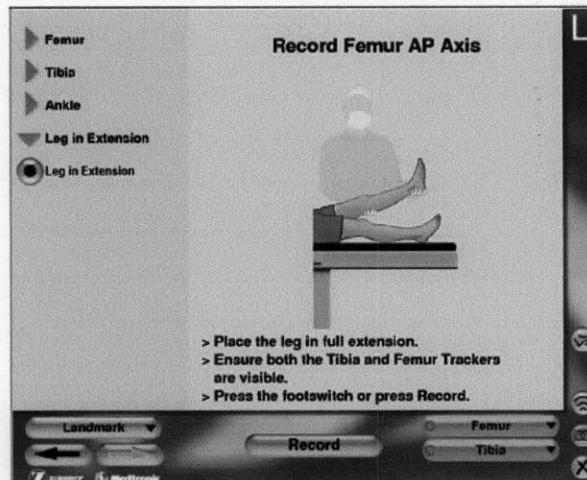
Place the tip of the pointer on each point in the list and press and release the footswitch or click [Record] to record each point. The application software will automatically advance to the next point on the list after a point has been successfully recorded.

1. Record the lateral malleolus.
2. Record the medial malleolus.



RECORD LEG IN EXTENSION

1. Maneuver the tibia and femur into a position of full extension.
If the leg cannot be put in full extension due to pathology, make certain that the tibial AP axis is rotationally aligned with the femoral AP axis as much as possible.
2. Make sure that both the femur and tibia tracker status indicators are green.
3. Press the footswitch or click [Record].



41

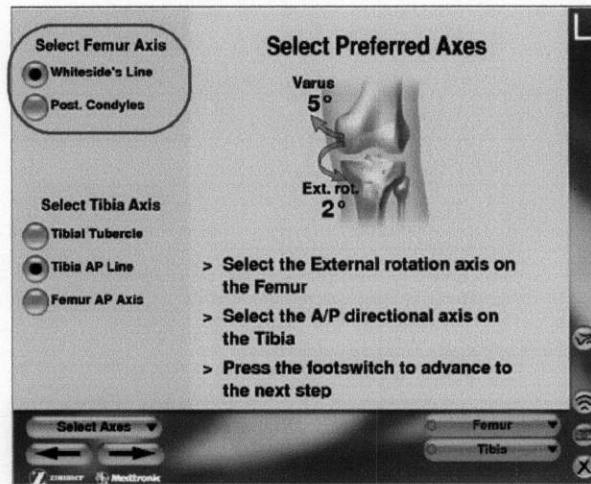
SELECT FEMUR AXIS

42

Select one internal/external rotation axis to be used as the femoral reference for pre-operative alignment.

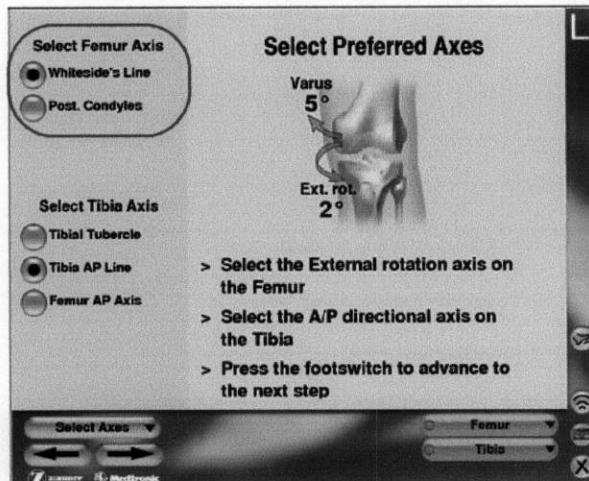
1. Select **Whiteside's Line** to assign Whiteside's Line as the femoral reference axis. This is the application software's default setting.
2. Select **Posterior Condyles** to use the posterior condyle landmarks as the femoral reference axis.

The Posterior Condyles option is not available until you proceed through the software to the Sizing task to digitize the posterior condyles and then return to the Select Axes task.



SELECT FEMUR AXIS (CONT.)

Avoid changing landmarks after bone resection (if possible). If a landmark is changed after resection, the application software displays a warning dialogue. If you choose to proceed, the application software will delete all stored values from the Pre-Op Data, V&V Stress Test, and Post-Op Data tasks. You then have the option to return to the Select Axes task and change the reference axes selections. The application software uses the new landmarks and reference axes selections to re-calculate Stress Test distraction values.



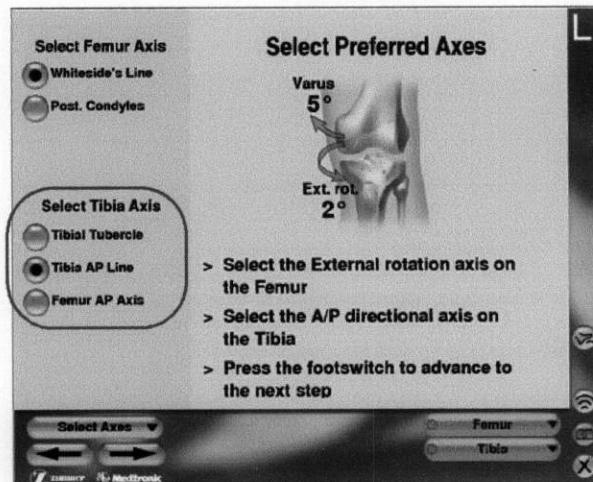
43

SELECT TIBIA AXIS

44

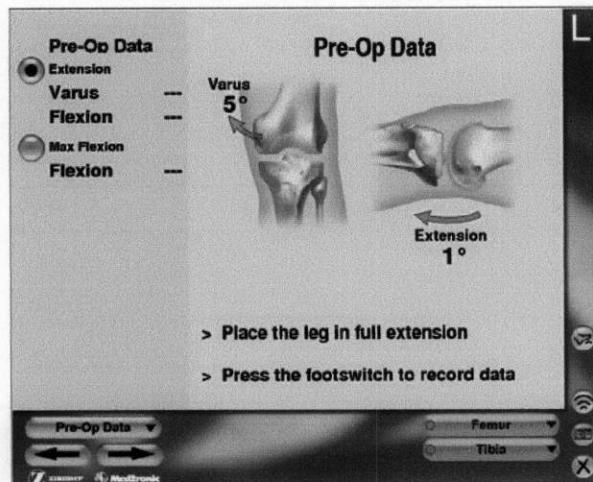
Select one AP directional tibial axis to be used as the tibial reference for pre-operative alignment.

1. Select **Tibial Tubercl**e to use the tibial tubercle as the baseline reference for the tibial AP axis.
2. Select **Tibia AP Line** to assign the tibia AP line as the baseline reference for data collection.
3. Select **Femur AP Axis** to use the femoral reference axis determined in "Select Femur Axis" on page 42 for the tibial AP axis. This is the application software's default setting.



RECORD PRE-OPERATIVE ALIGNMENT

1. Maneuver the tibia and femur into a position of full extension.
Make sure that both the femur and tibia tracker status indicators are green.
2. Press and release the footswitch to record the varus/valgus measurement and flexion angle at the full extension position.
3. Maneuver the leg into a position of full flexion. Make sure that both the femur and tibia tracker status indicators are green.
4. Press and release the footswitch to record the flexion angle at the full flexion position.



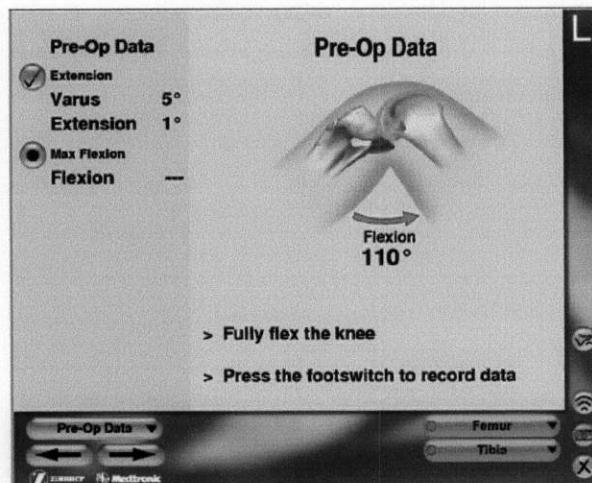
45

RECORD PRE-OPERATIVE ALIGNMENT (CONT.)

46

5. Carefully review the stored and live alignment values throughout the knee's range of motion. Values that do not match one's intuitive judgement may indicate possible error in recording landmarks. Do not proceed to navigation tasks until satisfied with the alignment data.

Note: Any stored pre-operative data will be deleted if any landmarks are changed after this point in the procedure.

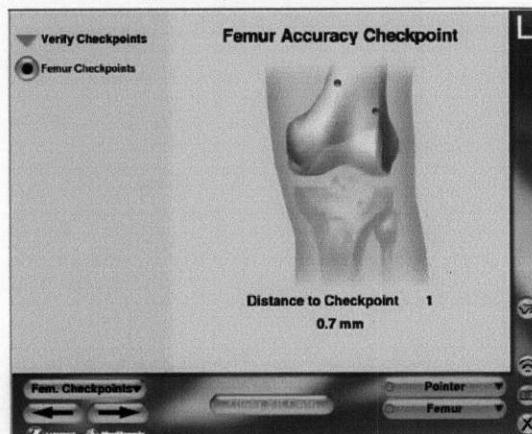


VERIFY FEMUR ACCURACY CHECKPOINT

Use the previously recorded accuracy checkpoints to determine whether the trackers have shifted with respect to the patient's anatomy.

1. Place the pointer on a saved Femur accuracy checkpoint.
2. Press and release the footswitch.
3. Observe the distance display and verify that the distance is less than 2mm.

After you successfully verify both femur checkpoints, the application software will automatically advance to the next task. If verification was not successful, you may re-record accuracy checkpoints and then re-digitize the hip center and re-record landmarks, or you may ignore the accuracy verification and continue with the current procedure, or you may abort use of the system.



47

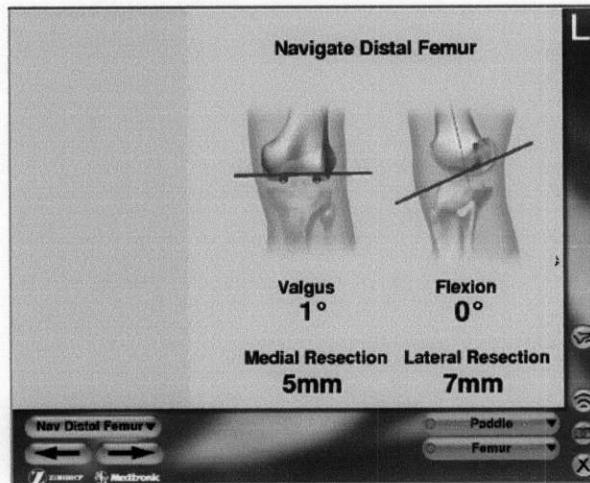
NAVIGATE DISTAL FEMUR CUT

48

The AxiEM™ Paddle's reference plane is displayed as a red line. Use on-screen information to navigate the cutting guides into place.

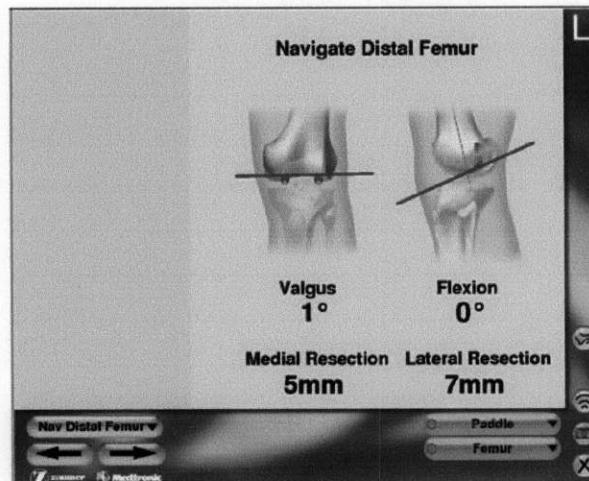
Visually inspect the AxiEM™ Paddle prior to use. Do not use the paddle if it appears bent or damaged. During navigation, check navigation values for consistency by placing the paddle against a flat surface and checking it again flipped upside down. If there is a visible difference in the flatness of the paddle, use another paddle.

Ensure that the femoral and tibial tracker status indicators are green during all navigation tasks. If the trackers are not being tracked, navigation will cease and real-time on-screen projections and measurements will disappear.



NAVIGATE DISTAL FEMUR CUT (CONT.)

1. Place the AxiEM™ Paddle into the cutting slot on the distal cutting guide.
2. Make final adjustments and affix the cutting guide firmly to the femur.
3. Remove the paddle from the cutting guide.
4. Use standard surgical technique to resect the distal femur.
5. Verify the distal cut by placing the AxiEM™ Paddle on the cut surface. Capture a screenshot for the patient file.
6. Remove the cutting guide.
7. Press and release the footswitch to advance to the next task.



49

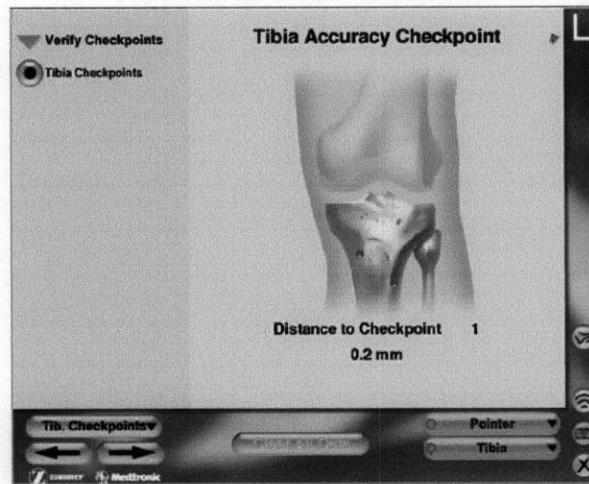
VERIFY TIBIA ACCURACY CHECKPOINTS

50

Use the previously recorded accuracy checkpoints to determine whether the trackers have shifted with respect to the patient's anatomy. This is especially important if the patient's bone is soft.

1. Place the pointer on a saved tibia accuracy checkpoint.
2. Press and release the footswitch.
3. Observe the distance display and verify that the distance is less than 2mm.

After you verify both tibia checkpoints, the application software will automatically advance to the next task.

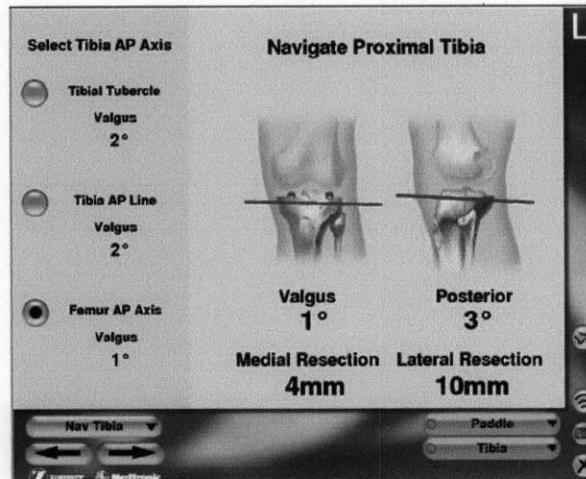


NAVIGATE PROXIMAL TIBIA CUT

Navigate the AxiEM™ Paddle in the proximal tibia cutting guide to determine an accurate location for the cutting guide.

The varus/valgus angle is displayed for each available axis. The selected axis is shown in the main image.

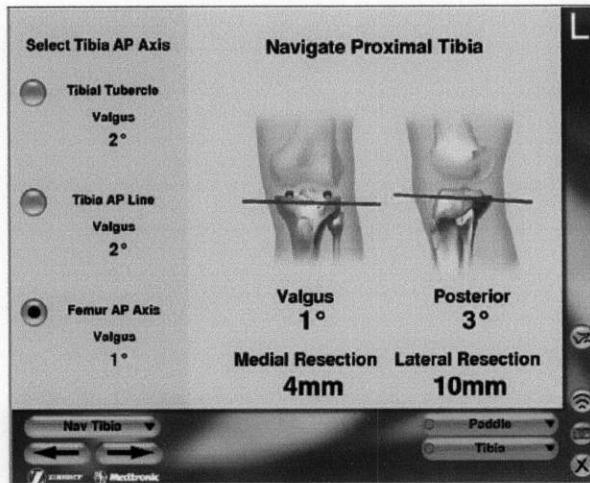
1. Place the AxiEM™ Paddle into the cutting slot on the proximal tibia cutting guide. The AxiEM™ Paddle's reference plane is displayed as a red line.
2. Use the on-screen depth and angles measurements to navigate the assembly into place.



NAVIGATE PROXIMAL TIBIA CUT (CONT.)

52

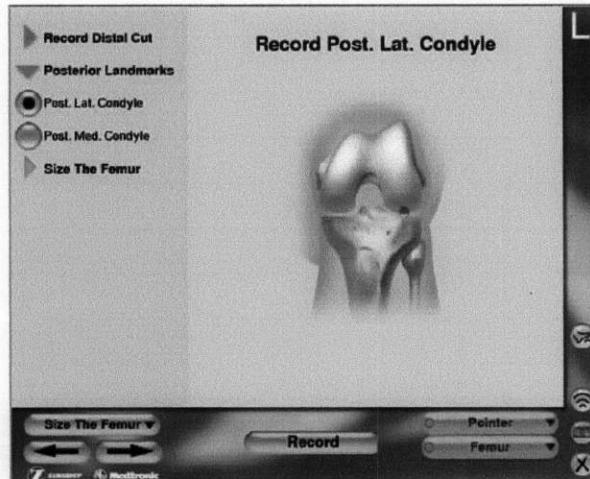
3. Use standard surgical technique to attach the proximal cutting guide to the tibia.
4. Remove the paddle from the cutting guide.
5. Use standard surgical technique to resect the proximal tibia.
6. Verify the tibial cut by placing the AxiEM™ Paddle on the cut surface. Capture a screenshot for the patient file.
7. Remove the cutting guide.
8. Press and release the footswitch to advance to the next task.



RECORD CONDYLES

1. Place the tip of the pointer on each point in the list and press and release the footswitch or click [Record] to record each point.
2. Record the posterior lateral condyle.
3. Record the posterior medial condyle.

After you record the condyles, the application software will automatically advance to the next task.



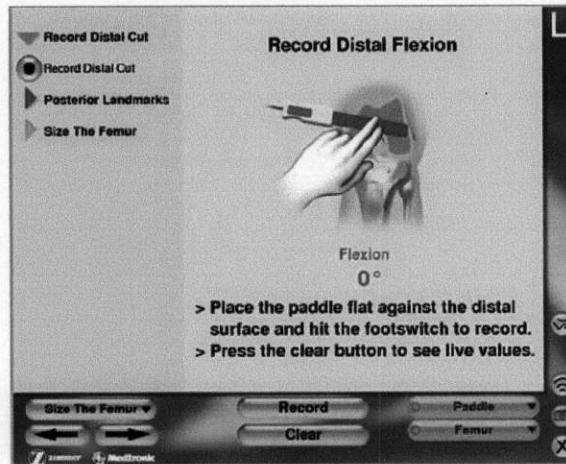
53

RECORD DISTAL CUT

54

1. Place the paddle flat against the distal surface of the femur.
The application software displays the current or live flexion value in black.
2. Press the footswitch or click [Record] to record the current flexion value.
After recording the distal flexion value, the application software will automatically advance to the next task.

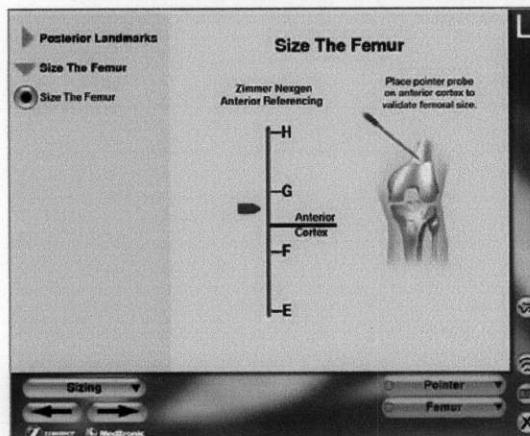
If you re-enter the Record Distal Flexion task to re-record the flexion value, the application software displays the previously recorded flexion value in gray. Click [Clear] to clear the recorded value and display a live flexion value. Press the footswitch or click [Record] to record the current live value.



SIZE THE FEMUR

The application software displays a Zimmer NexGen™ sizing scale to approximate the size of the patient's femur. The sizing scale uses anterior referencing as the default. Call Medtronic Navigation technical support for instructions to switch to posterior referencing.

1. Place the tip of the pointer on the anterior cortex of the patient's femur and slowly drag the pointer along the surface of the anterior cortex.
Note: When you drag the tip of the pointer along the surface of the anterior cortex, the software displays a real-time indicator on the sizing scale.
2. Observe the floating size indicator and note the appropriate femur size. Also note the pre-recorded anterior cortex point.
3. Press and release the footswitch to advance to the next task.



55

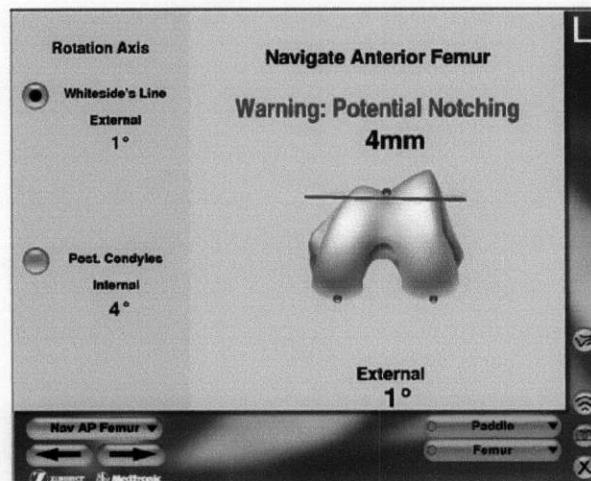
NAVIGATE POSTERIOR AND ANTERIOR

56

FEMUR CUTS

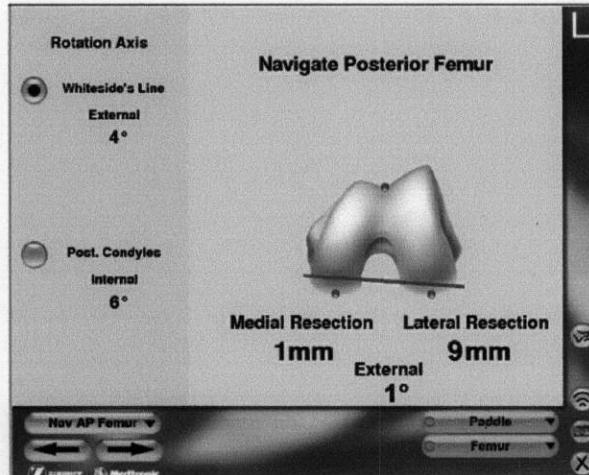
1. Place the AxiEM™ Paddle into the anterior cutting slot on the AP femur cutting guide.
2. Use the on-screen depth and angle measurements to navigate the cutting guide into position. Note the on-screen measurements.

The application software displays the internal/external rotation angle of the cutting guide and the distance (either above or below) the anterior cortex point. If the paddle is more posterior than (below) the anterior cortex point, the application software displays a message warning of potential posterior notching.



**NAVIGATE POSTERIOR AND ANTERIOR
FEMUR CUTS (CONT.)**

3. Note the final position of the guide and the corresponding on-screen measurements and remove the Paddle from the cutting guide.
4. Place the AxiEM™ Paddle into the posterior cutting slot on the AP femur cutting guide.
5. Use the on-screen depth and angle measurements to navigate the cutting guide into the same final position as in Step 3.
6. Note the position of the proposed posterior cut and if satisfactory, remove the paddle from the cutting guide, and attach the AP cutting guide using standard surgical technique.



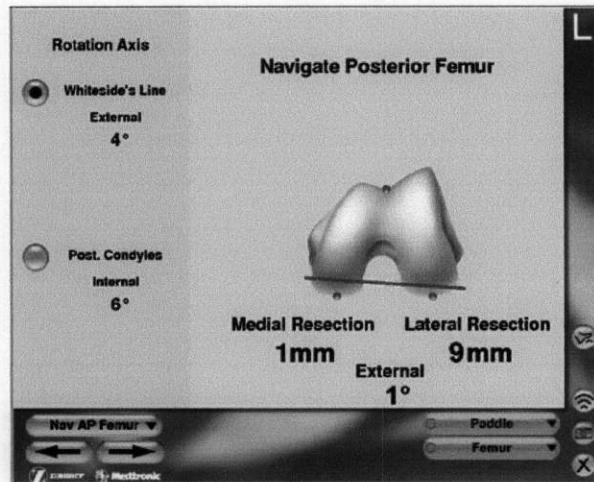
57

NAVIGATE POSTERIOR AND ANTERIOR

58

FEMUR CUTS (CONT.)

7. Use standard surgical technique to resect the posterior femur.
8. Use standard surgical technique to resect the anterior femur.
9. Verify the cuts by placing the AxiEM™ Paddle on the cut surfaces. Capture a screenshot for the patient file.
10. Remove the cutting guide.



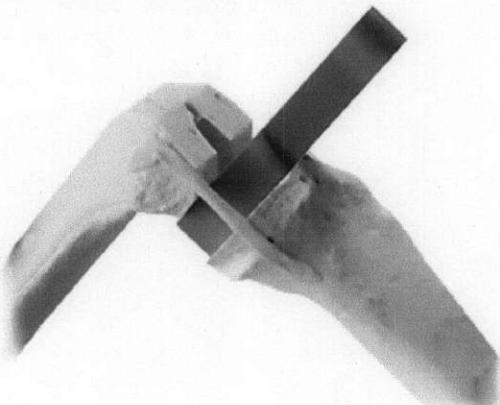
PERFORM STRESS TEST

Make certain that the femoral and tibial status indicators are green during stress testing. If the devices are not being tracked, data collection will cease, and all on-screen measurement graphics will not display.

Distraction values are only calculated and displayed when the flexion angle of the knee is at the required, predefined test angle. The table of stored values displays below the leg model.

When [Start] is pressed, the distraction values are set to zero (as a baseline) and any subsequent distraction is measured relative to that baseline.

1. Using standard surgical technique, place a spacer block in the knee gap or install the femoral and tibial trials.
2. Place the knee into the desired degree of flexion.

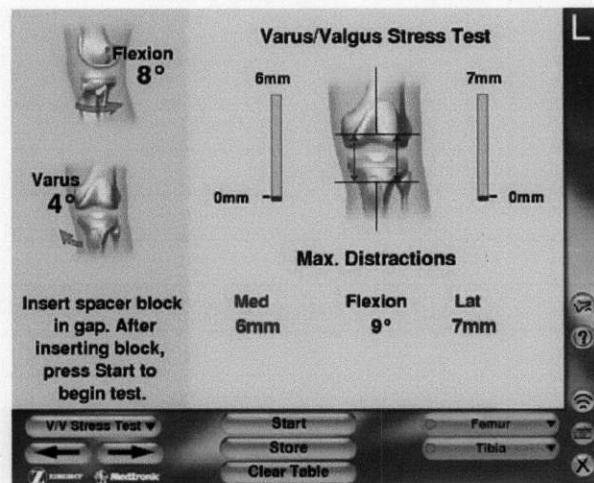


59

PERFORM STRESS TEST (CONT.)

60

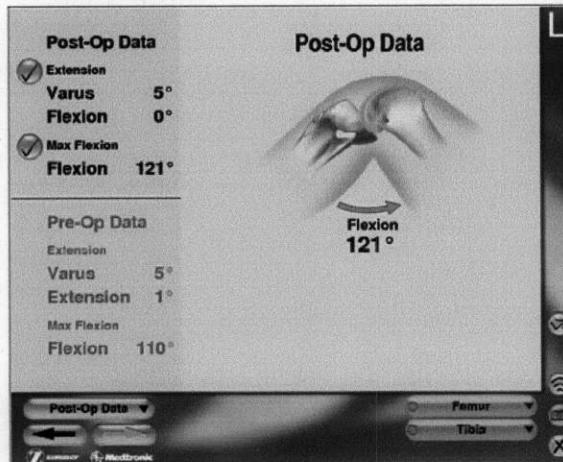
3. Click [Start] for the angle being sampled.
4. Apply varus/valgus loads to the knee.
The knee must be kept at the starting flexion angle $\pm 10^\circ$ (as established in Step 2) throughout the sampling process.
5. Click [Stop] to end sampling. Results will display on-screen.
6. Click [Store] to save the test results to the table.
7. Repeat Steps 2 - 6, placing the leg at various degrees of flexion.
8. Click [Clear Table] to erase all values stored in the table.



RECORD POST-OPERATIVE ALIGNMENT

After installing trials or implants, compile alignment information about the patient's affected leg. Use the data for comparison purposes against the pre-operative data.

1. With trials in place, maneuver the tibia and femur into a position of full extension. Make sure that both the femur and tibia tracker status indicators are green.
2. Press and release the footswitch to record the varus/valgus and full flexion/extension angle.
3. Maneuver the tibia and femur into a position of maximum flexion.
4. Press and release the footswitch to record the maximum flexion angle.



61

MINI INCISION TECHNIQUE

62

Follow the instructions on the following pages for the Mini Incision technique.

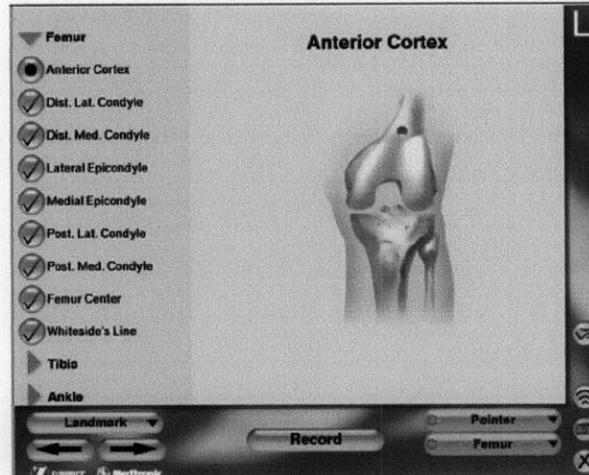
If you are using the Quad Sparing technique, please proceed to "Exit the Application Software" on page 88.

RECORD FEMUR LANDMARKS

△ Visually inspect the pointer before use. Do not use the pointer if it appears damaged.

Place the tip of the pointer on each point in the list and press and release the footswitch or click [Record] to record each point. The application software will automatically advance to the next point on the list after a point has been successfully digitized.

1. Record the anterior cortex.
2. Record the distal lateral condyle.
3. Record the distal medial condyle.
4. Record the lateral epicondyle.

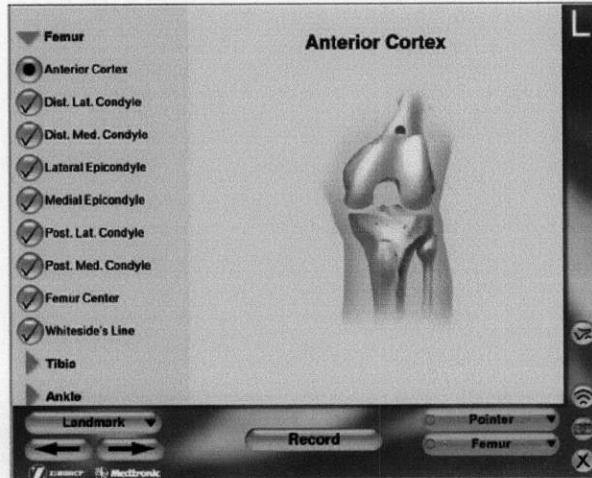


63

RECORD FEMUR LANDMARKS (CONT.)

64

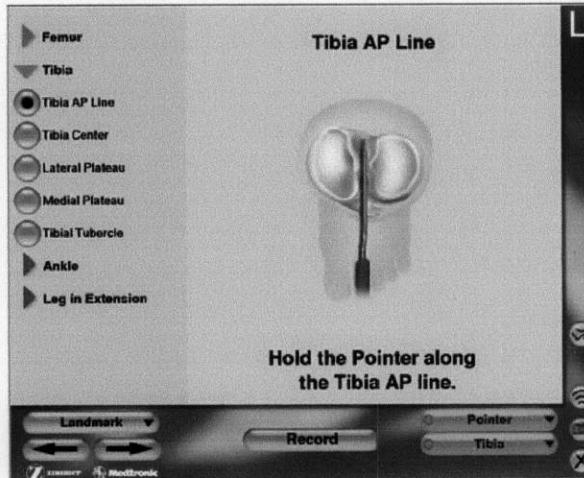
5. Record the medial epicondyle.
6. Record the posterior lateral condyle.
7. Record the posterior medial condyle.
8. Record the femur center.
9. Align the Pointer along Whiteside's line to record the femoral A/P axis.



RECORD TIBIA LANDMARKS

Place the tip of the pointer on each point in the list and press and release the footswitch or click [Record] to record each point. The application software will automatically advance to the next point on the list after a point has been successfully digitized.

1. Align the pointer along the tibial AP line to record the tibial AP axis.
2. Record the tibial center.
3. Record the deepest aspect of the lateral plateau.
4. Record the deepest aspect of the medial plateau.
5. Record the tibial tubercle.



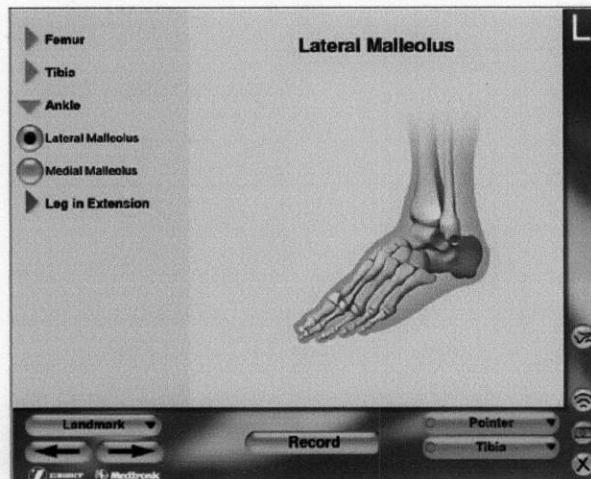
65

RECORD ANKLE LANDMARKS

66

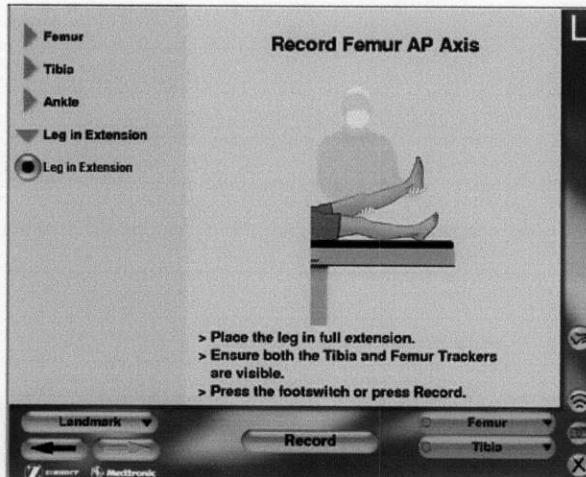
Place the tip of the pointer on each point in the list and press and release the footswitch or click [Record] to record each point. The application software will automatically advance to the next point on the list after a point has been successfully digitized.

1. Record the lateral malleolus.
2. Record the medial malleolus.



RECORD LEG IN EXTENSION

1. Maneuver the tibia and femur into a position of full extension.
If the leg cannot be put in full extension due to pathology, make certain that the tibial AP axis is rotationally aligned with the femoral AP axis as much as possible.
2. Make sure that both the femur and tibia tracker status indicators are green.
3. Press the footswitch or click [Record].



67

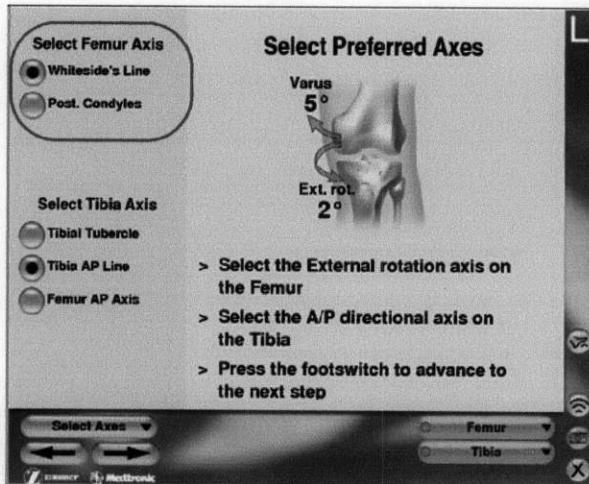
SELECT FEMUR AXIS

68

Select one internal/external rotation axis to be used as the femoral reference for pre-operative alignment.

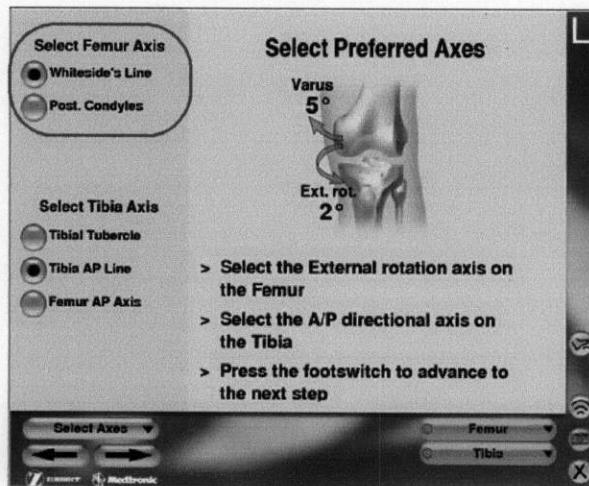
1. Select **Whiteside's Line** to assign Whiteside's Line as the femoral reference axis. This is the application software's default setting.
2. Select **Posterior Condyles** to use the posterior condyle landmarks as the femoral reference axis.

The Posterior Condyles option is not available until you proceed through the software to the Sizing task to digitize the posterior condyles and then return to the **Select Axes** task.



SELECT FEMUR AXIS (CONT.)

Avoid changing landmarks after bone resection (if possible). If a landmark is changed after resection, the application software displays a warning dialogue. If you choose to proceed, the application software will delete all stored values from the Pre-Op Data, V&V Stress Test, and Post-Op Data tasks. You then have the option to return to the Select Axes task and change the reference axes selections. The application software uses the new landmarks and reference axes selections to re-calculate all distraction values.



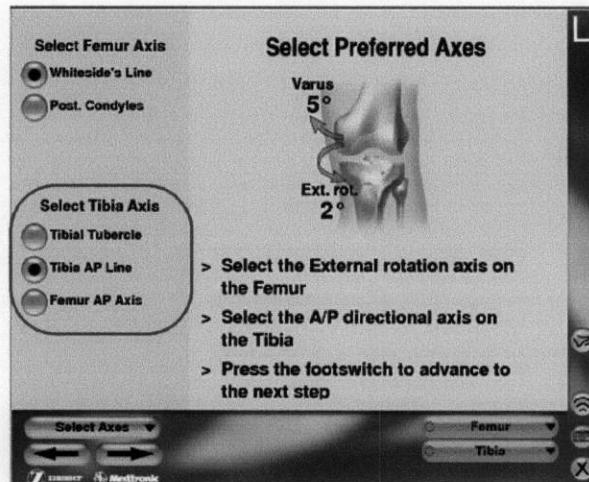
69

SELECT TIBIA AXIS

70

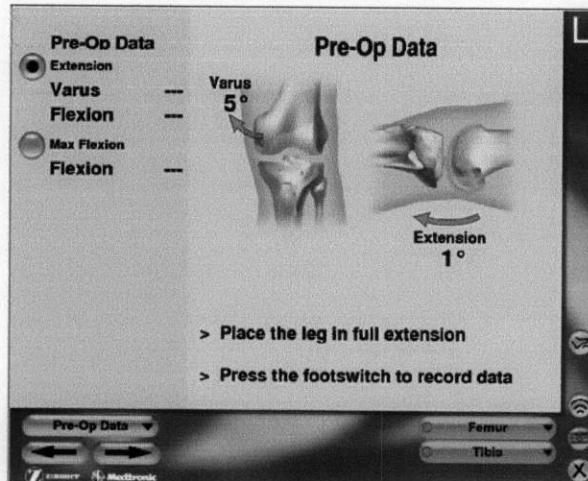
Select one AP directional tibial axis to be used as the tibial reference for pre-operative alignment.

1. Select **Tibial Tubercl**e to use the tibial tubercle as the baseline reference for the tibial AP axis.
2. Select **Tibia AP Line** to assign the tibia AP line as the baseline reference for data collection.
3. Select **Femur AP Axis** to use the femoral reference axis determined in "Select Femur Axis" on page 42 for the tibial AP axis. This is the application software's default setting.



RECORD PRE-OPERATIVE ALIGNMENT

1. Maneuver the tibia and femur into a position of full extension. Make sure that both the femur and tibia tracker status indicators are green.
2. Press and release the footswitch to record the varus/valgus measurement and flexion angle at the full extension position.
3. Maneuver the leg into a position of full flexion. Make sure that both the femur and tibia tracker status indicators are green.
4. Press and release the footswitch to record the flexion angle at the full flexion position.



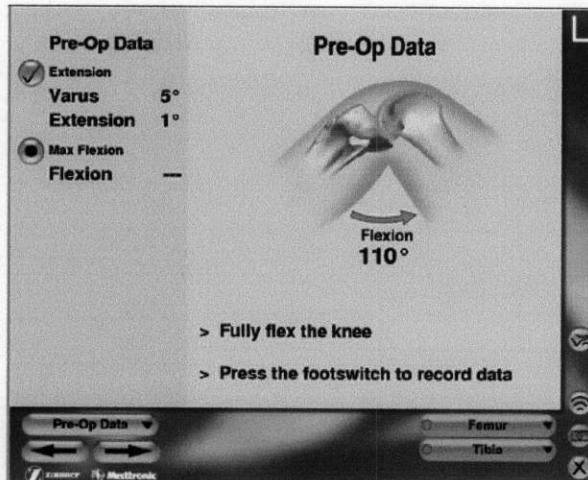
71

RECORD PRE-OPERATIVE ALIGNMENT (CONT.)

72

5. Carefully review the stored and live alignment values throughout the knee's range of motion. Values that do not match one's intuitive judgement may indicate possible error in recording landmarks. Do not proceed to navigation tasks until satisfied with the alignment data.

Note: Any stored pre-operative data will be deleted if any landmarks are changed after this point in the procedure.

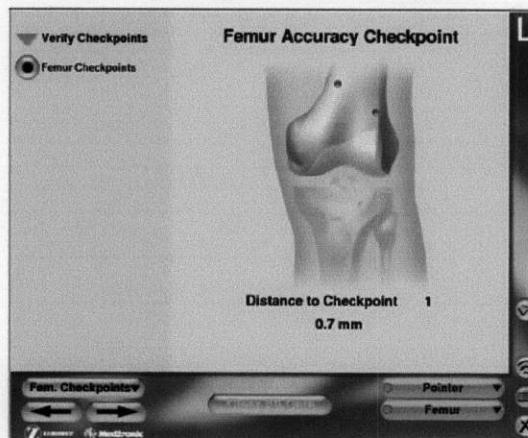


VERIFY FEMUR ACCURACY CHECKPOINT

Use the previously recorded accuracy checkpoints to determine whether the trackers have shifted with respect to the patient's anatomy.

1. Place the pointer on a saved Femur accuracy checkpoint.
2. Press and release the footswitch.
3. Observe the distance display and verify that the distance is less than 2mm.

After you successfully verify both femur checkpoints, the application software will automatically advance to the next task. If verification was not successful, you may re-record accuracy checkpoints and then re-digitize the hip center and re-record landmarks, or you may ignore the accuracy verification and continue with the current procedure, or you may abort use of the system.



73

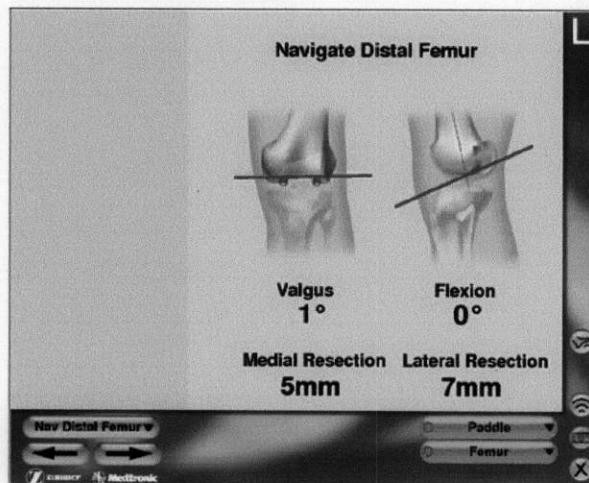
NAVIGATE DISTAL FEMUR CUT

74

The AxiEM™ Paddle's reference plane is displayed as a red line. Use on-screen information to navigate the cutting guides into place.

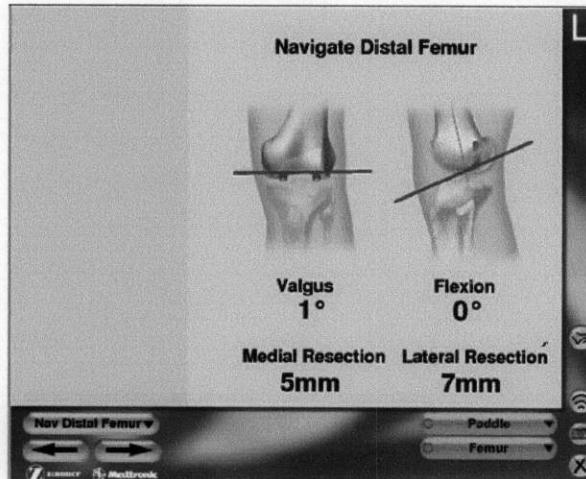
Visually inspect the AxiEM™ Paddle prior to use. Do not use the paddle if it appears bent or damaged. During navigation, check navigation values for consistency by placing the paddle against a flat surface and checking it again flipped upside down. If there is a visible difference in the flatness of the paddle, use another paddle.

Ensure that the femoral and tibial tracker status indicators are green during all navigation tasks. If the trackers are not being tracked, navigation will cease and real-time on-screen projections and measurements will disappear.



NAVIGATE DISTAL FEMUR CUT (CONT.)

1. Place the AxiEM™ Paddle into the cutting slot on the distal cutting guide.
2. Make final adjustments and affix the cutting guide firmly to the femur.
3. Remove the paddle from the cutting guide.
4. Use standard surgical technique to resect the distal femur.
5. Verify the distal cut by placing the AxiEM™ Paddle on the cut surface. Capture a screenshot for the patient file.
6. Remove the cutting guide.
7. Press and release the footswitch to advance to the next task.



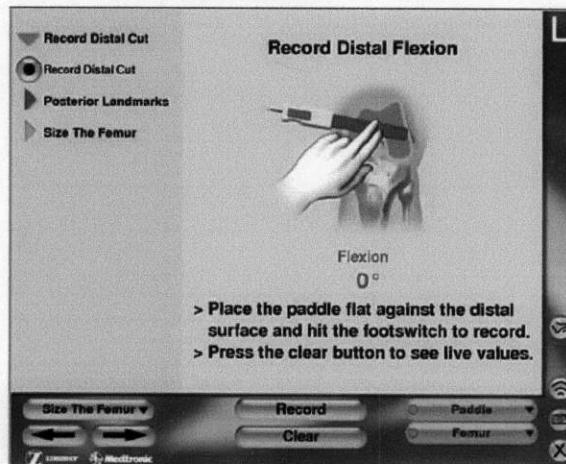
75

RECORD DISTAL CUT

76

1. Place the paddle flat against the distal surface of the femur.
The application software displays the current or live flexion value in black.
2. Press the footswitch or click [Record] to record the current flexion value.
After recording the distal flexion value, the application software will automatically advance to the next task.

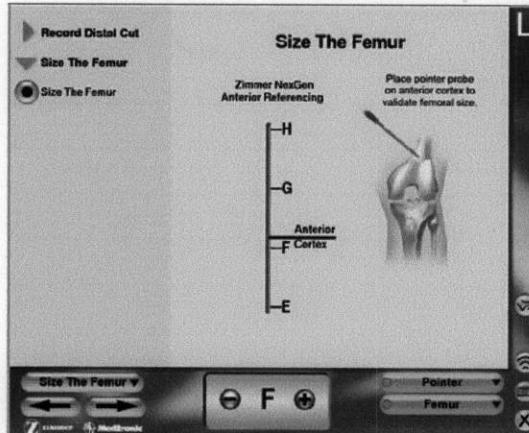
If you re-enter the Record Distal Flexion task to re-record the flexion value, the application software displays the previously recorded flexion value in gray. Click [Clear] to clear the recorded value and display a live flexion value. Press the footswitch or click [Record] to record the current live value.



