InMotion ARM

Instructions for Use

U.S. Distribution Only

BIONIK

Document: UM-G2_5-Y-0001
Revision: 2017-11-29

1 For Your Records

Please record the model number, serial number and the date of manufacture in the spaces provided below. This information is found on the Product Label located on the rear panel of the robot.

The Model Number is indicated by: 

The Serial Number is indicated by: 

The Model Number and Serial Number of the Arm Robot are found on the Product Label on the back of the system, on the right side.

Model Number: _____

Serial Number: _____

2 About this User Manual

This is the user manual for the BIONIK InMotion Arm Robot. It is intended for clinicians (e.g., licensed physical or occupational therapists) who will be using the robot. This is not a programming manual for researchers customizing the robot software; this manual covers routine operations of the robot. Also, this manual does not cover transport, installation, or disassembly. BIONIK should be contacted regarding questions in those areas.

This manual was originally written in English — these are the original instructions.

This user manual applies only to InMotion SE4 ARM robots, distributed in the United States, and manufactured on or after November 29, 2017 (Serial Numbers beginning with P0501).

The latest version of this user manual may be found online at:

http://eng.interactive-motion.com/usermanual/

3 U.S. Warranty Policy

PRODUCTS

The Products covered by this warranty policy include:

- InMotion ARM, Model SE4
- InMotion ARM w/HAND, Model SE4/HA4
- InMotion WRIST, Model WR4

WARRANTY PERIOD

BIONIK Inc. (the Company) warrants to the original purchaser (the Customer) that the products manufactured by, or manufactured for, the Company have been tested, inspected, and shipped in proper working order. The Company warrants all new products (hardware and software) to be free from defects in materials and workmanship for a period of (1) one year, measured from the date of shipment from a U.S. manufacturing site or warehouse.

REMOTE AND ON-SITE SERVICES

All product issues must be reported, upon occurrence, to BIONIK Customer Support at +1 (617) 926 4800 x 4814 or, support@bioniklabs.com. In the event an in-warranty product is not functioning correctly, BIONIK technical staff will initially diagnose and determine whether the incident shall be resolved via telephone/email support, a BIONIK service visit to the customer facility or by return of the Product to BIONIK Inc.

EXCLUSIONS and CONDITIONS

Use of the Product in the manner described below will void the warranty:

- Any hardware or software problems caused by misuse or unauthorized use of the Product (e.g. in a manner inconsistent with its intended use, or as described in the BIONIK User Manual supplied with the Product).
- Use of the Product that is contrary to standard clinical rehabilitation practice.
- Connecting the Product to equipment not expressly approved in writing by BIONIK.
- Negligent use of the hardware or software.
- Modifying the hardware or software.

The following conditions are not covered under the original warranty:

- Damage caused by water and/or other liquids, including spills, leaks and floods
- Damage caused by electrical power surges.
- Damage caused by events of nature, war or riot.

Please note that Products that are beyond their serviceable life, as determined by BIONIK, are not eligible for continued warranty or service plan support.

EXTENDED WARRANTIES, SERVICE PLANS AND RENTAL AGREEMENTS

Single and multi-year extended warranties / service plans are available for purchase. Please consult your BIONIK Regional Sales Manager for pricing and terms. Rental agreement warranty terms may take precedence over this warranty policy.

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5 Warnings

Read and understand the warnings in this section before operating this equipment.

1. To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
2. The motor cases can become hot.
3. Always power off the robot system using the computer's software as documented in Powering the Robot Off, Section 15.4. After the software is powered off, you may use the AC Power Toggle Switch to power off the Electrical Box. If you use the Toggle Switch without shutting down the software, the robot could jerk and/or computer files could be corrupted.
4. Only the BIONIK provided Computer Screen may be plugged into the Computer Screen Power Port.
5. Do not open the Electrical Box without authorization from BIONIK. If authorized, do not open the Electrical Box without unplugging the power cord. Do not rely on just the power switch to remove power for maintenance.
6. Do not modify this equipment without authorization from BIONIK.
7. Slots, openings and vents on the equipment are provided for ventilation. Do not block these. Never push objects or spill liquid into these.
8. Never place the equipment near or over a radiator or heat source.
9. Unplug the equipment during a lightning storm or if it will not be used for a long period of time. This will protect the equipment from damage due to power surges.
10. This equipment is not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
11. Portable and mobile RF communications equipment can affect Medical Electrical Equipment.
12. Only accessories, transducers, and cables supplied or approved by BIONIK may be used with the robot. Use of other accessories, transducers, and cables may result in increased electromagnetic emissions or decreased immunity of the robot.
13. The robot should not be used adjacent to or stacked with other equipment. If such use is necessary, the robot should be observed to verify normal operation in the configuration in which it will be used.
14. The system must be installed to allow easy access to the AC Power Plug.
15. The patient's unaffected arm and hand must be kept off the table.
16. Do not use the equipment if it has been damaged.

17. Connection of the InMotion Robot to a network (other than the WiFi direct connection to the printer) could result in previously unidentified risks to patients, operators or third parties. If the user nevertheless connects to such a network, the user should identify, analyze, evaluate and control these risks; the user needs to be aware that subsequent changes to the network or coupling to the network could introduce new risks and require additional analysis; and that changes to the network or coupling to the network include:

- changes in the configuration of the network or coupling to the network
- connection of additional items to the network/data coupling
- disconnecting items from the network/data coupling
- update of equipment connected to the network/data coupling
- upgrade of equipment connected to the network/data coupling.

6 Disclaimer

InMotion™ Robot systems are manufactured under exclusive license for U.S. Patent 5466213, held by the Massachusetts Institute of Technology, Cambridge, Massachusetts, USA. Any unauthorized use of this device or any unauthorized administration to any patient of robotic therapy is prohibited.

InMotion Robots are rehabilitative devices intended for medical purposes. The attending physician can best evaluate how to integrate these medical devices into the process of rehabilitation. They should be used only as directed by the attending physician, who has the ultimate medical responsibility for the patient's treatment. The attending physician must consider the potential benefits and risks before employing InMotion Robots. Medicine is an evolving field and the attending physician must keep current with advances in rehabilitation to best balance benefits and risks and to direct the optimal treatment.

InMotion Robots have not received regulatory clearance in all countries. You can consult BIONIK Support <support@bioniklabs.com> to determine whether we have clearance in your country. Nothing in this user manual should be considered a solicitation or promotion, or a recommendation for use which is not authorized by local laws and regulations.

Use of InMotion Robots must be according to their user manuals. Failure to do so may entail serious risks.

Use of the device's software, which includes the InMotion Robot control loop, additional control software, games, and other implementation and data reporting software, is permissible **solely** in connection with the accompanying hardware unless permission for another use is granted in writing by BIONIK. Any unauthorized use of this software with robot hardware other than BIONIK robots constitutes a violation of this agreement.

Changes to the software may only be made with the express written permission of BIONIK. Users who are granted permission by BIONIK to make software changes must acknowledge in writing that once changes are made, the device will no longer be recognized as conforming with the certifications and regulations of the certifying body, including but not limited to FDA and CE regulations, and as a result, certain protections for the user and BIONIK's obligations and liabilities may be discharged.

Technical information in this manual is provided solely for the benefit of authorized use, maintenance, and repair. The user is not authorized to attempt repair of any unit without express authorization from BIONIK. Materials in this manual are furnished for informational purposes only, are subject to change, and should not be construed as a commitment by BIONIK, which assumes no responsibility for liability for any inaccuracies that may appear in this manual. No part of this publication may be reproduced, stored in a retrieval system, or transmitted in any form or by any means without the prior written permission of BIONIK.

User hereby agrees not to remove, alter or destroy any copyright, trademark, credits, other proprietary notices, or confidential legends placed upon, contained within or, associated with the hardware and software.

While BIONIK hardware and software system designs are rehabilitative medical devices, BIONIK makes no representation that any particular patient will achieve any particular improvement following a course of therapy involving this InMotion Robot system.

If case of malfunction, the user's sole option is to power off the InMotion Robot system and contact BIONIK for instructions. There are no user-only serviceable components.

BIONIK, INC. SHALL NOT BE RESPONSIBLE FOR ANY LOSS OR DAMAGE TO THE PURCHASER, ITS CUSTOMERS, OR ANY THIRD PARTIES FOR ANY REASON WHATSOEVER, AND BIONIK, INC. SHALL NOT BE LIABLE FOR ANY ACTUAL, DIRECT, INDIRECT, SPECIAL, PUNITIVE, INCIDENTAL, OR CONSEQUENTIAL DAMAGES HOWEVER CAUSED, WHETHER IN CONTRACT, STRICT OR OTHER LEGAL THEORY OF LIABILITY, OR TORT (INCLUDING NEGLIGENCE OR OTHERWISE) ARISING IN ANY WAY OUT OF THE USE OF THIS HARDWARE AND SOFTWARE, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.

User agrees to hold BIONIK, Inc. harmless from any liability, loss, cost, damage or expense, including attorney's fees, as a result of any claims which may be made by any person, including but not limited to User, its agents and employees, its customers, or any third parties that arise out of or result from the manufacture, delivery, actual or alleged ownership, performance, use, operation or possession of the software furnished hereunder, whether such claims are based on negligence, breach of contract, absolute liability or any other legal theory.

For information please contact BIONIK Support <support@bioniklabs.com> or by phone at +1 617 926 4800.

7 FCC Statement

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his/her own expense.

8 Introduction

Welcome to the world-wide community of BIONIK (formerly Interactive Motion Technologies, IMT) InMotion Robot customers. This user manual provides an introduction to the usage and routine operation of the BIONIK InMotion ARM Robot. This resource is intended for clinicians (users) to explain the essential functions necessary to operate the system, and is not a programming manual for researchers. For questions regarding transportation, installation, disassembly or customization for research purposes, please contact BIONIK Inc. (BIONIK) Support.

In previous versions of the system, the InMotion ARM (SE4) Robot was called the Shoulder/Elbow Robot or the Planar Robot (because it moves in the horizontal plane). These terms are still sometimes used in the software. In clinical studies and publications, the InMotion Robot is also known as the MIT-Manus, InMotion 2.0, InMotion 3.0, or the InMotion CE Robot.

Researchers at Massachusetts Institute of Technology (MIT) originally developed the InMotion Robot's unique adaptive, interactive robotic technology. Researchers around the world now use InMotion Robots to gain insight into motor control and movement recovery. Clinicians choose BIONIK's InMotion ARM Robot to provide intensive, interactive, precise, effective and evidence based evaluation and treatment to facilitate recovery and quality of life for their patients. The InMotion Robot product today is the result of years of collaboration between engineers, medical professionals, therapists, technicians, and patients. In an effort to continue to optimize the user-experience and therapy outcomes of InMotion Robots, we encourage questions, feedback and suggestions from our valued users **(info@bioniklabs.com).**

9 Health and Safety Information

9.1 Intended Use

InMotion ARM:

- Is a rehabilitative robot intended for the evaluation and treatment of patients with upper-extremity motor impairments following a neurological condition or injury and;
- facilitates interactive therapy tasks intended to restore upper-extremity motor control and;
- facilitates evaluation assessments intended to objectively measure and report on the patient's upper-extremity motor impairment and the patient's respective progress during therapy.

Studies have demonstrated that the InMotion Robot is beneficial in the treatment of pediatric* and adult patients, during the acute, sub-acute and chronic stages of neurological recovery following:

- Stroke
- Cerebral Palsy
- Spinal Cord Injury
- Multiple Sclerosis
- Parkinson's Disease
- Other neurological conditions***.***

* Minimum developmental age of four years.

9.2 Contraindications

- Fixed joint contracture of the affected limb that prevents the dynamic range of movement required during robotic therapy.
- Seizures triggered by photosensitivity (e.g. patient cannot watch television or use a computer due to this condition)

9.3 Patient Precautions

- Significant joint pain (intense, long-lasting and debilitating) that occurs within the robot range of motion
- Any known bone or skin disease that might increase the risk of bone fracture or skin sensitivity and injury during robotic therapy
- Lack of attention, inability to learn or comprehension of robotic therapy exercises
- Conditions that prevent a patient from safely being positioned in sitting

- Other medical conditions that could serve as contraindications to intensive exercise (for example, recent MI (myocardial infarction), significant cardiac disease, PVD (peripheral vascular disease with claudication), etc.
- Patients requiring isolation precautions

9.4 Robot Forces During Therapy

- The InMotion Arm Robot's evaluation and therapy activities apply up to 24 N (2.5 kg) of force to a patient's arm.
- The attending physician should determine whether the robot forces and range of motion can be safely handled by the patient.

10 Overview

10.1 Robot Components

The InMotion ARM-HAND Robot is an integrated patient workstation that features the following components;

- Electrical Box
- Computer Monitor
- Arm Handle with Forearm Rest
- Stop Button
- Control Box with Stop Button
- Additional parts provided with the Arm Robot:
    - Wireless Printer
    - Keyboard with touchpad
    - Patient chair

10.2 InMotion ARM Robot

1. Monitor
2. Monitor Screen
3. Table Height Adjustment
4. Forearm Rest with pads/straps
5. Stop Button
6. Pronation / Supination adjustment
7. Arm Handle
8. Control Box
9. Robot Height Adjustment
10. Keyboard storage hangers (left shown)
11. Leveling Feet (4 total)
12. Wheel Locks (4 total)

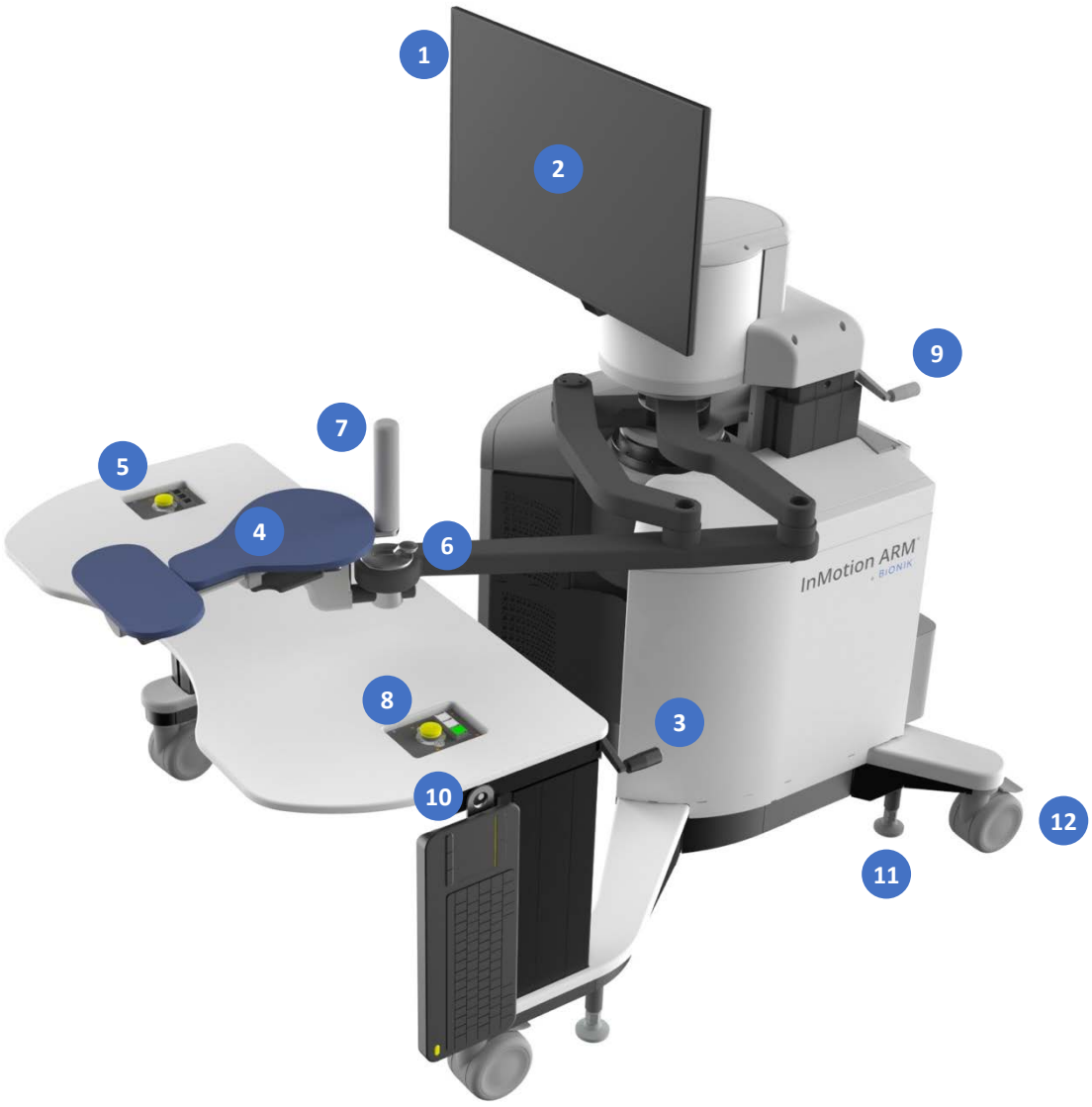


Figure 1 - InMotion ARM Robot

10.3 Rear Panel

The Electrical Box contains the ARM Robot motor and the integrated computer. At the back of the Electrical Box is the On/Off power switch, the power cord and all the important ports and connectors for the robot to operate (see Section 4.9.2 for Electrical Box Connector Symbols).

1. AC Power (ON/OFF) Switch

   Symbols: | On ◯ Off

   Use: Connects or removes electrical power to the system.