SIZE THE FEMUR

The application software displays a Zimmer NexGen™ sizing scale to approximate the size of the patient's femur. The sizing scale uses anterior referencing as the default. Call Medtronic Navigation technical support for instructions to switch to posterior referencing.

1. Place the tip of the pointer on the anterior cortex of the patient's femur and slowly drag the pointer along the surface of the anterior cortex.
Note: When you drag the tip of the pointer along the surface of the anterior cortex, the software displays a real-time indicator on the sizing scale.
2. Observe the floating size indicator and note the appropriate femur size. Also note the pre-recorded anterior cortex point.
3. Press and release the footswitch to advance to the next task.



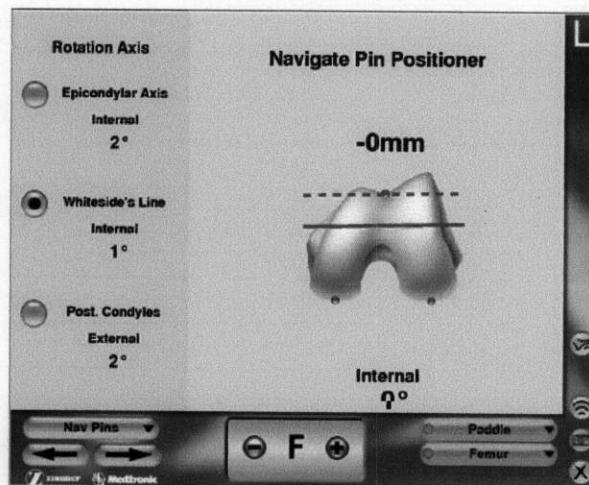
77

NAVIGATE PIN POSITIONER

78

1. Place the AxiEM™ Paddle into the slot on the Pin Positioner.
2. Use the on-screen depth and angle measurements to navigate the Pin Positioner into position. Note the on-screen measurements.
3. Note the final position of the Pin Positioner and the corresponding on-screen measurements.
4. Pin the Positioner to the femur using standard surgical technique.

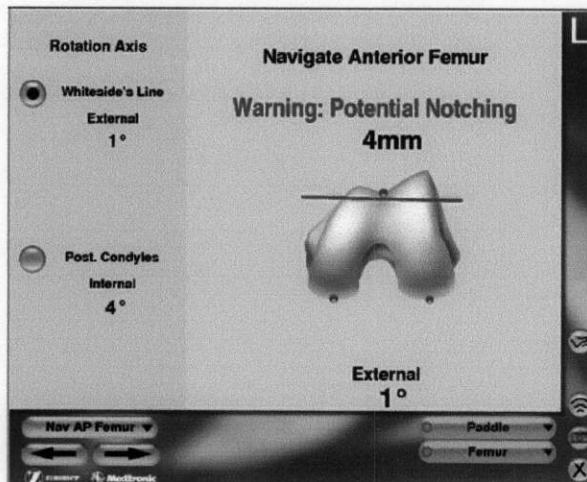
Note: The Pin Positioner instrument cannot be used on a size A femur.



NAVIGATE POSTERIOR AND ANTERIOR FEMUR CUTS

1. Place the AxiEM™ Paddle into the anterior cutting slot on the AP femur cutting guide.
2. Use the on-screen depth and angle measurements to navigate the cutting guide into position. Note the on-screen measurements.

The application software displays the internal/external rotation angle of the cutting guide and the distance (either above or below) the anterior cortex point. If the paddle is more posterior than (below) the anterior cortex point, the application software displays a message warning of potential posterior notching.



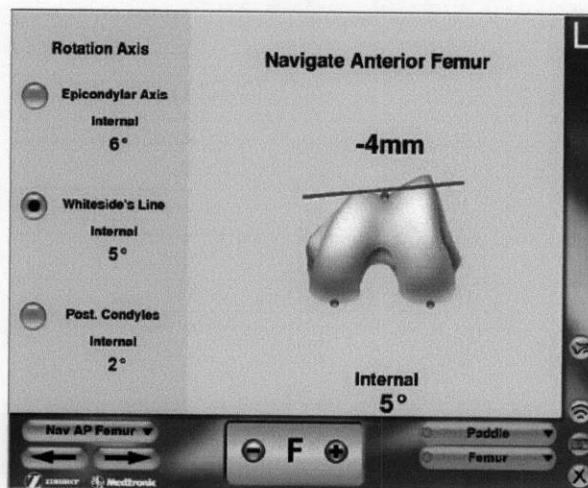
79

NAVIGATE POSTERIOR AND ANTERIOR

80

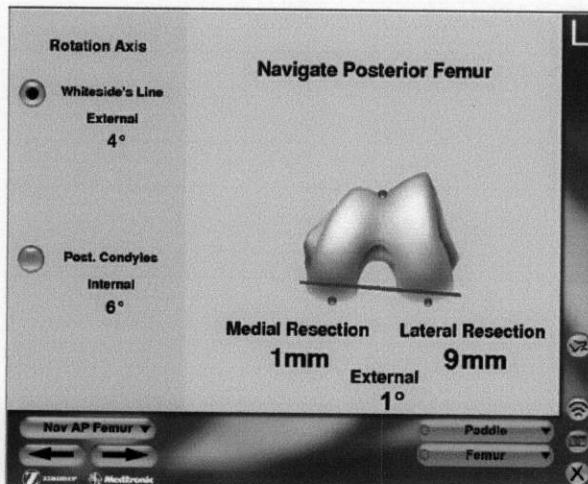
FEMUR CUTS (CONT.)

3. Note the final position of the guide and the corresponding on-screen measurements and remove the Paddle from the cutting guide.
4. Place the AxiEM™ Paddle into the posterior cutting slot on the AP femur cutting guide.
5. Use the on-screen depth and angle measurements to navigate the cutting guide into the same final position as in Step 3.
6. Note the position of the proposed posterior cut and if satisfactory, remove the paddle from the cutting guide, and attach the AP cutting guide using standard surgical technique.



**NAVIGATE POSTERIOR AND ANTERIOR
FEMUR CUTS (CONT.)**

7. Use standard surgical technique to resect the posterior femur.
8. Use standard surgical technique to resect the anterior femur.
9. Verify the cuts by placing the AxiEM™ Paddle on the cut surfaces. Capture a screenshot for the patient file.
10. Remove the cutting guide.



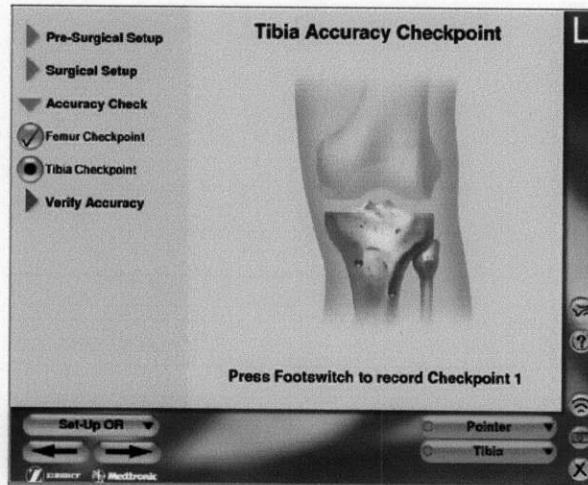
81

VERIFY TIBIA ACCURACY CHECKPOINTS 82

Use the previously recorded accuracy checkpoints to determine whether the trackers have shifted with respect to the patient's anatomy. This is especially important when the patient's bone is soft.

1. Place the pointer on a saved tibia accuracy checkpoint.
2. Press and release the footswitch.
3. Observe the distance display and verify that the distance is less than 2mm.

After you verify both tibia checkpoints, the application software will automatically advance to the next task.

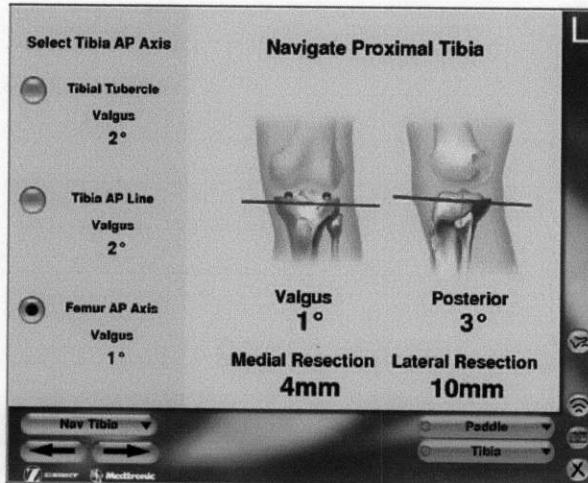


NAVIGATE PROXIMAL TIBIA CUT

Navigate the AxiEM™ Paddle in the proximal tibia cutting guide to determine an accurate location for the cutting guide.

The varus/valgus angle is displayed for each available axis. The selected axis is shown in the main image.

1. Place the AxiEM™ Paddle into the cutting slot on the proximal tibia cutting guide. The AxiEM™ Paddle's reference plane is displayed as a red line.
2. Use the on-screen depth and angles measurements to navigate the assembly into place.

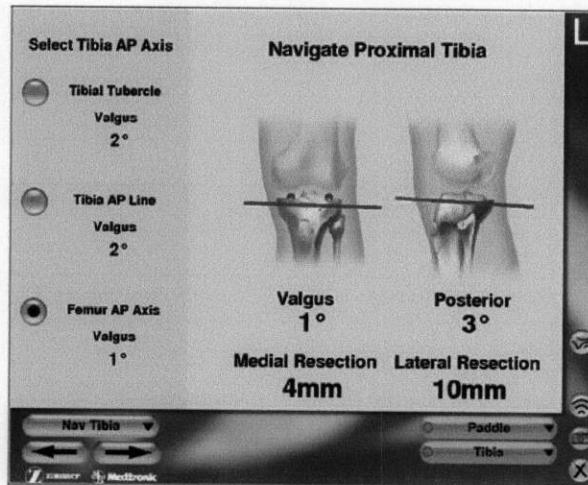


83

NAVIGATE PROXIMAL TIBIA CUT (CONT.)

84

3. Use standard surgical technique to attach the proximal cutting guide to the tibia.
4. Remove the paddle from the cutting guide.
5. Use standard surgical technique to resect the proximal tibia.
6. Verify the tibial cut by placing the AxiEM™ Paddle on the cut surface. Capture a screenshot for the patient file.
7. Remove the cutting guide.
8. Press and release the footswitch to advance to the next task.



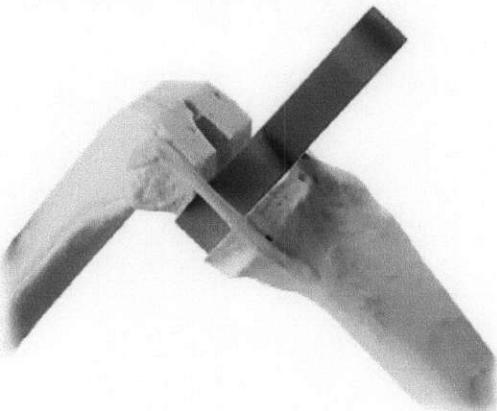
PERFORM STRESS TEST

Make certain that the femoral and tibial status indicators are green during stress testing. If the devices are not being tracked, data collection will cease, and all on-screen measurement graphics will not display.

Distraction values are only calculated and displayed when the flexion angle of the knee is at the required, predefined test angle. The table of stored values displays below the leg model.

When [Start] is pressed, the distraction values are set to zero (as a baseline) and any subsequent distraction is measured relative to that baseline.

1. Using standard surgical technique, place a spacer block in the knee gap or install the femoral and tibial trials.
2. Place the knee into the desired degree of flexion.

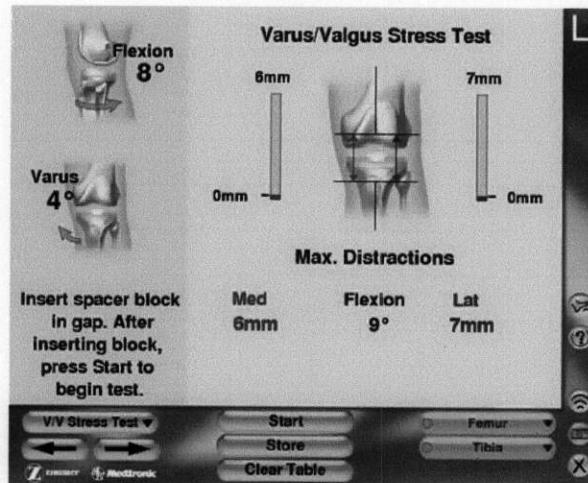


85

PERFORM STRESS TEST (CONT.)

86

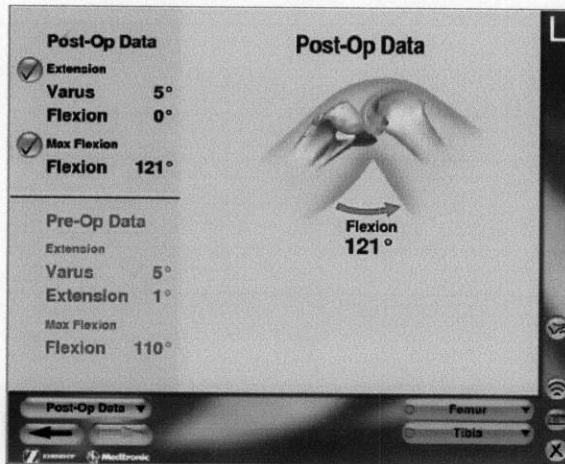
3. Click **[Start]** for the angle being sampled.
4. Apply varus/valgus loads to the knee.
The knee must be kept at the starting flexion angle $\pm 10^\circ$ (as established in Step 2) throughout the sampling process.
5. Click **[Stop]** to end sampling. Results will display on-screen.
6. Click **[Store]** to save the test results to the table.
7. Repeat Steps 2 - 6, placing the leg at various degrees of flexion.
8. Click **[Clear Table]** to erase all values stored in the table.



RECORD POST-OPERATIVE ALIGNMENT

After installing trials or implants, compile alignment information about the patient's affected leg. Use the data for comparison purposes against the pre-operative data.

1. With trials in place, maneuver the tibia and femur into a position of full extension. Make sure that both the femur and tibia tracker status indicators are green.
2. Press and release the footswitch to record the varus/valgus and full flexion/extension angle.
3. Maneuver the tibia and femur into a position of maximum flexion.
4. Press and release the footswitch to record the maximum flexion angle.



87

EXIT THE APPLICATION SOFTWARE

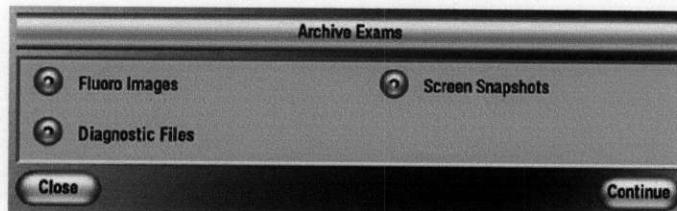
88

1. Click the **Exit** button in the main application window.
2. Click **[Yes]** to confirm that you want to exit.
The manage exams window displays.



ARCHIVE (OPTIONAL)

1. Click **[Archive]** in the manage exams window.
2. Select each patient exam you wish to archive.
3. Choose which type of data you would like to archive.
 - a. Select **[Screen Snapshots]** to save the images you captured by clicking the snapshot button.
 - b. Select **[Diagnostic Files]** to save the software log and other diagnostic files created during the exam.
4. Insert an exam archive disk in the CD drive.
Wait until the light on the drive stops blinking.
5. Click **[Continue]**.
Wait while the OS software archives the selected images to the CD.
6. Click the **[Close]** button to close the archive exam window or click the **[Back]** button to return to the manage exams window.



REMOVE EXAMS (OPTIONAL)

90

1. Click [Remove] in the manage exams window.
2. Highlight one or more exam directories. To deselect a patient exam, click it a second time.
3. Click [Remove] to permanently remove the selected exam(s) from the hard disk.



EXIT

1. Click [Exit] in the manage exams window and click [Yes] to confirm that you want to exit.
The log in screen displays.
2. From the log in screen, double-click the **Shutdown** icon. Wait until the system indicates it is okay to shut off the power.
3. Turn off the system power.



91

ATTACHMENT K

AXIEM™ IMAGELESS HIP MODULE FOR THE STEALTHSTATION® SYSTEM

CLINICAL LITERATURE

- **How does soft tissue distribution affect anteversion accuracy of the palpation procedure in image-free acetabular cup navigation. (Richolt, et al)**
This paper is referenced in the pocket guide to support the statements about accuracy/variation in imageless landmarking.
- **Pelvic tilt makes acetabular cup navigation inaccurate (Lembeck, et al)**
This paper explains the concept of pelvic tilt and how to adjust the target angles to compensation for it as we do in our software.
- **The Definition and Measurement of Acetabular Orientation (Murray)**
This paper defines the anterior pelvic plane and the three associated acetabular angle definitions. We use the radiographic definitions in the software.

1285

How does soft tissue distribution affect anteversion accuracy of the palpation procedure in image-free acetabular cup navigation? An ultrasonographic assessment

JENS A. RICHLIT, HARALD EFFENBERGER, & MARKUS E. RITTMEISTER

Orthopaedic University Clinic, Friedrichsheim Foundation, Marienburgstrasse 2, D-60528 Frankfurt am Main, Germany

(Received 3 June 2003; accepted 12 December 2004)

Abstract

Navigation of the acetabular cup in total hip replacement (THR) is used to improve the reproducibility of acetabular component positioning. When the palpation of anatomic landmarks, which is necessary to determine the pelvic coordinate system, is performed epicutaneously, the question as to how uneven soft tissue distribution can influence navigation accuracy arises.

To obtain data, the questionable soft tissue thickness was measured in 72 patients scheduled for THR. In addition, distances between the landmarks were recorded. On the basis of this information, we were able to calculate the expected misinterpretation of the anteversion given by a navigation system for each patient.

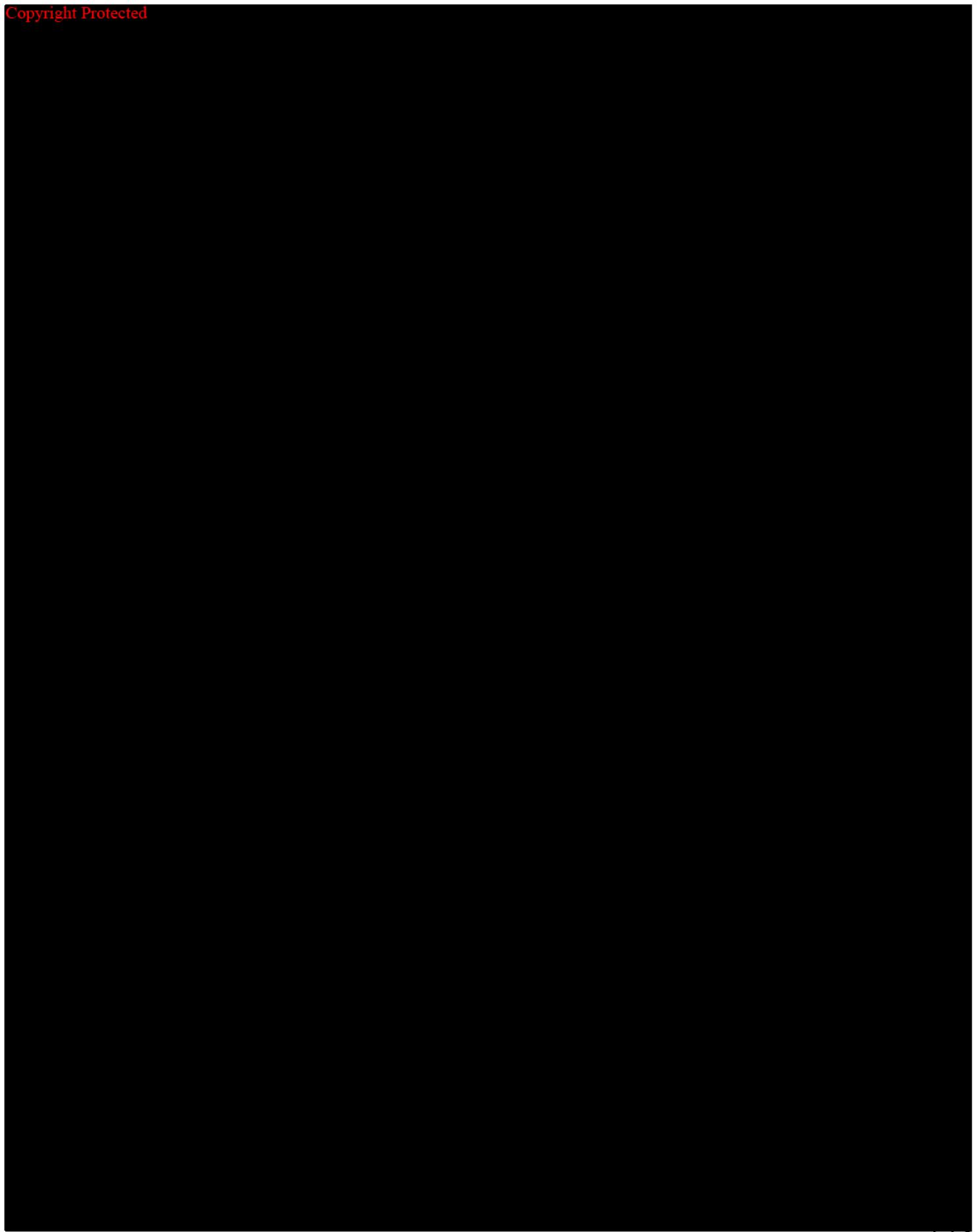
The calculations suggest that a navigation system would have underestimated the anteversion on average by $2.8^\circ \pm 1.8^\circ$. The median of anteversion misinterpretation was 2.4° and its 95% confidence interval was calculated to be 2.2° – 3.0° . No correlation with substantial significance between anteversion misinterpretation and the patients' biometrical data could be found. According to the current knowledge, acetabular cups in THR should be positioned within a range of 30° – 50° of inclination and 10° – 30° of anteversion. In comparison with these permitted $\pm 10^\circ$ windows, the amount of misinterpretation that was found due to uneven soft tissue distribution seems to be acceptable.

Keywords: Total hip replacement, computer-aided surgery, subcutaneous tissue

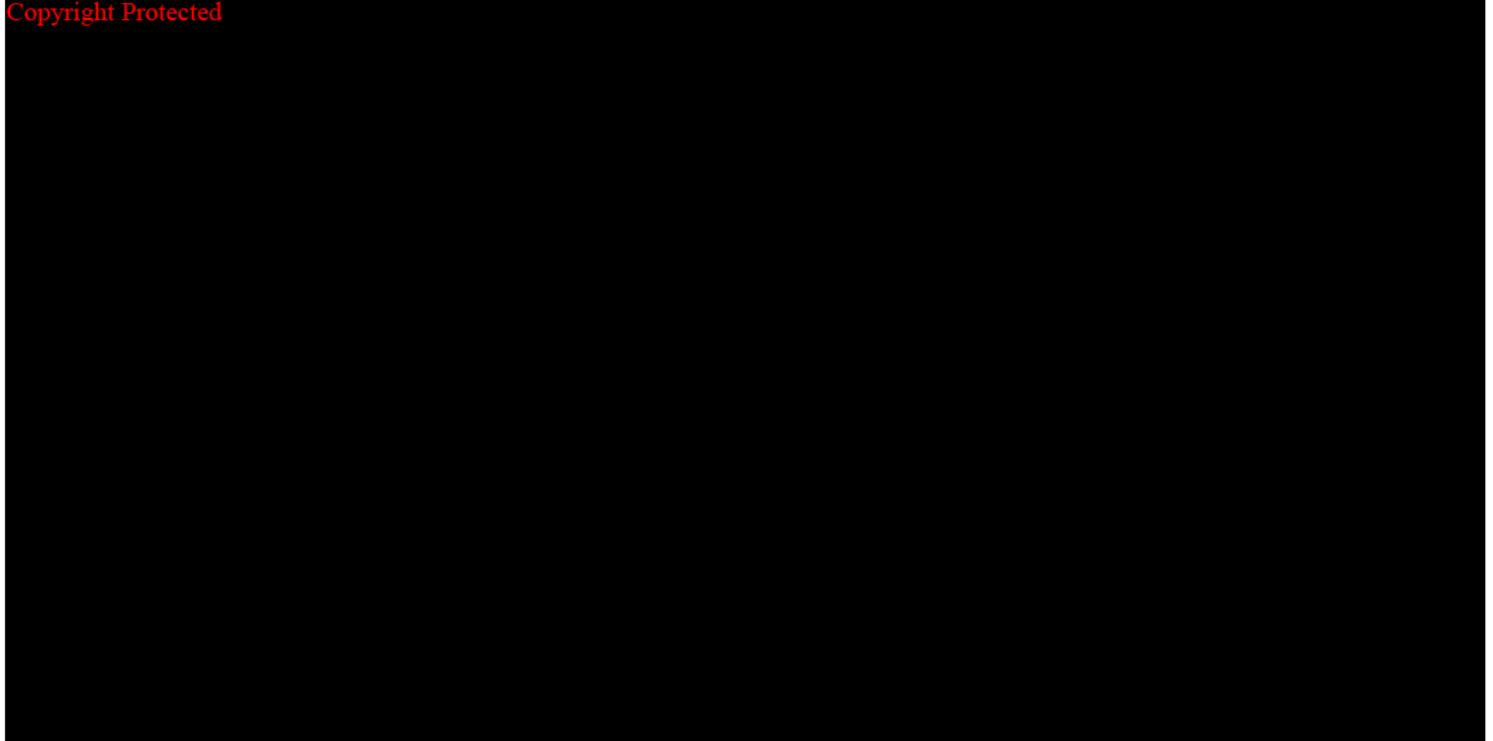
Copyright Protected

88 *J. A. Richolt et al.*

Copyright Protected



Copyright Protected



Pelvic tilt makes acetabular cup navigation inaccurate

Burkhard Lembeck, Otto Mueller, Patrik Reize and Nikolaus Wuelker

Department of Orthopaedic Surgery, University of Tuebingen, DE-72076 Tuebingen, Germany
Correspondence to: burkhard.lembeck@med.uni-tuebingen.de
Submitted 04-03-11. Accepted 04-10-05

Copyright Protected

Copyright Protected

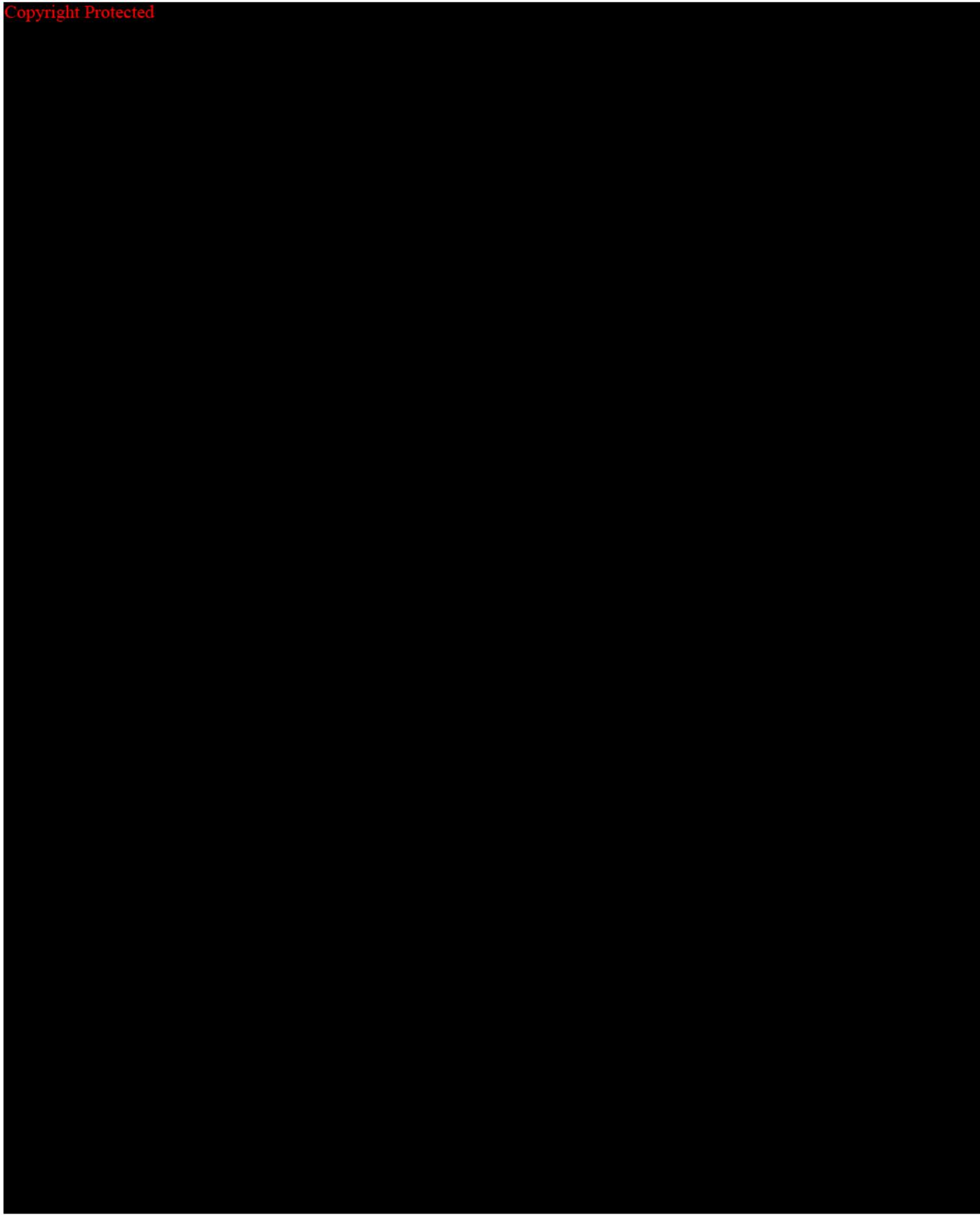
Copyright Protected

Medtronic Navigation, Inc.

CONFIDENTIAL

Page 868 of 877 1294

Copyright Protected



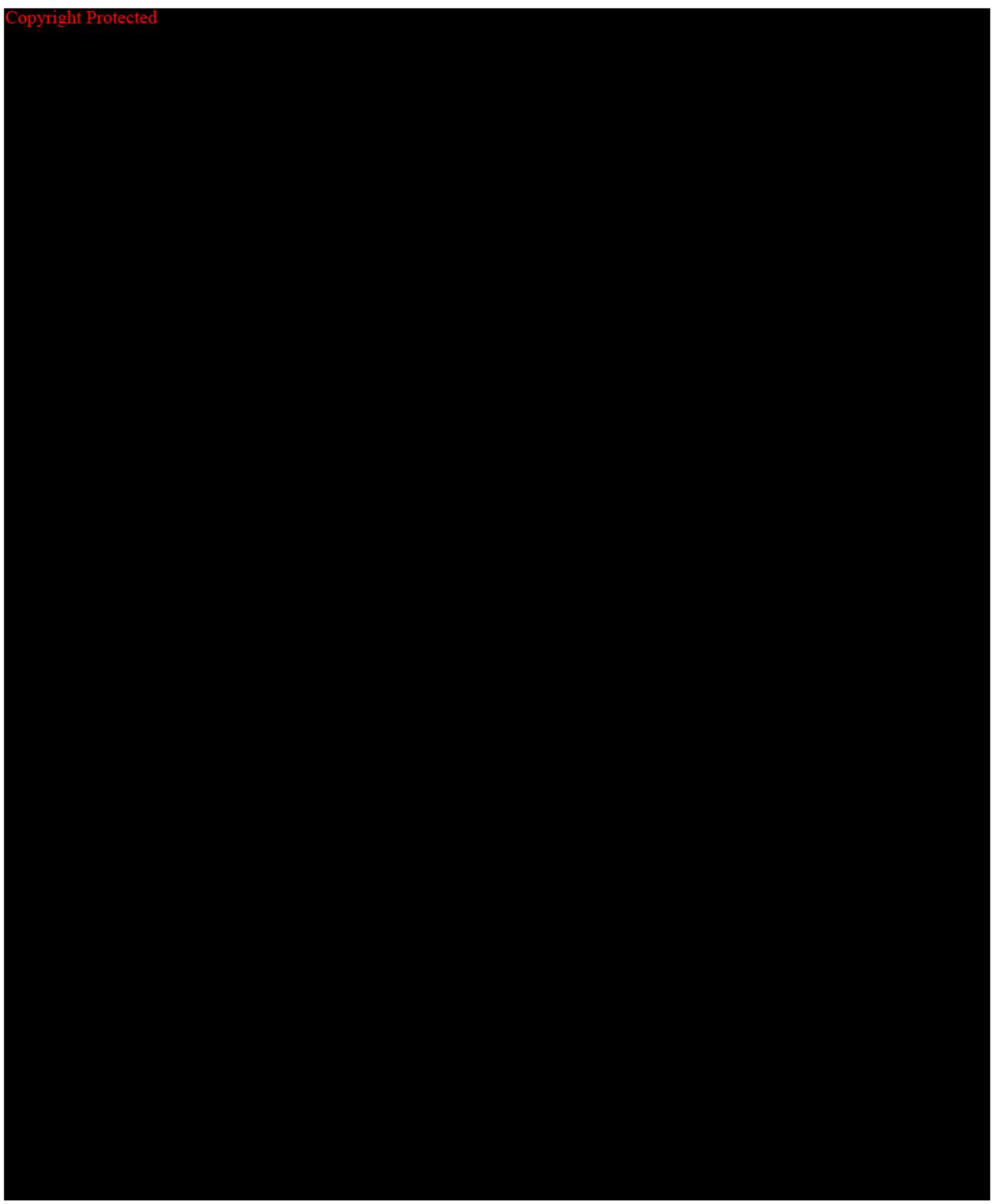
Medtronic Navigation, Inc.

CONFIDENTIAL

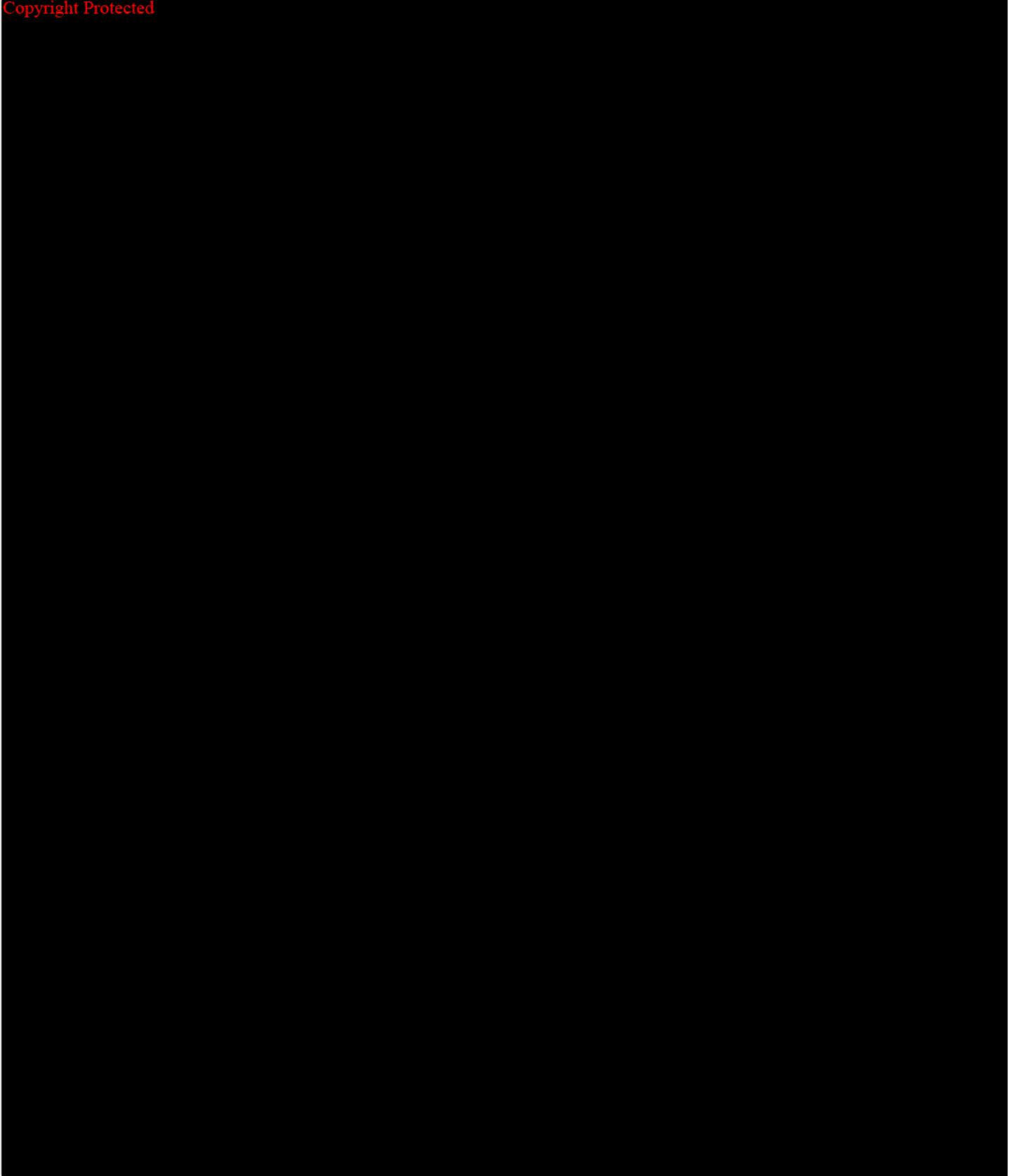
Page 869 of 877

1295

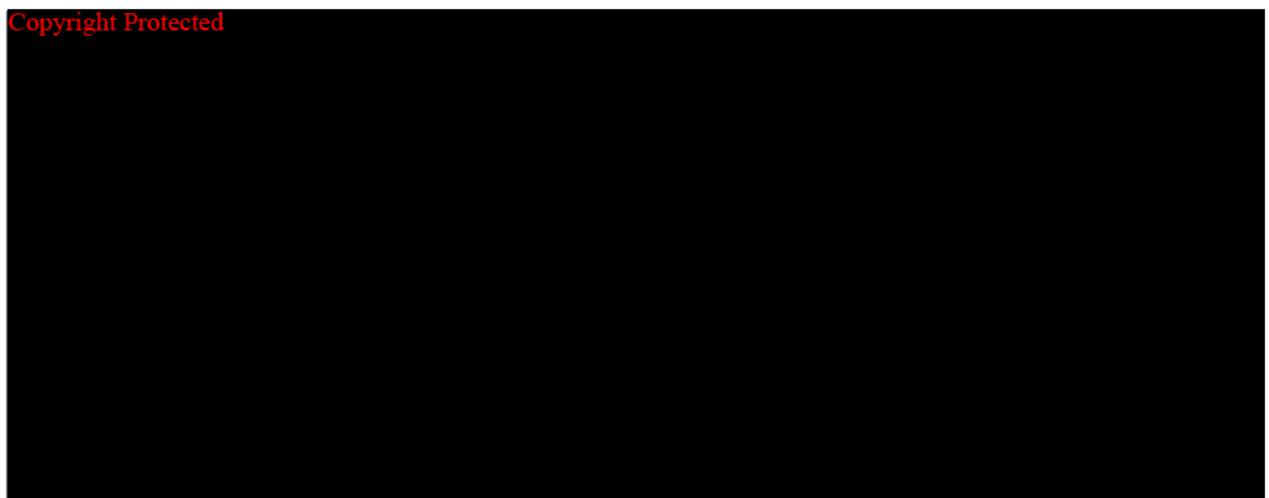
Copyright Protected



Copyright Protected



Copyright Protected





THE DEFINITION AND MEASUREMENT OF ACETABULAR ORIENTATION

D. W. Murray

From the Nuffield Orthopaedic Centre, Oxford, England

The orientation of an acetabulum or an acetabular prosthesis may be described by its inclination and anteversion. Orientation can be assessed anatomically, radiographically, and by direct observation at operation. The angles of inclination and anteversion determined by these three methods differ because they have different spatial arrangements. There are therefore three distinct definitions of inclination and anteversion. This paper analyses the differences between the definitions and provides nomograms to convert from one to another. It is recommended that the operative definitions be used to describe the orientation of prostheses and that the anatomical definitions be used for dysplastic acetabula.

*J Bone Joint Surg [Br] 1993; 75-B:228-32.
Received 29 May 1992; Accepted 29 July 1992*

Numerous terms are used to describe acetabular orientation. These include inclination, anteversion, cover, abduction, tilt, opening and flexion (Ackland, Bourne and Uthoff 1986; Herrlin, Pettersson and Selvik 1988). Inclination and anteversion are the most commonly used terms but they have several different and imprecise definitions (Herrlin, Selvik and Pettersson 1986; Calandruccio 1987). Different definitions are used in operative, radiographic and anatomical assessments of orientation and have been named accordingly. The aim of this investigation is to offer precise definitions and to develop a simple method for converting the results from one method of assessment to another. The definitions describe the orientation of the acetabular axis which passes through the centre of the socket and is perpendicular to the plane of the socket face (Calandruccio 1987).

Copyright Protected

Copyright Protected

230

D. W. MURRAY

Copyright Protected

Copyright Protected

232

D. W. MURRAY

Copyright Protected

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s)

Michel Janda

Subject: 510(k) Number

K061248/SI

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.).

Is this device subject to Section 522 Postmarket Surveillance?

 YES NO

Is this device subject to the Tracking Regulation?

 YES NO

Was clinical data necessary to support the review of this 510(k)?

 YES NO

Is this a prescription device?

 YES NO

Was this 510(k) reviewed by a Third Party?

 YES NO

Special 510(k)?

 YES NO

Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers

 YES NOTruthful and Accurate Statement Requested Enclosed A 510(k) summary OR A 510(k) statement The required certification and summary for class III devices *NA* The indication for use formCombination Product Category (Please see algorithm on H drive 510k/Boilers) *NA*Animal Tissue Source YES NO Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

 No Confidentiality Confidentiality for 90 days Continued Confidentiality exceeding 90 day

Predicate Product Code with class:

Additional Product Code(s) with panel (optional):

*HAW Class II*Review: *Neil R. Johnson*
(Branch Chief)(Branch Code) *GSPB*(Date) *8/30/06*Final Review: *RJ*
(Division Director)(Date) *1/30/16*

4

**THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K)
BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH
EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).**

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K061248

Reviewer: Michel Janda

Division/Branch: DGRND/GSDB

Device Name: AxiEMT™ Imageless Hip Module for the StealthStation® System

Product to Which Compared (510(K) Number If Known): K043088, K052623

	YES	NO	
1. Is Product A Device	Y		If NO = Stop
2. Is Device Subject To 510(k)?	Y		If NO = Stop
3. Same Indication Statement?		N	If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		N	If YES = Stop NE
5. Same Technological Characteristics?		N	If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?	Y		If YES = Go To 8
7. Descriptive Characteristics Precise Enough?			If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?		N	If YES = Stop NE
9. Accepted Scientific Methods Exist?	Y		If NO = Stop NE
10. Performance Data Available?	Y		If NO = Request Data
11. Data Demonstrate Equivalence?	Y		Final Decision: SE

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Intended Use:

The StealthStation® System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The StealthStation® System is indicated for any medical condition, in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

The AxiEM™ Imageless Hip Module for the StealthStation® is intended to precisely position instruments and implants in example procedures such as but not limited to:

Orthopedic Procedure:

Minimally Invasive Orthopedic Procedures
Total Hip Replacement (Primary and Revision)

2. Device Description:

The AxiEM™ Imageless Hip Module is a stereotactic system that uses electromagnetic tracking technology (EM) to facilitate the accurate placement and tracking of commercially available surgical instruments in hip procedures using digitized landmarks of the patient's anatomy. The device is a combination of specialized surgical hardware and EM-guidance software that allows a surgeon to visualize alignment of acetabular reaming (acetabular reamer navigation of inclination/aneteversion), cup navigation/placement, verification of final cup orientation (acquisition of three cup points), and pre/post-operative leg length and offset, to aid in Traditional Total Hip Arthroplasty (THA), MIS Anterolateral Mini THA, MIS Posterolateral Mini THA, and MIS Anterolateral THA. The user defined final acetabular reaming orientation is used for planning.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

The indications for use statement is slightly modified such that Minimally Invasive Orthopedic Procedures and Total Hip Replacement (Primary and Revision) are the only example surgical procedures.

4. Explain why there is or is not a new effect or safety or effectiveness issue:

- These procedures and the general indications for use are consistent with the cited predicate devices. The intended use is SE to the predicate devices.

5. Describe the new technological characteristics:

The primary difference between the subject device and the Imageless Hip Module for the StealthStation System (K052623) is that the subject device uses electromagnetic tracking technology rather than optical IR based tracking technology. The primary difference between the subject device and the AxiEM™ Imageless Knee Module (K043088) is the clinical application site.

6. Explain how new characteristics could or could not affect safety or effectiveness:

The submission describes the integration of an existing tracking technology with an existing surgical procedure. However, the integration of these two technical characteristics could impact safety and effectiveness and therefore appropriate validation is needed.

7. Explain how descriptive characteristics are not precise enough:

8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

The integration of these technical characteristics does not raise new types of safety and effectiveness questions. The same types of verification and validation activities are applicable to the subject device as compared to the predicate devices (accuracy, surgical procedure, etc.).

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:
The successfully completed verification and validation activities are summarized as follows:

Verification / Validation Activity Summary	Description
Functional Test	Confirms fulfillment of product requirements.
Labeling / User Manual Review	Confirms accuracy and appropriateness of labeling.
Freeform Validation Test	Robustness test – Random scenarios are simulated within changed software or software deemed sensitive.
Simulated Use Test	Confirms the performance and intended use in a simulated environment.
Accuracy Test	Confirms system accuracy.

ATTACH ADDITIONAL SUPPORTING INFORMATION

MEMO TO THE RECORD
510(k) REVIEW
K061248

DATE: August 28, 2006
FROM: Biomedical Engineer, (HFZ-410).
DIVISION: DGRND/GSDB

DEVICE NAME: **AxiEM™ Imageless Hip Module for the StealthStation® System**

COMPANY NAME: Medtronic Navigation
826 Coal Creek Circle
Louisville, CO 80027

CONTACT: Tina Dreiling
Associate Regulatory Affairs Specialist
Ph#: (720) 890-3217
tina.dreiling@medtronic.com

SUBJECT: The sponsor has submitted K061248 to notify the FDA of their intent to introduce the AxiEM™ Imageless Hip Module for the StealthStation® System into interstate commerce.

Background: The subject device is a stereotactic system which utilizes electromagnetic navigation technology to aid in the tracking of surgical tools and/or hip implants relative to imageless stereotactic coordinates. The system does not require pre-operative or intra-operative patient imagery. The final device will be marketed under the title of the **AxiEM™ Imageless Hip Module for the StealthStation® System**. The primary difference between the subject device and the Imageless Hip Module for the StealthStation System (K052623) is that the subject device uses electromagnetic tracking technology rather than optical IR based tracking technology. The primary difference between the subject device and the AxiEM™ Imageless Knee Module (K043088) is the clinical application site.

Device Description: The AxiEM™ Imageless Hip Module is a stereotactic system that uses electromagnetic tracking technology (EM) to facilitate the accurate placement and tracking of commercially available surgical instruments in hip procedures using digitized landmarks of the patient's anatomy. The device is a combination of specialized surgical hardware and EM-guidance software that allows a surgeon to visualize alignment of acetabular reaming (acetabular reamer navigation of inclination/aneteversion), cup navigation/placement, verification of final cup orientation (acquisition of three cup points), and pre/post-operative leg length and offset, to aid in Traditional Total Hip Arthroplasty (THA), MIS Anterolateral Mini THA, MIS Posterolateral Mini THA, and MIS Anterolateral THA. The user defined final acetabular reaming orientation is used for planning.

The subject device is composed of the following components:

1. AxiEM Pelvis Tracker – This surgical instrument functions to track the position of the patient's pelvis during the surgical procedure. The instrument is rigidly attached to the iliac crest via the bone screw end.
2. AxiEM Instrument Tracker – This instrument is intended to interface with various surgical instruments. Once securely attached and registered, it enables navigation of standard manual surgical instruments.
3. Navigation Probe Interface (NPI) – The surgical instruments are plugged in to the NPI system. The NPI functions to control data acquisition as well as pre-processing of probe data. The subject NPI is identical to the NPI component used in the GoldenEye System, K001284.
4. AxiEM Pointer – The pointer is used to digitize accuracy checkpoints and anatomical landmarks.
5. Click and Point Handle – The handle is designed to interface with the pointer.
6. Shell Inserter Calibration Tip – The calibration cone on the shell inserter is used to calibrate the instrument tip relative to a tracker. Instrument registration/calibration is required for accurate instrument navigation.
7. AxiEM Mobile Emitter (also known as the Transmitter Coil Array (TCA)) – This component functions to emit the EM field. The component emits low energy, low frequency AC signals into the receiving area directly above a set of receiving coils. These signals have precise field strengths and are varied throughout the Field of View (FOV) of the system. The receiving coils subsequently detect these signals and measure their strength. The TCA share identical technology with the GoldenEye System, K001284, but differs in dimensions and in the ability to be repositioned throughout the procedure. The TCA produces a navigation volume of approximately 600mm x 600mm x 400 mm directly centered over the TCA (50mm offset from its face).
8. AxiEM Ortho Screwdriver – The screwdriver is used to rigidly affix trackers to patient's bone.
9. Ratcheting T-Handle – The handle is used to hand tighten bone screws.
10. Navigation Probe Interface – The NPI is a junction box used to connect the wired instruments to the navigation system.
11. AxiEM Portable System – Similar to the NPI, this junction box serves to connect the wired instrument to the portable iNav™ systems.
12. System Footswitch – User interface to control system functions.