2. AC Power Socket
3. USB Port
4. LCD Status Display

Figure 2 - USB Port and LCD Display

Figure 3 - AC Power Switch & Receptacle

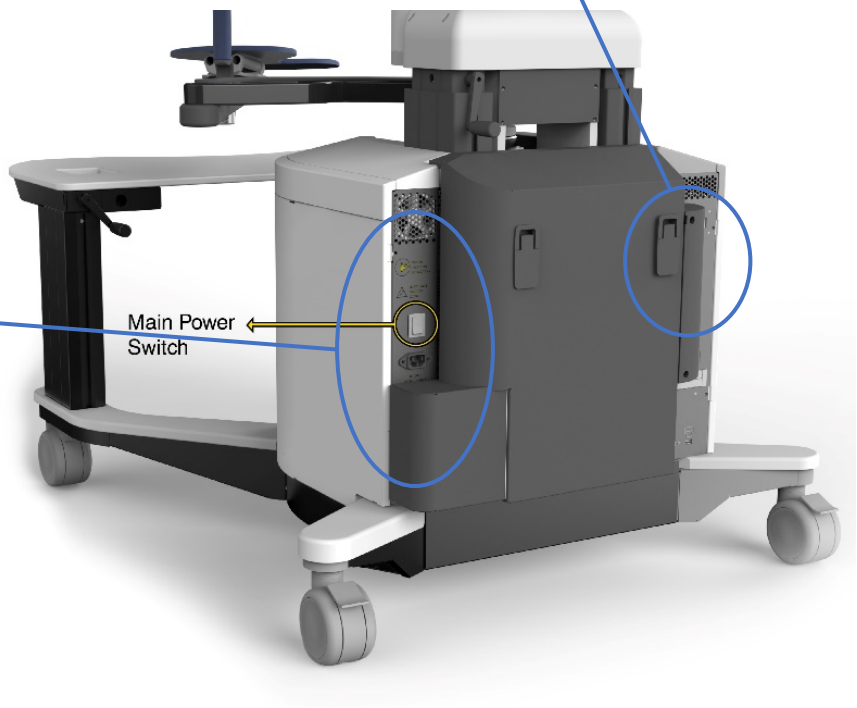


Figure 4 - Electrical Box - Rear View

10.4 Control Box and Stop Buttons

The Control Box is located on the right side of the robot table-top (when facing the monitor) and allows the clinician to operate the essential start and stop functions from the patient workstation. The Power and Active indicator lights allow the user to monitor the status of the robot while working with their patient. The Stop Buttons are located on both sides of the table-top, which allows the patient or clinician to quickly stop the activity of the robot motors from either side of the patient workstation.

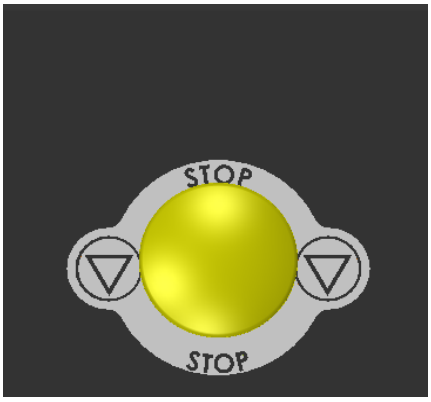


Figure 6 - Stop Button

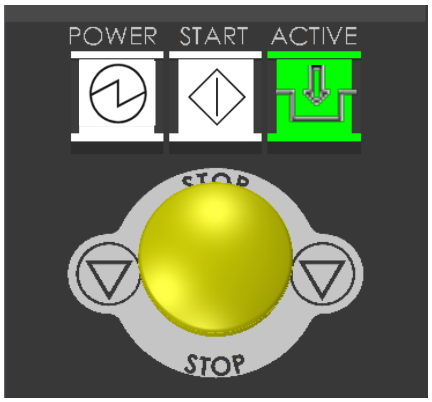


Figure 5 - Control Box

Control Box and Stop Button Symbols

Symbol	***Name***	***Use***
	Power (white lamp)	Lit when there is Control Power
	Start push-button and Ready Lamp.	Causes the robot motors to be powered. Lit (white indicating ready) when the motor drives are powered.
	Active (green lamp)	Lit when the motors are powered and the computer is directing motor movement.
	Stop Button (press-on, twist-to-release push-button)	Removes power from the motors. Can be pressed at the Control Box on the right side of the robot table or on the left side of the robot table. Both the Stop Buttons have the same effect. Press the Stop Button that is closest when required. To release a Stop Button, twist it clockwise.

10.5 Arm Handle with Forearm Support

The Arm Handle with Forearm Support provides a Velcro adjustable, soft and cushioned surface to rest the patient's arm on during therapy. The angle of pronation and supination can be adjusted 30 degrees (to the left or right) by pressing the black release button shown in Figure 7. This adjustment assists with comfortably positioning patients with increased tone or reduced joint range of motion.

Important - The use of the pronation/supination adjustment can allow the tip of the Arm Handle (Forearm Rest) to extend past the end of the table.

Forearm Rest Features

- Can be adjusted for varying length. Pull to lengthen. Push to shorten.
- Pivots (moves left and right). Hold Arm Handle frame while adjusting.
- Pads are fully adjustable. They may be removed and replaced.

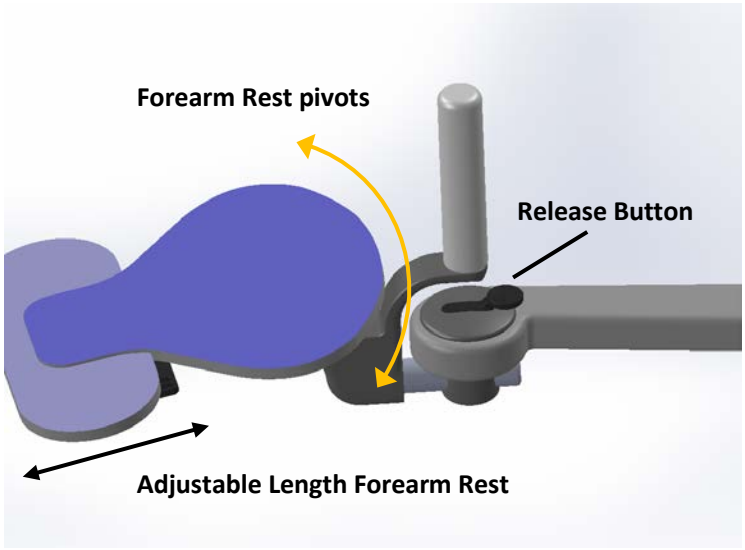


Figure 7 - Arm Handle with Forearm Support

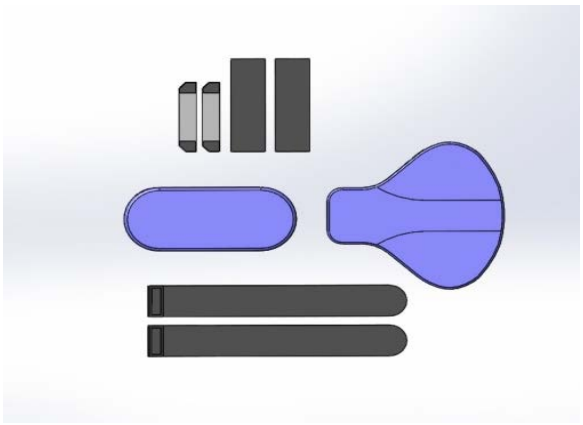


Figure 8 - Forearm Pad Components

10.6 Wrist Support

The Wrist Support can be added to the end of the Forearm Support, closest to the Arm Handle. Two holes in the rods of the sliding Forearm Support fit the two pegs seen in the design of the Wrist Support (Figure 9). The wrist support can assist with obtaining a comfortable positon for a patient with limited hand or wrist range of movement or tone. If a patient is unable to be positioned using the Arm Handle (Figure 7), the therapist may choose to rest the patient's hand and wrist on the Wrist Support during ARM Robot therapy.

Figure 9 - Wrist Support

10.7 Patient Chair

1. Description

The BIONIK supplied chair includes a shoulder harness that prevents the patient from possibly leaning or falling into the path of the moving robot arm. This harness system may also reduce compensatory trunk movements during the therapy exercises. The BIONIK provided chair has a capacity of 216lbs (98kg). Individuals weighing more than 216lbs will need to be positioned on an alternative chair with the appropriate weight capacity.

Figure 10 - Chair (Shown without its seat belt / shoulder harness)

2. Notes on the use of a Safety Constraint

If the BIONIK supplied chair is not used, a form of safety constraint should be employed to keep the patient from leaning forward and possibly sustaining an injury from the movement of the robot arm.

Ensure the chosen safety restraint system allows for rapid patient transportation away from the robot in case of an emergency. As of now, BIONIK does not provide a safety restraint other than the seat belt / shoulder harness attached to the BIONIK provided chair.

10.8 Logitech K400+ Wireless Keyboard

Tapping and scrolling on the K400+ keyboard

1. **Touch tapping**

   Press the Fn key and the left mouse button to enable and disable touch tapping.

   When touch tapping is enabled:

   - tap on the touchpad once to generate a single click
   - tap on the touchpad twice to generate a double-click
   - tap once with two fingers to generate a right-click

2. **Scrolling**

   Swiping two fingers horizontally on the touchpad scrolls left and right. Swiping two fingers vertically on the touchpad scrolls up and down, left, and right. You can also press the Fn key and slide one finger on the touchpad to scroll.

Figure 11 - Logitech K400+ Wireless Keyboard

11 Preparing for a Therapy Session

This section explains the basic operations of the robot, and the process of preparing for a therapy session. An explanation of the therapy protocols and activities is provided in the next section (6), Conducting a Therapy Session.

11.1 Turning On the InMotion Robot

Ensure the computer monitor is powered on during the system startup process. If the monitor is powered off during startup, the image may not display correctly.

Do not use the computer monitor power button. The computer monitor power is controlled by the robot. Turning off the computer monitor may result in no image displayed at power up.

1. Turn on the main power by pressing the AC Power (ON/OFF) Switch located on the rear panel. See item 1 in figure 14.
2. Wait for the system login screen to appear.
3. Push the Start Button on the Control Box (right side of patient table). See figure 5.

Note: If the Start button is pressed too soon (relative to the computer booting up), the system will not start and the button will not light. If this occurs, wait a moment and press the button again.

Figure 14 - Main Power Switch

11.2 Logitech K400+ Wireless Keyboard

1. If the keyboard is new, pull to remove the yellow battery tab.
2. Make sure that the keyboard switch is in the ON position.
3. The ON/OFF sliding switch is located at the top of the keyboard.

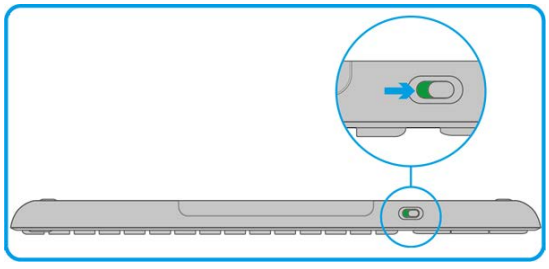


Figure 15 - Keyboard Switch

4. When the background is green, the keyboard is ON.
5. Turning the keyboard off when not in use can extend its battery life.

11.3 System Login

1. Once the system login appears, type the password (default= inmotion2) and press the Enter key. A loading screen will show while the robot is processing this command.

2. The Home Screen Login should then appear.

11.4 Home Login

Entering a Clinician ID

To beginning a therapy session, enter a clinician ID and then click the 'Continue' button.

Notes

- **The Clinician ID must use a-z letters, or numbers, or both.**
- **No spaces, non-English alphabets, or special characters.**
- **Use the clinician's name, initials or ID in the clinician ID field.**
- **The clinician's ID is recorded on patient reports.**

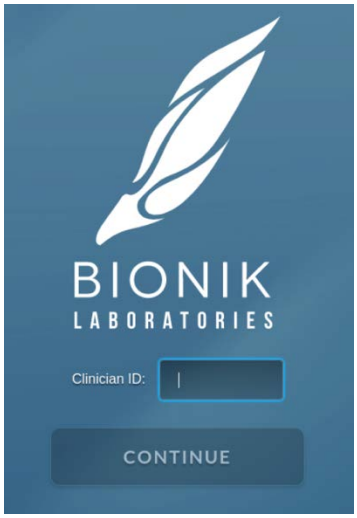


Figure 16 - Home Screen Login

11.5 Home Screen and Navigation Bar

Note: in order to secure patient data, the user must logout to the system login screen.

The Home Screen displays after the robot powers up. The Home Screen consists of a Navigation Bar at the top of the screen (items a - e) and the Main Menu (items f - k).

1. HOME Button - Displays (items a - e), the HOME Screen with the main menu
2. PATIENT DASHBOARD Button - Displays the patient dashboard with patient specific tasks such as: Therapy History, View Reports, and Edit Patient Info.
3. TIME, DATE, ROBOT STATUS - The current time, date and status of the Robot (ready, not ready or warning).
4. CLINICIAN ID & PATIENT ID - The name or initials of the logged in clinician and the patient ID code for the current patient.
5. HELP Button - Displays an onboard PDF version of the InMotion ARM user manual.
6. SET-UP ROBOT Button - Initiates the setup process which includes calibrating the robot for use.
7. FIND A PATIENT Button - Displays a search function that allows the clinicians to enter text to quickly find an existing patient record.
8. ADD A PATIENT Button - Displays a data entry screen where the clinician is required to enter a unique patient ID, and may enter additional optional data fields (if enabled in ADMIN).
9. REPORTS & ANALYTICS Button - Display the REPORTS and ANALYTICS screen which features a menu of reports that can be viewed, printed and saved to a USB drive.
10. ADMIN Button - Displays a screen that allows management of patient files, robot testing and settings (Show Patient Info Section).
11. LOGOUT Button - logs the clinician out to the home login screen.

Figure 17 - Home Screen

11.6 Activating the Home Screen Buttons

Preparing for therapy involves either Adding or Finding a patient. The robot must first be set-up in order to access these HOME screen buttons. The ADD A PATIENT and FIND A PATIENT will remain inactive until the SET-UP process is complete.

11.7 Set-Up Robot

Both patient and therapist should be away from the table during calibration. The forearm rest can move past the end of the protective table when it is moving freely.

Robot therapy games will not run unless the robot has first been set up.

1. Ensure the Start Button on the Control Box (right side of patient table) has been pressed.
2. Ensure that Start Button (also known as the Ready Lamp) Indicator is lit.
3. From the Home Screen, click the SET UP ROBOT button.
   a. Observe the screen message.
   b. Ensure the patient is removed from the robot, is away from the table, and the workspace is clear.
2. Click the Calibration Button.
   a. During set-up the robot arm will retract towards the motor housing and then move from one side to the other.
   b. Screen messages will show progress:
      - Loading Motor Configuration,
      - Calibration in Progress,
      - Good Calibration.
4. When the GOOD CALIBRATION message appears, click on the OK button.
5. SET-UP is now complete. The HOME screen reappears.

If a Bad Calibration message appears:

- **Check for any obstacles preventing the robot's mechanical components from moving freely (e.g. keyboard left on the table, monitor too low, table height obstructing robot path etc.). Remove obstacle and retry the SET-UP process.**
- **Ensure the Stop buttons have been released and the Active and Start indicator lights are lit on the Control Box (Figure 5). Retry calibration process.**
- **There is some other robot fault. investigate the reason for failure by consulting the Troubleshooting Section (19).**
- **Close all windows by pressing the letter "q" on the keyboard or clicking on the '"x" in the top right corner of each window.**
- **If after troubleshooting, setup continues to fail, please contact BIONIK customer support using the contact information located at the end of this manual.**

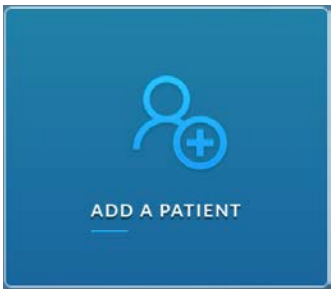
11.8 Add a Patient

The format of the Patient ID will be specific to the organization.

ePHI (electronic protected health information) that contains individually identifiable information should not be used.

BIONIK suggests using sequential ID numbers, such as a string of lower-case letters a-z and/or digits 0-9. No spaces, no non-English alphabet, no special characters.

1. To add a Patient ID to the robot database:



a. Click on the ADD A PATIENT button on the HOME Screen.

b. The ADD NEW PATIENT screen appears.

c. Enter data into the fields. Patient ID is mandatory.

d. Once data entry is complete, click the SAVE and START THERAPY SESSION button to begin the therapy session.

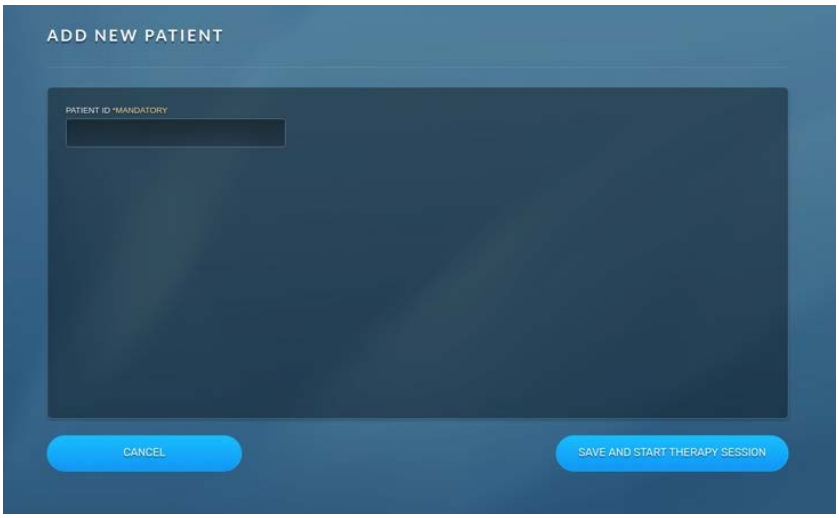


Figure 18 - Add New Patient Screen

2. About Patient ID Codes

- A unique ID code for each patient is required when using the InMotion Robot.
- The Patient ID allows data recorded from the patient evaluation and treatment sessions to be logged under one file and generate reports unique to that patient.
- The minimum data entry requirement for adding a new patient is the Patient ID Code
- Use a-z letters, numbers, or a mixture of both.
- Do not use spaces, non-English alphabetic or special characters.
- If a patient will be receiving bilateral, upper-extremity therapy with the robot, two Patient IDs must be created (e.g. 012345left, 012345right).
- Each organization is encouraged to establish a consistent Patient ID format that is

compliant with HIPAA regulations and organizational policies.

- If more than one Patient ID is created for a patient, the data cannot be merged into a single record.
- If at the end of a patient's therapy, the patient session is not closed and another patient begins a session, the data for both patients will be combined and cannot be separated.
- Clinicians should take care to only create a single Patient ID for a given patient.

3. Additional Patient Information

The optional Patient Info Section is intended for Research Use only.

Enabling the Patient Info Section may result in the collection and storage of ePHI (electronic protected health information). This ePHI may contain individually identifiable patient information.

For healthcare facilities required to comply with HIPAA (Health Insurance Portability and Accountability Act of 1996), BIONIK recommends restricting data entry to a HIPAA compliant patient ID only (as described in section 11.8 -1, -2).

a. Additional patient information fields may be added to the patient's record (such as patient diagnosis, age, gender, and impairments etc.).

b. To enable these data entry fields, go to the HOME screen, click on the ADMIN button, and check the box marked 'Show Patient Info Section.' See figures 19.