The Transmitter Coil Array is positioned near the operative hip and encompasses the hip with a low-energy, magnetic field (navigation field). Because every point in the navigation field has an unique field strength, the system can determine the spatial relationship of a receiving coil by measuring the field strength at that location. Localization of tracked devices may be adversely affected by excess metal in the navigation area, instrument placement too close to the edge of the navigation field, damaged instrument, and excess motion of the tracked instrument. The system tracks these "geometric errors" and will disable navigation when a threshold error level is reached. System accuracy may be confirmed throughout the navigation process by confirming the location of user defined reference points.

The registration method (three point palpation - Affected ASIS, Non-Affected ASIS, and Pubic Tubercl) is similar to that used in imageless Hip K052623. The user is prompted to acquire “pelvic tilt” by digitizing three points on the table surface to resemble a triangle. This plane is compared to the patient’s anterior pelvic plane to determine the patient’s natural pelvic tilt (flexion/extension). During navigation acetabular angles are adjusted for A/P pelvic tilt. The unadjusted standard radiographic angles are also presented. In addition, the user is prompted to acquire pre-operative leg length and offset measurements (greater trochanter digitization). The digitization of this point is compared to post-operative position and the difference is displayed as a change in leg length/offset.

Labeling: The sponsor has elected to include a contraindication for patients with abnormal anatomy and the following discussion regarding manual registration: (Software screenshots are provided in Attachment D.)

“Nominal accuracy of angle measurements displayed by the software is obtained if the anterior pelvic plane landmarks are recorded without soft tissue between the probe tip and the bone or with equal amounts of soft tissue covering each landmark. The accuracy of angle measurements will be affected by how accurately the landmarks are recorded. If the landmarks cannot be closely palpated on soft tissue and accurately recorded, percutaneous landmarking may be performed through a puncture or small incision. Proper sterile preparation of the landmark sites should be considered based on the landmarking method chosen. Published data has indicated that landmarking on the skin could cause misinterpretation of measured angles by up to about 3° under normal conditions as compared to percutaneous landmarking. While the angle calculations in the software are less sensitive to variation in the location of the ASIS landmarks than to differences in the soft tissue depth over landmarks, care should be taken to record the ASIS points symmetrically on the patient.”

Predicate Device(s): StealthStation® AxiEM Imageless Knee Module, **K043088**; Imageless Hip Module for the StealthStation® System, **K052623**.

Intended Use/Indications for Use: The StealthStation® System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The StealthStation® System is indicated for any medical condition, in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

The AxiEM™ Imageless Hip Module for the StealthStation® is intended to precisely position instruments and implants in example procedures such as but not limited to:

Orthopedic Procedure:

- Minimally Invasive Orthopedic Procedures
- Total Hip Replacement (Primary and Revision)

Contraindications: The Stealth Station System is contraindicated for any medical condition for which surgery itself is contraindicated. Not for use during the programming or interrogation of any implantable device.

Predicate Device Indications for Use:

Imageless Hip Module for the StealthStation® System (K052623) - The StealthStation® System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The StealthStation® System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy. The Imageless Hip Module for the StealthStation® is intended to precisely position instruments and implants and implants such as but not limited to:

Orthopedic Procedures: Minimally Invasive Orthopedic Procedures, Total Hip Replacement (Primary and Revision), Tumor Resection and Bone/Joint Reconstruction, Placement of Iliosacral Screws, Femoral Revision, Stabilization and Repair of Pelvic Fractures (Including But Not Limited To Acetabular Fractures)

StealthStation® AxiEM™ Imageless Knee Module (K043088) - The StealthStation® System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The StealthStation® System is indicated for any medical condition, in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

Example procedures include, but are not limited to:

Cranial Procedures:

Cranial Biopsies
Tumor Resections
Craniotomies/ Craniectomies
Skull Base procedures
Thalamotomies/Pallidotomies
Pituitary Tumor Removal
CSF Leak Repair
Pediatric Catheter Shunt Placement
General Catheter Shunt Placement

ENT Procedures:

Transphenoidal Procedures
Intranasal Procedures
Orbital Nerve Decompression Procedures
Optic Nerve Decompression Procedures
Polypsis Procedures
Endoscopic Dacryocystorhinostomy
Encephalocele Procedures
Sinus procedures, such as Maxillary Antrostomies, Ethmoidectomies, Sphenoidotomies / Sphenoid Explorations, Turbinate Resections, and Frontal Sinusotomies

Spinal Procedures:

Spinal Implant Procedures, such as Pedicle Screw Placement

Orthopedic Procedures:

Total Knee Arthroplasty (Primary and Revision)
Unicompartmental Knee Arthroplasty
Minimally Invasive Orthopedic Procedures

The indications for use statement is slightly modified such that Minimally Invasive Orthopedic Procedures and Total Hip Replacement (Primary and Revision) are the only example surgical procedures. These procedures and the general indications for use are consistent with the cited predicate devices. The intended use is SE to the predicate devices. (**Chart 3 & 4**)

Technical and Performance: The primary difference between the subject device and the Imageless Hip Module for the StealthStation System (K052623) is that the subject device uses electromagnetic tracking technology rather than optical IR based tracking technology. The primary difference between the subject device and the AxiEM™ Imageless Knee Module (K043088) is the clinical application site. **(Chart 5)** The submission describes the integration of an existing tracking technology with an existing surgical procedure. However, the integration of these two technical characteristics could impact safety and effectiveness and therefore appropriate validation is needed. **(Chart 6)** The integration of these technical characteristics does not raise new types of safety and effectiveness questions. The same types of verification and validation activities are applicable to the subject device as compared to the predicate devices (accuracy, surgical procedure, etc.). **(Chart 8)** The sponsor has provided documentation outlining performance testing (summarized as follows) and engineering drawings with physical and general specifications. **(Chart 9)** In addition, the sponsor has provided a substantial equivalence comparison report with a side by side comparison describing the device's physical and performance characteristics (pg 17-18). The successfully completed verification and validation activities are summarized as follows **(Chart 10 & 11):**

Verification / Validation Activity Summary	Description
Functional Test	Confirms fulfillment of product requirements.
Labeling / User Manual Review	Confirms accuracy and appropriateness of labeling.
Freeform Validation Test	Robustness test – Random scenarios are simulated within changed software or software deemed sensitive.
Simulated Use Test	Confirms the performance and intended use in a simulated environment.
Accuracy Test	Confirms system accuracy.

Accuracy Test Protocol and Report (VV1102) –

- Acceptance Criteria:
 - o Reamer/Shell Orientation (b)(4) [REDACTED] (95% confidence interval)
 - o (b)(4)
 - o [REDACTED]
 - o [REDACTED]
 - o [REDACTED]
- Performance Testing: The accuracy testing is conducted on a predefined accuracy jig. The test jig has been designed to resemble the clinical situation and applicable metal tools have been included (posterior retractors) to simulate worst case conditions.
 - o Registration is accomplished using predefined landmark “divots” that are arranged in an idealized pattern.
 - o Pelvic tilt was tested by simulating a 5 degree posterior, anterior, left and right lateral slope. The process was repeated after rotating the portable emitter approximately 45 degrees from the initial starting point.
 - o Leg length and offset testing was conducted by defining a “pre-operative”

condition (divot) and applying a linear movement in the x or y direction (as defined by a metric ruler). The process was repeated after rotating the portable emitter approximately 45 degrees from the initial starting point.

- Shell orientation testing was conducted by rigidly fixating the shell inserter to the cup shell and then orienting the assembly at a 12 o'clock position relative to the emitter. The assembly is then fixated in this orientation using a plastic spanner nut and the cup position (angular alignment) was recorded. The process was repeated after rotating the portable emitter approximately 45 degrees from the initial starting point. The process was further repeated of realigning the assembly in 3, 6, and 9 o'clock orientations.
- Shell verification orientation testing was conducted using the same procedure as in shell orientation testing except that cup orientation was acquired by digitizing three points on the cup rim. The process was repeated after rotating the portable emitter approximately 45 degrees from the initial starting point. The process was further repeated of realigning the assembly in 3, 6, and 9 o'clock orientations.
- Reamer orientation was tested by attaching the reamer shell to the reamer handle and then orienting the assembly at a 12 o'clock position relative to the emitter. The assembly is then fixated in this orientation using a plastic spanner nut and the cup position (angular alignment) was recorded. The process was repeated after rotating the portable emitter approximately 45 degrees from the initial starting point. The process was further repeated of realigning the assembly in 3, 6, and 9 o'clock orientations.

- **Results:** $(\text{Accuracy})_{\text{mean}} + \text{(b)(4)} [\text{Accuracy})_{\text{StDev}}]$ (b)(4)

- (b)(4)

(b)(4): Adjusted angles for both version and inclination matched those calculated manually.

- Conclusion: All predetermined criteria were met. This test establishes the system's navigational accuracy in a controlled bench-top setting. It is inappropriate to extrapolate these results directly to the clinical environment. Additional error is introduced under clinical conditions due to the variation in acquiring patient landmarks during the registration process.

Functional Test Protocol and Report (VV1103) –

- Purpose: Verification that all device software inputs have been appropriately implemented.
- Performance Testing: The software design requirements are tested on a Treon+/iNav hardware setup with a sawbone model. Predetermined success criteria for "Pass" and "Fail" conditions have been established for each individual test.
- Results: All functional testing passed with concessions. Numerous anomalies were

discovered during testing and were analyzed for their affect on patient safety and probable prevalence. Most were related to cosmetic appearance of the user interface and did not represent design flaws. All anomalies were judged to be either negligible or slight risk to patient safety. These anomalies are listed within VV1103. It was noted that a significant portion of the tests were either "NA" or found "Fail." Further clarification regarding these results was provided in Supplement 1.

Simulated Use Test Protocol and Report (VV1105)

- Purpose: Verification that user need and intended use has been adequately fulfilled.
- Performance Testing: Simulated use testing involves using the subject device in an environment that simulates the real end-user environment (saw bones). The software application was tested on a Treon+/iNav hardware setup. Predetermined success criteria for "Pass" and "Fail" conditions have been established for each individual test.
- Results: The simulated testing passed with concessions. Numerous anomalies were discovered during testing and were analyzed for their affect on patient safety and probable prevalence. Most were noted to be redundant from the previous functional testing. All anomalies were judged to be either negligible or slight risk to patient safety. These anomalies are listed within VV1105.

Freeform Validation Protocol and Report (VV1016)

- Purpose: Robustness testing. Random scenarios, as created by the user, are simulated within changed software or software deemed sensitive.
- Performance Testing: The protocol calls for the tester to creatively test new or highly modified functions of the software for a predetermined period of time. There is no set protocol for testing. Success is determined if all functions perform as designed. Failure is noted if justification for the observed performance is not available.
- Results: The freeform validation tests passed with concessions. One moderate anomaly was fixed and confirmed in RC5. Additional slight anomalies remain.

Hazards Verification Protocol and Report

- Purpose: To verify the implementation of labeling mitigation and instructions for use.
- Performance Testing: Label and Instruction for use review.
- Results: All mitigation and instructions for use requirements were fulfilled.

Literature: (Attachment K and S001)

1. Richolt, J.A., et al. "How does soft tissue distribution affect anteversion accuracy of the palpation procedure in image-free acetabular cup navigation? An ultrasonographic assessment." Computer Aided Surgery, March 2005; 10(2):87-92.
2. Lembeck, B., et al. "Pelvic tilt makes acetabular cup navigation inaccurate." Acta Orthop 2005 Aug;76 (4):517-23.
3. Murray, D.W. "The Definition and Measurement of Acetabular Orientation." J Bone Joint Surg [Br] 1993' 75-B:228-32.
4. Hassan, Douglas M., et al. "Accuracy of Intraoperative Assessment of Acetabular Prosthesis Placement." Journal of Arthroplasty. Vol 13, No 1 1998.

5. Kennedy, J.G., et al. "Effect of Acetabular Component Orientation on Recurrent Dislocation, Pelvic Osteolysis, Polyethylene Wear, and Component Migration." *Journal of Arthroplasty* Vol 13, No 5 1998.
6. McCollum, D. E., et al. "Dislocation after Total Hip Arthroplasty." *Clinical Orthopedics and Related Research*, Number 261 December 1990.

Sterility, Packaging, and Labeling: The subject device includes the following non-sterile components which are not indicated for use within the sterile field: Transmitter Coil Array, Navigation Probe Interface, and the Coil Array Computer.

The following are single-use components which are provided sterile: Reference frames, Reference frame bone screws, Instrument tracker, and Pointer. The following components are intended for sterile reprocessing: Calibration tip, Click and point (Pointer holder), and Screwdrivers. These instruments are similar to previously validated sterile instruments. EtO validation has been conducted according to ISO guidance ISO-11135, *Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization*. Sterility Assurance Level (SAL) of 10^{-6} . The Calibration Tip, Click-and-Point Handle, and DRF Screwdriver are delivered non-sterile and are intended for sterile reprocessing. The provided sterilization parameters are summarized as follows:

- EtO Gas Sterilization
 - Temperature: 130°F
 - Relative Humidity: 70±5%
 - Concentration: 725±25 mg/L
 - Exposure Time: 4 hrs
 - Aeration Time: 11-12 hrs
- Steam Sterilization
 - Pre-vacuum
 - Five (5) minutes at 270°F
 - Gravity (US)
 - Fifteen (15) minutes at 270°F

The sponsor has provided draft labeling and instruction for proper use that has been evaluated as satisfactory (Attachment C). The subject device's user manual is limited to a "Pocket Guide," which is intended to supplement the general StealthStation® user manual.

Materials: All patient contacting surfaces are summarized as follows:

Component	Material
Reference frames	Medical grade plastics
Reference frame bone screws	Medical grade stainless steel
Instrument tracker	Medical grade plastics and adhesives
Pointer	Medical grade stainless steel and plastic
Calibration tip	Medical grade titanium
Click and Point (Point holder)	Medical grade stainless steel
Screw drivers	Medical grade stainless steel and plastic

These materials are generally equivalent to the predicate device. There are no biocompatibility issues.

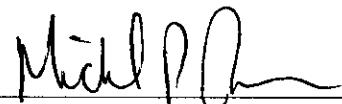
Software Verification and Validation: As recommended by the “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices,” the following was found to be complete and satisfactory:

Software Document	Description	Submission
Level of Concern Indication	Moderate Concern	Pg 11.
Software Description	Summary overview of the features and software operating environment.	Section X
Device Hazard Analysis	Tabular description of identified hardware and software hazards, including severity assessment and mitigation.	Attachment I
Software Requirements Specifications (SRS)	List of functional, performance, interface, design, developmental, and other requirements for the software.	Attachment G
Architecture Design Chart	Detailed depiction of functional units and software modules. May include state diagrams as well as flow charts.	Attachment E
Software Design Specification	Description of the implementation of the requirements from the SRS.	Pg 12, Attachments E, F, G, H, and I
Traceability Analysis	Traceability among requirements, specifications, identified hazards and mitigation, and Verification and Validation testing.	Pg 12.
Software Development Environment Description	Summary of software life cycle development plan, including a summary of the configuration management and maintenance activities.	Attachment F
Validation, Verification, and Testing (VV&T)	Description of V&V activities at the unit, integration, and system level. System level test protocol, including pass/fail criteria, and tests results.	Attachment H
Revision Level History	Revision history log, including release version number and date.	Version 1.01
Unresolved anomalies	List of remaining software anomalies, annotated with an explanation of the impact on safety or effectiveness, including operator usage and human factors.	Listed within Attachment H and analyzed in S001

Summary of Safety and Effectiveness Information & Truthful and Accurate Statement:

The sponsor has provided a Truthful and Accurate Statement (Preface) and a 510(k) Summary of Safety and Effectiveness (Attachment B).

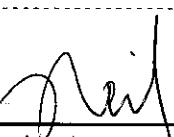
Recommendation: The device, **AxiEM™ Imageless Hip Module for the StealthStation® System**, is SE to the predicate devices K043088 and K052623. The device is classified as a Stereotactic Instrument (**21 CFR § 882.4560** Product Code: **HAW**) and is a **Class II** device.



8/28/06

Michel D. Janda, Biomedical Engineer (mm/dd/yyyy)
General and Surgical Devices Branch
Division of General, Restorative, and Neurological Devices

Contact History: Additional information was requested on June 28, 2006 and received on August 10, 2006.



(Supervisor)

Concur Do Not Concur

(Division Director)

Concur Do Not Concur

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
 Food and Drug Administration
 Memorandum

From: Reviewer(s) - Name(s) Michel Janda

Subject: 510(k) Number K 061248

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 Postmarket Surveillance?

YES NO

Is this device subject to the Tracking Regulation?

YES NO

Was clinical data necessary to support the review of this 510(k)?

YES NO

Is this a prescription device?

YES NO

Was this 510(k) reviewed by a Third Party?

YES NO

Special 510(k)?

YES NO

Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers

YES NO

Truthful and Accurate Statement Requested Enclosed

A 510(k) summary OR A 510(k) statement

The required certification and summary for class III devices NA

The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) NA

Animal Tissue Source YES NO Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

No Confidentiality Confidentiality for 90 days Continued Confidentiality exceeding 90 days

Predicate Product Code with class: Additional Product Code(s) with panel (optional):

HAW Class II

Review: Michel Janda
 (Branch Chief)

650B
 (Branch Code)

6/28/06
 (Date)

Final Review:
 (Division Director)

(Date)

418

Revised: 4/2/03

Janda, Michel D

From: Janda, Michel D
Sent: Wednesday, June 28, 2006 4:23 PM
To: Dreiling, Tina'
Cc: Ogden, Neil
Subject: AxiEM™ Imageless Hip Module for the StealthStation® System, K061248.

Attachments: Picture (Metafile)

Tina Dreiling
Associate Regulatory Affairs Specialist

Medtronic Navigation
826 Coal Creek Circle
Louisville, CO 80027

Ph#: (720) 890-3217
tina.dreiling@medtronic.com

Re: AxiEM™ Imageless Hip Module for the StealthStation® System, K061248.

Dear Ms. Tina Dreiling,

After reviewing the subject 510(k) submission it appears that addition information is required.

1. The submission includes a draft AxiEM Imageless Hip Module for the StealthStation System Pocket Guide (Attachment C). The following deficiencies are associated with this draft labeling:
 - a. The labeling includes an intended use statement (submission, pg 29) which states that, "The Zimmer Imageless Hip for AxiEM is intended to precisely position instruments and implants in procedures including MIS Total Hip Replacement (Primary and Revision)." This statement differs from the Indications for Use listed within Attachment A. Please revise the labeling to include the subject device's indications for use.
 - b. The labeling provides a list of implant families that are supported by the subject device (submission, pg 43). It is unclear if these implant systems have been cleared for sale within the United States. Specifically, the Fitmore, Cedior Kappa, Cedior Kappa w/ sealed screw holes, and Cedior Alpha systems do not appear to be cleared by the FDA. Please clarify if the list of compatible implant systems includes only systems which have received FDA clearance.
 - c. The labeling includes a discussion regarding landmark and coordinate system definition (submission, pg 53-55). This discussion indicates that the system has been designed to provide radiographic anteversion and radiographic inclination angles. The definition of these angles differs from that used within the predicate Imageless Hip Module for the StealthStation® System device (K052623). The predicate device relied upon anatomic defined output angles as opposed to radiographic defined output angles. Furthermore, the submission contains a discussion by Murray (The Definition and Measurement of Acetabular Orientation, Attachment K) which suggests that whenever possible radiographic angles should be converted to anatomical angles. Please clarify why the radiographic definition is preferred within this software application.
2. The submission describes the subject device as supporting the following surgical procedures:

Traditional Total Hip Arthroplasty (THA), MIS Anterolateral Mini THA, MIS Posterolateral Mini THA, and MIS Anterolateral THA. It is unclear how the system's output and workflow is affected by the selection of the supported surgical procedures. Please provide a description of each procedure and how the selection of a given procedure modifies the software workflow and/or output.

3. The subject device is described as including several hardware components including an AxiEM Mobile Emitter. It appears that this emitter has been modified from the predicate device's Transmitter Coil Array to allow movement during the surgical procedure. Please clarify if this component or any other hardware component has been modified and is intended to be included within this 510(k) submission. For any component which has been modified, please provide a summary of the modification(s), a comparison to the predicate device's component, and any verification/validation activity that was used to test the modified component.
4. The submission includes a Functional Test Report (VV1103, Attachment H). This test functions to verify that all device software inputs have been appropriately implemented. Review of the testing results document noted that a significant number of anomalies were reported and a significant number of test criteria were determined to be Not Applicable (NA). While these anomalies were analyzed for their affect on patient safety, due to the significant number of existing anomalies further discussion is necessary. Please provide additional analysis regarding the existing anomalies impact upon the safety and effectiveness of the subject device. In addition, summary rationale should be provided to explain why NA was determined for the exempted tests.

As per this email, K061248 has been placed on hold until further correspondence is received.

Please feel free to contact me if you would like to discuss any of these deficiencies or if you have questions. Additions submissions may be submitted via email or fax. Hard copies are required and can be directed to the FDA document center. Thank you.

Sincerely,

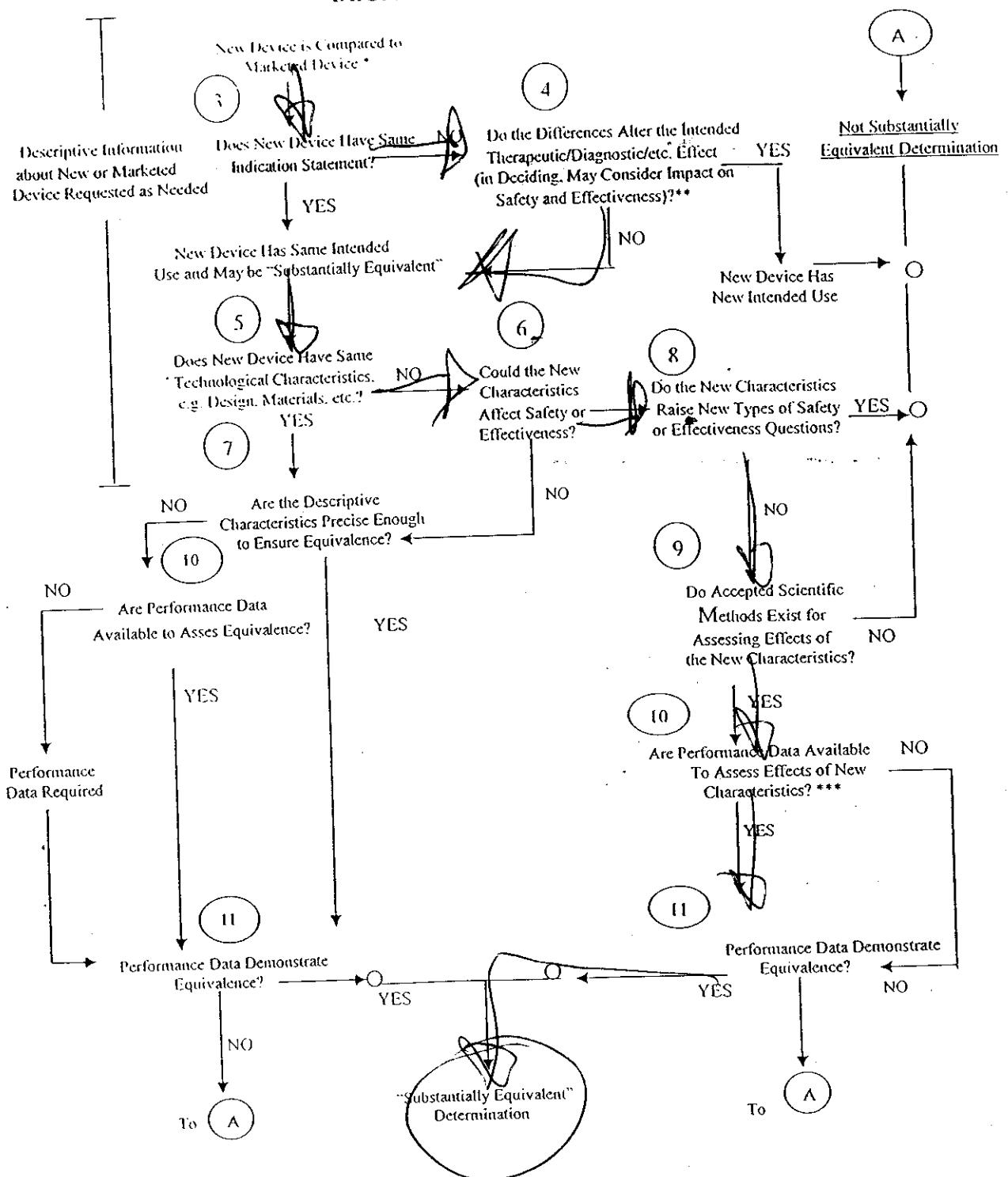
Michel Janda
Biomedical Engineer
Phone #: (301) 594-1307 x 137
Fax #: (301) 827-4350
ODE/DGRND/GSDB



T concurred with AJ
Neil 6/28/06
Protecting and Promoting Public Health

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone.

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



- 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- This decision is normally based on descriptive information alone, but limited testing information is sometimes required. 5
- Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

August 10, 2006

MEDTRONIC NAVIGATION, INC.
826 COAL CREEK CIR.
LOUISVILLE, CO 80027
ATTN: TINA DREILING

510(k) Number: K061248
Product: AXIEM IMAGELESS
HIP MODULE FOR
THE
STEALTHSTATION

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1567.html>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

19

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

K061248/S/1



Medtronic

Medtronic Navigation
826 Coal Creek Circle
Louisville, CO 80027 USA
www.medtronicnavigation.com

tel 720.890.3200
fax 720.890.3500

8/9/2006

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

Re: AxiEM™ Imageless Hip Module for the StealthStation® System, K061248
Trade Name: Imageless Hip Module for the StealthStation® System
Dated: April 28, 2006
Received: May 3, 2006

Dear Sirs:

The content of this response is being provided in support of the submission referenced above and the request for additional information dated June 28, 2006.

An original and two copies of the response materials are being provided. The response is being provided in two sections. The first section is formatted such that the original question of the reviewer is in **bold**, followed by the response from the sponsor un-bolded. The second section contains a large body of attachments in support of information and questions detailed in the first section.

Confidentiality of Information

The enclosed materials and descriptions contain information with is trade secret, privileged, or confidential information under 21 CFR 20.61 and should not be disclosed to the public under the Freedom of Information Act (FOIA).

Questions regarding this response should be directed to either:

Tina Dreiling, Assoc. RA Specialist
Tel :(720) 890.3217
Email: tina.dreiling@medtronic.com

John Adams, RA Manager
Tel: (720) 890.3325
Email: john.g.adams@medtronic.com

Thank you for your consideration.

Regards,

John G. Adams
Regulatory Affairs Manager
Medtronic Navigation, Inc.

K12

K061248 - AxiEM™ Imageless Hip Module for the StealthStation® System

- 1. The submission includes a draft AxiEM Imageless Hip Module for the StealthStation System Pocket Guide (Attachment C). The following deficiencies are associated with this draft labeling:**

a. The labeling includes an intended use statement (submission, pg 29) which states that, "The Zimmer Imageless Hip for AxiEM is intended to precisely position instruments and implants in procedures including MIS Total Hip Replacement (Primary and Revision)." This statement differs from the Indications for Use listed within Attachment A. Please revise the labeling to include the subject device's indications for use.

RESPONSE: Medtronic is updating the Pocket Guide intended use text to the following:

Zimmer Imageless Hip for AxiEM is intended to precisely position instruments and implants in example procedures such as but not limited to:

*Orthopedic Procedures:
Minimally Invasive Orthopedic Procedures
Total Hip Replacement (Primary and Revision)*

The brand name of the commercial product "Zimmer Imageless Hip for AxiEM" is used in the Pocket Guide as indicated in first paragraph of Section X.C (p.6) in the AxiEM Imageless Hip Module submission K061248. The material content of the intended use statement is now verbatim from the submission.

In addition, the cover page and contraindications section of the Pocket Guide are being updated to reflect the brand name to avoid inconsistency. A copy of the updated draft Pocket Guide is attached to this response letter (**Attachment A**).

b. The labeling provides a list of implant families that are supported by the subject device (submission, pg 43). It is unclear if these implant systems have been cleared for sale within the United States. Specifically, the Fitmore, Cedior Kappa, Cedior Kappa w/ sealed screw holes, and Cedior Alpha systems do not appear to be cleared by the FDA. Please clarify if the list of compatible implant systems includes only systems which have received FDA clearance.

The AxiEM Imageless Hip Module is intended to be marketed globally in geographies for which appropriate regulatory clearances have been issued. As such, the instructions for use lists all the global implant systems supported. To clarify, the list of supported implant systems listed in the Instructions for Use (Pocket Guide) on page 43 of the original submission has been changed to identify which implant systems are not available in the United States (**Attachment A**).

The Fitmore, Cedior Kappa, Cedior Kappa w/ sealed screw holes, and Cedior Alpha systems are now listed in the Instructions for Use as not available in the United States. The remaining implant systems were cleared in the United States as follows:

K061248 - AxiEM™ Imageless Hip Module for the StealthStation® System

Product Family	Registration/ License Number(s)	Clearance Date(s)	Submitted by
Allofit	K003758	7-Mar-01	Sulzer Orthopedics
Converge	K032348	27-Oct-03	Centerpulse
	K012739	14-Nov-01	Sulzer Orthopedics
	K022985	5-Dec-02	Sulzer Orthopedics
	K012961	18-Oct-01	Sulzer Orthopedics
	K970705	22-May-97	Sulzer Orthopedics
Trabecular Metal™ Modular (TM Modular)	K021891	5-Sep-02	Zimmer
Trilogy	K021826	20-Dec-02	Zimmer
	K953490	20-Oct-95	
	K003478	5-Feb-01	
	K954698	17-Jan-96	
	K002960	11-Dec-00	
	K990135	12-Jul-99	
	K934765	29-Apr-94	

c. The labeling includes a discussion regarding landmark and coordinate system definition (submission, pg 53-55). This discussion indicates that the system has been designed to provide radiographic anteversion and radiographic inclination angles. The definition of these angles differs from that used within the predicate Imageless Hip Module for the StealthStation(r) System device (K052623). The predicate device relied upon anatomic defined output angles as opposed to radiographic defined output angles. Furthermore, the submission contains a discussion by Murray (The Definition and Measurement of Acetabular Orientation, Attachment K) which suggests that whenever possible radiographic angles should be converted to anatomical angles. Please clarify why the radiographic definition is preferred within this software application.

RESPONSE: The AxiEM Imageless Hip Module was designed and reviewed in coordination with a panel of orthopaedic surgeons providing input and expertise in the area of total hip replacement surgery. The panel unanimously agreed that radiographic angles are the preferred choice for both conventional and navigated assessment of acetabular shell placement. These angles are the same as those assessed on a post-operative standing x-ray of a total hip replacement which they suggested is the standard post-operative imaging technique. As such, the clinicians prefer to have the same angles presented by the navigation software permitting one-to-one comparison with conventional post-operative assessment technique. Based on the physician input, Medtronic selected to display the radiographic definition of acetabular angles on the software screens. Radiographic angles are also used by imageless hip applications developed and distributed by OrthoSoft (Montreal, Canada).

The Murray paper discussion does suggest the use of different angles in different situations. For example, it suggests using operative angles with an image intensifier (fluoroscope) during surgery (p.231 of the paper) and anatomical angles when assessing a dysplastic hip (p231-232 of the paper). While the clinical community seems to have agreed on the three definitions for acetabular angles and the associated nomenclature presented in the paper, in practice they have not adopted Murray's recommendations regarding when to use each definition. Instead, common practice is to use radiographic angles to describe the acetabular implant placement, especially when using a navigation system providing intraoperative quantification. We propose a few reasons for this. Surgeons do not typically have fluoroscopes in the operating theater for hip replacement

K061248 - AxiEM™ Imageless Hip Module for the StealthStation® System

surgery so Murray's suggestion to use one in the assessment of prosthesis angles has not been widely adopted. A lack of fluoroscopy in typical hip procedures is also one of the factors driving physicians' preference for imageless navigation software over fluorobased applications. Hospitals are not currently reimbursed for CT scans for total hip replacements so the use of CT is also not widely adopted for hips.

The 3-Dimensional spatial tracking of instruments by the navigation system is the same whether the screen is displaying anatomic, operative, or radiographic angles. The display choice only depends on which angle transform is applied to the navigated pose of the instrument relative to the patient-specific landmarks.

To supplement the clinical literature supplied with submission K061248 for the subject device, several additional papers are attached here (**Attachment B**) to demonstrate the use of radiographs as a common pre-operative templating and post-operative assessment technique adopted for acetabular implant placement. These papers are not intended to indicate the sufficiency of radiographs (in fact most of these publications identify deficiencies when using non-navigated conventional methods), but rather to demonstrate common usage of radiographic assessment of acetabular angles.

- 2. The submission describes the subject device as supporting the following surgical procedures: Traditional Total Hip Arthroplasty (THA), MIS Anterolateral Mini THA, MIS Posterolateral Mini THA, and MIS Anterolateral THA. It is unclear how the system's output and workflow is affected by the selection of the supported surgical procedures. Please provide a description of each procedure and how the selection of a given procedure modifies the software workflow and/or output.**

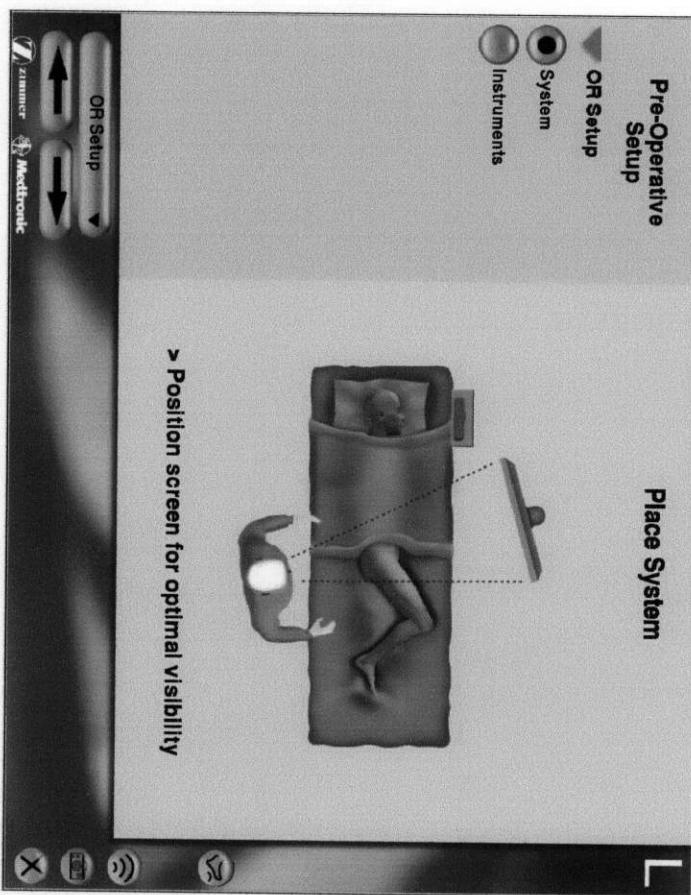
RESPONSE: The quantitative output and workflow of the application is unchanged by the selection of surgical approach. The workflow steps/sequence and the displayed acetabular angles remain unchanged. This procedure selection is made available to the end user only as a mechanism for customizing the illustrative images onscreen during software operation. In other words, the selection customizes the onscreen "help images" which may show the illustrative view of the acetabulum from a slightly different orientation based on the procedure selection made. In this specific case of the AxiEM Imageless Hip Module, only the following illustrative onscreen image changes based on the procedure selection:

OR Setup → Place System
(p.126 in Attachment D of original submission)

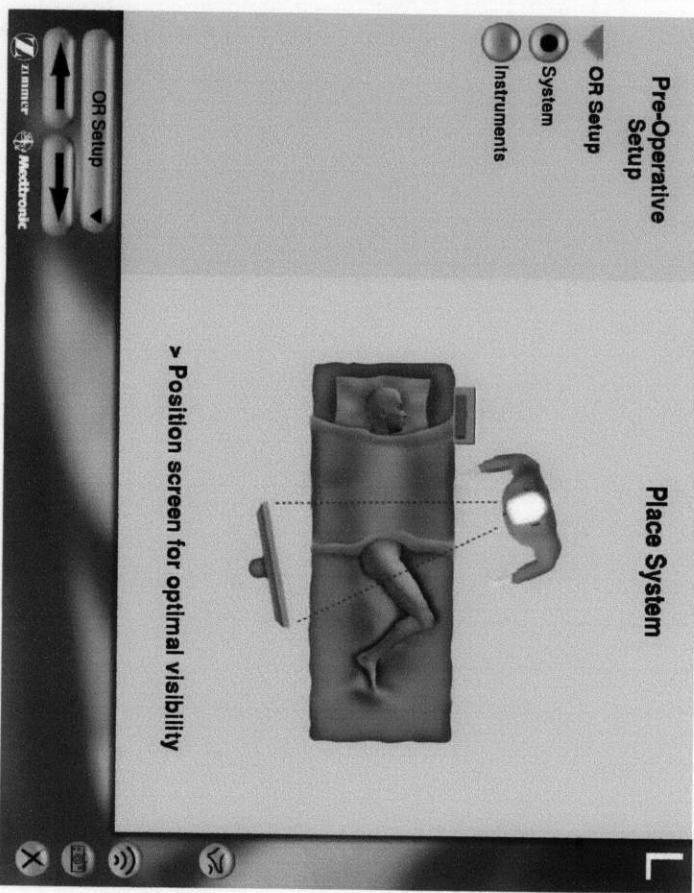
The software was written to support potential future enhancements to onscreen images based on the selection of surgical procedure. However, v1.01 of the software modulates only this one image as shown below.

K061248 - AxiEM™ Imageless Hip Module for the StealthStation® System

Traditional Total Hip Arthroplasty (THA)
MIS Posterolateral Mini THA



MIS Anterolateral THA
MIS Anterolateral Mini THA



K061248 - AxiEM™ Imageless Hip Module for the StealthStation® System

3. The subject device is described as including several hardware components including an AxiEM Mobile Emitter. It appears that this emitter has been modified from the predicate device's Transmitter Coil Array to allow movement during the surgical procedure. Please clarify if this component or any other hardware component has been modified and is intended to be included within this 510(k) submission. For any component which has been modified, please provide a summary of the modification(s), a comparison to the predicate device's component, and any verification/validation activity that was used to test the modified component.

RESPONSE: The AxiEM™ Mobile Emitter (also known as the TCA) was included on pages 4, 46, and 171 of the AxiEM™ Imageless Knee Module for the StealthStation® System (K043088) cleared January 5, 2005. This 510(k) clearance is listed within the current submission as a predicate device. No significant changes have been made to the TCA referenced in K043088, therefore, it is not our intention to request clearance for this specific system component under this submission.

4. The submission includes a Functional Test Report (VV1103, Attachment H). This test functions to verification that all device software inputs have been appropriately implemented. Review of the testing results document noted that a significant number of anomalies were reported and a significant number of test criteria were determined to be Not Applicable (NA). While these anomalies were analyzed for their affect on patient safety, due to the significant number of existing anomalies further discussion is necessary. Please provide additional analysis regarding the existing anomalies impact upon the safety and effectiveness of the subject device. In addition, summary rationale should be provided to explain why NA was determined for the exempted tests.

RESPONSE: The standard software design control procedures at Medtronic include a process for software change and effects analysis. This analysis looks at the input, output, and isolation of code changes and/or bug fixes that occur as a result of verification testing. The analysis is used to help determine the tests that should be run or rerun to verify software after changes are made. In some cases the analysis may be used to justify a reduced set of testing after the changes are made to create a new release candidate (RC).

The AxiEM Imageless Hip Module submission K061248 included only the results from testing on the last release candidate (RC5) which became the completed development version 1.01. Attached to this response letter is the complete history for the software functional test (**Attachment C**) including report revisions 1 & 2 and the software change effect analyses performed for changes to each RC (RC0 thru RC5). This complete history includes results for items marked N/A in the final report revision 3 supplied with the original submission. The test reports taken together represent the sum of all testing and, in combination, contain the results for concluding the software "Passes with Concessions" and may be released for distribution pending regulatory clearance:

K061248 - AxiEM™ Imageless Hip Module for the StealthStation® System

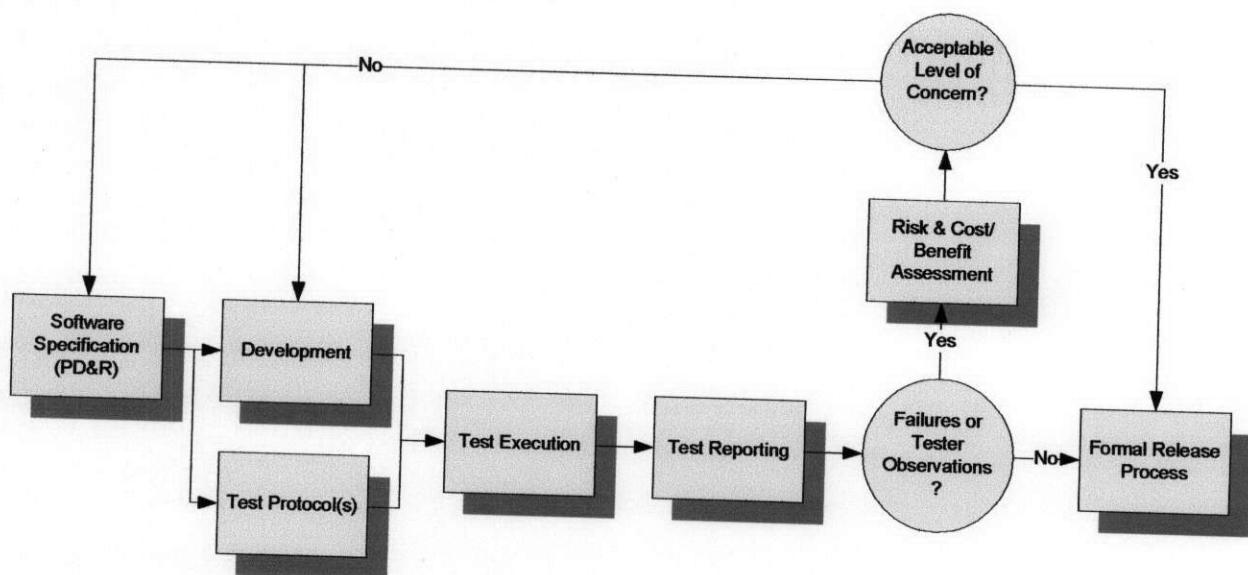
FUNCTIONAL TEST HISTORY SUMMARY				
Test Report Rev 1	Software Change Effect Analyses RC0 to RC1 RC1 to RC2 RC2 to RC3	Test Report Rev 2	Software Change Effect Analyses RC3 to RC4 RC4 to RC5	Test Report Rev 3
RC0 & RC1 failed functional test Broad software code fixes implemented	Analyses recommended repeating full test protocol on RC2	RC2 failed Simulated Use testing prior to execution of functional testing. RC3 failed functional test Isolated software code fixes implemented	Analyses recommended subset of test cases be repeated on RC4 to verify isolated code changes. Recommended subset of test cases be repeated on RC5 to verify isolated code changes.	RC4 passed the functional test based on assessment of issues listed by the tester but failed separate FreeFrom testing. RC5 passed or passed with concessions, all tests repeated for RC5

The procedure for verification and validation testing includes a provision for the tester to note any and all miscellaneous observations made during formal software testing whether or not the observation is an anomaly or failure in a specific protocol test case. All tester comments, including but not limited to explicit test failures, are captured in one category of testing "Issues" as listed in the testing reports. In some cases this process can result in a large list of miscellaneous observations, all of which are assessed with an overall level of concern based on the probability of occurrence (PoO) and severity of the issue (this process parallels the Hazard Analysis process). Medtronic documents and assesses all issues with the same high level of scrutiny as a conservative approach to evaluating test results. Issues with a level of concern of moderate or greater are addressed by software changes unless the cost of doing so far outweighs the benefit. Items causing a patient safety or product efficacy issue (i.e. a Hazard) are always addressed.

In the case of the AxiEM Imageless Hip Module there were a large number of observations made by the tester and recorded in the issues list, but all were assessed to be of minor or negligible level of concern except for the observation made during test cases 343 & 344 where some screen elements in a utility screen were difficult to see. This item had a level of concern of moderate because the probability of occurrence was high (it will occur every time the utility is used). However, this utility is provided as a convenience feature for aiding in optimizing the position of the mobile emitter and is helpful to the user but not required for safe and effective operation of the software. Based on the significant development cost to change the visual appearance of this utility weighed against the low benefit for addressing the observation, we elected to document the observation for reassessment in a future software release.

With respect to the number of issues documented in the final functional test report, these issues are assessed individually and as a whole to gauge the overall impact on the product. Observations about cosmetic items or about non-essential requirements (business-related features or preferences) do not necessarily combine to produce a larger cumulative impact on navigation software. This is the case with Zimmer Imageless Hip for AxiEM.

K061248 - AxiEM™ Imageless Hip Module for the StealthStation® System

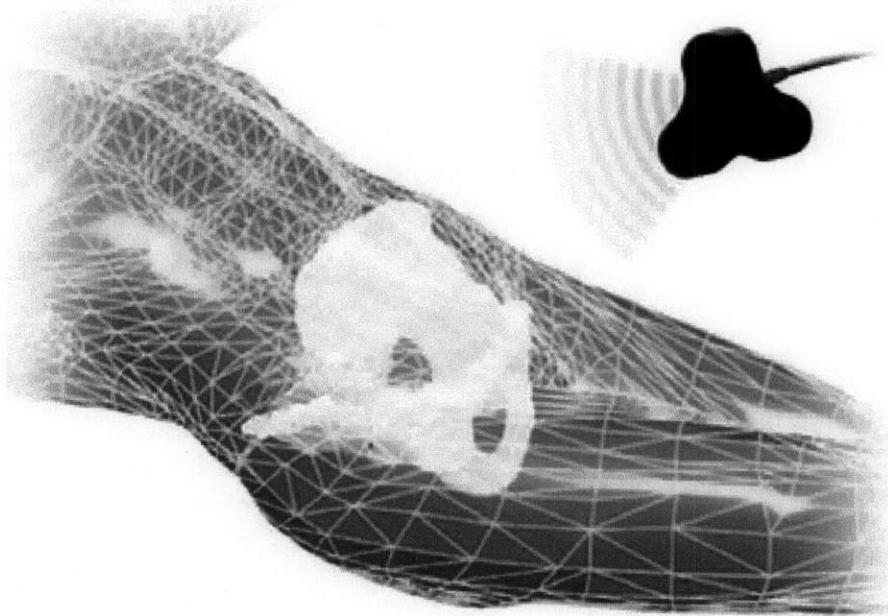




Medtronic

**Zimmer® Imageless
Hip for AxIEM™
Application**

POCKET GUIDE



©2005 MEDTRONIC NAVIGATION
9732770, REVISION 1



Rx

Medtronic Navigation
826 Coal Creek Circle
Louisville, CO 80027

Main 720 890 3200

Fax 720 890 3500

Technical support 800 595 9709

www.stealthstation.com

EC REP

Medtronic B.V
Earl Bakkenstraat 10
6422 PJ Heerlen
Netherlands

Tel 31 45 566 80 00

CONTENTS

INTENDED USE.....	5
CONTRAINdications.....	5
WARNINGS.....	5
CAUTIONS	8
STANDARD EQUIPMENT	9
PROCEDURE.....	11
LOG IN.....	12
ENTER PATIENT NAME.....	14
SOFTWARE OVERVIEW	15
SELECT PROCEDURE.....	17
SELECT OPERATIVE SIDE.....	18
SELECT IMPLANT	19
RECOMMENDED SYSTEM AND CONNECTOR Box PLACEMENT.....	20
CONNECT INSTRUMENTS	21
SWITCHING INSTRUMENTS DURING THE PROCEDURE....	23
CALIBRATE SHELL INSERTER	24
CALIBRATE ACETABULAR REAMER	26
ATTACH PELVIS TRACKER	28

LANDMARKS AND COORDINATE SYSTEM	29
DIGITIZE PELVIC LANDMARKS.....	32
CREATE PELVIS CHECKPOINT	37
VERIFY PELVIS CHECKPOINT	38
RECORD PRE-OP LEG LENGTH AND OFFSET.....	39
SELECT REAMER.....	40
NAVIGATE REAMER	42
SELECT SHELL SIZE.....	43
NAVIGATE SHELL	44
VERIFY SHELL.....	46
CAPTURE POST-OP LEG LENGTH & OFFSET	47
EXIT THE APPLICATION SOFTWARE	48
ARCHIVE	49
REMOVE EXAMS.....	50
EXIT.....	51
SYMBOLS	52

INTENDED USE

Zimmer® Imageless Hip for AxiEM™ is intended to precisely position instruments and implants in example procedures such as but not limited to:

- Orthopedic Procedures:
- Minimally Invasive Orthopedic Procedures
- Total Hip Replacement (Primary and Revision).