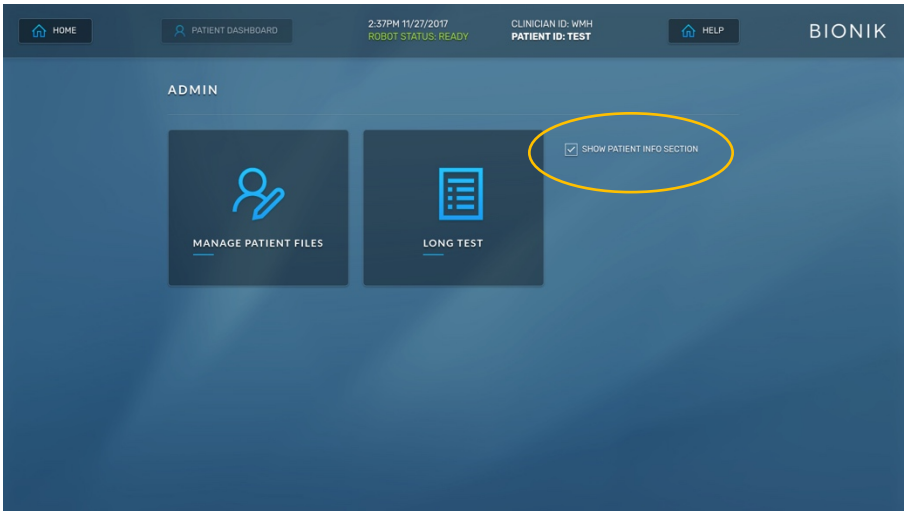


Figure 19 - ADMIN Screen (SHOW PATIENT INFO SECTION highlighted)

11.9 Find a Patient

1. To find a Patient ID that was previously added the to the robot:
   a. Click on the FIND A PATIENT button.
   b. The SEARCH PATIENT screen appears.
2. Type the Patient ID into the search field box and select the correct Patient ID from the list of matching results.
3. When the resulting Patient ID is displayed in the highlighted box, click the 'Start Therapy' button to transition to the Therapy Session.

11.10 Adjusting the Workstation Height

After positioning the patient centrally in front of the robot, lower the table until it just clears their knees. Have the patient hold the robot handle. Adjust the robot arm height so the patient's forearm is parallel to the floor, and their shoulder girdle is symmetrical and level. Read the height on the side ruler on the robot support pillars. Write down the robot arm and table height ruler measurements for future use with this patient.

Warning

The sequence in which you lower and raise the robot height is very important to prevent damage to the robot arm and table.

To lower the height of the robot, first lower the table height, then lower the robot arm.

To raise the height of the robot, first raise the robot arm, and then raise the table height.

11.11 Patient Positioning Considerations

Note: The patient's unaffected arm and hand must be kept off the table or out of the path of the moving robot arm.

The elbow is supported by the Forearm Pad during all evaluation procedures. The elbow should be positioned in 30 to 40 degrees flexion when the yellow circle pointer is resting on the center target during the green circle activities.

The robot is designed to accommodate persons of average height and build. In the event of a patient with a smaller body frame or other musculoskeletal impairments, it may be necessary to provide seat and/or back cushions to achieve a supported neutral spine position.

If a patient has a larger body frame that prevents positioning them in proximity to the table, it may be necessary to provide upper-back support to bring the patient's upper trunk forward and achieve a neutral position over the center target

All patients must be positioned and fastened correctly in the chair so that they do not make compensatory movements that interfere with the efficacy of the evaluation or therapy. Clinicians may consider using wedges, pillows, towel rolls, etc. to support the trunk and achieve the desired trunk position. For people with impaired trunk control, clinicians may support the trunk to prevent lateral trunk flexion, however patients with poor trunk control usually have a special adaptive wheelchair and the use their own wheelchair during robot training.

A safety strap or equivalent must be used with patients who cannot reliably hold themselves upright.

11.12 Patient's Arm Length

For a patient to benefit from the InMotion ARM therapy activities, the patient's upper extremity must be long enough to reach the far targets of the green circle interface.

Reaching the far targets of the standard 14cm green circle requires a patient's arm length (mid-shoulder to mid-hand) to be at least 22 inches (56 cm). Reaching the far targets of the small 10cm green circle requires a patient's arm length to be at least 17.5 inches (44.5 cm).

Note that the comfortable range of motion should be the determining factor, not whether the patient's motor control allows them to reach the far targets of the green circle.

The clinician may determine the appropriate size of the evaluation and therapy interface during the orientation phase of a therapy session. See section10.1.

11.13 Forearm Pronation Supination Angle

The Arm Handle allows for 30 degrees of pronation/supination angle adjustment, to accommodate patients with limited wrist and/or forearm rotation. Secure patient's forearm to the forearm support using Velcro straps. Position patient's forearm at a comfortable supination/pronation angle by pressing the white button located at the base of the HAND robot motor (on the end of the robot arm) and gently rotate the handle.

11.14 Therapist Location

The Therapist conducting the robot session should be located within reach of the system's Control Box or Stop button in case of emergency.

12 Conducting a Therapy Session

12.1 Overview

The Therapy Session Screen will guide you through an initial patient evaluation and treatment in 4 steps;

- **Patient Orientation**
- **Evaluation**
- **Therapy**
- **Report**

We recommend that each of these steps be completed, in order, during the patient's first InMotion ARM Robot session. The clinician may choose to move between, skip, or repeat these steps during subsequent sessions, according to the patient's individual needs. The Therapy Session Screen is only accessible once a Patient ID has been selected through 'Add a Patient' or 'Find a Patient,' by clicking 'Start Therapy Session.'

12.2 Patient Orientation

The Orientation step allows the clinician to choose the appropriate interface circle size of 14cm (5.51") or 10cm (3.94"), assess the patient's comfort and positioning, and familiarize the patient with the different robotic modes and range of movement.

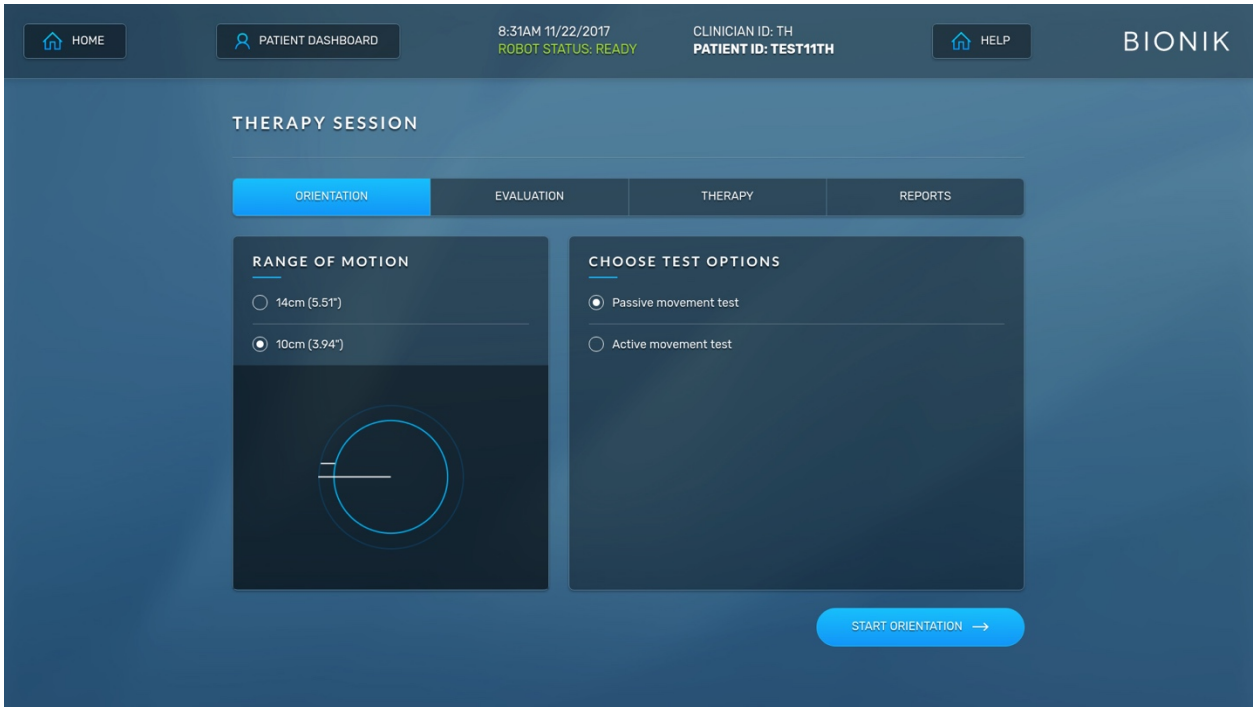


Figure 20 - Therapy Session, Orientation Tab

1. **Select Range of Motion (Circle Size)**
   Select either the 14cm or 10cm circle size based on the patient's comfortable arm range of motion. The patient's available arm range of motion may be influenced by many factors including their arm length, muscle tone, trunk position, and pain. See section 9.1.2 for more information.

2. **Select Orientation Activity**
   To familiarize the patient with the different robotic modes, select an orientation activity.

   - **Passive movement test** moves the robot arm to each of the targets, for one rotation of the green circle, whilst the patient remains passive. The robot will pre-position the patient's arm at the center target before the activity starts. Check the robot moves the handle to the flashing red targets shown on the screen, and that the yellow circle pointer follows the robot handle. If the patient is observed to be pulled forward with each movement away from their body, you will need to adjust their position (see Sections 5.9 & 5.11) or change the circle size from 14cm to 10cm and repeat this step.
   - **Active movement test** allows the patient to move the robot arm to each of the targets, for one rotation of the green circle, without any robotic assistance. The robot will pre-position the patient's arm at the center target before the activity starts. Check for the patient's understanding of the task.

   Note: The above activities will not collect patient data and will not change the patient record.

3. **Start Orientation**

   a. Prior to performing orientation, ensure the patient is positioned properly (see section 9.11 , Patient Positioning Considerations), their imparied arm is secured comfortably on the forearm rest, and their unimparied arm is not in the active therapy area.

   b. Click on the Start Orientation Button. The green circle task will appear.

   c. To begin the orientation task, Press the spacebar on the keyboard.

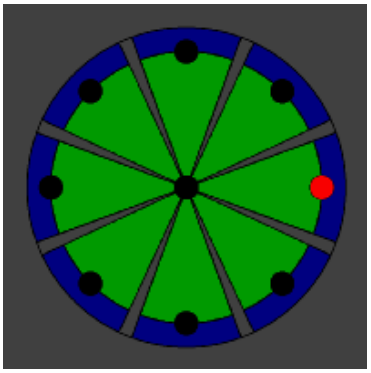


Figure 21 - Clock Therapy

   d. To pause the orientation task, Press the spacebar on the keyboard.

   e. Press 'q' on the keyboard to quit and return to the Therapy Session Screen.

   f. To perform additional orientation tasks, repeat the above step, choosing one of the two activities above.

12.3 Evaluation

The InMotion Robot has sophisticated evaluation technology that allows clinicians to assess motor performance before initiating treatment, periodically to measure progress, and at the end of a series of treatments to measure therapy outcomes. The InMotion Evaluation includes a series of 4 assessments (7 tasks) that precisely measure motor control components. The data generated from the InMotion Evaluation forms the Evaluation Report; which uses kinematic data to objectively document the progress of motor recovery.

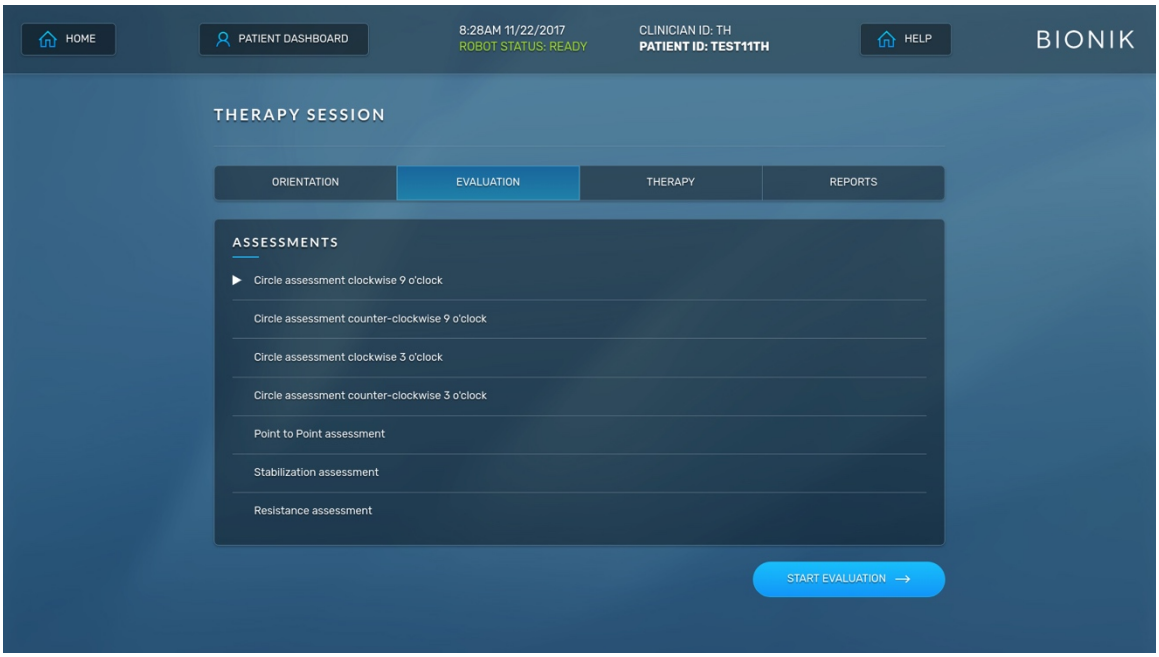


Figure 22 - Therapy Session, Evaluation Tab

Important Note: Before commencing the patient's evaluation, ensure that you have selected the correct Patient ID by checking the Navigation Bar. If evaluation data is collected under the wrong Patient ID, this will lead to inaccurate reporting and loss of data.

12.3.1 Selecting Assessments

The InMotion Evaluation is made up of the following kinematic assessments;

- 4 Circle Assessments
- Point to Point Assessment
- Stabilization Assessment
- Resistance Assessment

Precaution: It is recommended that, whenever clinically possible, all assessments are completed to ensure accurate data collection and calculation to generate the patient's Evaluation Report.

1. Circle Assessment (4 tasks)

The patient is required to complete 5 unassisted attempts to draw a circle, in a clockwise and counterclockwise direction, from 2 different starting positions (3 o'clock and 9 o'clock). The patient should aim to move freely and smoothly in one continuous circle movement, not to trace the circle on the screen. The 4 tasks are as follows:

- Circle Assessment Clockwise 9 o'clock
- Circle Assessment Clockwise 3 o'clock
- Circle Assessment Counterclockwise 9 o'clock
- Circle Assessment Counterclockwise 3 o'clock

a. Clinician Instructions

- Select the Evaluation tab on the Therapy Session screen
- The Circle Assessment Clockwise 9 o'clock task will be pre-selected
- Click 'Start Evaluation' to commence the assessment
- The clinician must pre-position and hold the patient's arm/robot handle so the yellow circle pointer is positioned on the base of the arrow provided on the screen
- Start the assessment by pressing the keyboard spacebar (this starts the data recording), whilst simultaneously releasing the patient's arm/robot handle
- Allow the patient to complete their movement, then press the spacebar again to finish (this stops the recording of movement)
- If the patient is unable to express any movement, or only a very small amount of movement, allow adequate time and opportunity (such as 5 red flashes of the center target) for the patient to complete the task before pressing spacebar and ending the recording
- Repeat these steps 5 times to complete the Circle Assessment Clockwise 9 o'clock task
- Once finished, the screen will change to the Therapy Session Evaluation page with the list of assessments. The next assessment will be automatically selected.
- Press 'Start Evaluation' to commence the next assessment. Continue this process until all Circle Assessments have been completed.

b. Patient Instructions

"Your goal is to draw a circle, starting at the arrow, in a clockwise/counterclockwise direction. The aim is to draw the circle in a single, smooth movement. Please wait to move until instructed and stop once you have completed the movement. You will be doing this task five times, please tell me when you are ready."

2. Point to Point Assessment

The patient is required to move the yellow circle pointer to each of the red flashing targets, for 5 rotations of the green circle (80 movements), without robotic assistance.

a. Clinician Instructions

- Ensure 'Point to Point Assessment' is selected within the Evaluation tab on the Therapy Session screen
- Click 'Start Evaluation' to commence the assessment
- The robot will pre-position the patient's arm at the center target.
- Press spacebar to start the assessment
- Allow the patient to make their best possible attempt to move toward each target in a single motion.
- Once finished, the screen will change to the Therapy Session Evaluation page with the list of assessments. The next assessment will be automatically selected.

b. Patient Instructions

"Your goal is to reach toward each of the red flashing targets, in a single smooth movement, aiming for the center of each target. If you are able to reach a target, the robot will prompt you to move toward the next one. You will complete five rotations around the circle in a clockwise fashion. Please tell me when you are ready."

4. Stabilization Assessment

The patient is required to hold the yellow circle pointer on the center flashing red target, while the robot attempts to move the patient's arm/robot handle towards the outer edge of the circle. This evaluation assesses the patient's ability to perform an isometric hold with their upper extremity.

a. Clinician Instructions

- Ensure 'Stabilization Assessment' is selected within the Evaluation tab
- Click 'Start Evaluation' to commence the assessment
- The robot will pre-position the patient's arm at the center target.
- Clarify the patient's understanding before commencing the assessment
- Press spacebar to start the assessment
- If the patient is unable to resist the robot force and hold the yellow circle pointer on the center target, you will see the robot move the patient's arm/robot handle to each of the red flashing targets
- Once finished, the screen will change to the Therapy Session screen with the list of assessments. The next assessment will be automatically selected.

b. Patient Instructions

"The robot is going to try to move your arm from the center target to the various targets. Do your best to resist the robot force and hold your arm steady over the red flashing center target (point to target for reference). Please tell me when you are ready."

2. Resistance Assessment

The patient is required to move against increasing resistance as they move the yellow circle pointer toward the outer red flashing targets. The robot will attempt to hold the patient's arm/robot handle on the center target.