CONTRAINDICATIONS

Zimmer® Imageless Hip for AxiEM™ is contraindicated for any medical condition for which surgery itself is contraindicated.

⚠️ WARNINGS

- The system and its associated applications should be used only by qualified medical professionals who are trained on and familiar with the proper operation of Medtronic computer-assisted surgery systems.
- The system and its associated applications should be used only as an adjunct for surgical guidance. They do not replace the surgeon's knowledge, expertise, or judgement.
- If system navigation seems inaccurate and steps to restore accuracy are unsuccessful, abort use of the application.
- Discard before use any pre-sterilized component whose sterile packaging appears to be compromised.

- There is currently no effective sterilization method for components that are tainted with the virus that causes Creutzfeld-Jakob Disease (CJD). Therefore, you must discard immediately after surgery any components that come into contact with biologic material from patients who carry or are suspected to carry this virus. As a precaution, drape all non-disposable components that could otherwise come into contact with such material.
- Frequently confirm localization accuracy and system responsiveness during live navigation. Observe the correspondence between movement of instrument and movement of the virtual instrument on-screen.
- Do not operate the AxiEM™ Mobile Emitter (Localizer) in an ambient temperature of more than 86° F (30° C).
- Never use an AxiEM™ instrument as a lever or prying device.
- Physically examine all instruments and frames before use. Do not use a device that is bent or damaged.
- Do not connect multiple low isolation instruments.

- AxiEM™ system technology has been tested for compatibility with the following Medtronic® implantable cardiac device families:

- Marquis®
- GEM III®
- Kappa®
- Sigma®
- EnPulse®
- EnRhythm®
- EnTrust®

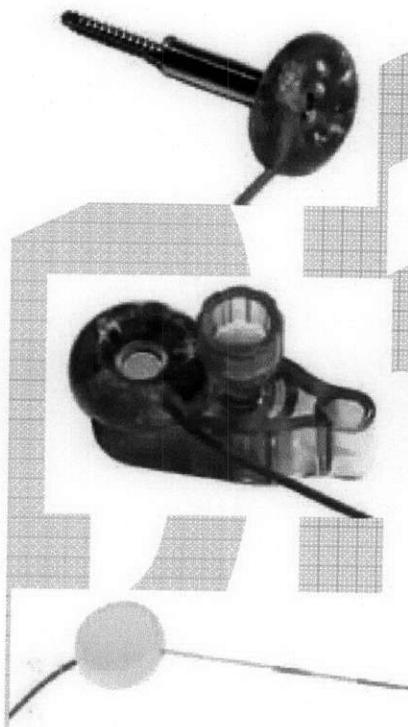
Testing indicates that AxiEM™ systems do not adversely affect the function of these devices and do not constitute a patient hazard. However, the system may interfere with the programming or interrogating of these implantable devices and any other implantable device. Do not use an AxiEM™ system while programming or interrogating any implantable device.

- Do not change or edit configuration files. Only Medtronic Navigation service and field personnel, who have been trained to know which parameters and associated values can be changed, are authorized to modify application configurations. Any modification of the application software by the user is considered off-label use.

△ CAUTIONS

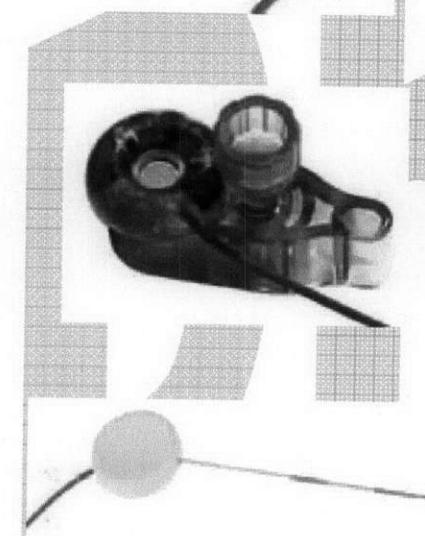
- Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.
- The system and its associated applications contain no user-repairable parts. For repair or replacement of any part of the system or application, contact a technical support representative.
- The patient-specific coordinate system created by the software from user-identified landmarks assumes typical anatomy at the landmark sites. Significant deformity or irregularity at these sites may produce unexpected navigation angles.
- Verify that all relevant instrumentation has been properly cleaned and sterilized before surgery. Clean and sterilize the components according to the parameters in the *Equipment Cleaning and Sterilization sheet* (pn 9730713).

STANDARD EQUIPMENT



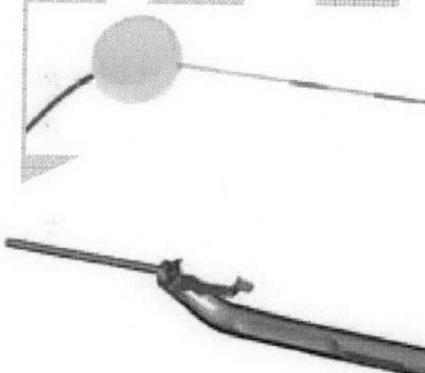
AxiEM™ Pelvis Tracker (pn 9732724)

Use the Pelvis Tracker to track the position of the patient's pelvis during the procedure.



AxiEM™ Instrument Tracker (pn 9732726)

Use the Instrument Tracker to track the position of surgical instruments during the procedure.



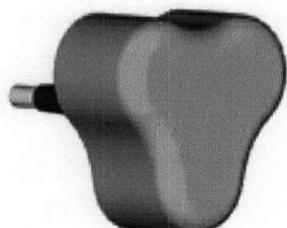
AxiEM™ Pointer (pn 9660236)

Use the AxiEM™ Pointer for digitizing accuracy checkpoints and landmarks.



Shell Inserter Calibration Tip (pn 9732727)

Use the Calibration Tip on the Shell Inserter to calibrate the instrument for accurate navigation.



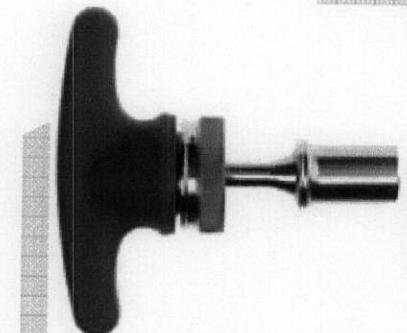
AxiEM™ Mobile Emitter (pn 9660812)

The AxiEM™ Mobile Emitter produces the electromagnetic field used to track instruments.



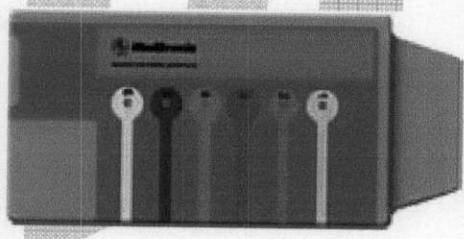
AxiEM Ortho Screwdriver (pn 9732133)

Use the AxiEM Screwdriver to drive the Tracker fixation screws into bone.



Ratcheting T-Handle (pn 9731974)

Use the Ratcheting T-Handle to hand tighten screws into bone.



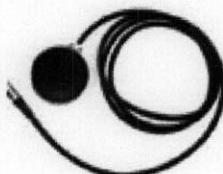
Navigation Probe Interface (pn 9660700)

The Navigation Probe Interface or Connector Box is a junction box used to connect wired instruments to the system.



AxiEM™ Portable System (pn 9660560)

The AxiEM™ Portable system connects to the iNav™ Portable system. It is a junction box used to connect AxiEM™ instruments to the portable system.



System Footswitch (pn 960-135)

The system footswitch controls software functions.

DRAFT

PROCEDURE

LOG IN

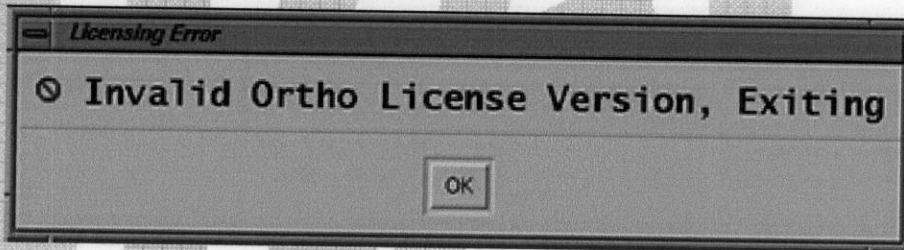
12

1. If necessary, scroll down until you can see the **Zimmer** icon.
2. Double-click the **Zimmer** icon on the login screen.
The group screen (below) displays.
3. Click the **[Zimmer Imageless Hip for AxiEM]** icon at the top of the group screen, or
4. Click the **[Zimmer Imageless Hip for AxiEM Portable]** icon (AxiEM™ Portable systems only).



LOG IN (CONT.)

For Treon® and Tria™ systems only: If you do not own an Orthopaedic OS license, you will not be able to start and run the Zimmer Imageless Hip for AxiEM™ application software. The following message displays if you do not own the license.

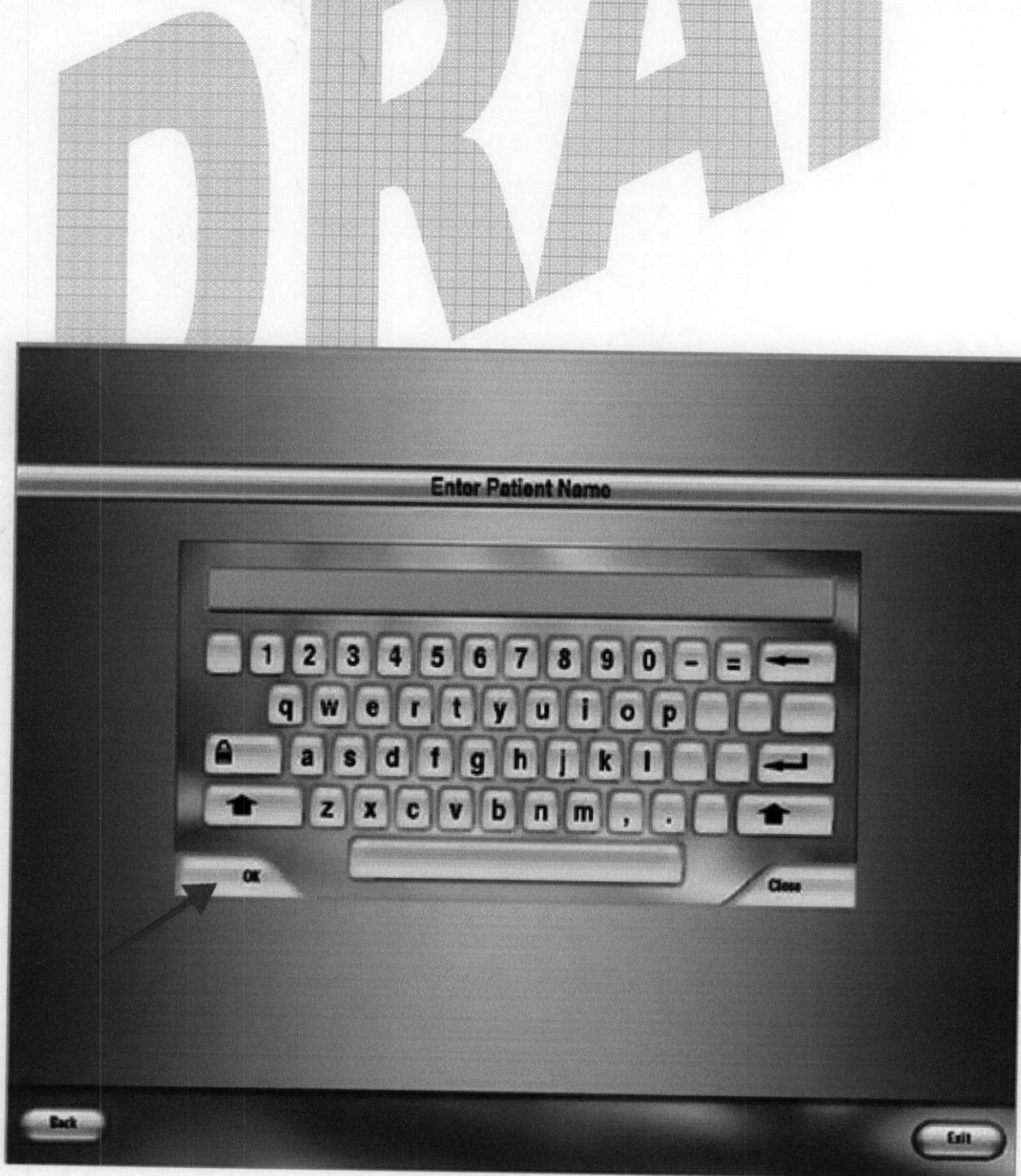


Please contact your local Medtronic Navigation representative or call Medtronic Navigation to obtain information on purchasing an Orthopaedic OS license.

ENTER PATIENT NAME

14

1. Enter the patient's name or an identification name for the exam using the virtual keyboard on-screen or the system keyboard.
If you are using the system keyboard, make sure that the mouse cursor is in the text box.
2. Click the [OK] button.

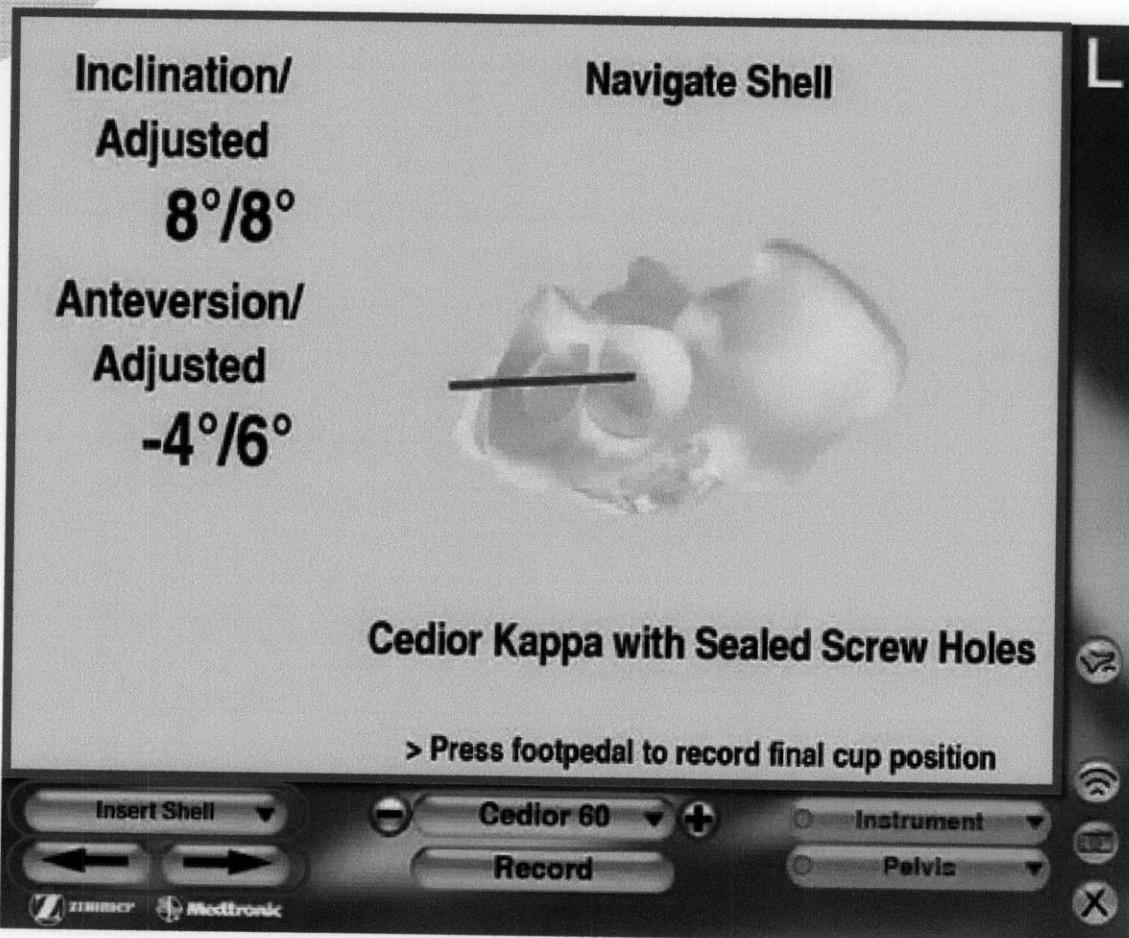


42

SOFTWARE OVERVIEW

1. **Image Window:** Interpretive images and measurement data for each task appear in this area.
2. **Task Bar:** Each active task for the procedure displays on the task bar. Click the bar to jump to any active task.
3. **Next/Back Buttons:** Click the right-pointing Arrow to go forward to the next task. Click the left-pointing Arrow to return to the previous task.

1



2
3

15

- 16
4. Task-Specific Area: Each task has its own specific set of buttons and other controls. The colors of the status indicators in the right side of the area correspond to instrument and reference frame visibility.
 5. General Control Buttons: Use the general control buttons to access system-level features at any time during the procedure.



– Acts as a footpedal press



– Opens the emitter field viewer



– Takes a snapshot of the screen



– Exits the application

Inclination/

Adjusted

8°/8°

Anteversion/

Adjusted

-4°/6°

Navigate Shell



Cedior Kappa with Sealed Screw Holes

> Press footpedal to record final cup position

Insert Shell	Cedior 60	Instrument
← →	Record	Pelvis
Zimmer Medtronic		

5

4

44

SELECT PROCEDURE

1. Select the type of procedure to be performed.

Pre-Operative Setup

Surgery Options

- Procedure
- Operative Side
- Implant

Select Procedure

- Traditional THA
- MIS Anterolateral Mini THA
- MIS Posterolateral Mini THA
- MIS Anterolateral THA

Surgery Options ▾

KINROSS **Medtronic**

A black arrow points to the "MIS Anterolateral THA" option in the list.

SELECT OPERATIVE SIDE

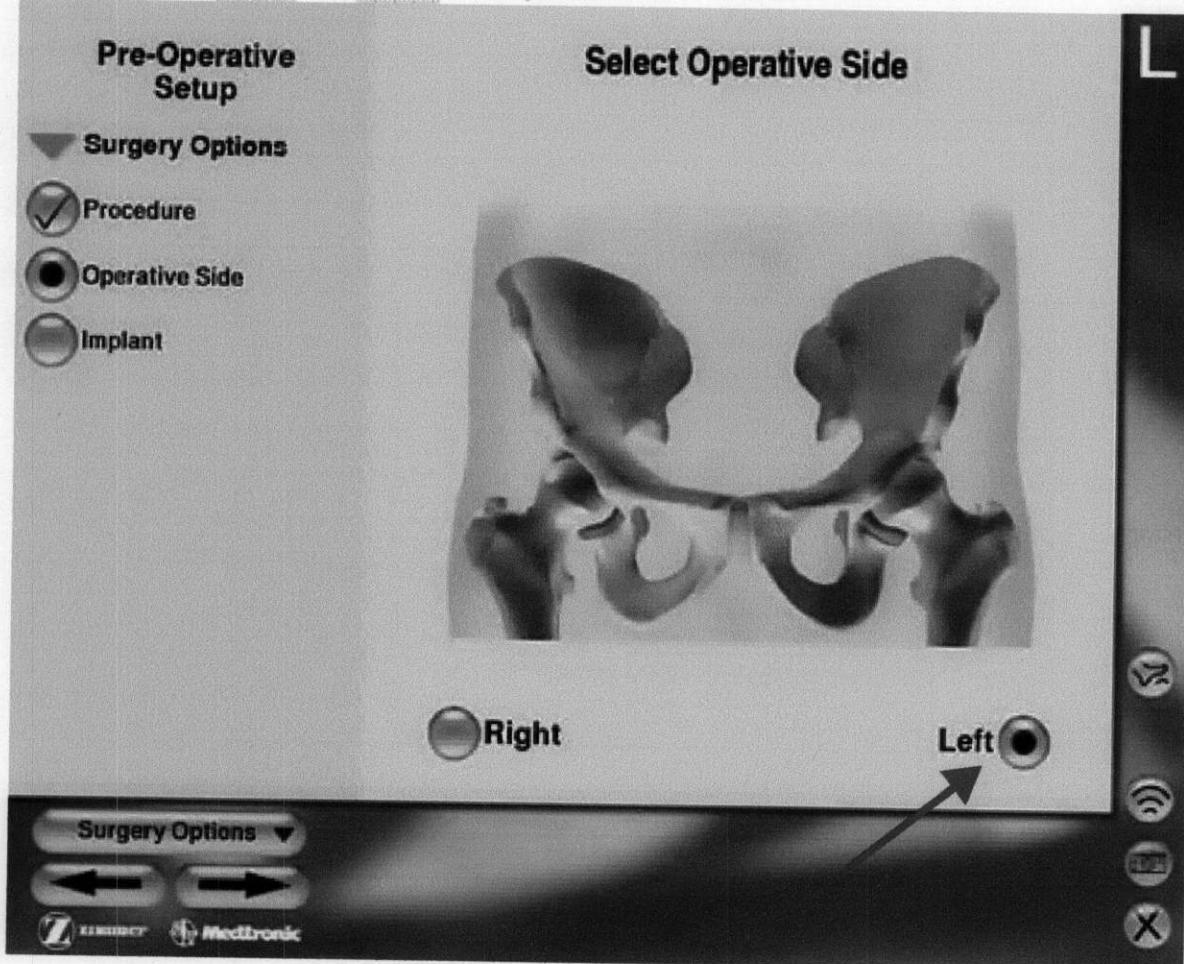
18

⚠ Measurements in the inclination/anteversion of the acetabular cup and reamer will appear abnormal if the wrong hip side is selected.

Select the side of the patient on which the procedure will be performed.

1. Click [Right] or [Left].

The application software will automatically advance to the next screen after selecting the operative side.



SELECT IMPLANT

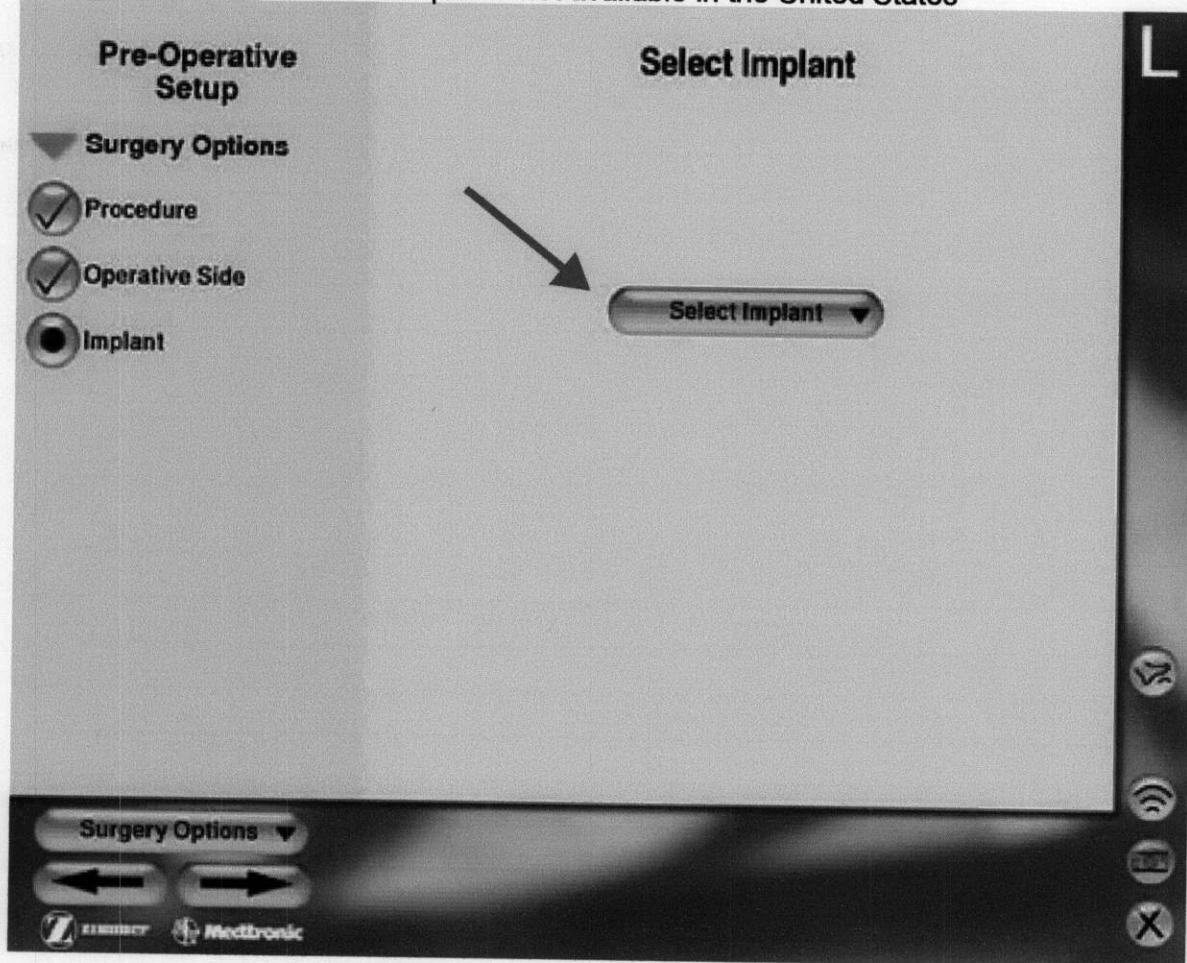
1. Select the implant system to be used for the procedure.

This step ensures that the application software uses the correct implant data for all calculations.

The application software supports the following implant families.

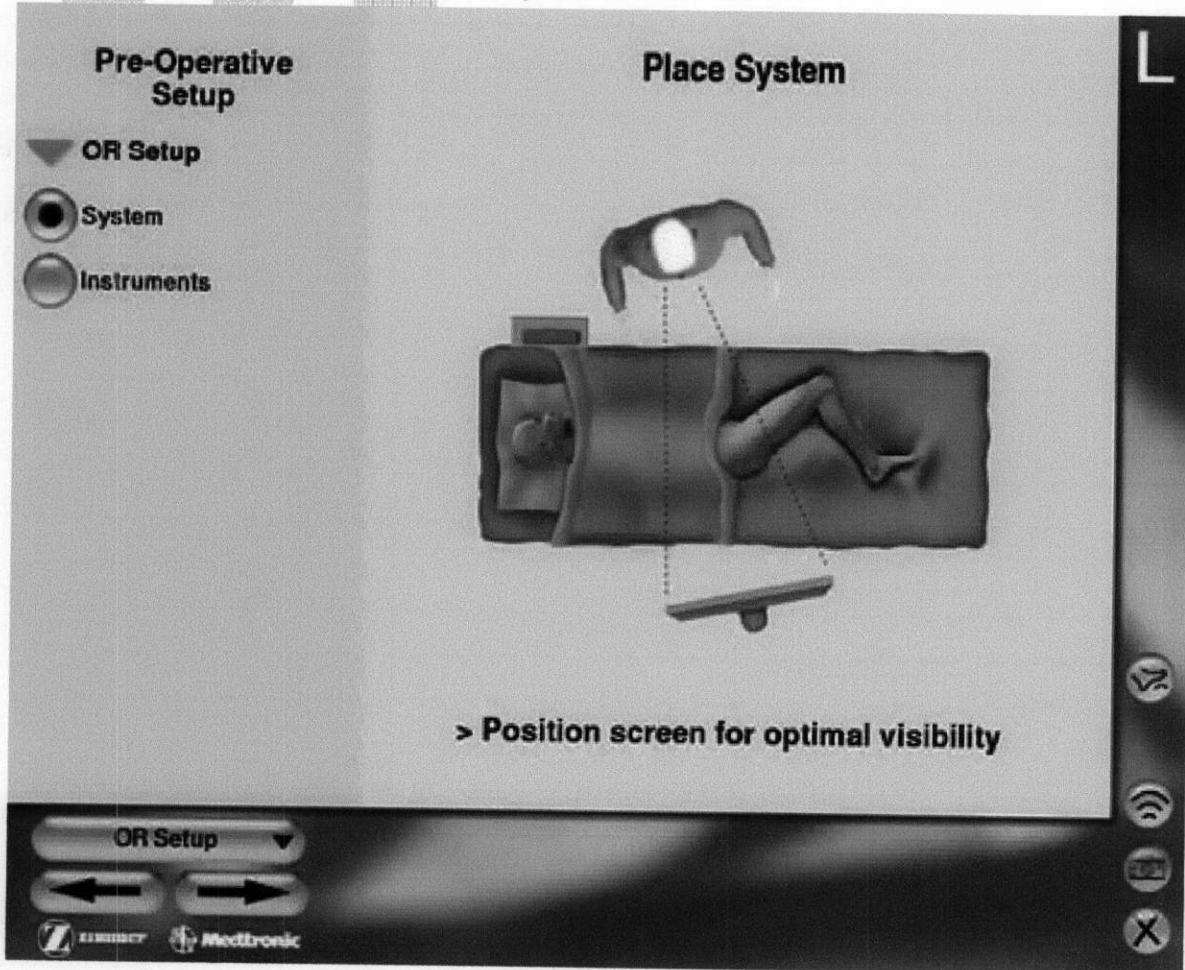
- Trilogy
- Converge
- Converge Protrusio
- TM Modular
- Fitmore*
- Allofit
- Cedor Kappa*
- Cedor Kappa w/
sealed screw holes*
- Cedor Alpha*

*these implants not available in the United States



RECOMMENDED SYSTEM AND CONNECTOR BOX PLACEMENT

1. Place the AxiEM™ Unit to the side of the patient's head on the opposite side of the scrub nurse's table.
2. Move the touchscreen monitor into a position where both the surgeon and the assistant can see the screen.
3. Hang the Navigation Probe Interface (AxiEM™ Connector Box) on the operating table side rail.

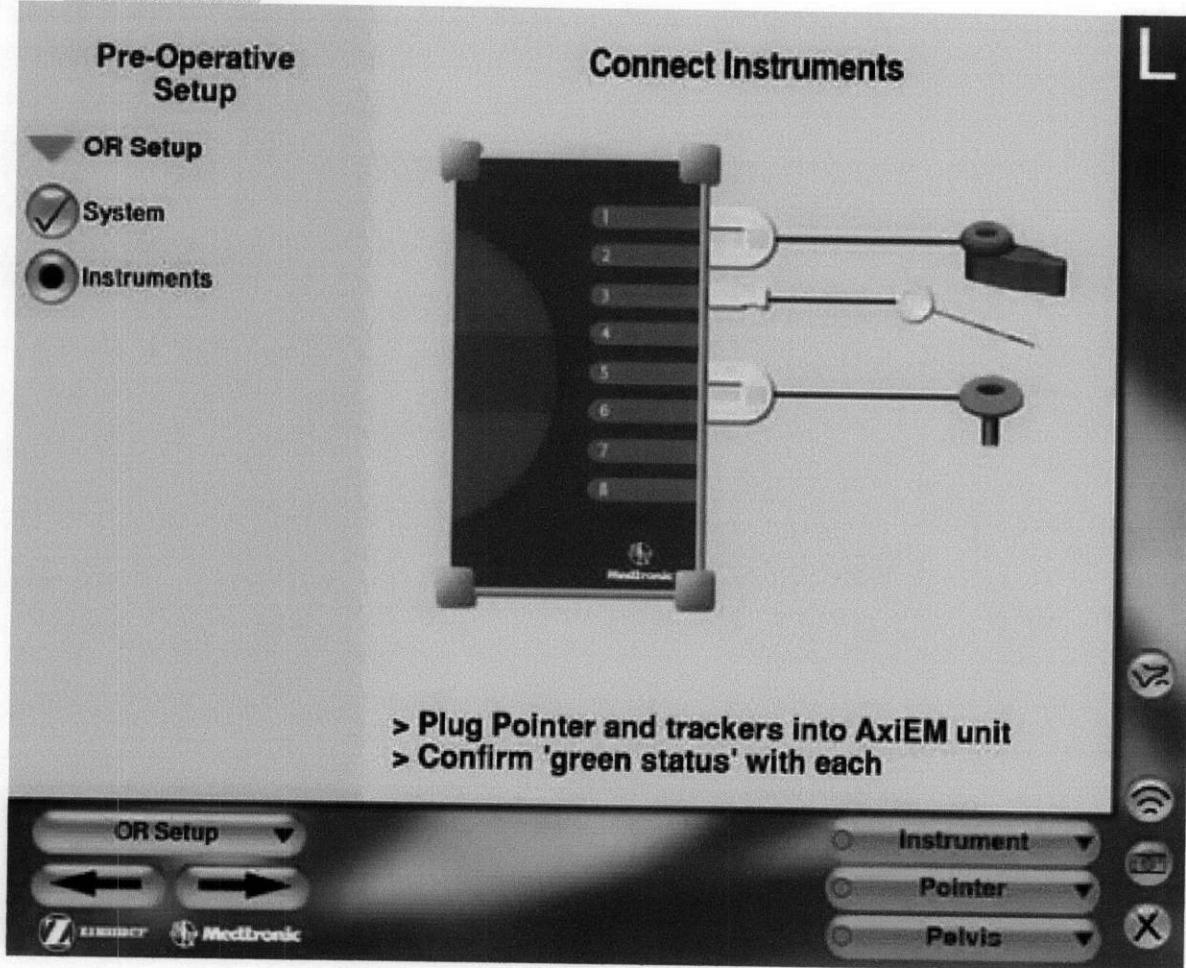


CONNECT INSTRUMENTS

Plug the instruments into any open port on the Connector Box.

⚠ Inspect all probes and trackers for loose cabling or exposed wiring. Never use a device with wiring defects.

⚠ Do not simultaneously connect multiple low isolation instruments (for example, the Pointer). If the application software detects more than one low isolation instrument, a warning message displays instructing the user to disconnect one of the low-isolation instruments (not applicable to the portable AxiEM™ system).

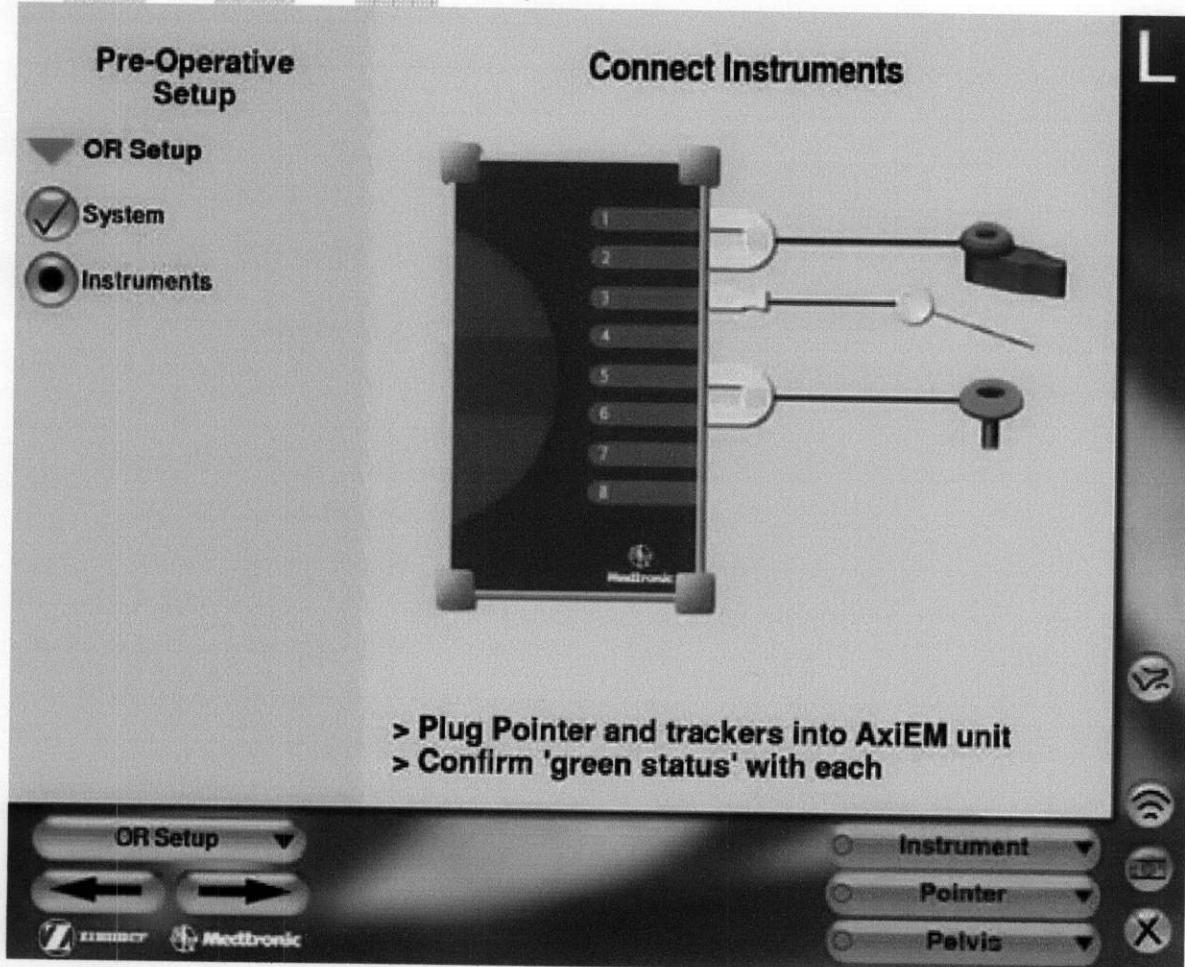


CONNECT INSTRUMENTS (CONT.)

22

1. Plug the AxiEM™ Pointer into an open port on the Connector Box.
2. Plug the AxiEM™ Pelvis Tracker's connector into two open ports on the Connector Box.
3. Plug the AxiEM™ Instrument Tracker's connector into two open ports on the Connector Box.
4. Make sure the indicator lights on the Connector Box change from orange to green indicating a successful connection for each instrument.

Note: The Zimmer Imageless Hip for AxiEM™ application only tracks one tracker of each type at any given moment in time.



SWITCHING INSTRUMENTS DURING THE PROCEDURE

You may replace ("hot swap") an instrument at any time during the procedure.

1. Unplug the instrument you wish to replace from the Connector Box.
2. Plug the new instrument into the open port on the connector box.
3. Make sure the indicator light on the Connector Box changes from orange to green indicating a successful connection.

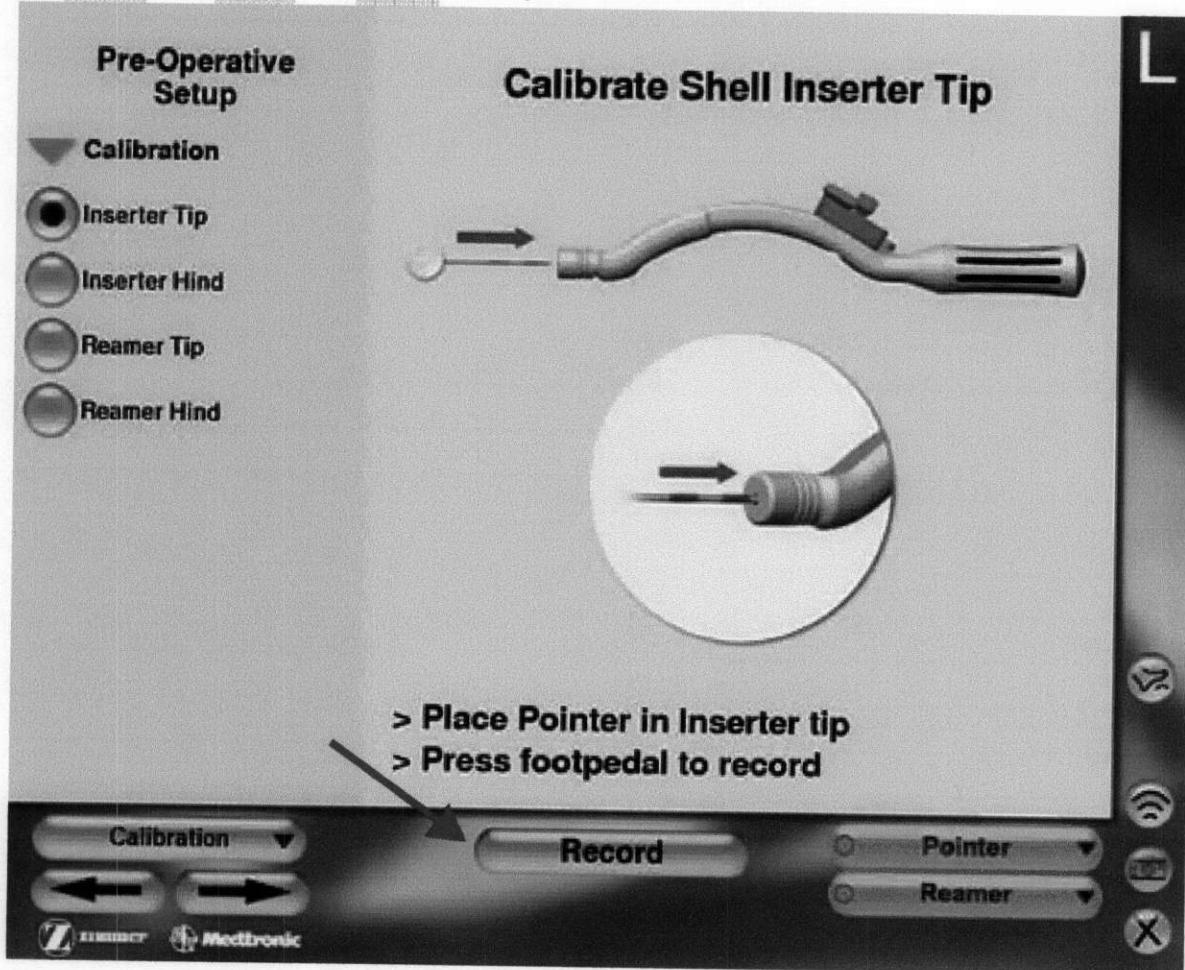
If you switch pelvis trackers after the **Digitize Pelvic Landmarks** task, the application software will prompt you to confirm switching trackers and that all landmarks saved with the tracker being replaced will be cleared.

If you switch instrument trackers after calibration, the application software will prompt you to confirm switching trackers and that all instrument calibration data will be cleared.

CALIBRATE SHELL INSERTER

24

1. Attach the AxiEM™ Instrument Tracker to the Shell Inserter.
 - a. If necessary, wipe clean the handle attachment site.
 - b. Slide the AxiEM™ Instrument Tracker onto the pins located on the Inserter handle.
 - c. Tighten the AxiEM™ Instrument Tracker mounting screw.
2. Make sure that the AxiEM™ Instrument Tracker is plugged into the Connector Box and the status indicator is green.
3. Make sure the AxiEM™ Pointer is plugged into the Connector Box and the status indicator is green.
4. Attach the calibration tip to the Shell Inserter.

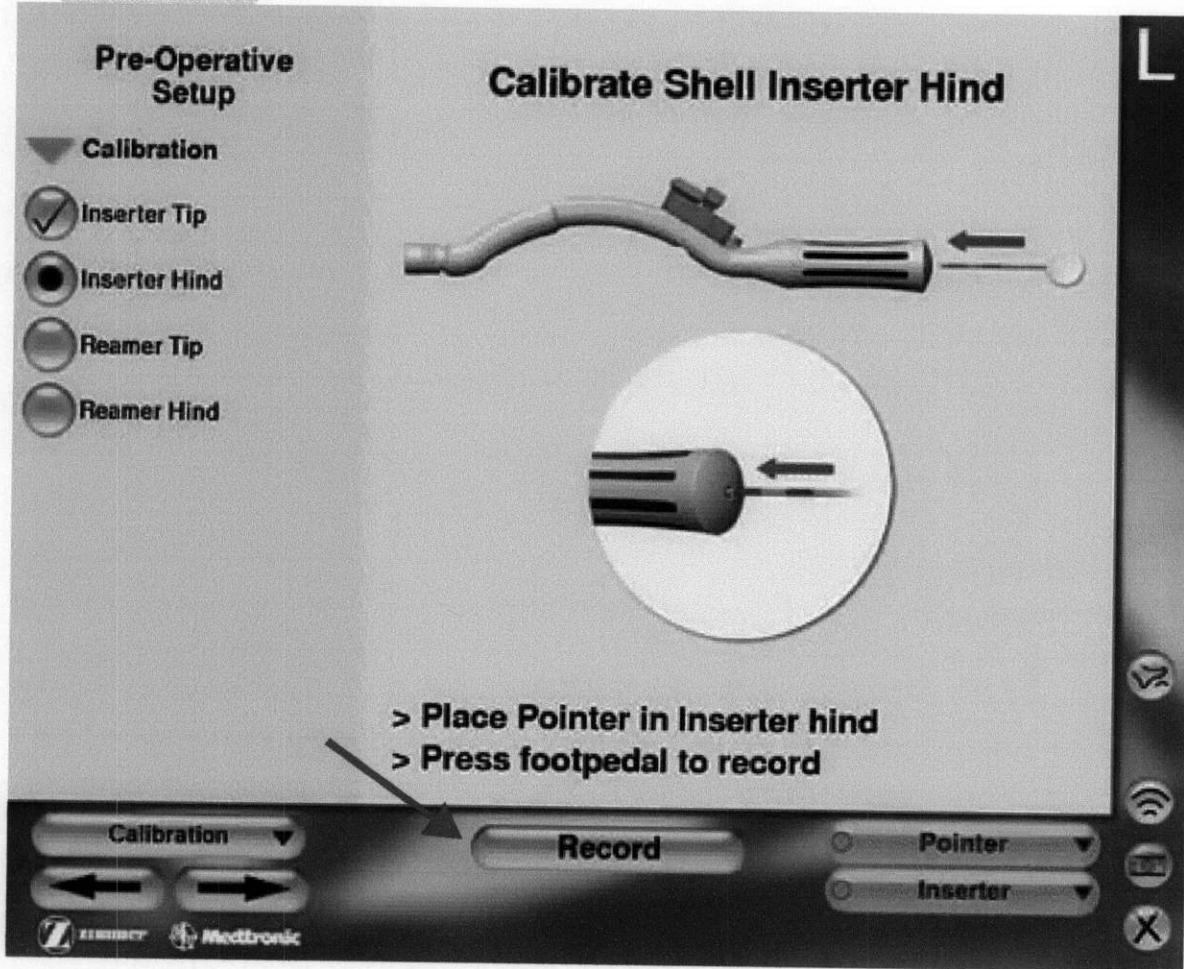


CALIBRATE SHELL INSERTER (CONT.)

5. **Inserter Tip** - Place the tip of the AxiEM™ Pointer in the divot located in the calibration tip, hold the pointer steady, and press the footswitch or click the **[Record]** button.
6. **Inserter Hind** - Place the tip of the AxiEM™ Pointer in the divot located in the hind of the Inserter handle, hold the pointer steady, and press the footswitch or click the **[Record]** button.

The system emits a positive audio tone (bink) for the Tip and Hind steps when the calibration point is successfully recorded.

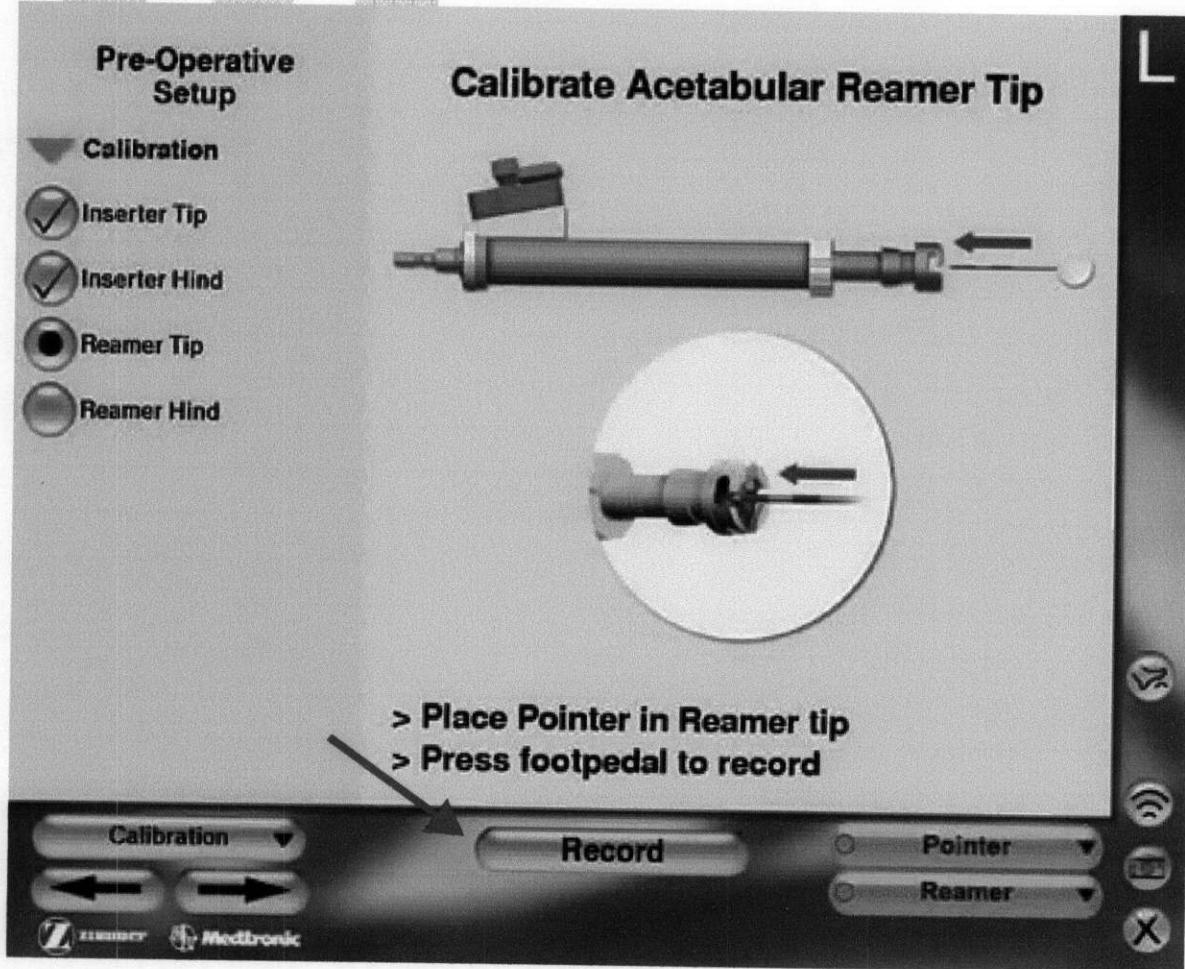
The application software displays an error message and the system emits a negative audio tone (bonk) if the attempted calibration point is more than 4mm from the nominal position.



CALIBRATE ACETABULAR REAMER

26

1. Attach the AxiEM™ Instrument Tracker to the Reamer Handle.
 - a. If necessary, wipe clean the handle attachment site.
 - b. Slide the AxiEM™ Instrument Tracker onto the pins located on the Reamer Handle and Tighten the AxiEM™ Instrument Tracker mounting screw.
2. Make sure that the AxiEM™ Instrument Tracker is plugged into the Connector Box and the status indicator is green.
3. Make sure the AxiEM™ Pointer is plugged into the Connector Box and the status indicator is green.

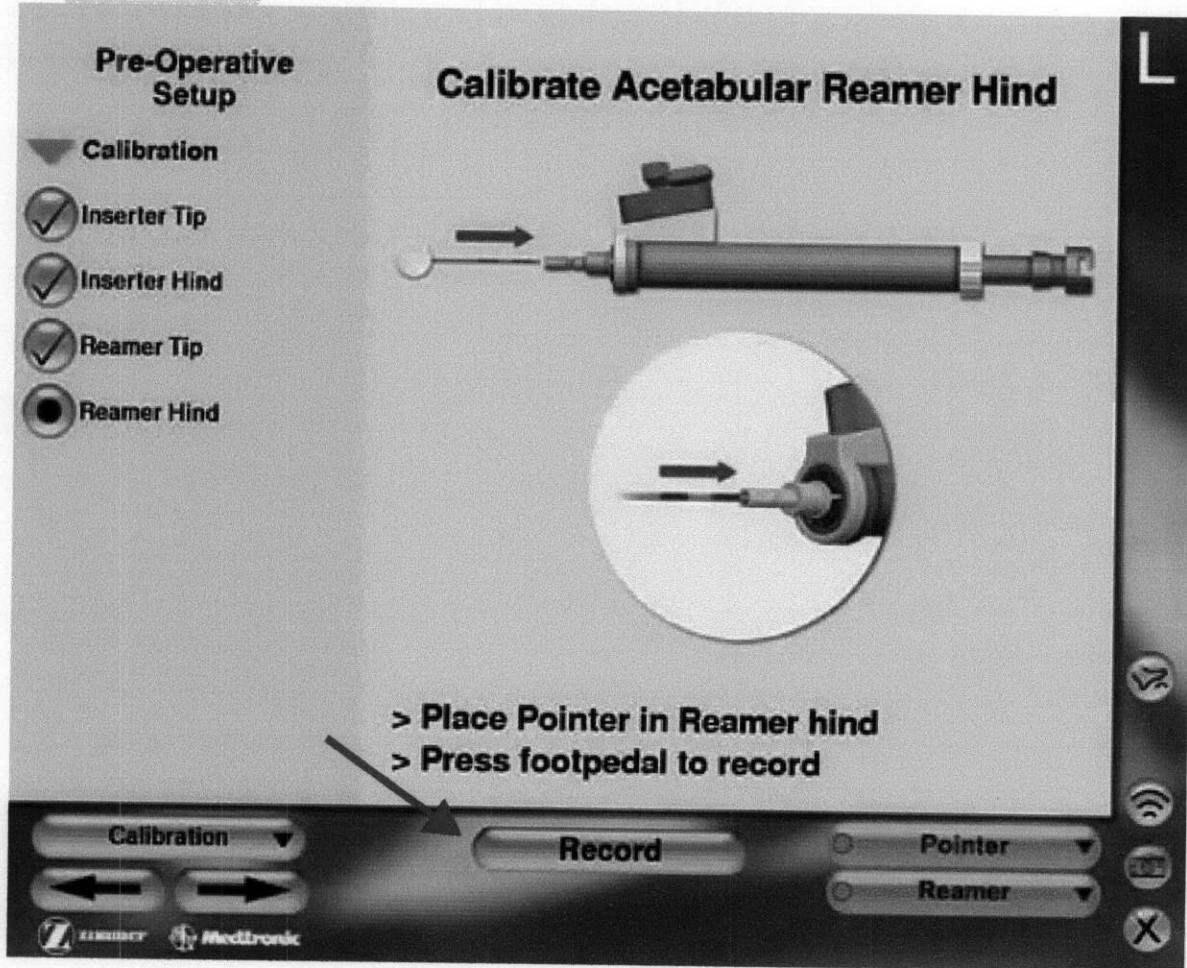


CALIBRATE ACETABULAR REAMER (CONT.)

4. **Reamer Tip** - Place the tip of the AxiEM™ Pointer in the divot located in the tip of the Reamer shaft, hold the pointer steady, and press the footswitch or click the **[Record]** button.
5. **Reamer Hind** - Place the tip of the AxiEM™ Pointer in the divot located in the hind of the Reamer shaft, hold the pointer steady, and press the footswitch or click the **[Record]** button.

The system emits a positive audio tone (bink) for the Tip and Hind steps when the calibration point is successfully recorded.

The application software displays an error message and the system emits a negative audio tone (bonk) if the attempted calibration point is more than 4mm from the nominal position.

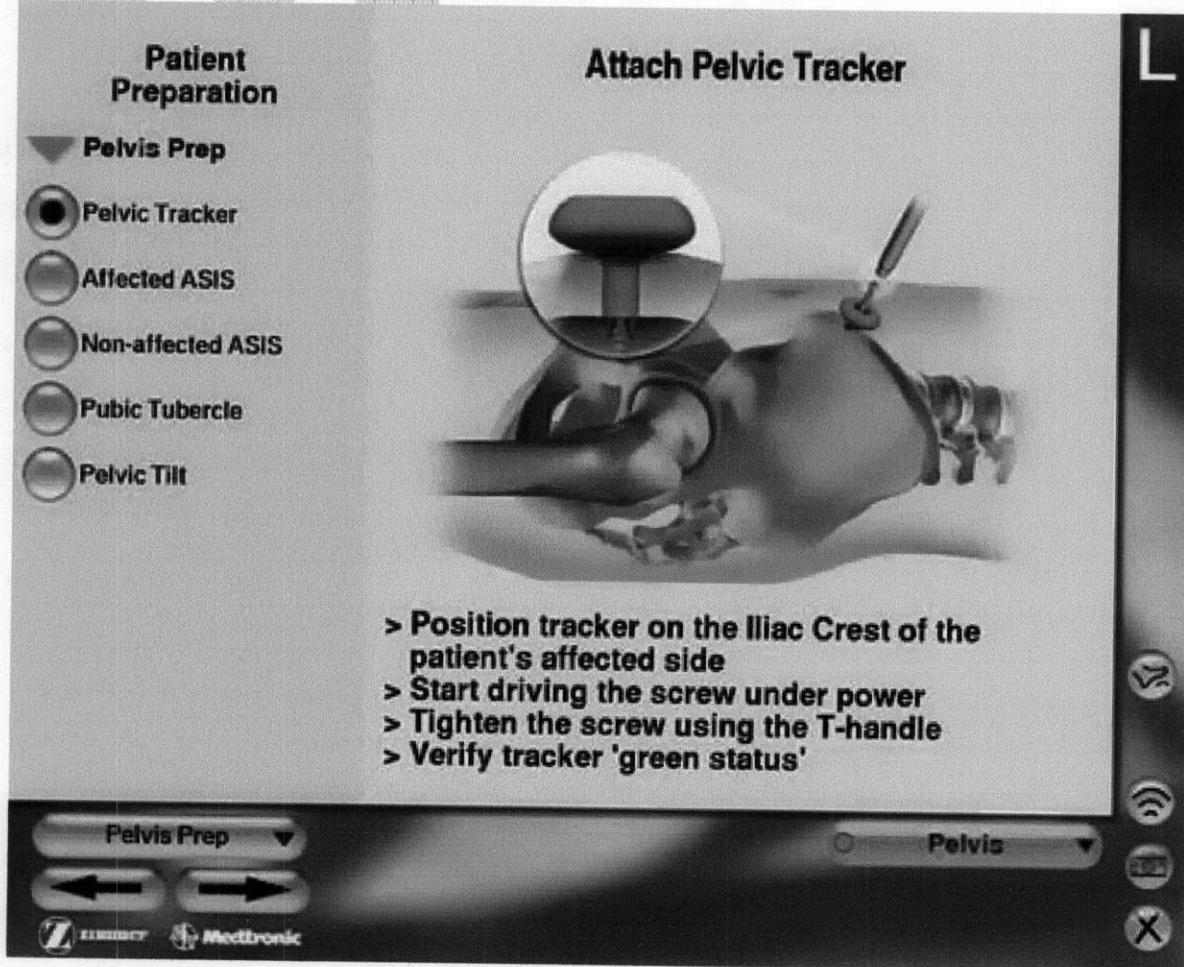


ATTACH PELVIS TRACKER

28

Attach the AxiEM™ Pelvis Tracker to the patient's iliac crest.

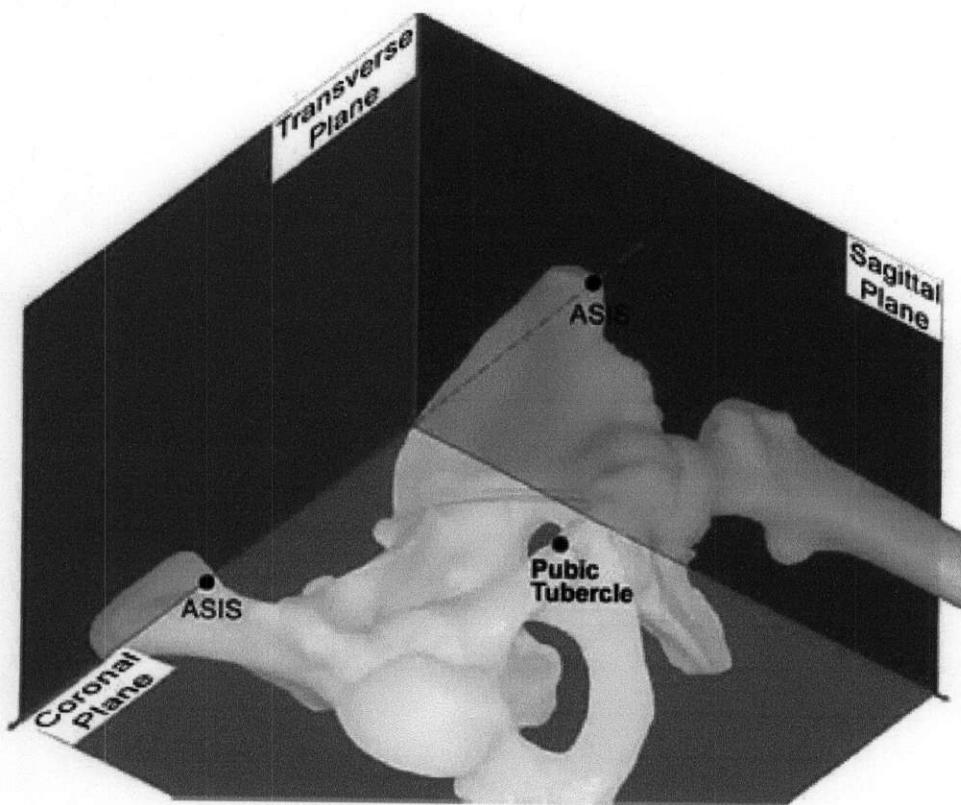
1. Make a small incision at the attachment location.
2. Place the tracker cannula through the incision onto the iliac crest so that the tracker's mounting teeth contact bone.
3. Drive the mounting screw into the bone under power.
4. Tighten the screw by hand with the ratcheting T-handle.
5. Make sure that the Pelvis Tracker status indicator is green.



LANDMARKS AND COORDINATE SYSTEM

- △ The patient-specific coordinate system created by the software from user-identified landmarks assumes typical anatomy at the landmark sites. Significant deformity or irregularity at these sites may produce unexpected navigation angles.

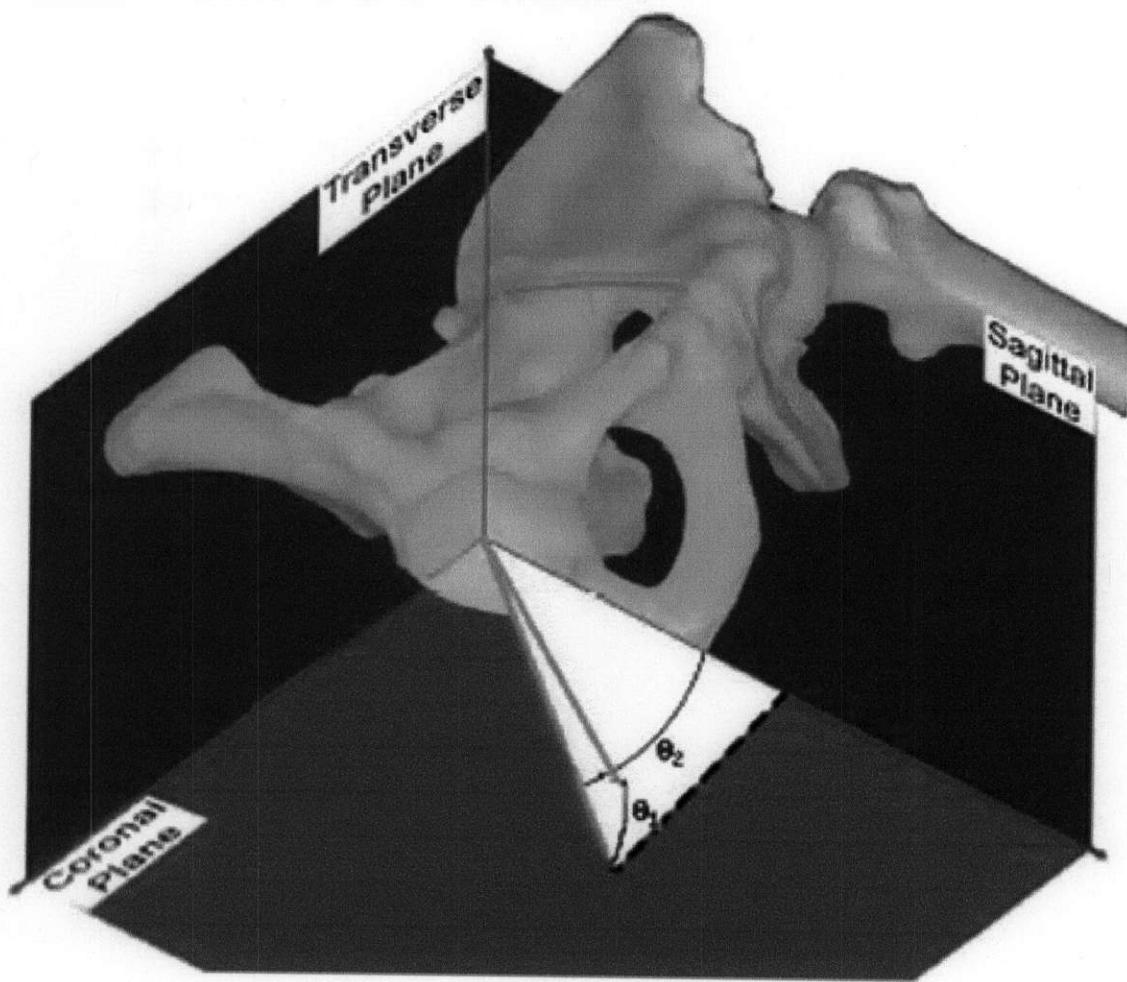
The Anterior Pelvic Plane (APP) can be described as the coronal plane passing through both Anterior-Superior Iliac Spine points and both Pubic Tubercles. The sagittal plane is perpendicular to the APP along the midline of the body. And the transverse plane is perpendicular to the APP and Sagittal planes. The anteversion and inclination values reported by the application software are directly related to the orientation of the surgical instrument with respect to these planes. The diagram below shows the anatomic planes constructed by the landmarks.



LANDMARKS AND COORDINATE SYSTEM (CONT.)

30

The angle θ_1 in the image below (known as radiographic anteversion) is the acetabular anteversion value reported by the application software. This is the angle between the axis of the shell implant (normal to the face of the shell) and the anterior coronal plane. The angle θ_2 (also known as radiographic inclination) is the acetabular inclination value reported by the application software. This is the angle between the projection of the surgical instrument onto the coronal plane and the SI axis of the pelvis.



58

LANDMARKS AND COORDINATE SYSTEM (CONT.)

Nominal accuracy of angle measurements displayed by the software is obtained if the anterior pelvic plane landmarks are recorded without soft tissue between the probe tip and the bone or with equal amounts of soft tissue covering each landmark. The accuracy of angle measurements will be affected by how accurately the landmarks are recorded. If the landmarks cannot be closely palpated on soft tissue and accurately recorded, percutaneous landmarking may be performed through a puncture or small incision. Proper sterile preparation of the landmark sites should be considered based on the landmarking method chosen.

Published data has indicated that landmarking on the skin could cause misinterpretation of measured angles by up to about 3° under normal conditions as compared to percutaneous landmarking¹. While the angle calculations in the software are less sensitive to variation in the location of the ASIS landmarks than to differences in the soft tissue depth over landmarks, care should be taken to record the ASIS points symmetrically on the patient.

¹Richolt JA, et al, "How Does Soft Tissue Distribution Affect Anteversion Accuracy of the Palpation Procedure in Image-Free Acetabular Cup Navigation? An Ultrasonic Assessment.", Computer Aided Surgery, March 2005; 10(2): 87-92.

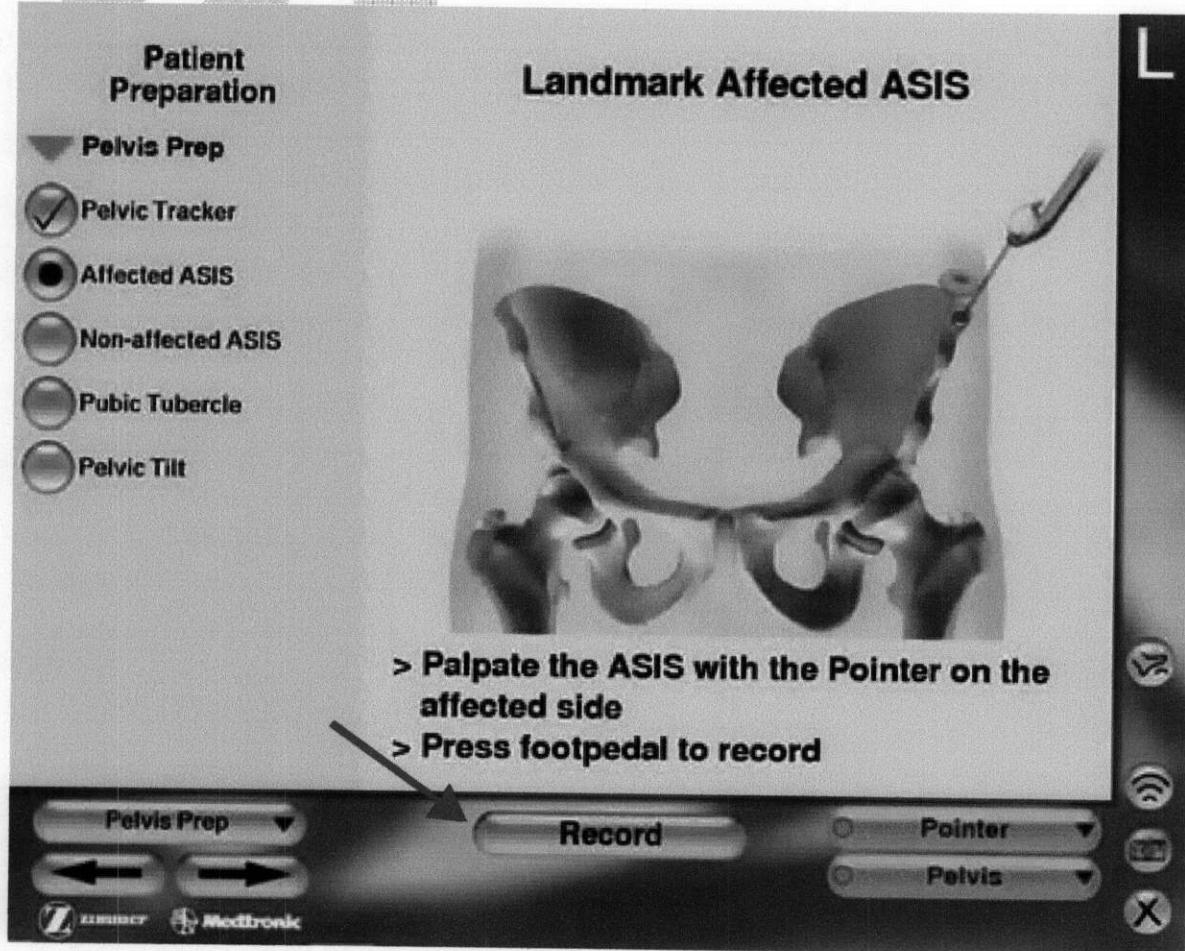
DIGITIZE PELVIC LANDMARKS

32

When digitizing landmarks, keep the Medtronic Logo on the emitter parallel to the floor. Do not rotate the AxiEM™ Mobile Emitter about its central axis. Make sure that the AxiEM™ Pointer and the Pelvic Tracker status indicators are green. If a tracker status indicator is red, the application software will not record landmarks.

1. Place the tip of the AxiEM™ Pointer on the affected anterior superior iliac spine (ASIS) and press the footswitch or click the [Record] button.

The system emits a positive audio tone (bink) when a landmark is successfully recorded and a negative audio tone (bonk) when a landmark is not recorded.

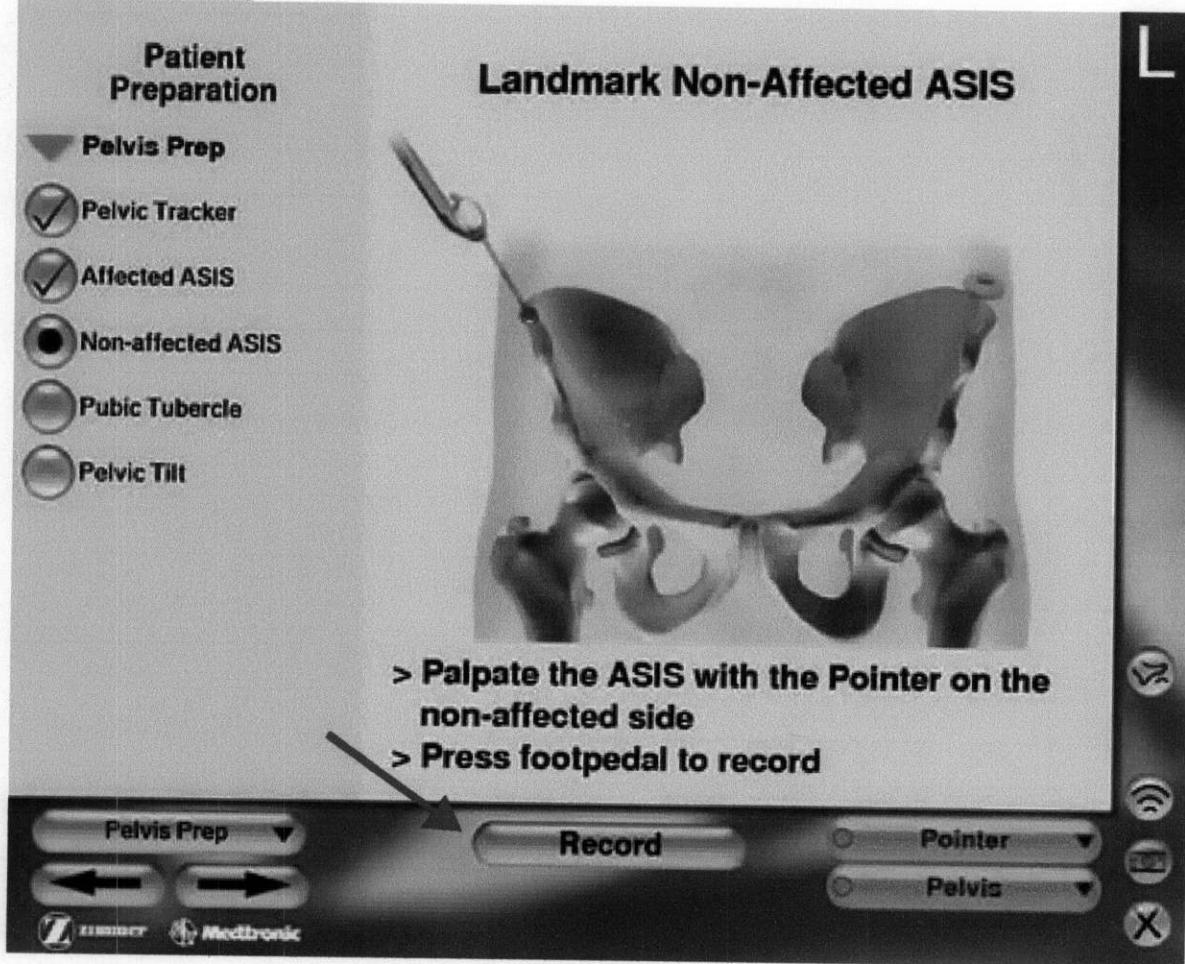


DIGITIZE PELVIC LANDMARKS (CONT.)

You may re-capture a landmark at any time during patient preparation by clicking the button to the left of the landmark and re-digitizing the landmark on the anatomy.

2. Place the tip of the Pointer on the non-affected ASIS and press the footswitch or click the [Record] button.

Note: The ASIS is actually a region of bone, not an exact point. The key to recording these two landmarks is to pick the same point within the ASIS region on both the affected and non-affected sides. Acetabular inclination will be most affected by the symmetry of these landmarks.



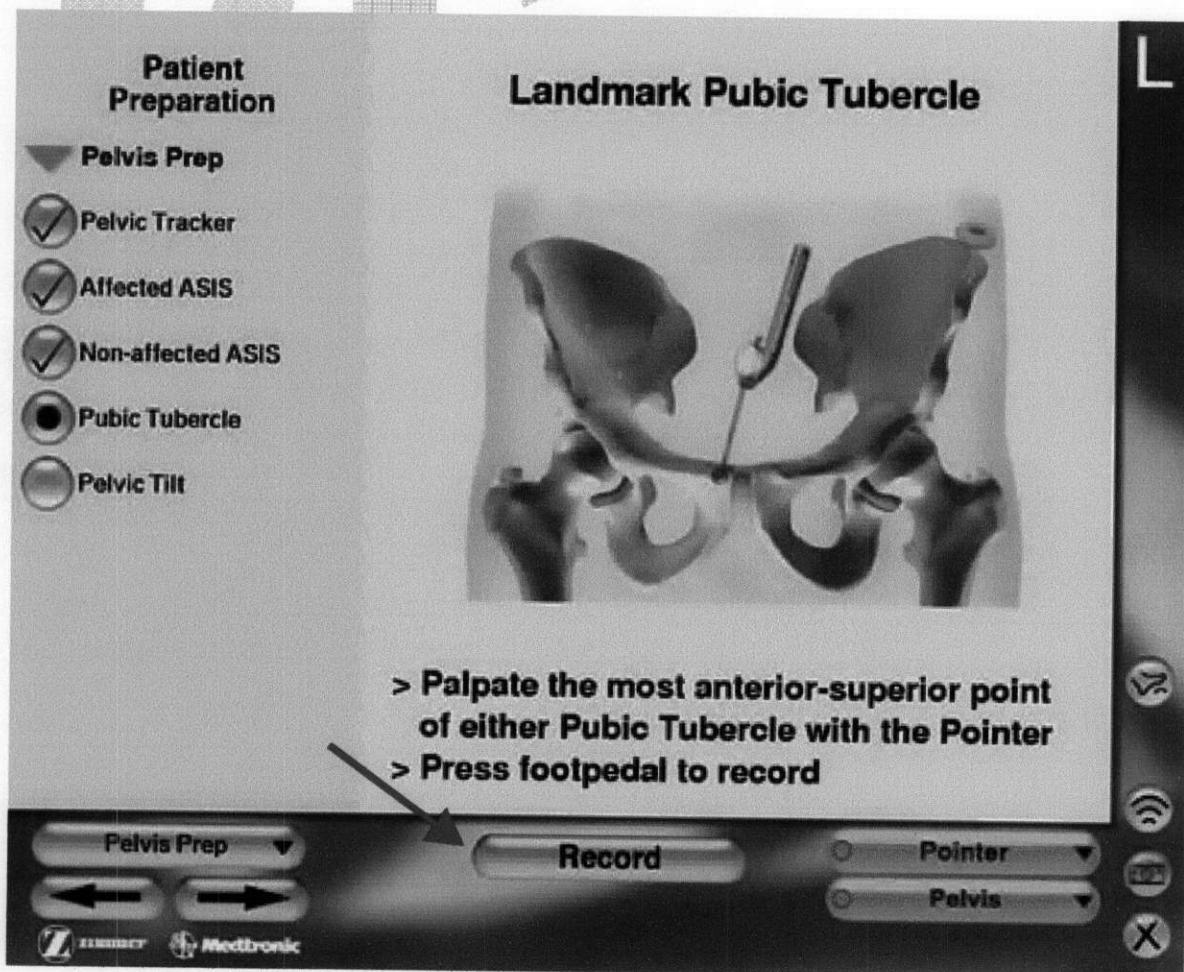
DIGITIZE PELVIC LANDMARKS (CONT.)

34

3. Place the tip of the Pointer on one of the pubic tubercles and press the footswitch or click the [Record] button.

Note: The pubic tubercles may be difficult to palpate so a point on the anterior-most aspect of the pubic bone may be used to establish the APP. Acetabular anteversion will be most affected by the depth of this landmark to the bone.

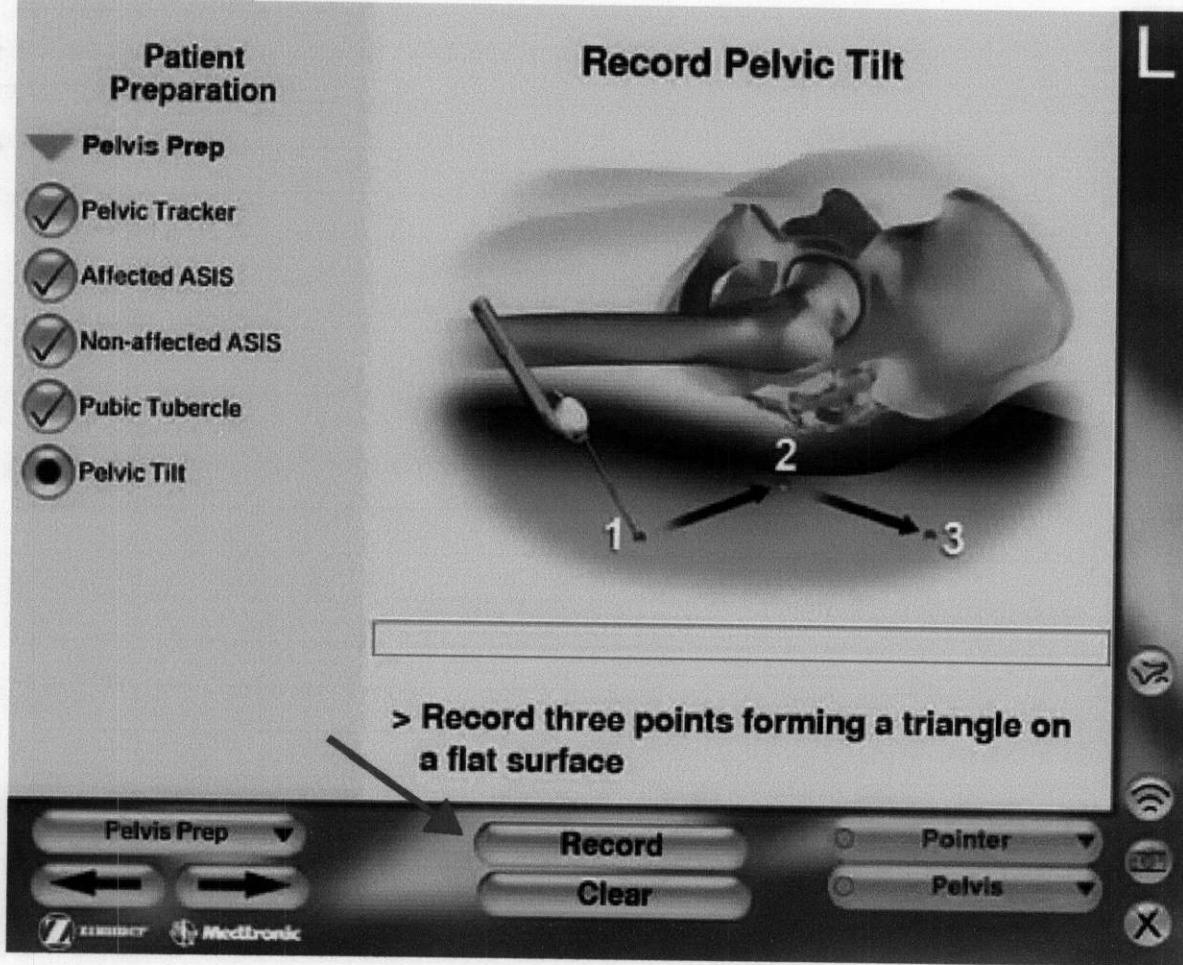
After successfully digitizing all pelvic landmarks, the application software automatically advances to the next task.



RECORD PELVIC TILT

The digitized points used to estimate Pelvic Tilt must be at a minimum distance of 100mm from each other and must form a near-triangular shape (they must not lie in a straight line). The software will report the angles between the patient's anterior pelvic plane and the plane digitized during this step to approximate the patient's natural pelvic tilt.

1. Hold the AxiEM™ Pointer on the table (supine) or back support (lateral) and press the footswitch or click the [Record] button.
2. Move the pointer to a second location (at least 100mm away) and press the footswitch or click the [Record] button.

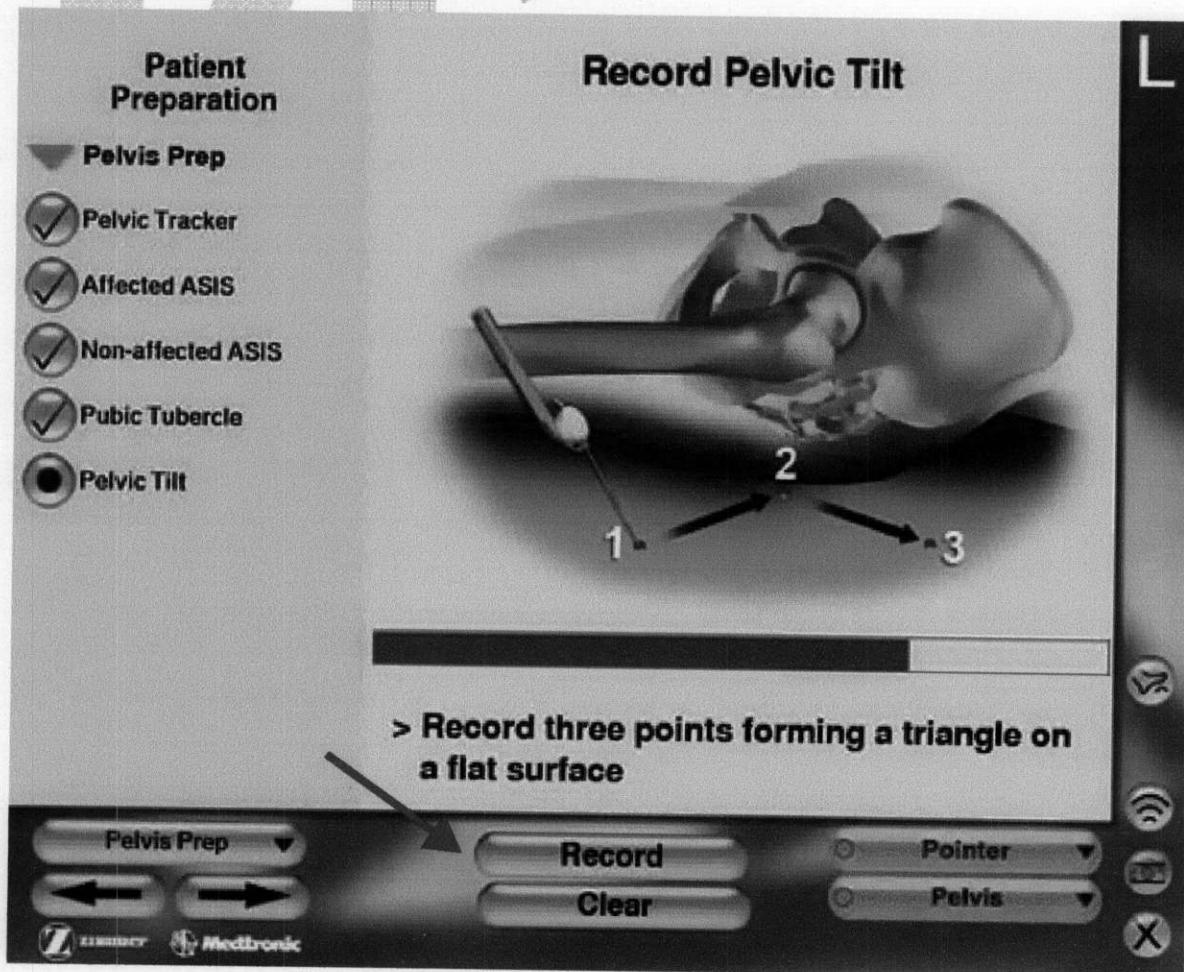


RECORD PELVIC TILT (CONT.)

3. Move the pointer to a third location to form a triangle and press the footswitch or click the **[Record]** button.

You may re-capture the previous checkpoint by clicking **[Clear]** and re-digitize the checkpoint on the anatomy.

The software application will calculate the tilt (flexion/extension) of the pelvis relative to the digitized plane. During navigation, acetabular angles adjusted for A/P pelvic tilt are displayed in addition to the standard radiographic angles.



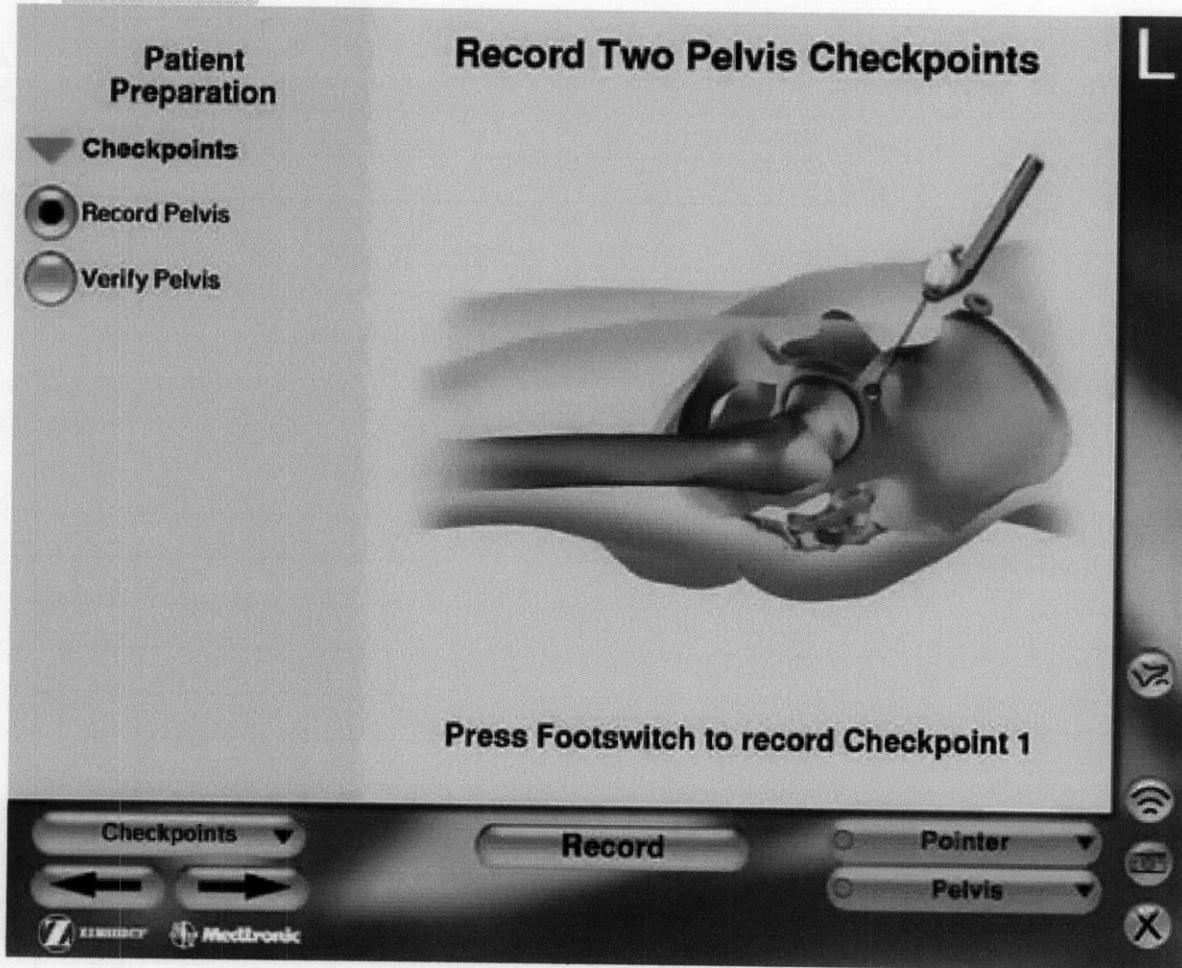
64

CREATE PELVIS CHECKPOINT

Digitize accuracy checkpoints to create a fixed reference used to determine if the AxiEM™ trackers have shifted with respect to the patient's anatomy at any time during the procedure.

1. Place the AxiEM™ Pointer on a recognizable anatomic point or user-created mark near the acetabulum
2. Hold the Pointer steady and press the footswitch or click the [Record] button. This records the pelvis checkpoint.

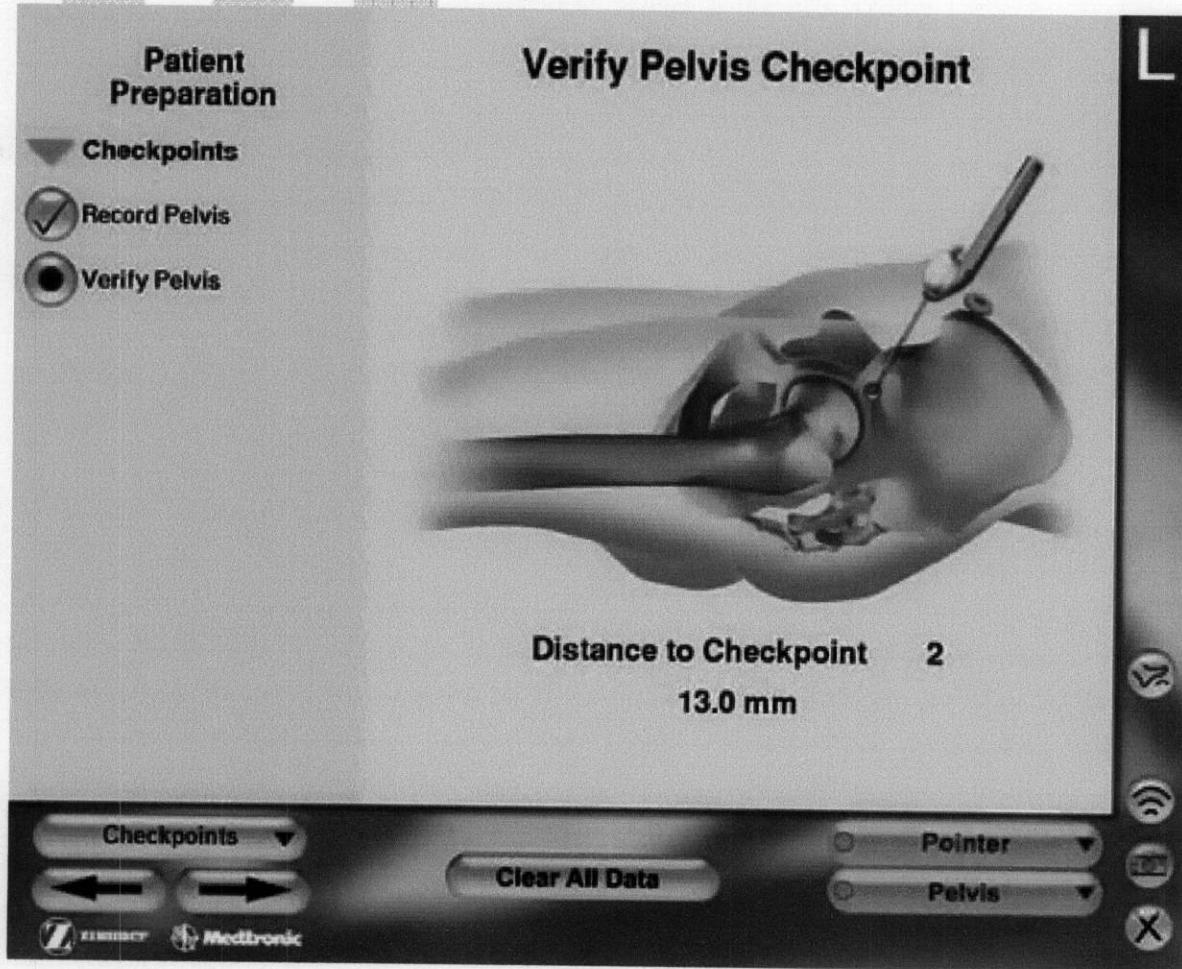
You may re-capture a checkpoint by clicking [**Clear All Data**] and re-digitizing the checkpoint on the anatomy.



VERIFY PELVIS CHECKPOINT

1. Remove the Pointer from the navigation field and return it to the pelvis checkpoint
2. Observe the relationship between the position of the Pointer on-screen and its physical location on the anatomy. Observe the distance display and verify that the distance is less than 2mm.