1. Clinician Instructions

a. Ensure 'Resistance Assessment' is selected within the Evaluation tab

b. Click 'Start Evaluation' to commence the assessment

c. The robot will pre-position the patient's arm at the center target.

d. Clarify the patient's understanding before commencing the assessment

e. Press spacebar to start the assessment

f. If the patient is unable to move against the robot's force, the yellow circle pointer will remain on the center target

g. Once finished, the screen will change to the Therapy Session screen with the list of assessments. The next assessment will be automatically selected.

2. Patient Instructions

a. "The robot is going to try to hold your arm on the center target. Do your best to move your arm to the red flashing targets against the robot's resistance. If you are unable to hit the target, relax and allow the yellow circle pointer to move back toward the center target. Please tell me when you are ready."

12.4 Therapy Principles and Protocols

This section describes the therapy principles and outlines the therapy protocols available with the InMotion ARM Robot. Please refer to Section 3 (Health and Safety) and 5 (Preparing for Therapy) for a description of the correct patient selection and setup before commencing therapy.

Important Note: Based on a comprehensive evaluation, clinicians must select a therapy protocol appropriate to achieve their patient's goals. It is important to select research-proven therapy protocols to optimize a patient's rehabilitation outcomes with InMotion ARM Robot Therapy.

The green circle protocols have been extensively studied since 1994. The Active-Assisted protocols have been used in the majority of clinical studies and have the most evidence demonstrating clinical efficacy.

There are Additional Therapy Activities available on the InMotion ARM Robot. These activities may facilitate or challenge motor, cognitive, visual, or perceptual impairments, however the efficacy of these activities has not been verified, and using these activities routinely may not provide evidence based, best-practice therapy.

12.4.1 Therapy Mode

The 30 therapy protocols available with the InMotion ARM Robot can be accessed by selecting the 'Therapy' tab on the 'Therapy Session' page. The therapy protocols have been organized into categories, to facilitate easy navigation and a better understanding of the therapeutic goal of each protocol. The first step is to select the 'Therapy Mode' from the following options:

1. **Active Assisted therapy:** adaptive, assisted-as-needed therapy protocols.
2. **Stabilization therapy:** protocols requiring the patient to co-contract and stabilize the shoulder and elbow through an isometric hold.
3. **Resistance therapy:** protocols that provide robotic resistance and facilitate muscle strengthening.
4. **Error Augmentation therapy:** protocols that visually magnify movement errors.
5. **Curl Perturbation therapy:** protocols that emphasize motor learning through adaptation to an external force.
6. **Additional Activities:** resemble games that challenge motor, cognitive, visual, and perceptual impairments.

12.4.2 Selecting Therapy Protocol

Once a Therapy Mode has been selected, a list of corresponding therapy protocols will be shown. A description of the therapy activity of each protocol is included in Table 1-6;

12.4.2.1 Active-Assisted Protocols

Protocol Options	Description
Active-Assisted (AA) 14 Therapy	'Assistance-as-needed therapy' using the 14cm (large) green circle. The robot adapts the level of assistance based on the patient's performance. Red flashing targets are displayed in a clockwise direction. Performance Metrics Window appears after every 80 movements to provide the patient and clinician with feedback.
AA 14 Random Therapy	'Assistance-as-needed' therapy using 14cm (large) green circle. Red flashing targets are displayed in a random, unpredictable order. The random target sequence may maintain a patient's attention for longer periods of time. This may require heightened attention, adaptive motor planning skills, and surveillance of a larger visual field. Performance Metrics Window appears after every 80 movements to provide the patient and clinician with feedback.
AA 14 Fan North/South/East/West	Assistance-as-needed therapy' using the 14cm (large) green circle. The robot adapts the level of assistance based on the patient's performance. Red flashing targets are displayed only in (North/South/East/West) half of the green circle. Performance Metrics Window appears after every 80 movements to provide the patient and clinician with feedback. This protocol allows a clinician to focus motor training in a range relevant to the individual's impairment.
Active Assisted (AA) 10	Assistance-as-needed' therapy using 10cm (small) green circle. The robot adapts the level of assistance based on the patient's performance. Red flashing targets are displayed in a clockwise direction. Performance Metrics Window appears after every 80 movements to provide the patient and clinician with feedback.
AA 10 Graphical Therapy/ Random/A/BAc	'Assistance-as-needed' therapy using 10cm (small) circle with pictures and laser-beam pointer. These protocols provide the same features and treatment principles as the corresponding Active-Assisted 10cm/14cm protocols. They are named 'A' (for pictures of aliens, rockets, and fireworks) and 'B' (for bunnies, bears, and toys) The only difference between the 'A' and 'B' protocols are the images used. The yellow circle pointer has a laser beam animation that points in the direction of movement and then explodes once the yellow circle reaches the correct red flashing target, providing additional visual feedback.

Table 1 - Active-assisted therapy protocols and description.

12.4.2.2 Resistance Protocols

Protocol Options	Description
Resistance 50/100/150/200 Therapy	Strengthening task. Set of 80 movements with graded resistance (50/100/150/200 N/m), increasing as the cursor is moved away from the center of the circle. These protocols aim to increase strength or improve the patient's ability to move against resistance. No robotic assistance. No performance metrics are provided.

Table 2 - Resistance therapy protocols and description

12.4.2.3 Stabilization Protocols

Protocol Options	Description
Stabilization 50/100/150/200 Therapy	Isometric hold task. Set of 80 robotic perturbations of 50/200/150/200 N/m force. The patient is required to hold the yellow circle pointer on the center flashing red target, while the robot attempts to move the patient's arm/robot handle towards the outer edge of the circle. This protocol is intended to promote shoulder stabilization. No robotic assistance. No performance metrics are provided.

Table 3 - Stabilization therapy protocols and description

12.4.2.4 Error Augmentation Protocols

Protocol Options	Description
Error Augmentation 2/3/4 Therapy	Error augmentation task. Using the point-to-point 14cm green circle task, the robot visually magnifies movement errors perpendicular to the direction of movement by a factor of 2x/3x/4x. This protocol may assist with fine tuning motor control and refining path deviation errors. Error Augmentation training is a good option for patients with motor, visual and/or attention impairments. If Error Augmentation 2 is selected, a movement deviation of 1 cm, appears as a 2 cm error on screen. Set of 320 movements with performance metrics after every 80 movements.

Table 4 - Error Augmentation therapy protocols and description

12.4.2.5 Curl Perturbation Protocols

Protocol Options	Description
Curl Perturbation CW 12/24 Therapy	Movement adaptation training task. Set of 160 movements. A perturbation is applied perpendicular to the direction of movement, proportional to the velocity of movement, in a clockwise direction at a force of 12/24 Ns/m. No robotic assistance. The Perturbation Therapy 24 protocol is twice as strong as the Perturbation 12 activity. This exercise is suited for patients needing to improve their ability to adapt to changes in the environment.
Curl Perturbation CCW 12/24 Therapy	Movement adaptation training task. Set of 160 movements. A perturbation is applied perpendicular to the direction of movement, proportional to the velocity of movement, in a counterclockwise direction at a force of 12/24 Ns/m. No robotic assistance. The Perturbation Therapy 24 protocol is twice as strong as the Perturbation 12 activity. This exercise is suited for patients needing to improve their ability to adapt to changes in the environment.

Table 5 - Perturbation protocols and description

12.4.2.6 Additional Activities

Activity Name	Description
Maze	The aim of this activity is to move the yellow circle pointer through the maze using the yellow blinking light as a guide until the center is reached. The goal is to stay on path, whilst promoting movement efficiency by timing the task. Upon selecting the activity there is an option to Send the Forces, which means the robot will provide assistance-as-needed. This activity may be therapeutic for patients with visual field, spatial awareness, attention, or motor control deficits.
4-Way Pong	This activity is a simple variation on a classic Pong video game. The robot does not provide assistance. The player is successful when they can use the colored paddles to keep the yellow ball within the gray square. Controlling the robot arm, a patient moves a paddle to block the yellow ball from hitting the outer walls. The 4-way pong activity may be therapeutic for patients with motor planning, coordination, visual tracking, delayed responses or attention deficits.
Obstacle Training	This is a one-dimensional activity. The patient moves and holds a yellow oval shaped pointer through a series of openings in the moving barriers/walls. The goal is to control the yellow oval so it passes through each opening, avoiding the barriers.
Squeegee	The Squeegee activity is based on a window washing metaphor. An initial menu gives a choice of different image collections, some more suitable for children and others for adults. The patient moves the squeegee shaped pointer across the screen to remove the fog and reveal a clear picture. No robotic assistance. The Squeegee activity may be used for a number of purposes; to orient the patient to the concept that movement of the robot arm translates to movements on the screen, assess visual neglect by asking the patient to clear the screen, and to differentiate between visual neglect and motor impairments.

Table 6 - Additional training activities and description

12.4.3 Therapy Protocol Activities

Each of the protocols listed in section 7.3.2. will follow the same structure. The protocols have been designed to integrate regular re-assessment of the patient's motor control within the therapy session. A protocol consists of 4 Active Movement Tests and 3 therapy activities described below. Clear instructions for the clinician and the patient are provided for each therapy activity.

12.4.3.1 Active Assisted Protocol Activities (14cm and 10cm)

Activity Name	Description
Active Movement Test 1, 2, 3, 4	The patient is instructed to move the robot arm to each of the red flashing targets, for one rotation of the green circle, without any robotic assistance. The robot sensors collect data and map the patient's movement on a graph. The data collected from these tests during a therapy session are used to generate the Daily Therapy Report. All active movement tests (1-4) are the same, however a test must not be repeated within the same therapy session as this will cause the data to be overwritten.
(Therapy protocol name) 1, 2, 3	Each set of the therapy activities (1-3) are the same and comprise between 80-320 movements (depending on the protocol selected). Therapy activities can be repeated during a session without impacting the patient's data record. Each set of 320 movements in the active-assisted protocols takes approximately 15-20 minutes to complete.