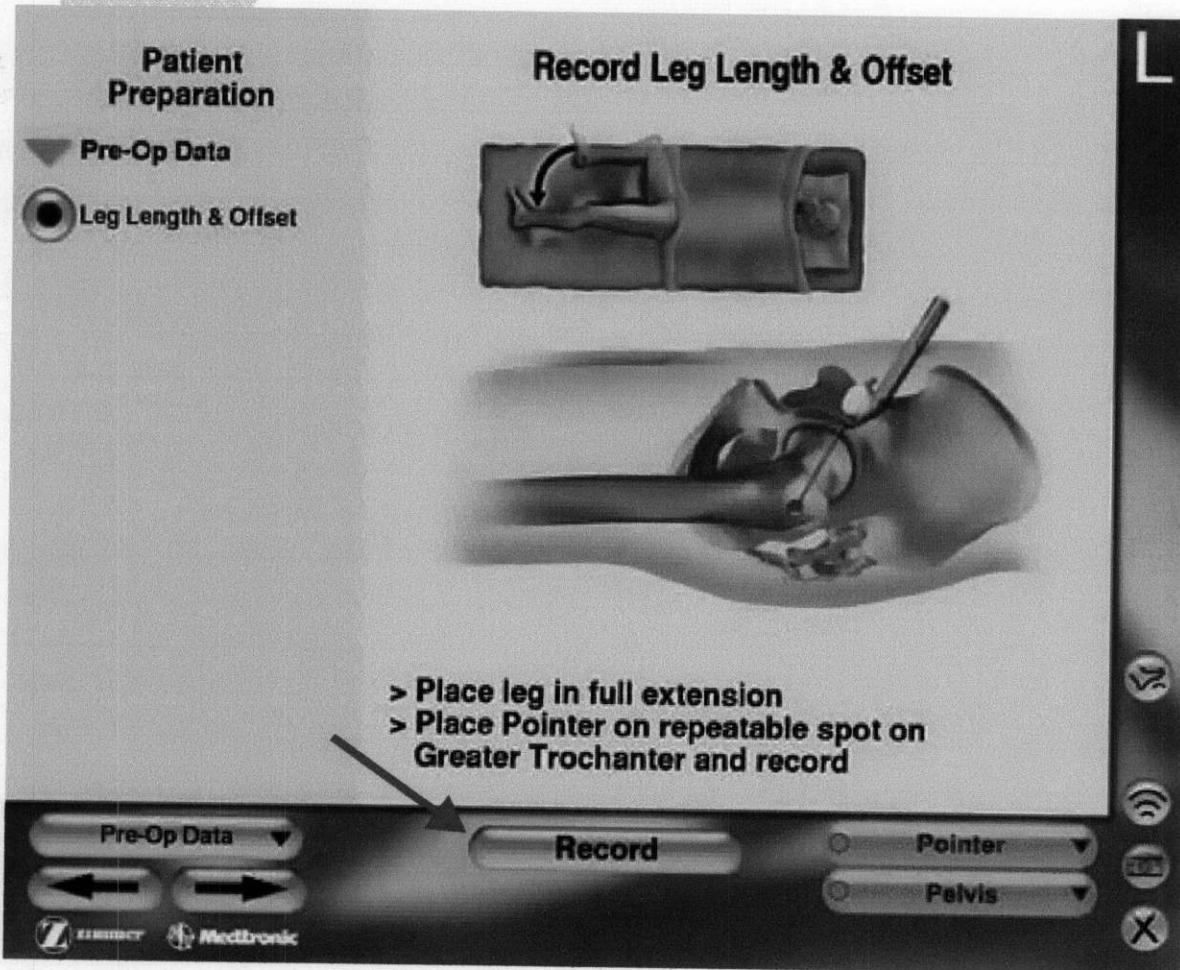
Note: if you suspect the Pelvis Tracker has moved or become dislodged during the procedure, return to the Checkpoint task and use the Pointer to verify that the checkpoint distance is still less than 2mm. If checkpoint verification fails, you may go back to the Pre-Operative Setup task and re-digitize landmarks.



RECORD PRE-OP LEG LENGTH AND OFFSET

1. Place the leg in full extension, parallel to the anterior pelvic plane. Make note of this leg position in order to return the leg to this position for post-op leg length and offset assessment.
2. Place the tip of the AxiEM™ Pointer on the apex of the greater trochanter.
3. Press the footswitch or click the [Record] button.

The system emits a positive audio tone (bink) when the pre-op data is successfully recorded and a negative audio tone (bonk) when the data is not recorded.

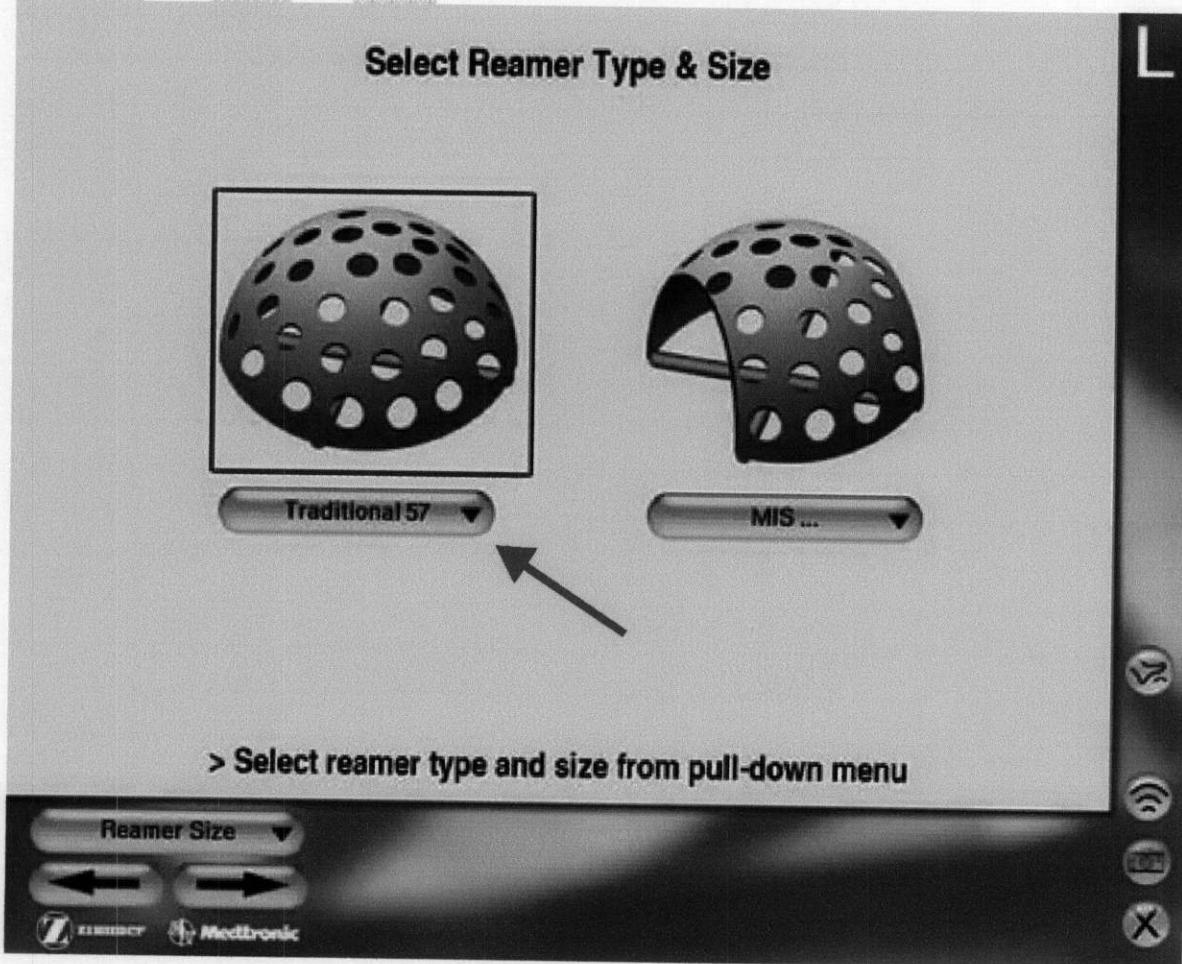


SELECT REAMER

40

Select the type and size of reamer to be used in the procedure.

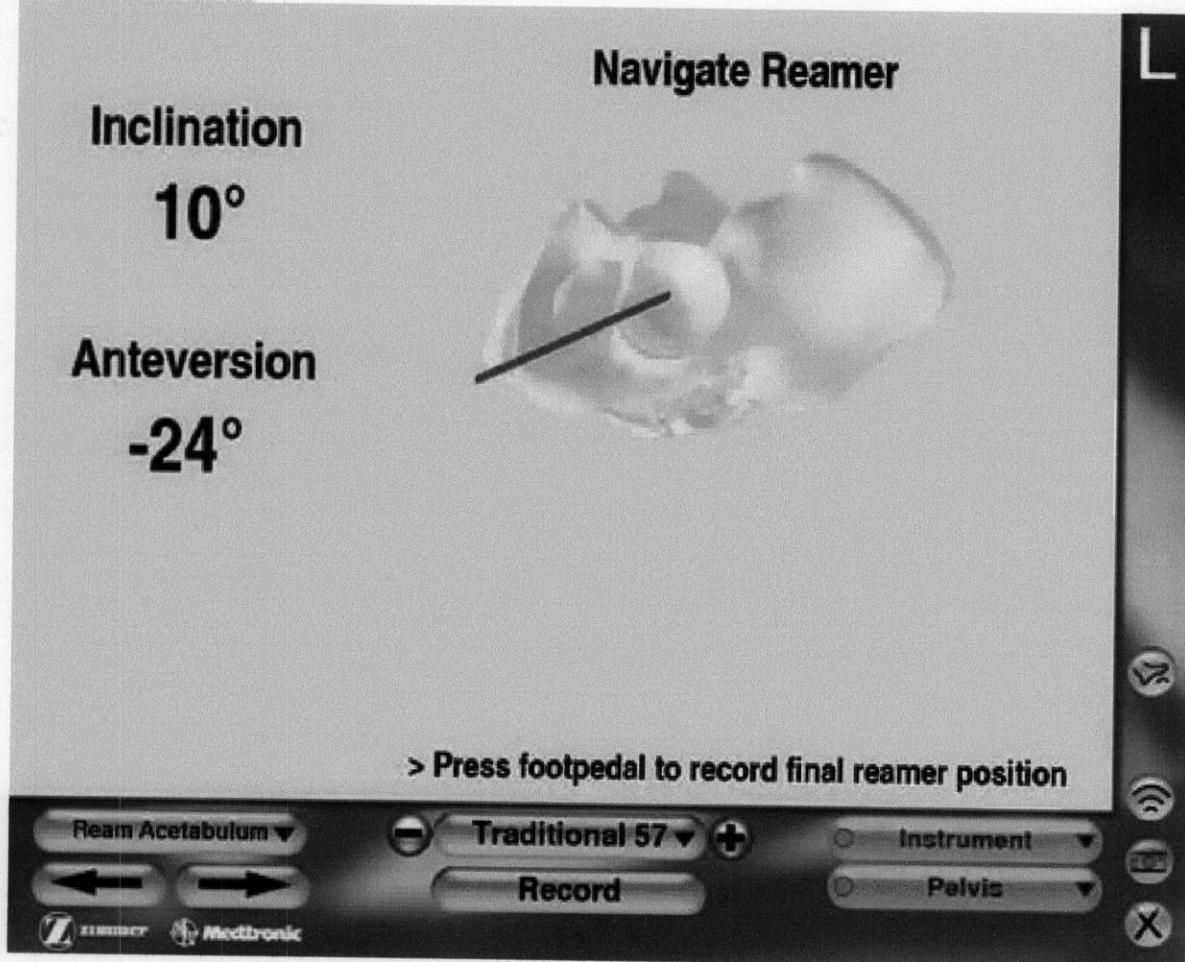
1. If you are using a traditional style (full dome) reamer, click **[Traditional]** to select the initial traditional reamer size.
2. If you are using the MIS style (truncated sides) reamer, click **[MIS]** to select the initial MIS reamer size.



NAVIGATE REAMER

When navigating, keep the Medtronic Logo on the AxiEM™ Mobile Emitter parallel to the floor. Do not rotate the emitter about its central axis. Make sure that the Pelvic Tracker status indicator is green, and that the acetabular reamer is selected and the status indicator is green.

1. Attach the correctly sized reamer dome to the reamer shaft.
Make sure that the dome is locked into the tip of the shaft.
2. Position the pelvic reamer in the anatomy.
Use the targeting values to orient the reamer to the target anteversion and inclination angles.



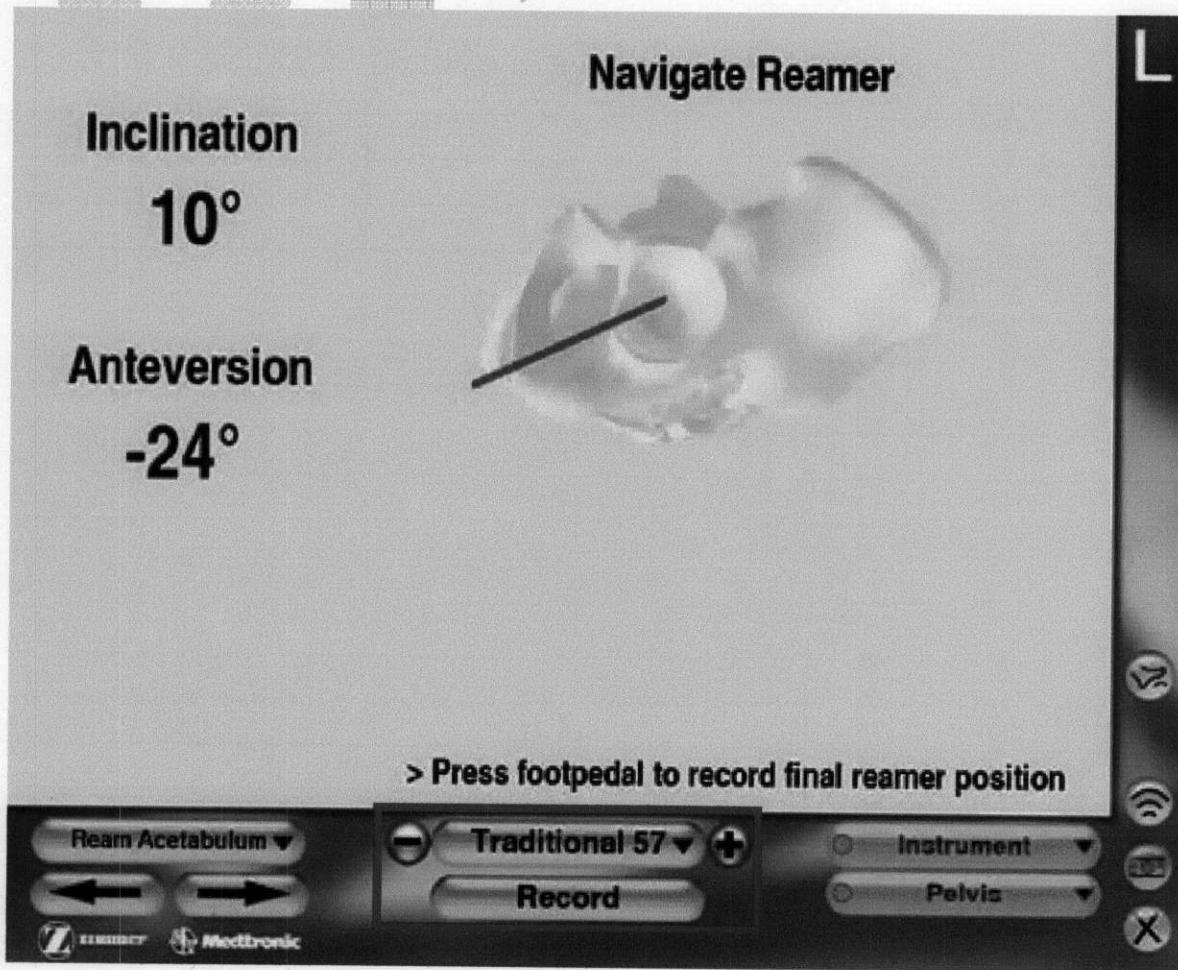
NAVIGATE REAMER (CONT.)

3. Ream the acetabulum according to standard surgical technique.

The software displays the real-time inclination and anteversion angles.

4. Make sure to increment the reamer size in the software using the pull-down menu or the [+] and [-] each time a new reamer shell size is used.
5. Click the **[Record]** button to record the final reamer position for the patient file.

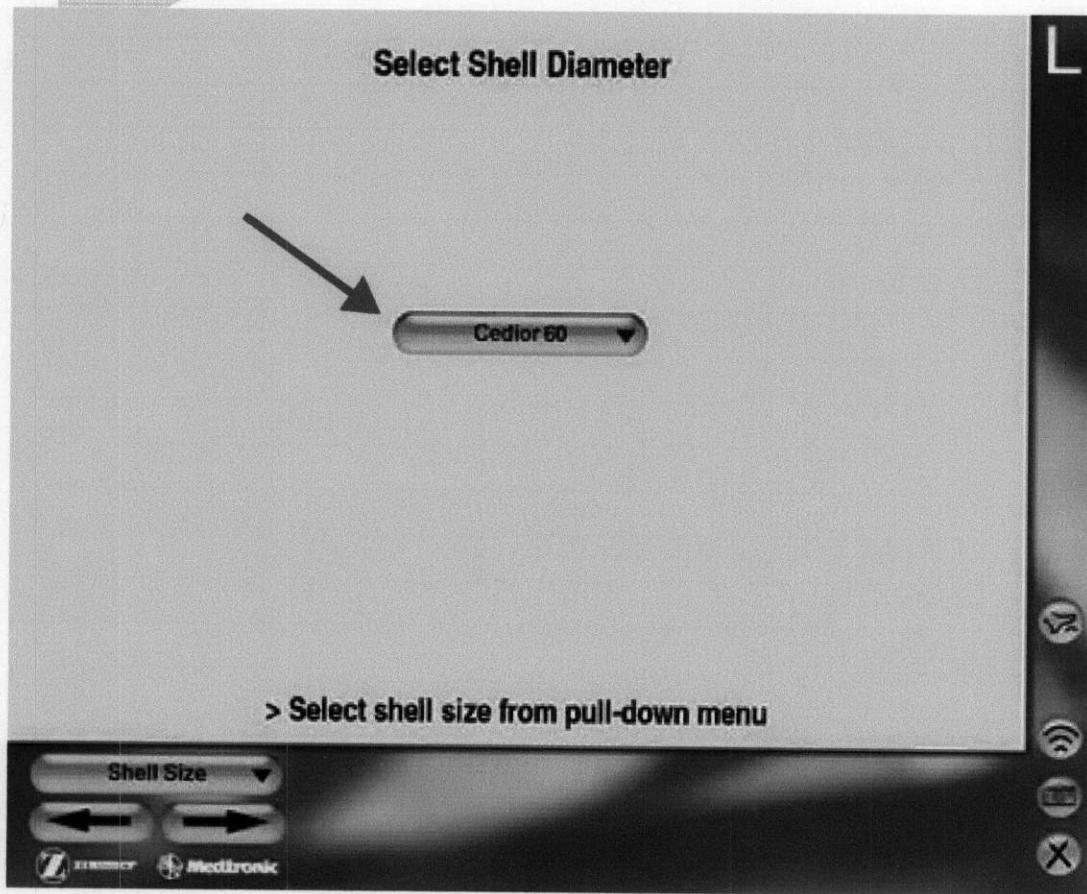
The final reamer position values are frozen on-screen.



SELECT SHELL SIZE

Select the size of the acetabular shell to be used in the procedure.

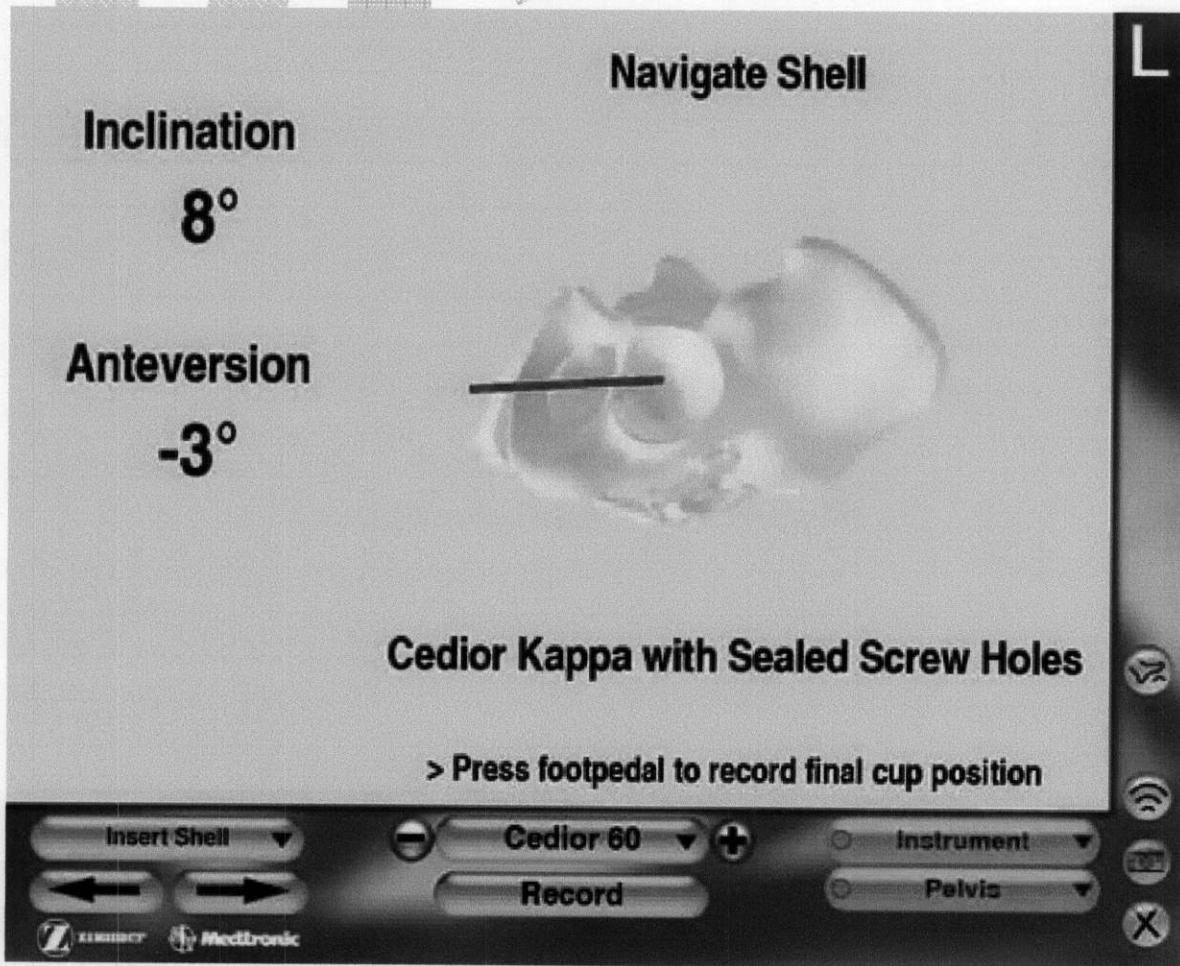
1. Select the shell size from the pull-down menu.



NAVIGATE SHELL

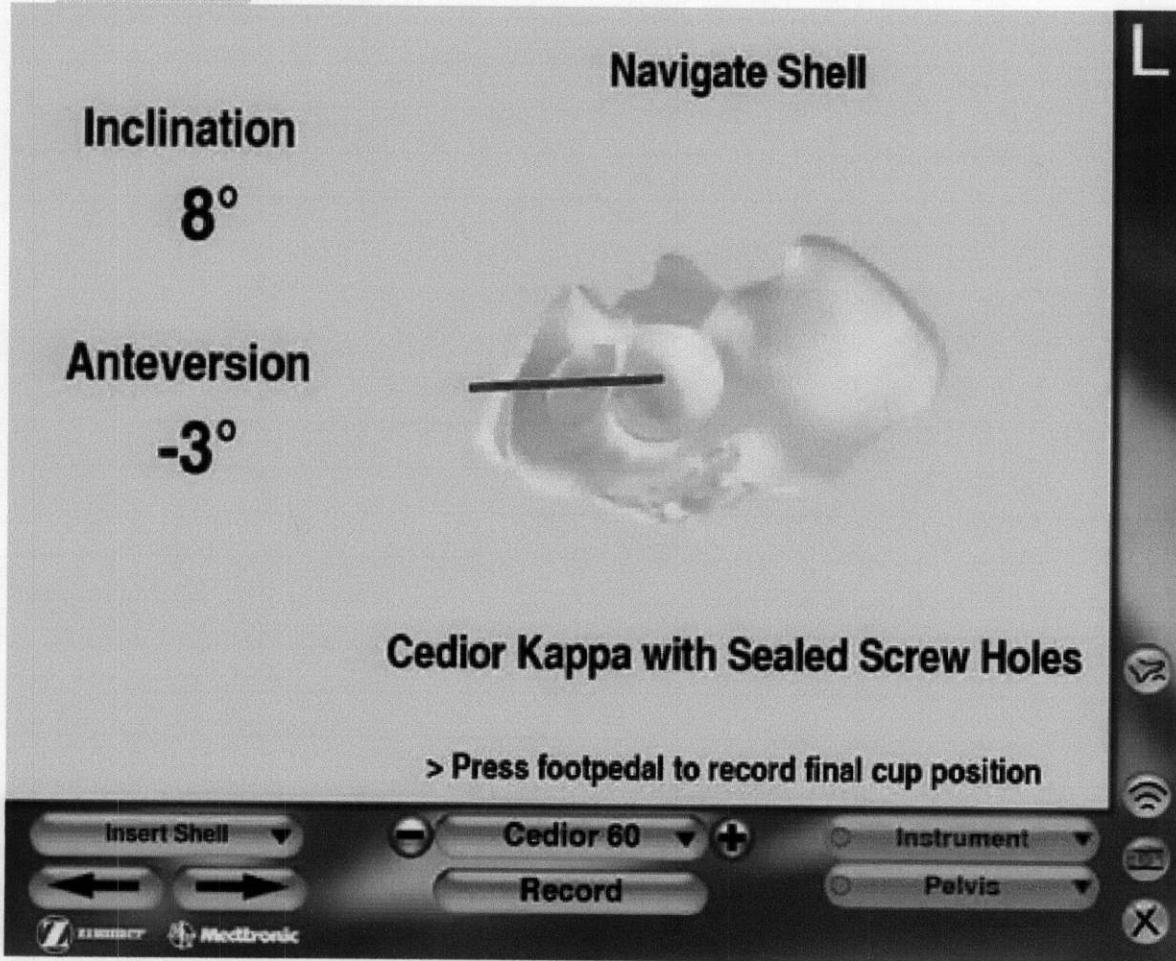
When navigating, keep the Medtronic Logo on the AxiEM™ Mobile Emitter parallel to the floor. Do not rotate the emitter about its central axis. Make sure that the Pelvic Tracker status indicator is green, and that the inserter is selected and its status indicator is green.

1. Make sure that the Pelvic Tracker status indicator is green.
2. Make sure the shell inserter is selected and the status indicator is green.
3. Attach the correctly sized acetabular shell to the inserter.



NAVIGATE SHELL (CONT.)

4. Insert the shell prosthesis into the anatomy.
Use the targeting views to orient the shell to the target anteversion and inclination angles.
5. Implant the prosthesis within the acetabulum using standard surgical technique.
6. Press and release the footswitch or click [Record] to freeze the final acetabular shell position in the software. Final position information displays on-screen.
7. Detach the implant from the inserter according to standard surgical technique, and remove the shell inserter.

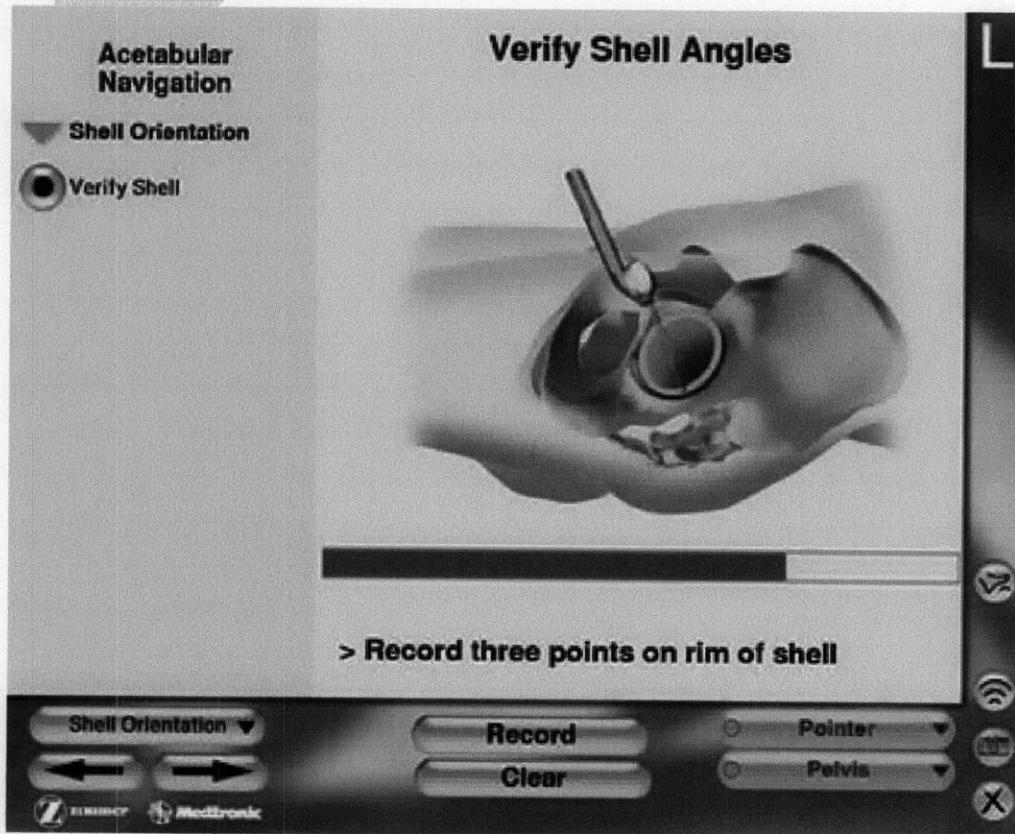


VERIFY SHELL

Verify that the acetabular prosthesis has not moved since insertion (for example, when inserting fixation screws) by digitizing three points in the face of the shell.

1. Place the AxiEM™ Pointer on a discreet point on the face of the implanted shell and press the footswitch or click [Record].
2. Place the AxiEM™ Pointer on another discreet point 20mm away from the first point on the face of the implanted shell. Press the footswitch or click [Record].
3. Place the AxiEM™ Pointer on a third discreet point 20mm away from the other points on the face of the implanted shell. Press the footswitch or click [Record].

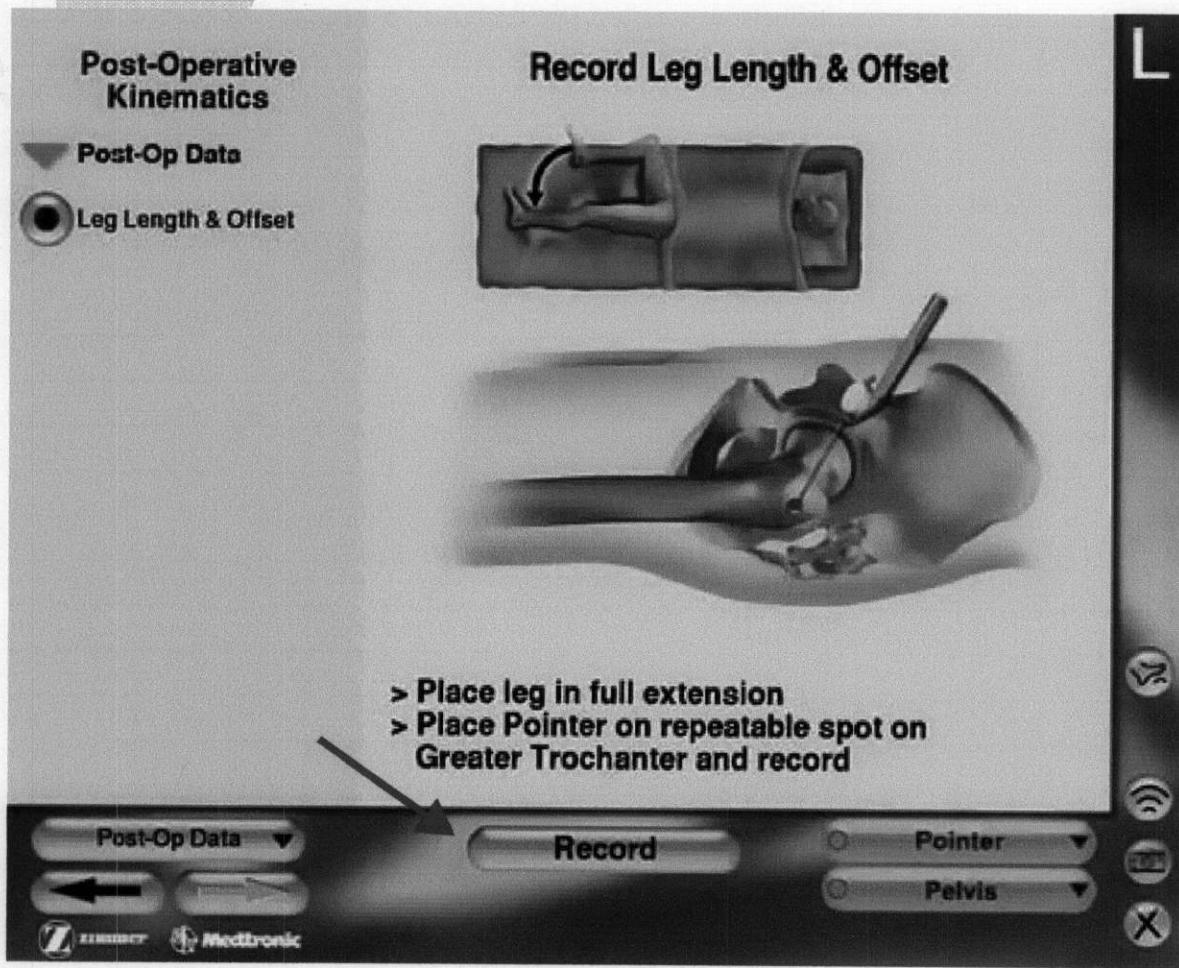
The application software displays the inclination and anteversion angles of the cup.



CAPTURE POST-OP LEG LENGTH & OFFSET

1. Place the leg in full extension, parallel to the anterior pelvic plane in the same manner and position that was used to record the pre-operative leg length and offset.
2. Place the tip of the AxiEM™ Pointer on the apex of the greater trochanter in the same spot used to record the pre-operative point.
3. Press the footswitch or click the [Record] button.

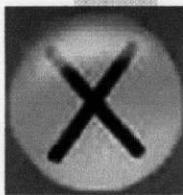
The application software displays the change in leg length and offset.



EXIT THE APPLICATION SOFTWARE

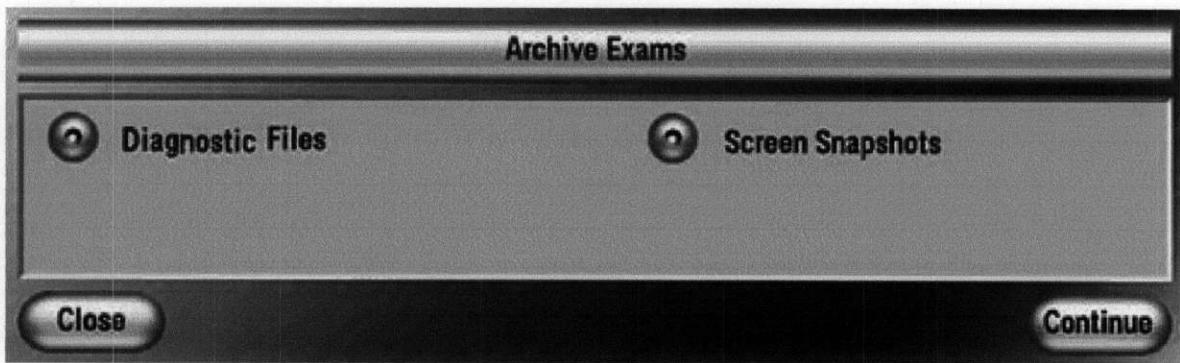
1. Click the **Exit** button in the main application window.
2. Click **[Yes]** to confirm that you want to exit.

The manage exams window displays.



ARCHIVE

1. Click **[Archive]** in the manage exams window.
2. Select each patient exam you wish to archive.
3. Choose which type of data you would like to archive.
 - a. Select **Screen Snapshots** to save the images you captured by clicking the snapshot button.
 - b. Select **Diagnostic Files** to save the software log and other diagnostic files created during the exam.
4. Insert an exam archive disk in the CD drive. Wait until the light on the drive stops blinking.
5. Click **[Continue]**. Wait while the OS software archives the selected images to the CD.
6. Click **[Close]** to close the archive exam window or click **[Back]** to return to the manage exams window.



49

77

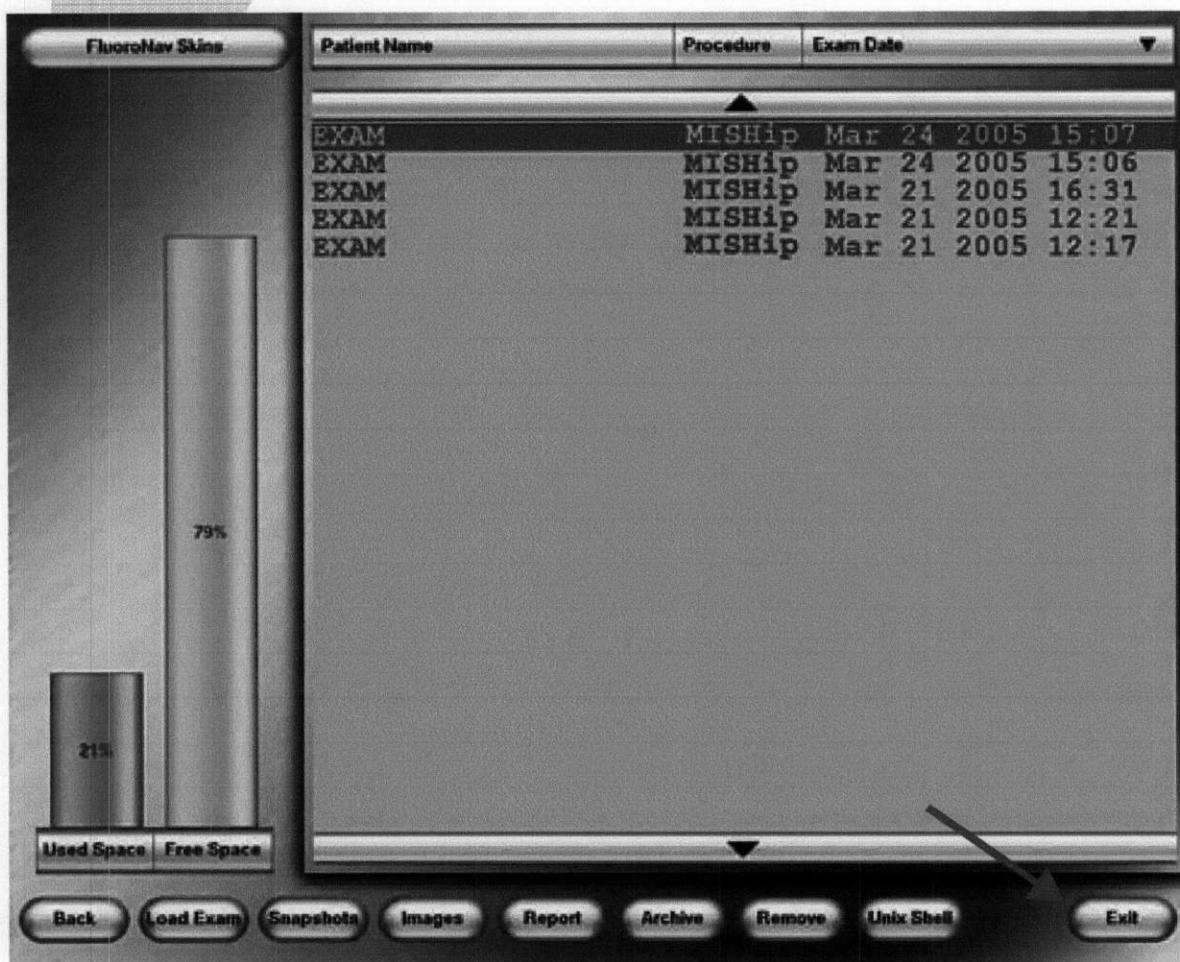
REMOVE EXAMS

1. Click **[Remove]** in the manage exams window.
2. Select one or more patient exams. To deselect a patient exam, click it a second time.
3. Click **[Remove]** to permanently remove the selected exam(s) from the hard disk.



EXIT

1. Click **[Exit]** in the manage exams window and click **[Yes]** to confirm that you want to exit.
The log in screen displays.
2. From the log in screen, double-click the **Shutdown** icon. Wait until the system indicates it is okay to shut off the power.
3. Turn off the system power.



51

79

SYMBOLS

52



The device complies with European Directive MDD 93/42/EEC.



Classified by Underwriters Laboratories Inc. with respect to electric shock, fire, mechanical, and other specified hazards only in accordance with UL2601-1/CAN/CSA C22.2 NO.601.1. Control number 87HJ



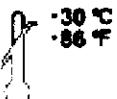
When found in this guide, this symbol means: "Warning! Failure to observe could result in injury or death." When found on equipment, this symbol means: "Attention: consult accompanying documentation."



Caution! Failure to observe could result in damaged equipment, forfeited time or effort, or the need to abort use of the system.



Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.



Do not use in ambient (room) temperature greater than 30° C.



Use by date specified



Single use only. Do not reuse.



Quantity



Sterilized using ethylene oxide.



Sterilized using irradiation.



Protective Earth (Ground)

80

NOTES

53

81

Accuracy of Intraoperative Assessment of Acetabular Prosthesis Placement

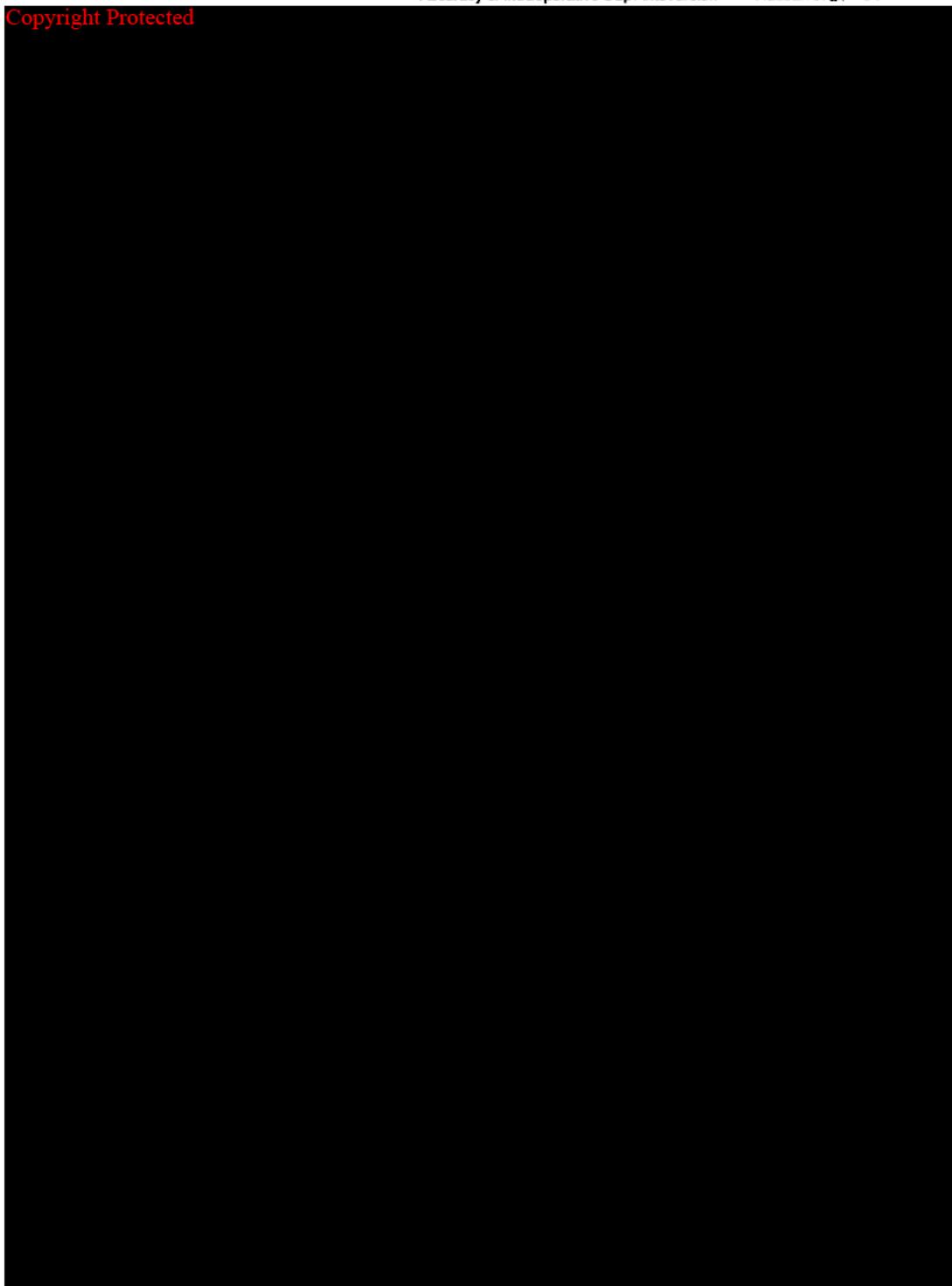
Douglas M. Hassan, MD, FRCSC, Geoffrey H. F. Johnston, MD, FRCSC, FACS,
William N. C. Dust, MD, FRCSC, FACS, Glen Watson, PhD, PEng,
and Allan T. Dolovich, PhD

Abstract: Anteversion and vertical tilt of the acetabular prostheses in 50 consecutive total hip arthroplasties were prospectively evaluated during surgery (by the surgeon, using an alignment guide) and radiographically (calculated). From postoperative standardized radiographs vertical tilt was measured directly and anteversion was calculated. The mean error of vertical tilt was 5° (range, 0°–20°). The mean error of version was 9° (range, 0°–24°). The reliability of prosthesis placement in a predetermined zone was examined. Although the surgeons believed that all 50 cups were inside this zone, radiographic measurements revealed that 21 of the cups were actually outside. It is concluded that vertical tilt can be reasonably assessed during surgery. Anteversion, however, cannot be accurately assessed during surgery, despite use of the alignment guide. **Key words:** hip arthroplasty, cup anteversion, intraoperative accuracy, radiographic calculation.

Copyright Protected

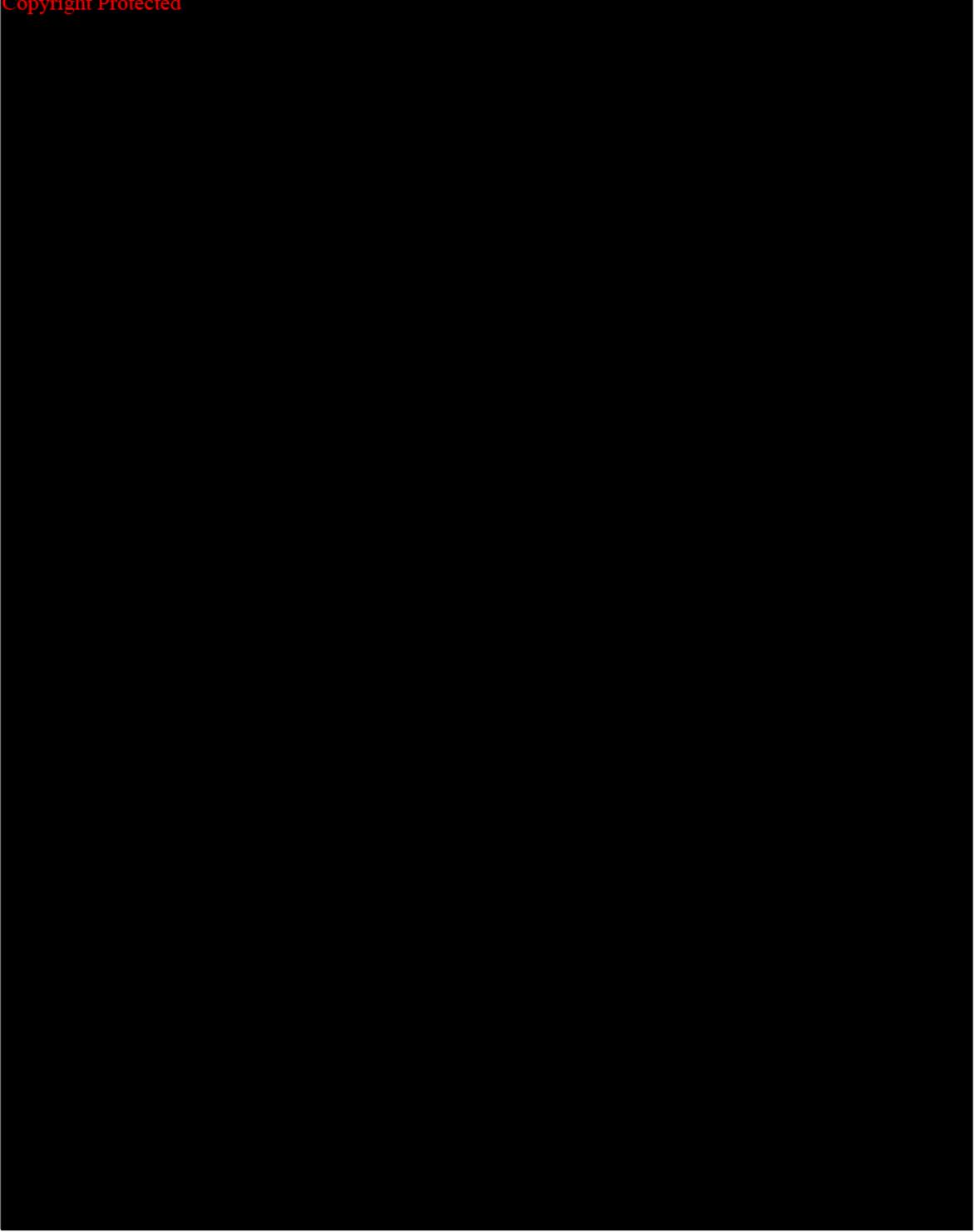


Copyright Protected



83

Copyright Protected



Effect of Acetabular Component Orientation on Recurrent Dislocation, Pelvic Osteolysis, Polyethylene Wear, and Component Migration

J. G. Kennedy, MMSc, FRCSI,* W. B. Rogers, MD,† K. E. Soffe, MB,* R. J. Sullivan, MD,‡ D. G. Griffen, MD,‡ and L. J. Sheehan, MD‡

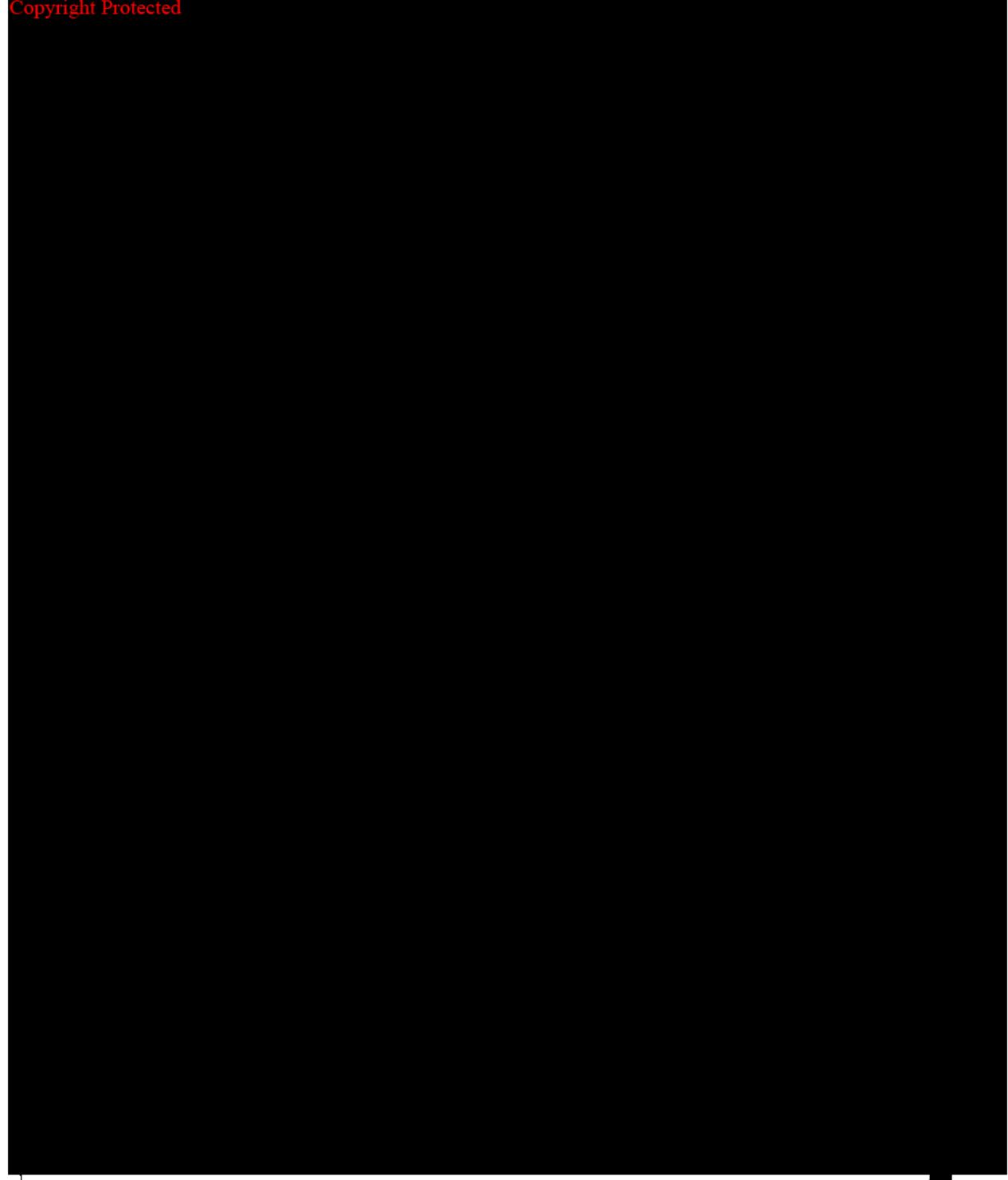
Abstract: We retrospectively reviewed 75 total hip arthroplasties to examine the effect of acetabular component position. In group A, 38 of the components were implanted according to manufacturer's instructions with all peripheral fins in contact with acetabular bone; as such, the acetabular components were in a relatively vertical position with a mean angle of inclination of 61.9°. Three of these patients developed recurrent dislocations necessitating revision of the acetabular component. In group B, 37 hips, a more horizontal orientation was used despite the fact that all of the peripheral fins of the acetabular component did not engage acetabular bone; in this group the mean angle of inclination was 49.7°. Only one of these hips recurrently dislocated and required revision. There were no problems in this group associated with provisional component stability caused by inadequate peripheral fixation. Radiographs of all patients were obtained at 4 years after surgery (range, 4.0–4.3 years). Pelvic osteolysis had occurred in 24% of hips in group A and 13% of group B. Asymmetric polyethylene wear was observed in 5.1% of the hips in group A; no hip in group B showed wear asymmetry. Acetabular component migration developed in 19% of group A hips and 5% of group B hips. The Mayo clinical hip score was excellent in both groups: group A 71/80, group B 73/80. At an intermediate follow-up it is clear that significant problems can be encountered when this component is positioned in a relatively vertical position to facilitate engaging all four peripheral fins in bone. We have addressed this problem by placing the cup in a more anatomic position of inclination while maintaining provisional rim fixation. This has resulted in a decreased incidence of pelvic osteolysis and fewer complications overall.

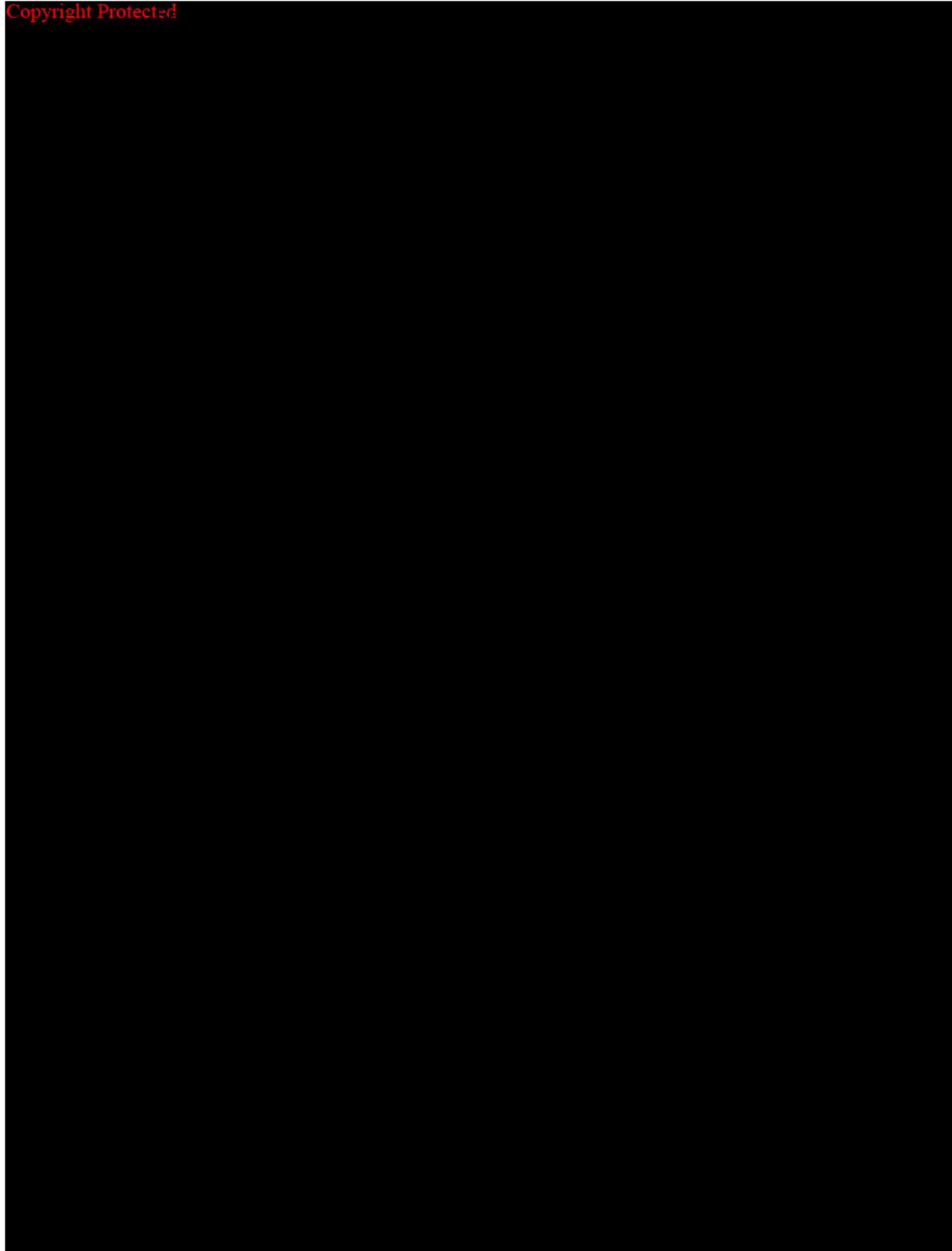
Key words: total hip arthroplasty, osteolysis, polyethylene wear, orientation.

Copyright Protected

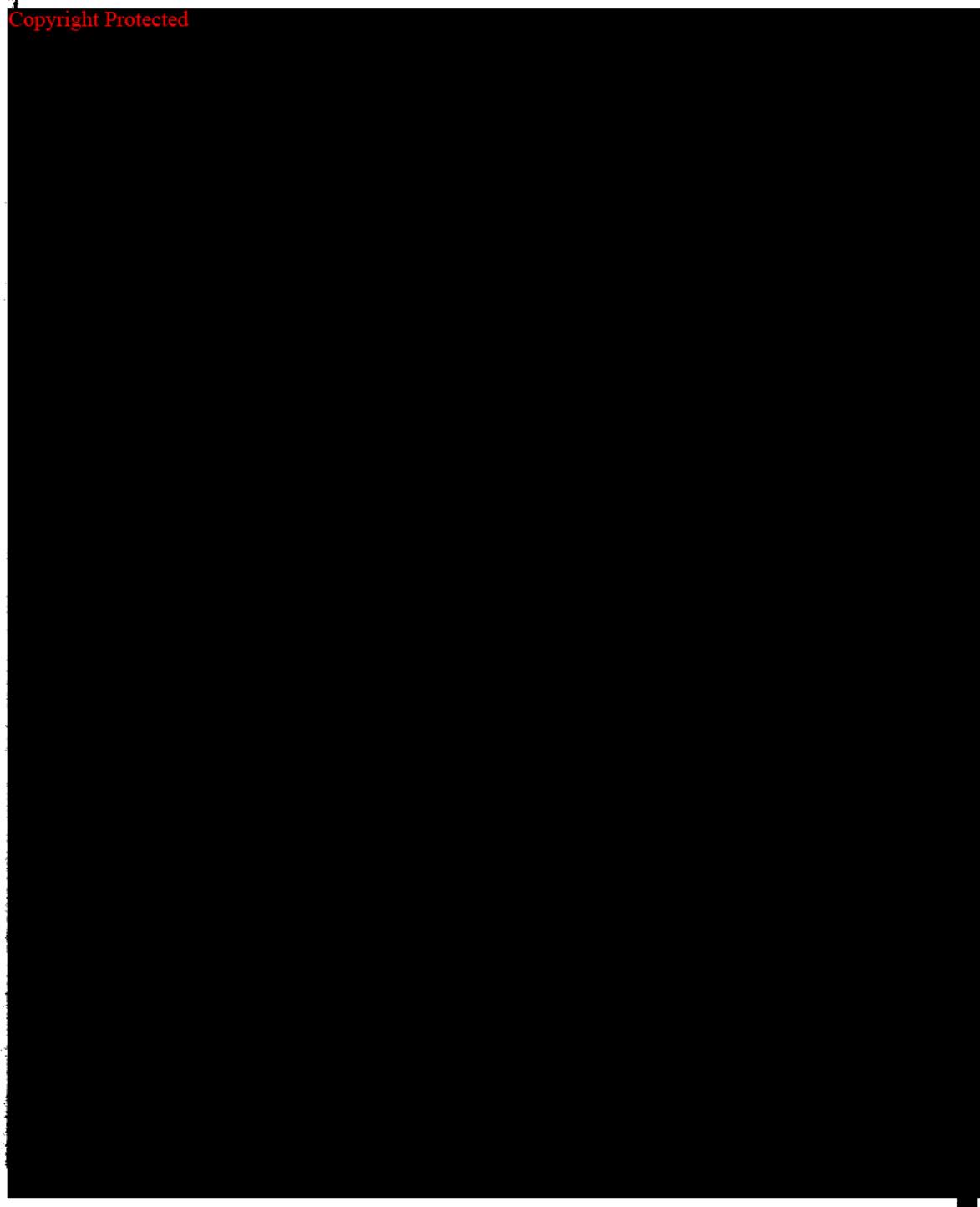


Copyright Protected



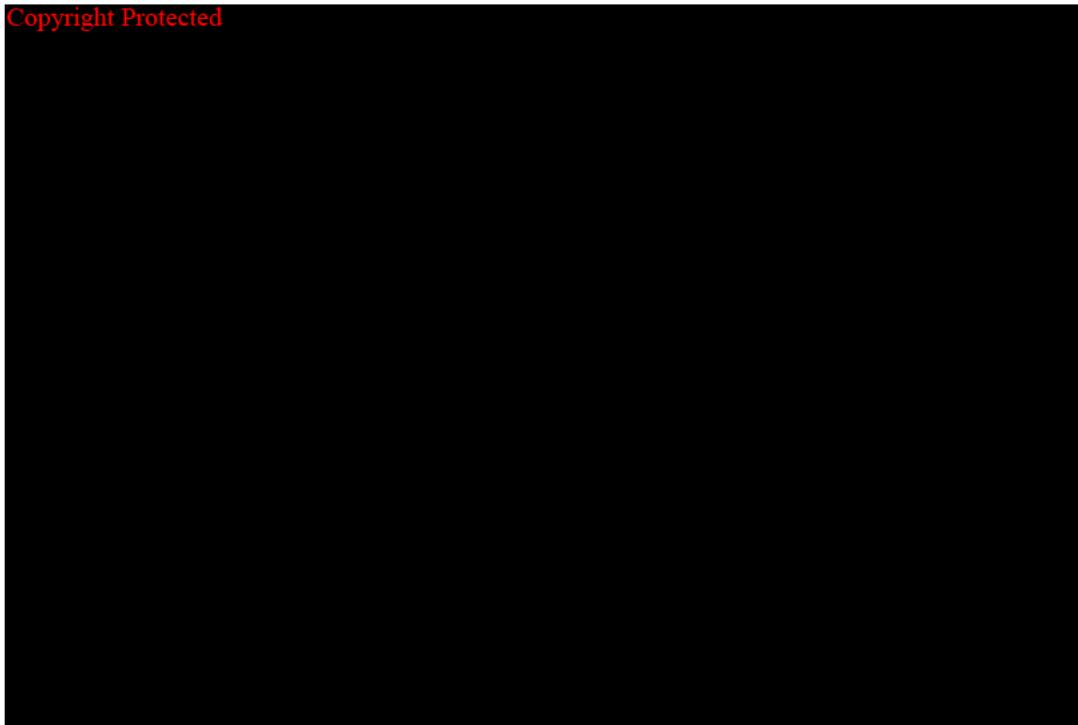


Copyright Protected



90

Copyright Protected

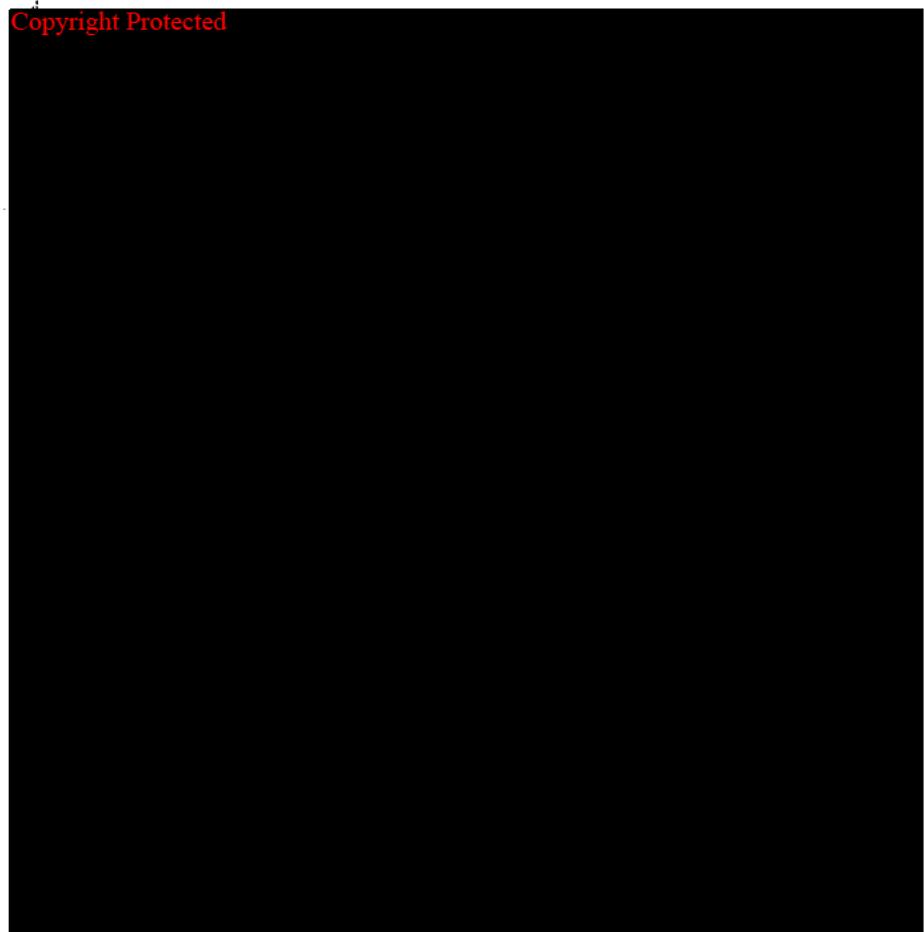


Dislocation After Total Hip Arthroplasty

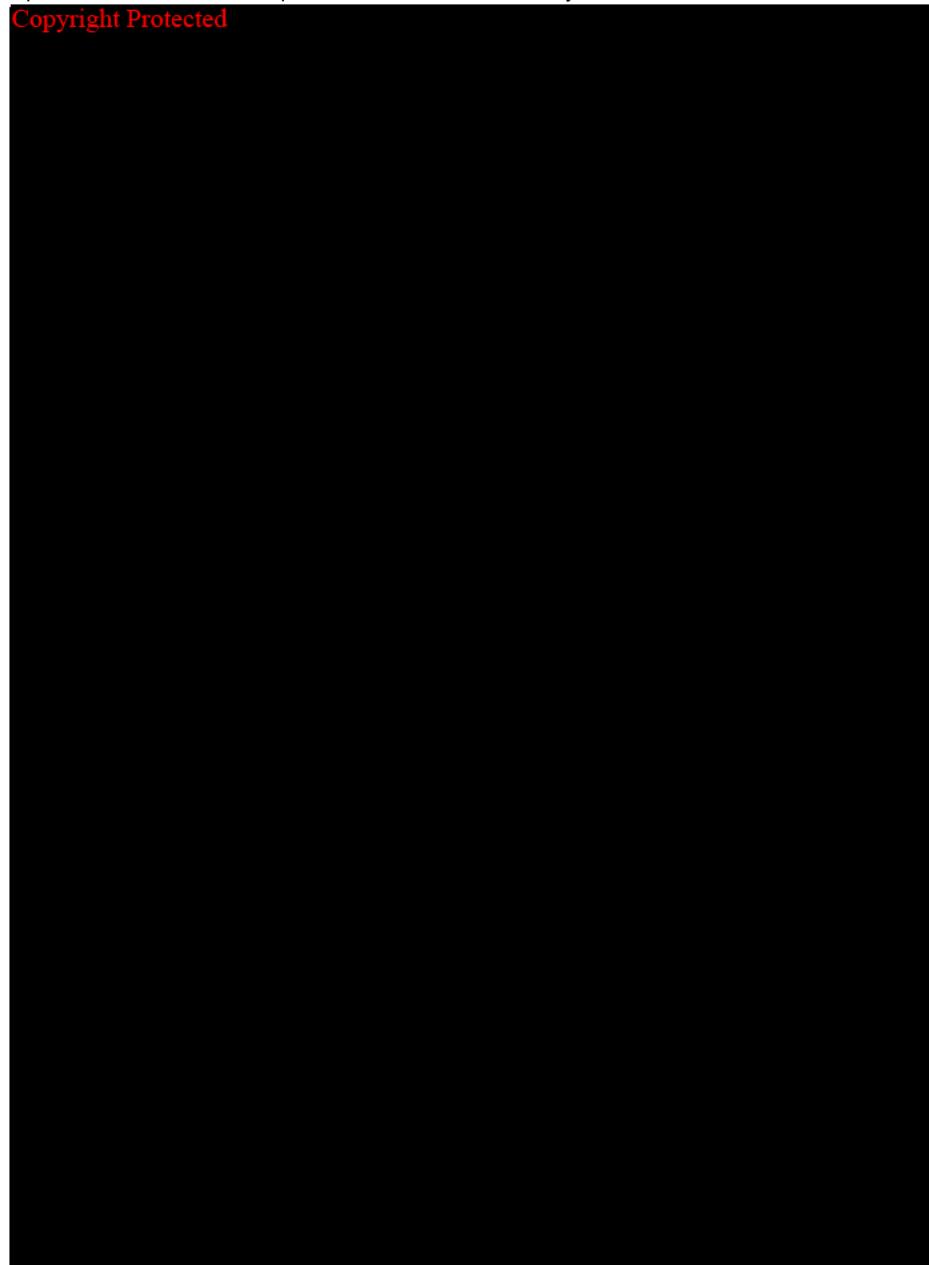
Causes and Prevention

DONALD E. MCCOLLUM, M.D., AND WILLIAM J. GRAY, M.D.

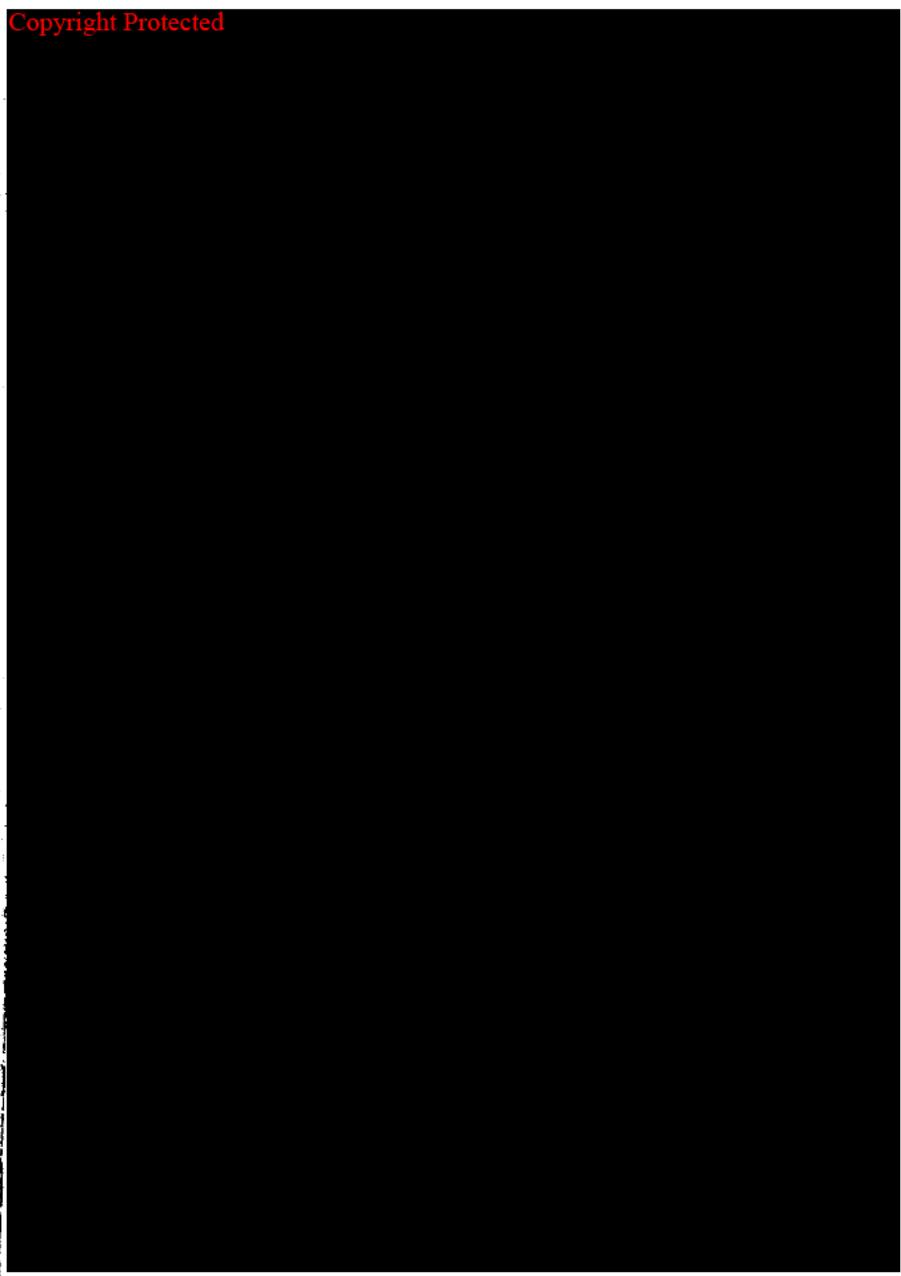
Copyright Protected



Copyright Protected



Copyright Protected

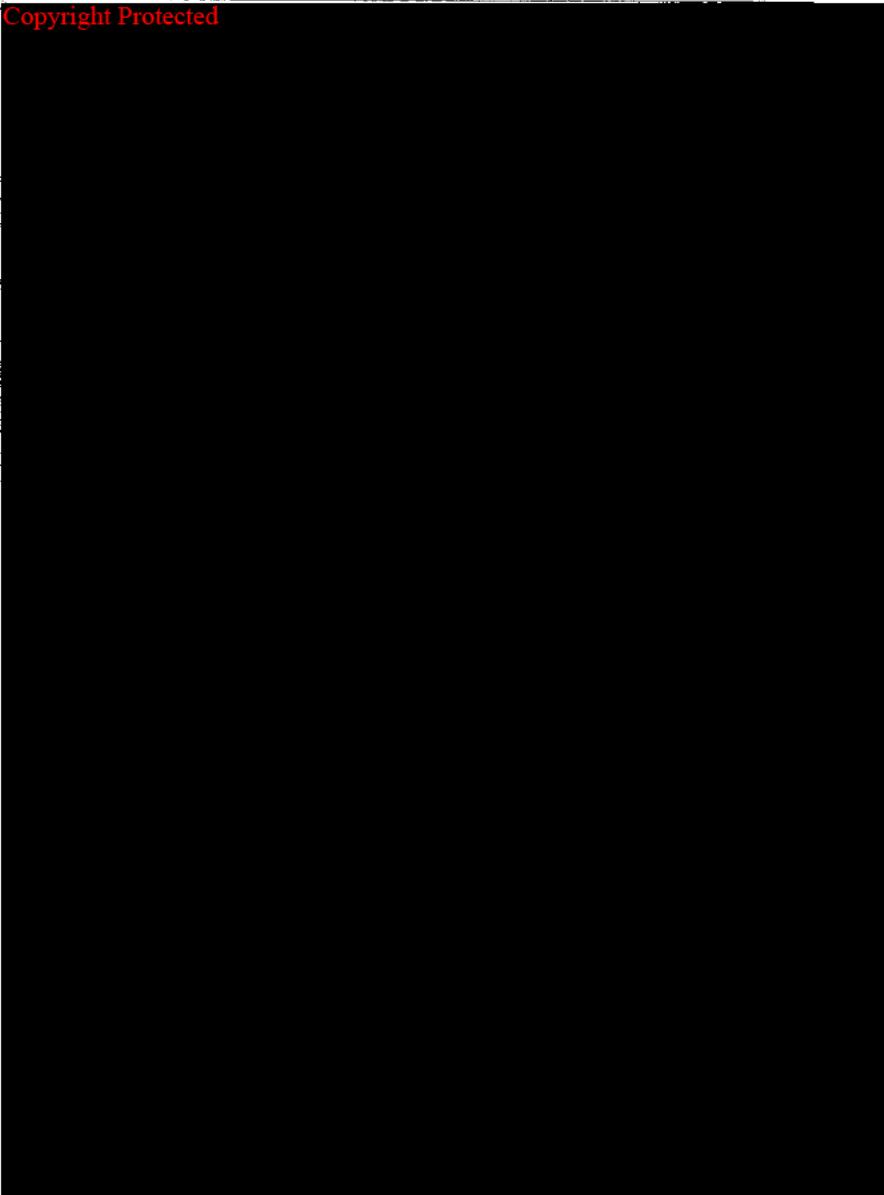


94

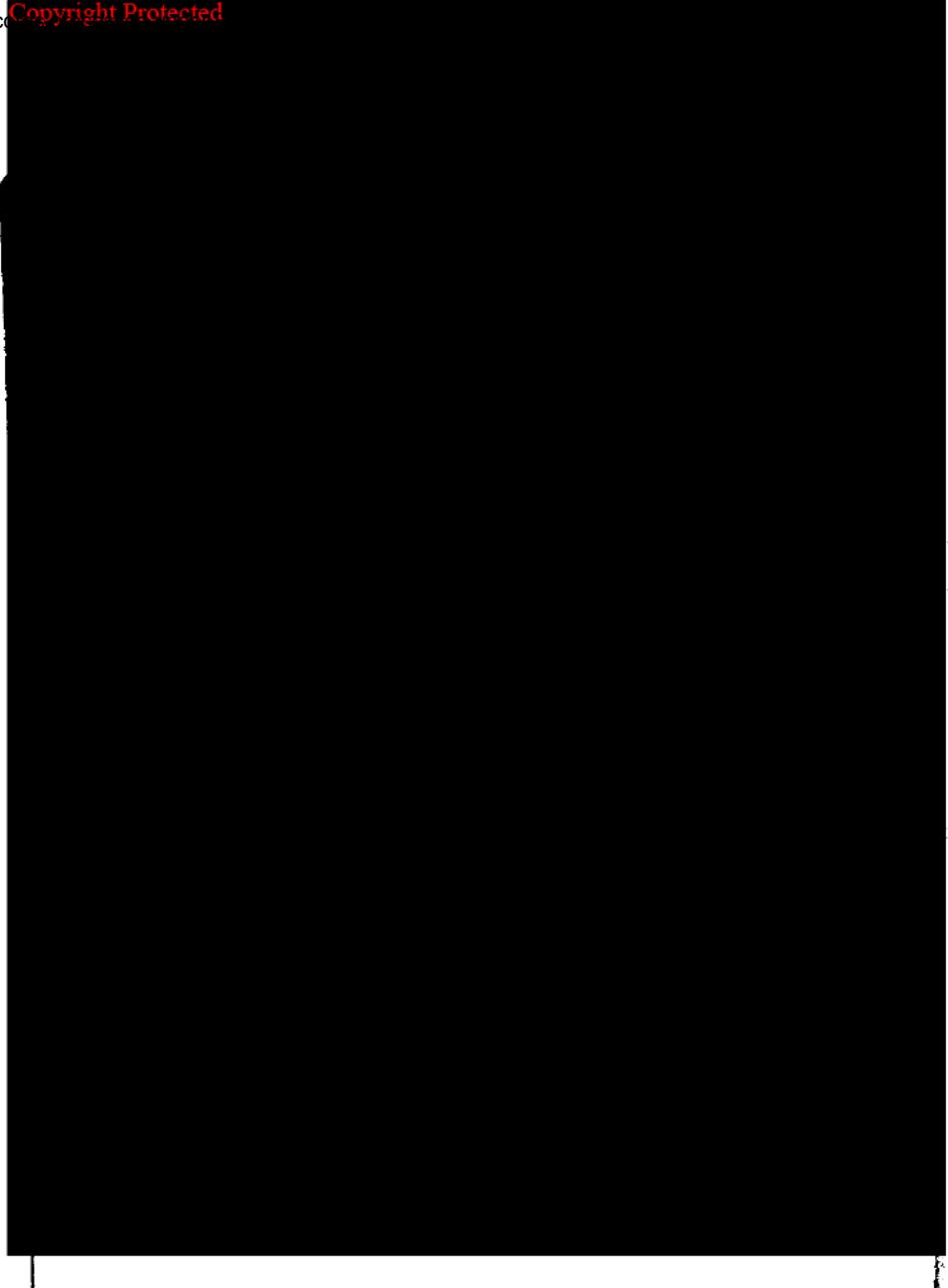
Number 287
December, 1986

Dislocation After THA 163

Copyright Protected



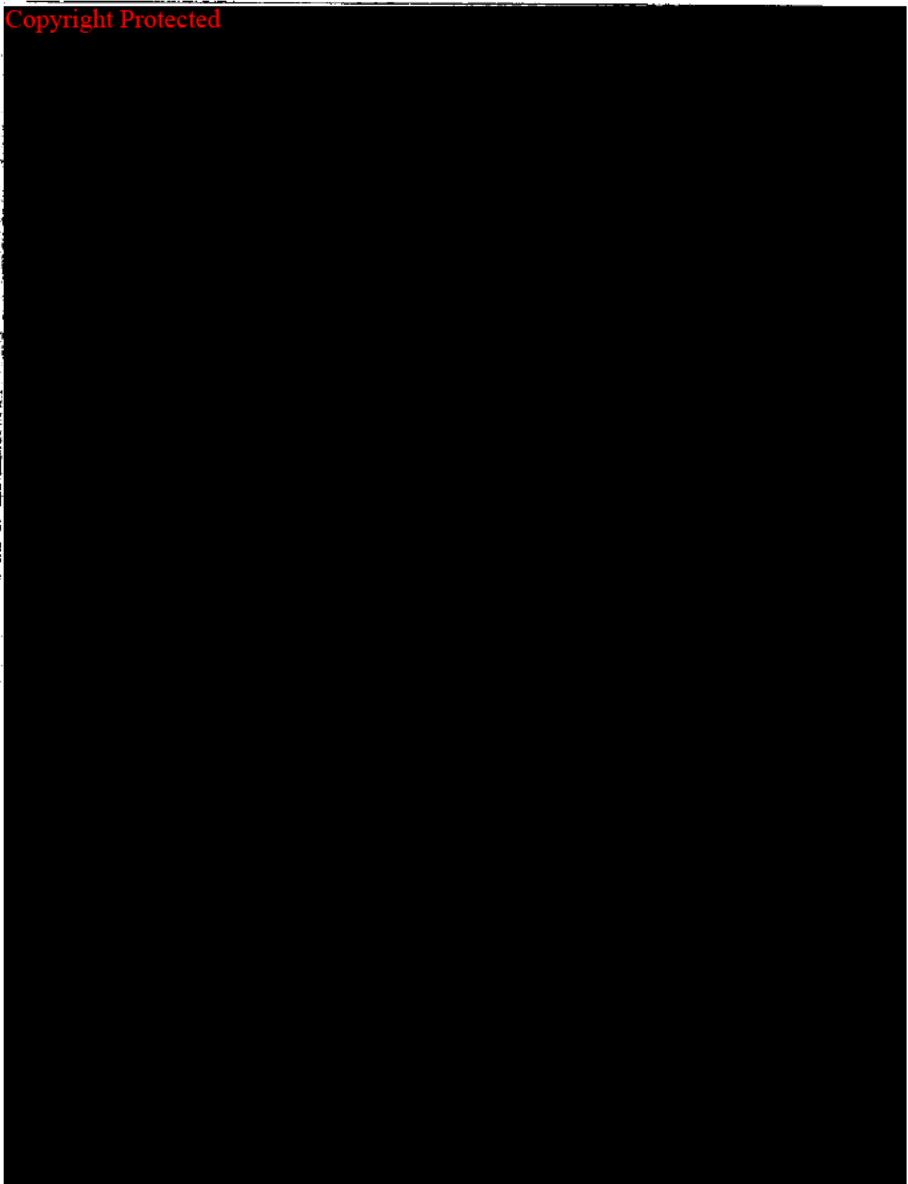
96



Number 291
December, 1990

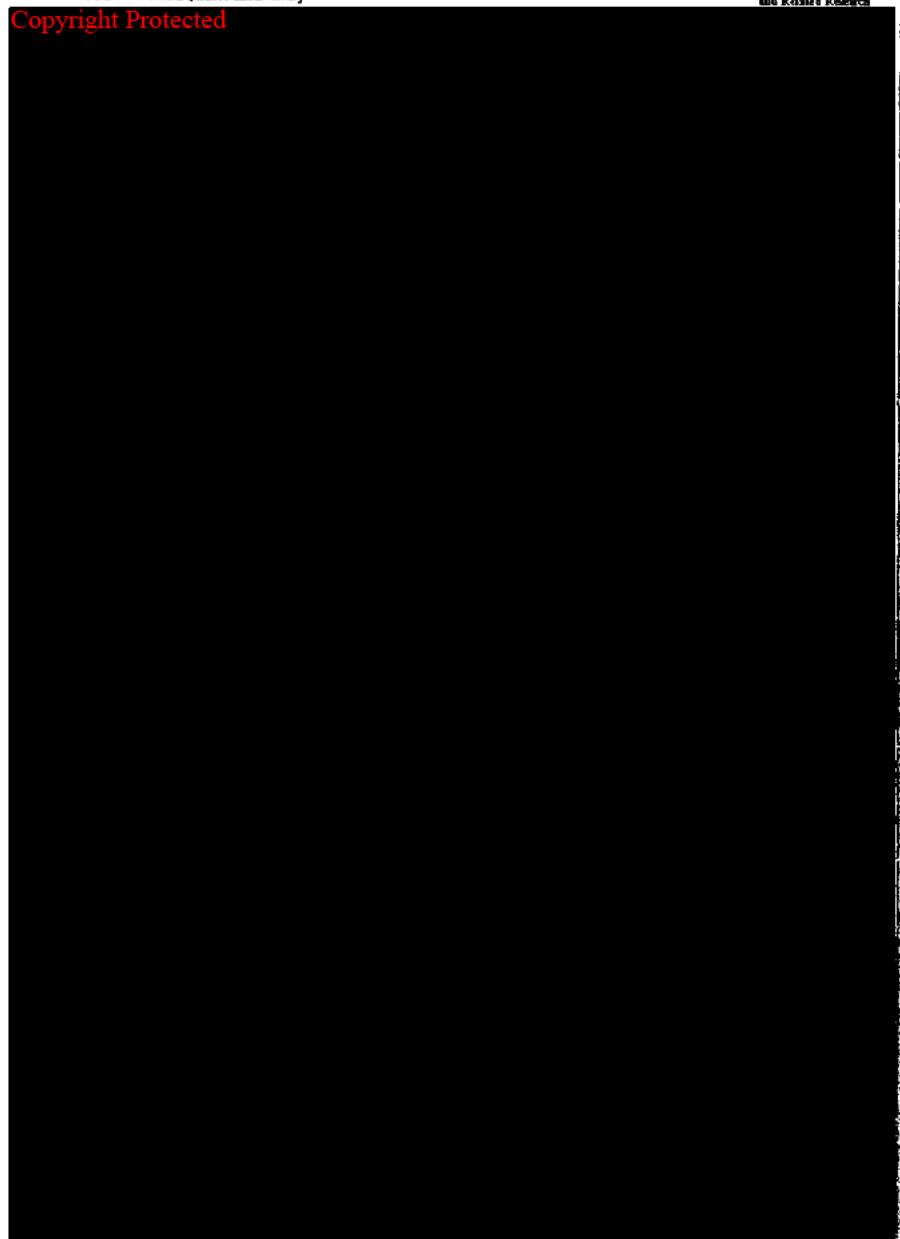
Dislocation After THA 165

Copyright Protected



98

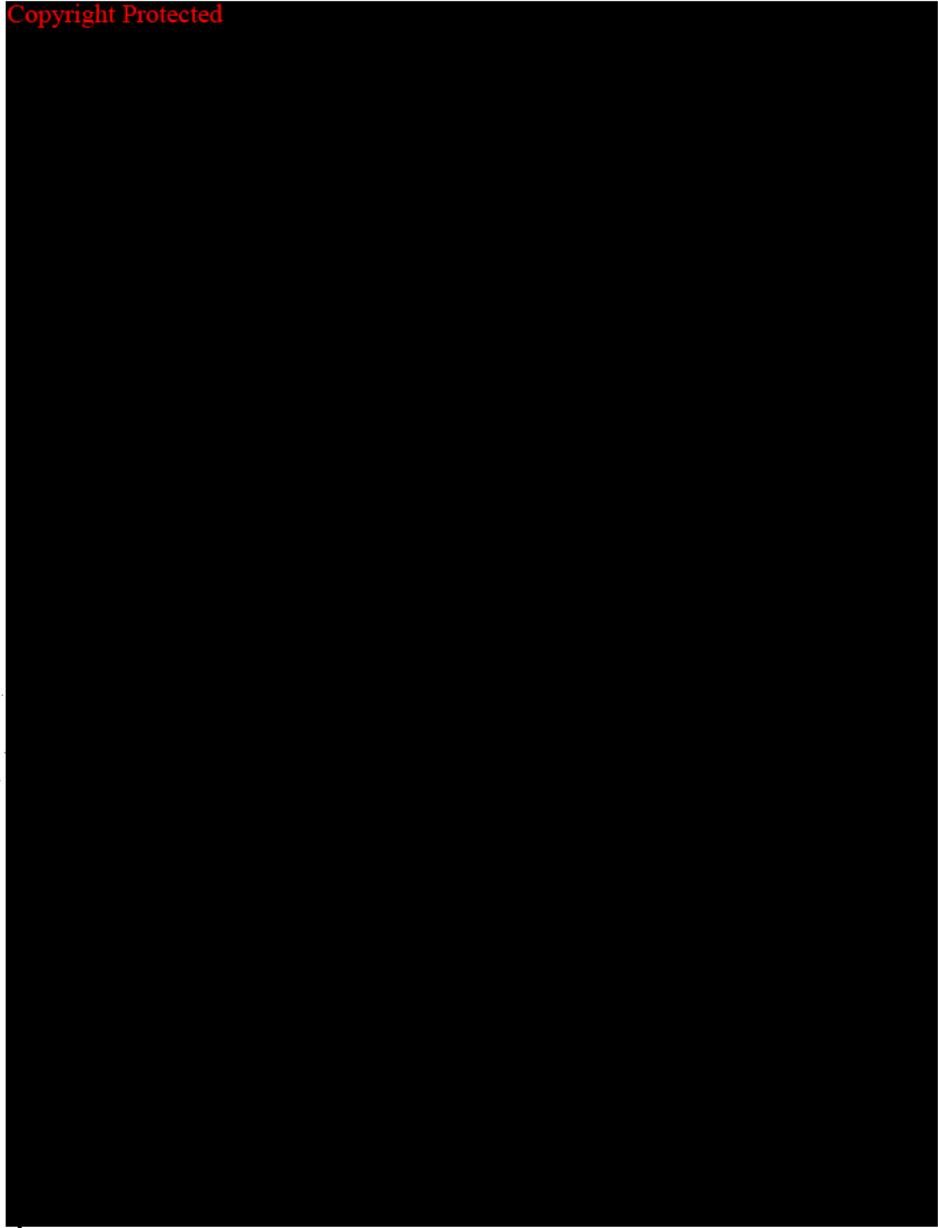
Copyright Protected



Number 251
December, 1990

Dislocation After THA 167

Copyright Protected



100

Copyright Protected

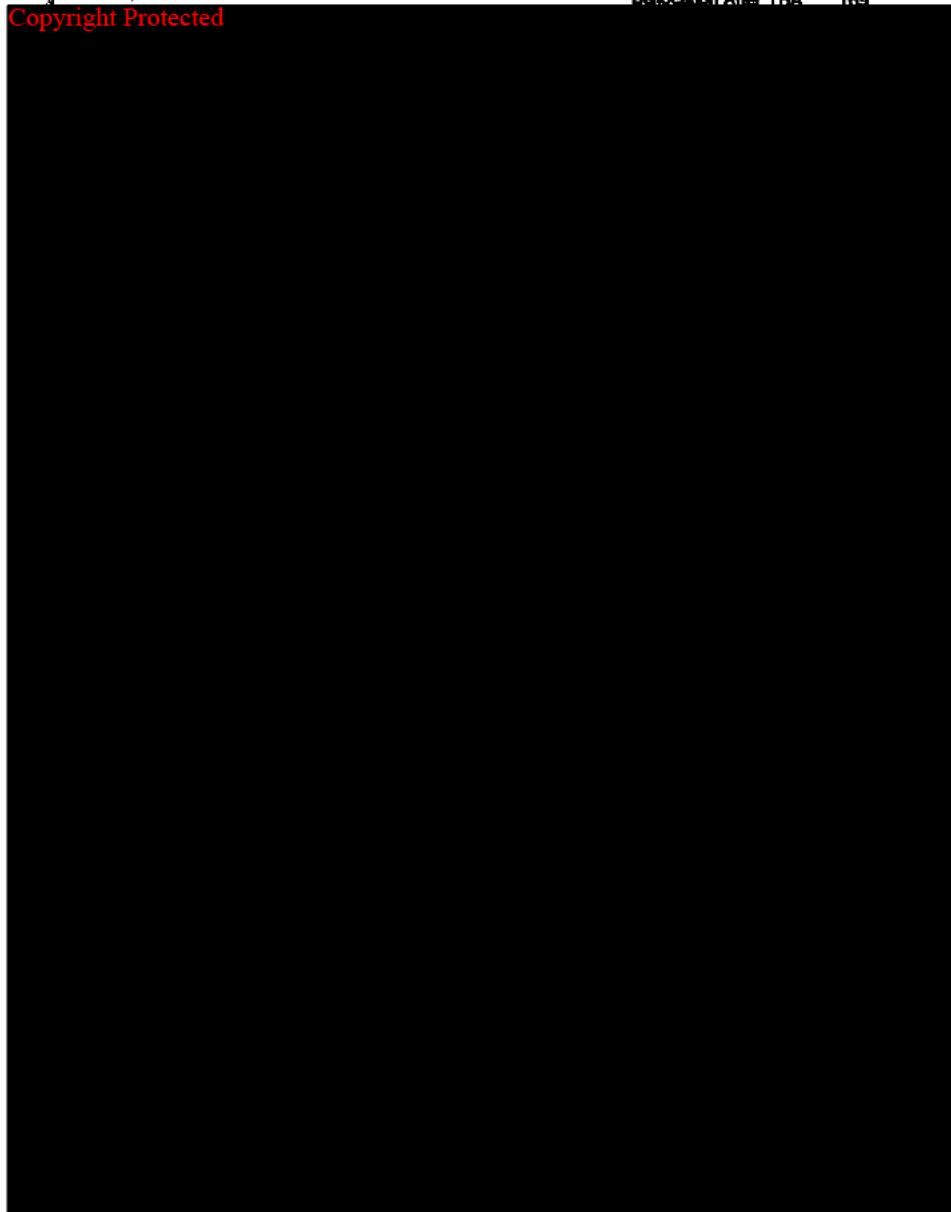


101

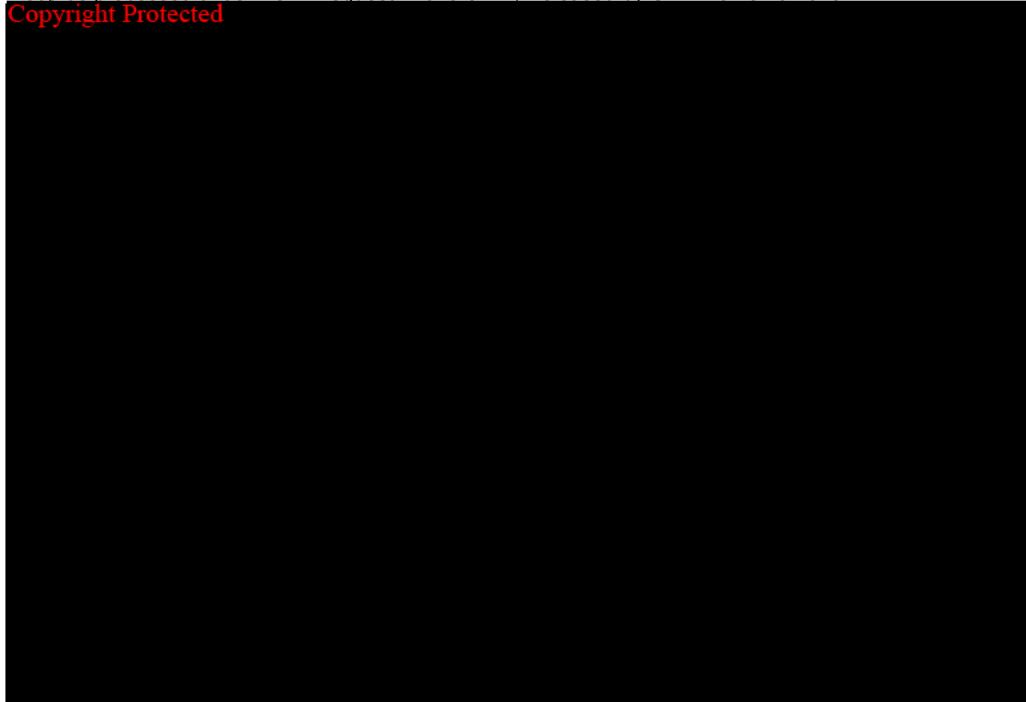
Number 261
December, 1960

Dislocation After THA 169

Copyright Protected



102



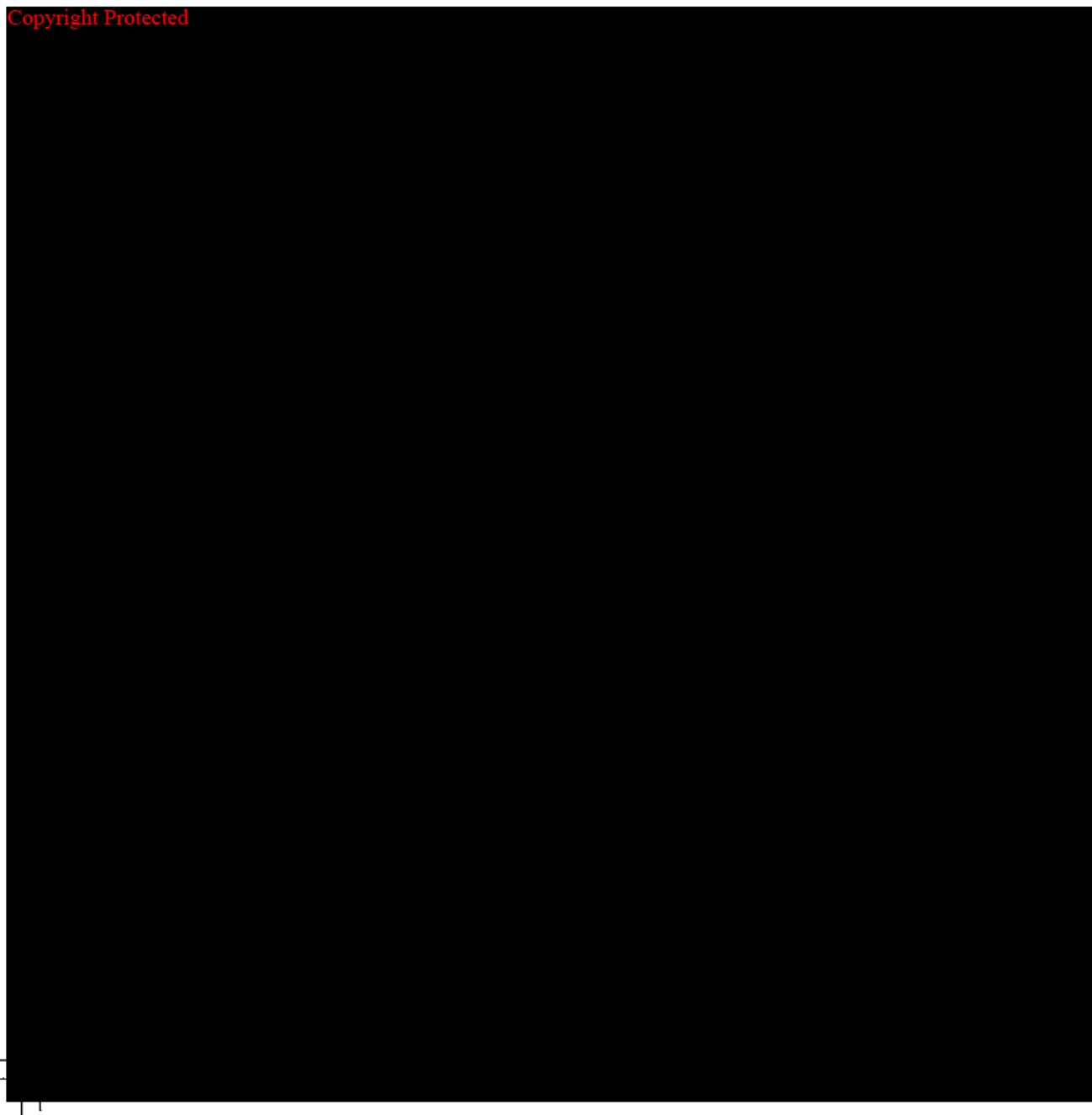
103

Pelvic tilt makes acetabular cup navigation inaccurate

Burkhard Lembeck, Otto Mueller, Patrik Reize and Nikolaus Wuelker

Department of Orthopaedic Surgery, University of Tuebingen, DE-72076 Tuebingen, Germany
Correspondence BL: burkhard.lembeck@med.uni-tuebingen.de
Submitted 04-03-11. Accepted 04-10-05

Copyright Protected

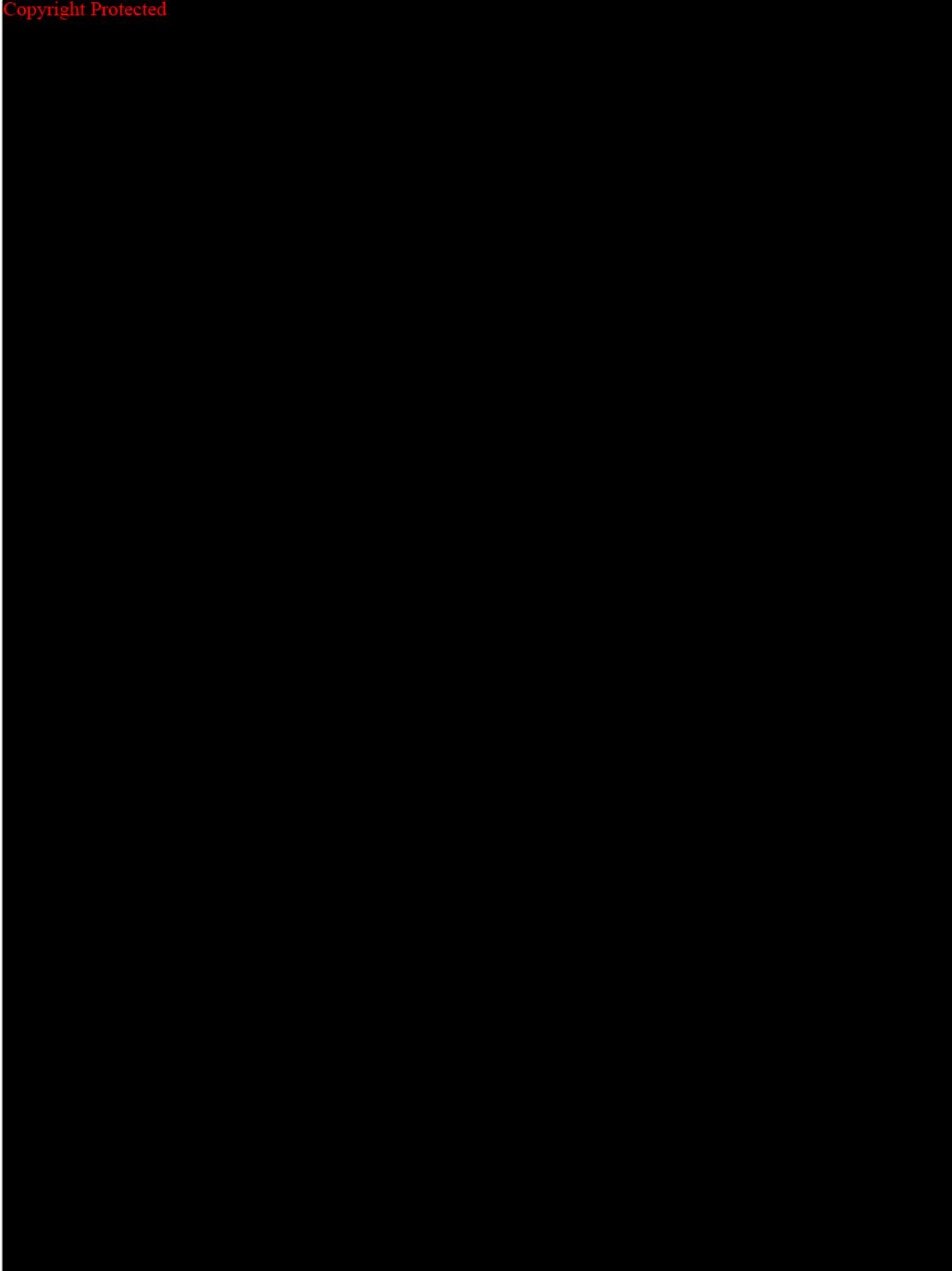


104

518

Acta Orthopaedica 2005; 76 (4): 517-523

Copyright Protected

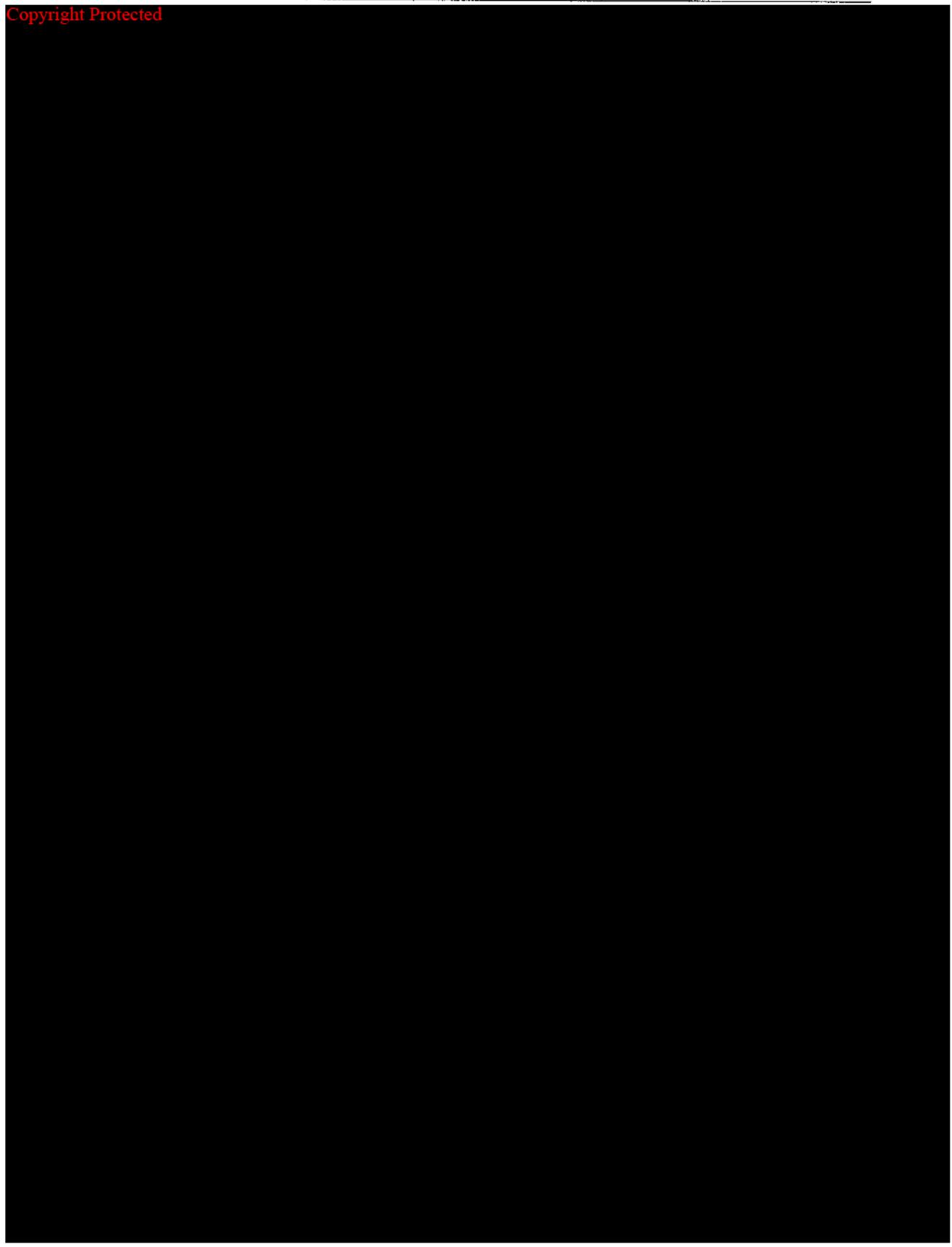


105

Acta Orthopaedica 2005; 76 (4): 517–523

519

Copyright Protected



106

520

Acta Orthopaedica 2005; 76 (4): 517–523

Copyright Protected

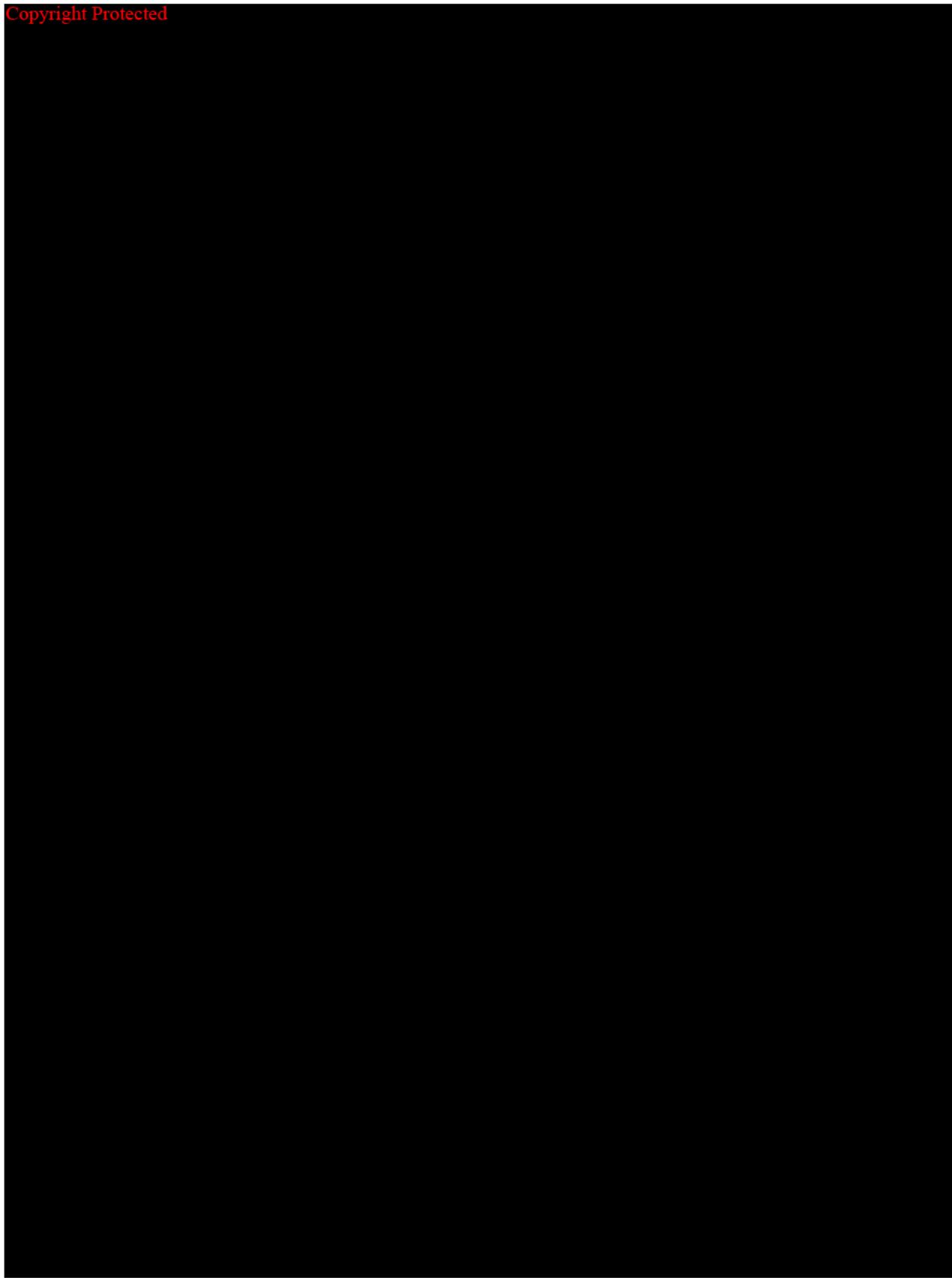


107

Acta Orthopaedica 2005; 76 (4): 517–523

521

Copyright Protected

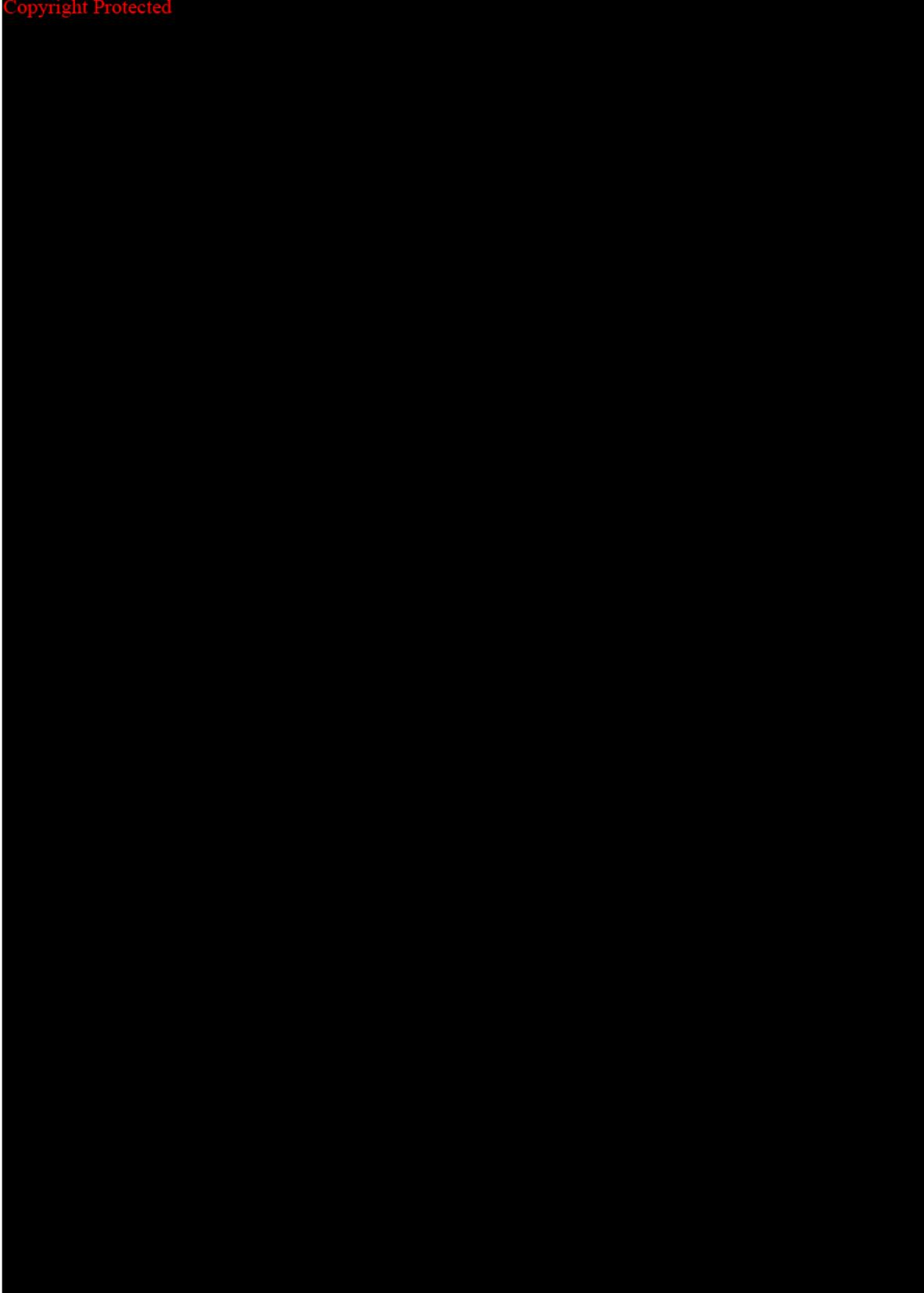


108

522

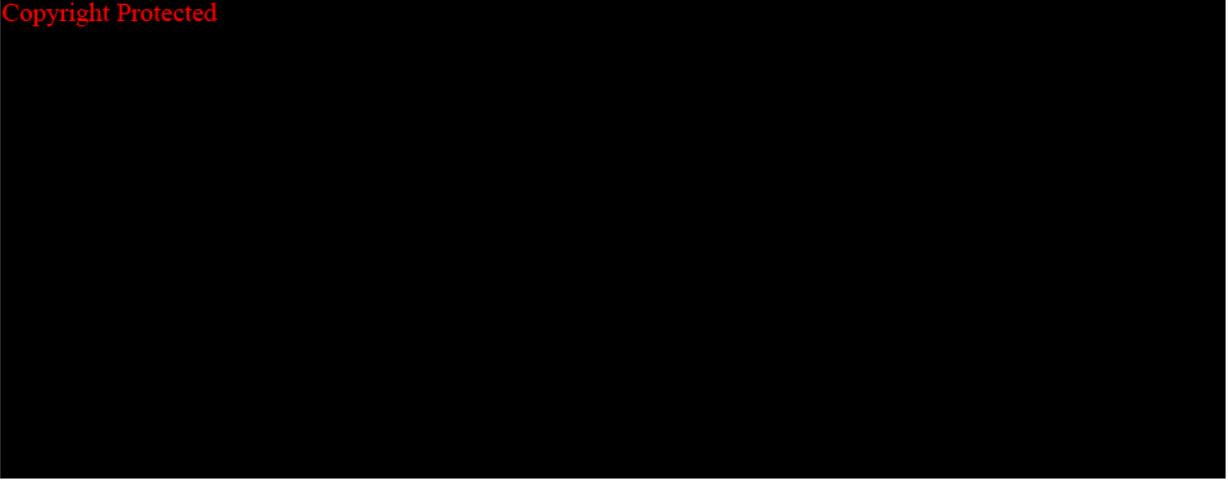
Acta Orthopaedica 2005; 76 (4): 517-523

Copyright Protected



log

Copyright Protected

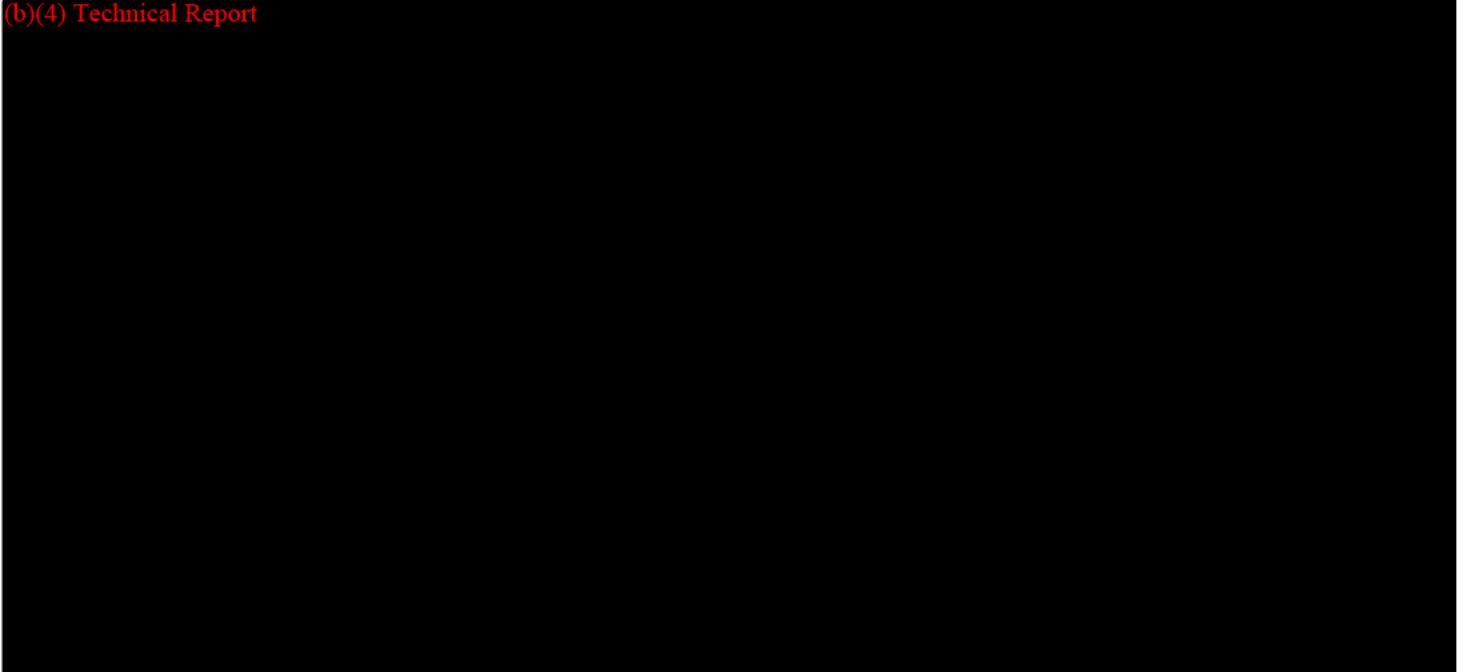




Zimmer Imageless Hip
DHF# 268
Software Change Effect Analysis Report
03/16/2006

RC 4 to RC 5

(b)(4) Technical Report



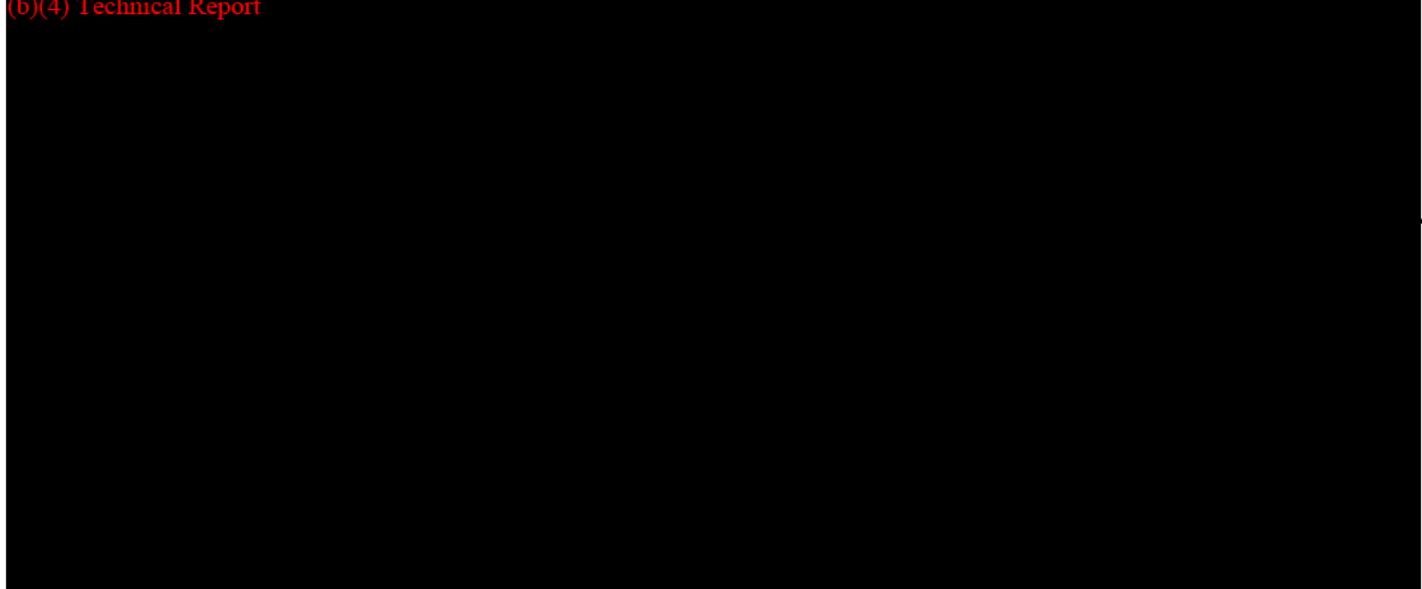
Medtronic-SNT Confidential
C-530, Software Change Effect Analysis Report (Rev 1)



Zimmer Imageless Hip
DHF# 268
Software Change Effect Analysis Report
03/16/2006

RC 3 to RC 4

(b)(4) Technical Report

A large rectangular area of the page is completely blacked out, indicating redacted content. The text "(b)(4) Technical Report" appears in red at the top left corner of this redacted area.

Medtronic-SNT Confidential
C-530, Software Change Effect Analysis Report (Rev 1)

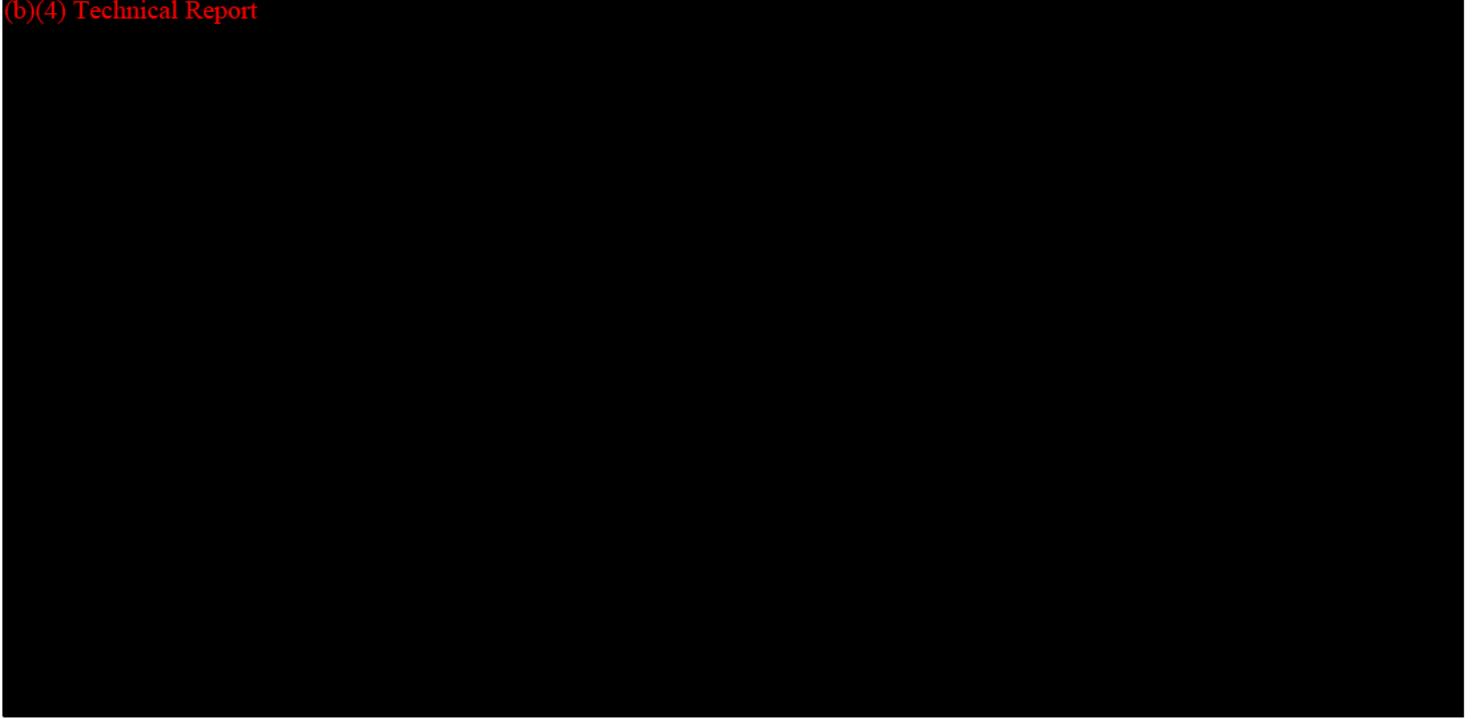
116



Zimmer Imageless Hip
DHF# 268
Software Change Effect Analysis Report
03/28/2006

RC 2 To RC 3

(b)(4) Technical Report

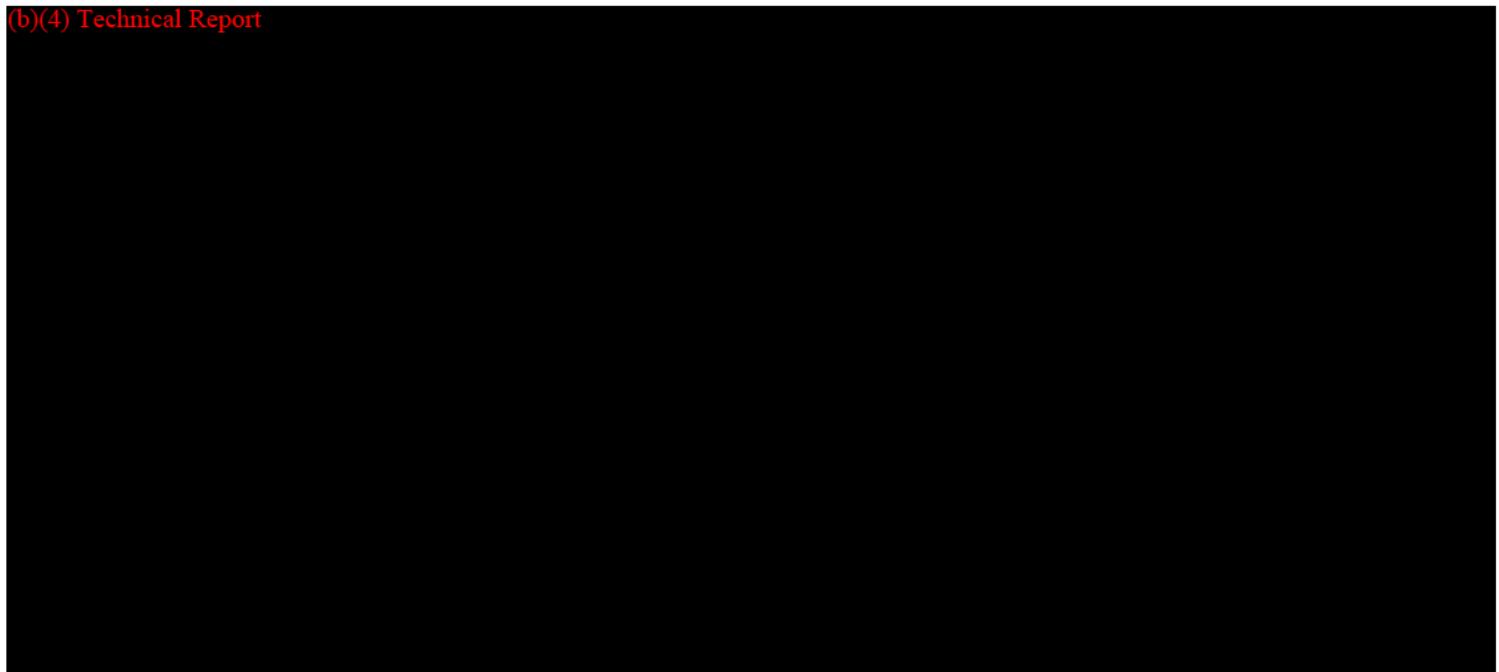




Zimmer Imageless Hip
DHF# 268
Software Change Effect Analysis Report
03/28/2006

RC 1 To RC 2

(b)(4) Technical Report



Medtronic-SNT Confidential

C-530, Software Change Effect Analysis Report (Rev 1)

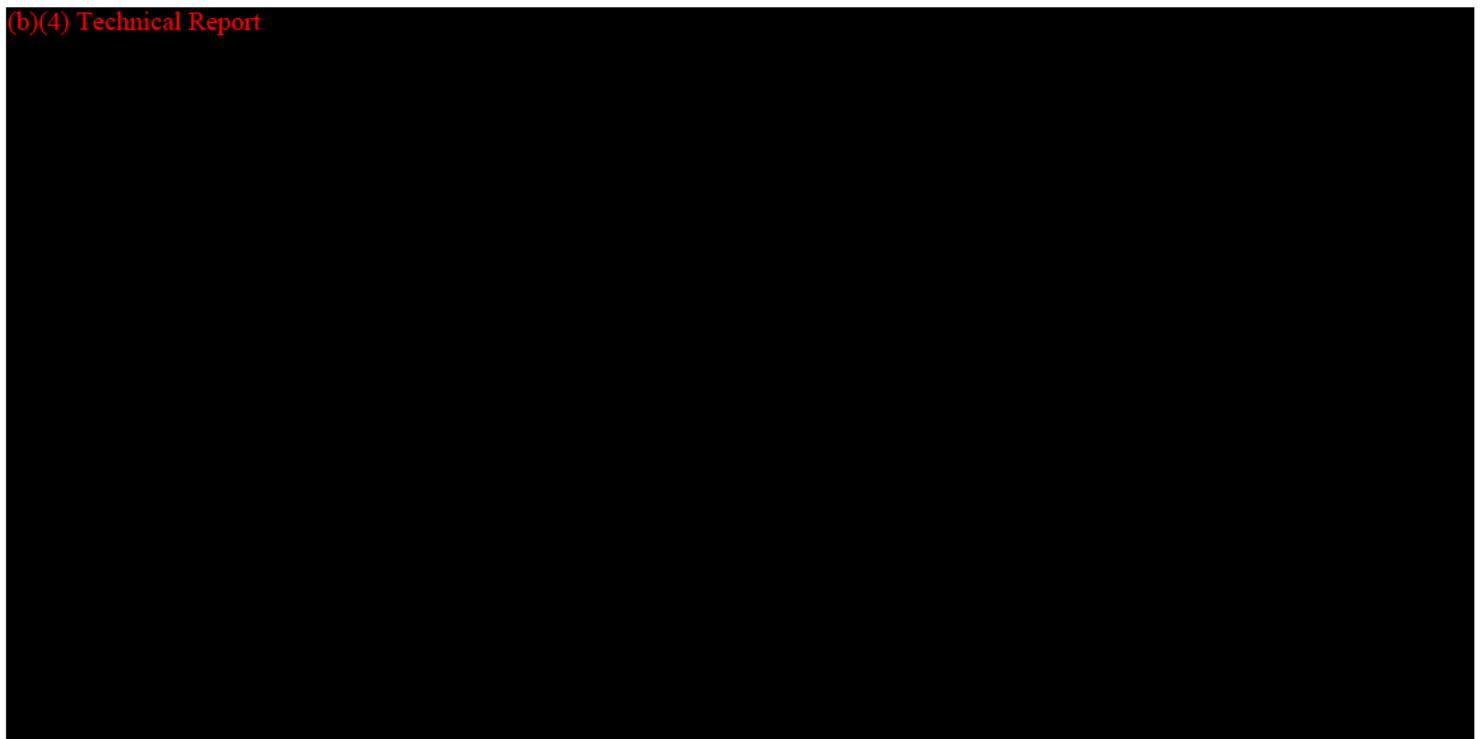
137



Zimmer Imageless Hip
DHF# 268
Software Change Effect Analysis Report
03/28/2006

RC 0 To RC 1

(b)(4) Technical Report



Medtronic-SNT Confidential

C-530, Software Change Effect Analysis Report (Rev 1)

142



Medtronic

SURGICAL NAVIGATION TECHNOLOGIES

Imageless AxiEM Hip Functional Report

DHF# 0268

Product Design V&V Report

03/06/2006

Report Type

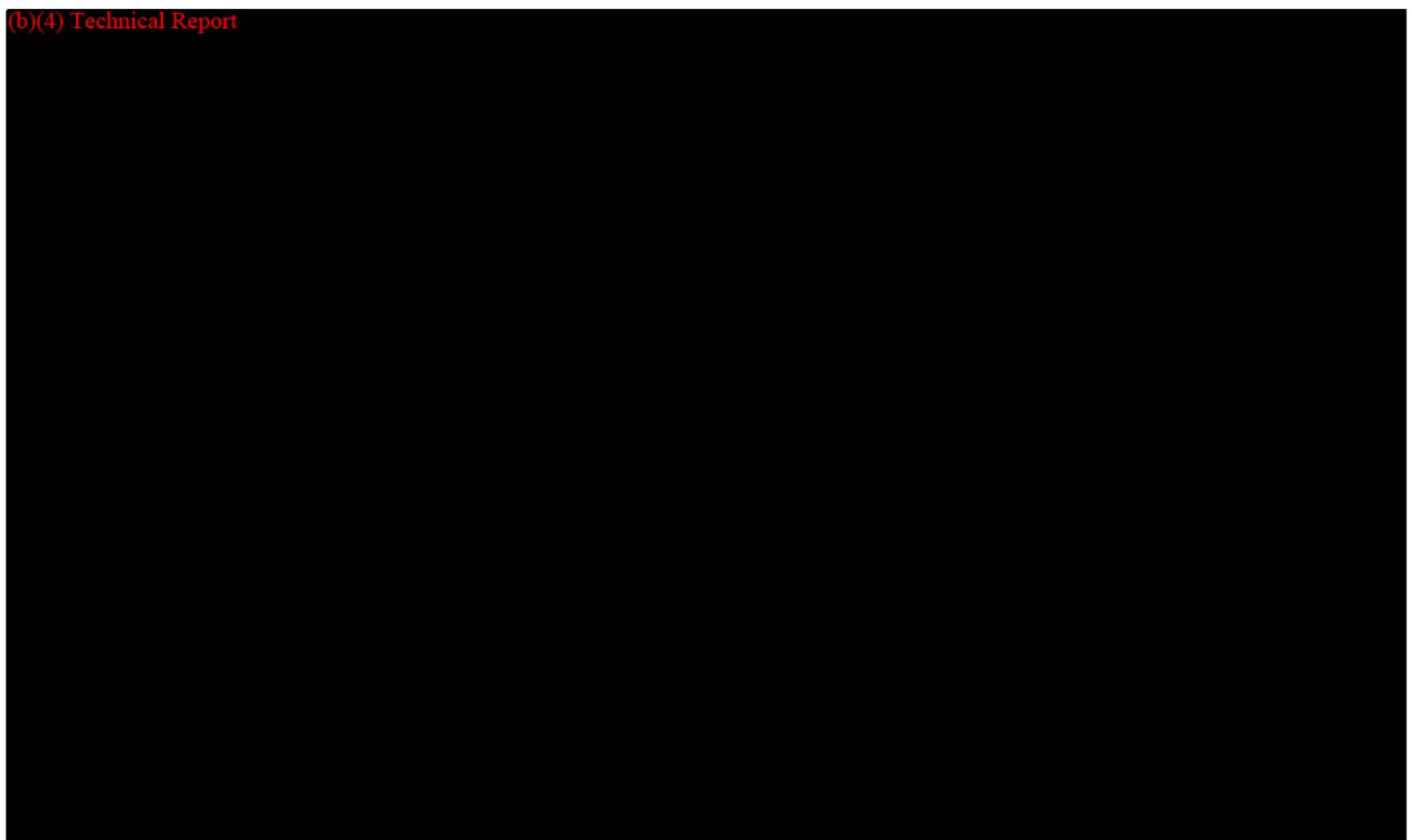
- Validation
 Verification

Protocol Document Retention # VV1103

Report Document Retention # VV1103

Protocol Revision Level # 2,3

(b)(4) Technical Report



¹ Signature required if software testing is involved.



Medtronic

SURGICAL NAVIGATION TECHNOLOGIES

Imageless AxiEM Hip Functional Report

DHF# 0268

Product Design V&V Report

03/10/2006

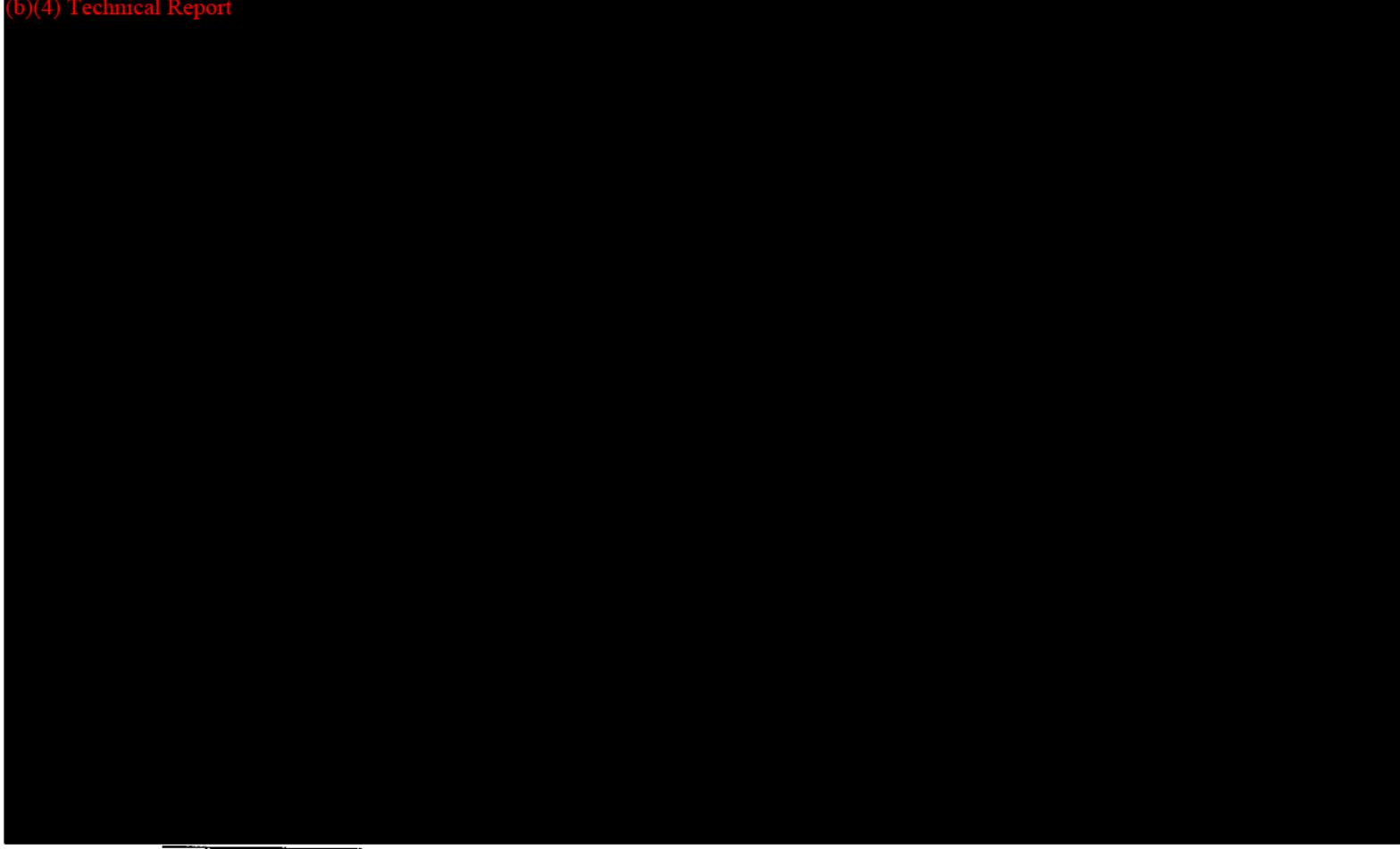
Report Type Validation
 Verification

Protocol Document Retention # VV1103

Report Document Retention # VV1103

Protocol Revision Level # 3

(b)(4) Technical Report



¹ Signature required if software testing is involved.