12.4.3.2 Active Movement Test

1. Clinician Instructions

- Ensure 'Active Movement Test' is selected within the Therapy tab on the Therapy Session screen
- Click 'Start Therapy' to commence the test
- The robot will pre-position the patient's arm at the center target.
- Press spacebar to start the test
- Allow the patient to make their best possible attempt to move toward each target in a single motion.
- If a patient has high tone, their arm may need to be held on the starting position. When spacebar is pressed, the arm must be released. Their arm is likely to move towards their

body due to flexor muscle synergy; it is important to record this movement.

- Once finished, the screen will change to the Therapy Session Therapy page with the list of therapy activities. The next therapy activity will be automatically selected.

2. Patient Instructions

"In this activity, I will ask you perform 16 movements without robotic assistance. The robot is recording your performance. Your goal is to reach toward each of the red flashing targets with the yellow circle pointer, in a single smooth movement, aiming for the center of the target. It is important for you to initiate movement as soon as you see the target change color. Please tell me when you are ready."

12.4.3.3 Active Assisted Protocol Activity Instructions

1. Clinician Instructions

a. Ensure the Active Assisted therapy activity is selected within the Therapy tab.

b. Click 'Start Therapy' to commence the activity.

c. The robot will pre-position the patient's arm at the center target.

d. Press spacebar to start the activity.

e. Press 'b' to activate or deactivate the beeping cue that occurs with the completion of a movement to a target (either actively by the patient or with robotic assistance).

f. For the AA 10 Graphical Therapy protocols (select 10cm range of motion in 'Orientation'), If the yellow circle pointer moves faster, the laser beam gets wider. If the pointer moves toward the target, the laser turns green, and if the movement is not accurate, it turns red. The patient should try to move the robot so that the beam is wide and green. There is also a score posted in the upper-left corner of the display, which increases more when the motion is fast and accurate.

g. The patient will complete 4 sets of 80 movements (5 rotations) within each therapy activity (1-3). After every 80 movements, the Performance Metrics Window will appear. See section 13, Performance Metrics for further details.

h. Press 'q' to exit Performance Metrics Window and spacebar to start activity again

i. Once finished, the screen will change to the Therapy Session Therapy page with the list of therapy activities. The next 'Active Movement Test' will be automatically selected.

2. Patient Instructions

"Use the yellow circle pointer to reach towards each of the red flashing targets, aiming for the center of the target, in a single smooth movement. The robot will help you by providing assistance-as-needed. Based on your performance, the robot will either increase or decrease the assistance provided to reach the targets. After 5 rotations of the green circle, we will take a break and the robot will give us some feedback on your arm movement. Please tell me when you are ready."

12.4.3.4 Stabilization Protocols

1. Clinician Instructions

- Ensure the 'Orientation' range of motion is set to 14cm, and the stabilization protocol is selected within the Therapy tab.
- Click 'Start Therapy' to commence therapy.
- The robot will pre-position the patient's arm at the center target.
- Clarify the patient's understanding before commencing the therapy.
- Press spacebar to start.
- If the patient is unable to resist the robot force and hold the yellow circle pointer on the center target, you will see the robot move the patient's arm/robot handle to each of the red flashing targets. Consider reducing the robot force if this occurs (50 is the smallest force and 200 is the largest force).
- Once finished, the screen will change to the Therapy Session page with the list of activities. The next Active Movement Test will be automatically selected.

2. Patient Instructions

"The robot is going to try to move your arm from the center target to the various targets. Do your best to resist the robot force and hold your arm steady over the red flashing center target (point to target for reference). Please tell me when you are ready."

12.4.3.5 Resistance Protocols

1. Clinician Instructions

- Ensure the 'Orientation' range of motion is set to 14cm and one of the resistance protocols has been selected within the Therapy tab
- Click 'Start Therapy' to commence the therapy
- The robot will pre-position the patient's arm at the center target.
- Clarify the patient's understanding before commencing
- Press spacebar to start
- If the patient is unable to move against the robot's force, the yellow circle pointer will

remain on the center target. If this occurs, consider reducing the robotic force (50 is the smallest force, 200 is the largest).

- Once finished, the screen will change to the Therapy Session, Therapy page with the list of activities. The next activity will be automatically selected.

2. Patient Instructions

"The robot is going to try to hold your arm on the center target. Do your best to move your arm to the red flashing targets against the robot's resistance. If you are unable to hit the target, relax and allow the yellow circle pointer to move back toward the center target. Please tell me when you are ready."

12.4.3.6 Error Augmentation Protocols

1. Clinician Instructions

- Ensure the 'Orientation' range of motion is set to 14cm, and error augmentation therapy mode is selected within the Therapy tab.
- Click 'Start Therapy' to commence the activity.
- The robot will pre-position the patient's arm at the center target.
- Press spacebar to start the activity.
- The patient will complete 4 sets of 80 movements (5 rotations) within each therapy activity (1-3). After every 80 movements, the Performance Metrics Window will appear. See section 13, Performance Metrics for further details.
- Press 'q' to exit Performance Metrics Window and spacebar to start activity again
- Once finished, the screen will change to the Therapy Session Therapy page with the list of therapy activities. The next 'Active Movement Test' will be automatically selected.

2. Patient Instructions

"Use the yellow circle pointer to reach towards each of the red flashing targets, aiming for the center of the target, in a single smooth movement. The robot will magnify any movement errors, making your movements look wobbly. There is no robotic assistance. This task may help you fine tune and control your movement accuracy. After 5 rotations of the green circle, we will take a break and the robot will give us some feedback on your arm movement. Please tell me when you are ready."

12.4.3.7 Curl Perturbation Protocols

3. Clinician Instructions

Precaution: Due to the circular and velocity dependent robotic forces of the Perturbation Protocols, a clinician must be present throughout this therapy activity.

a. Ensure the 'Orientation' range of motion is set to 14cm and the Curl Perturbation therapy activity is selected within the Therapy tab.

b. Click 'Start Therapy' to commence the activity

c. The robot will pre-position the patient's arm at the center target

d. Press spacebar to start the activity

e. The patient will complete 1 sets of 160 movements (10 rotations) within each therapy activity (1-3).

f. Once finished, the screen will change to the Therapy Session Therapy page with the list of therapy activities. The next 'Active Movement Test' will be automatically selected.

4. Patient Instructions

"Use the yellow circle pointer to reach towards each of the red flashing targets, aiming for the center of the target, in a single smooth movement. The robot will add a circular clockwise/counterclockwise force to the robot arm during your movement to the target. There is no robotic assistance with this activity. The aim is to preempt and adapt to this circular force and continue to reach to the targets in accurate, smooth, straight lines. This activity may help you adapt to changes in your environment and control your movement accuracy. Please tell me when you are ready."

12.4.3.8 Additional Therapy Activities

1. Additional therapy activities include:

- MAZE
- 4-WAY PONG
- OBSTACLE TRAINING
- SQUEEGEE

2. Clinician Instructions for Additional Therapy Activities

Commands for

Start an activity:	Press '**n**'
Quit an activity:	Press '**q**'
Display activity menu:	Press '**Alt M'** (See Activity Modifications for each activity)
Move about the screen:	Use **Arrow Keys**

3. MAZE Therapy Activity

To complete this activity, a player must move the yellow circle pointer through the maze using the blinking light as a guide until the center is reached. The goal is to stay on path. At the beginning of the activity there is an option to Send the Forces, this means the robot will provide assistance-as-needed.

This activity may be therapeutic for patients with visual field, spatial awareness and attention and motor control deficits. The number in top upper right-hand corner of the screen records time taken to complete the activity.

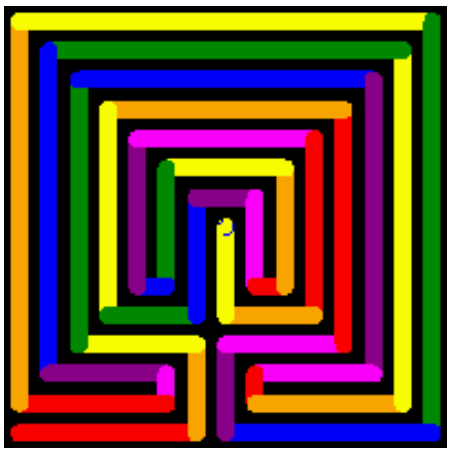


Figure 23 - MAZE Therapy Activity

Patient Instructions

"Begin by moving the yellow circle pointer to the beginning of the maze in the bottom left corner of the screen. Move your yellow circle towards the blinking dot at the next corner of the maze. Continue until you have reached the end of the maze."

4. 4-WAY PONG Therapy Activity

This is a simple variation on a classic Pong video game. There is no robotic assistance for this activity. The player is successful when they can use the colored paddles to keep the yellow ball within the gray square. Controlling the robot arm, a patient moves a paddle to block the yellow ball from hitting the outer walls.

The Pong activity may be therapeutic for patients with motor planning, coordination, visual tracking, delayed responses and attention deficits. It can be used as an adjunct to standing balance training.

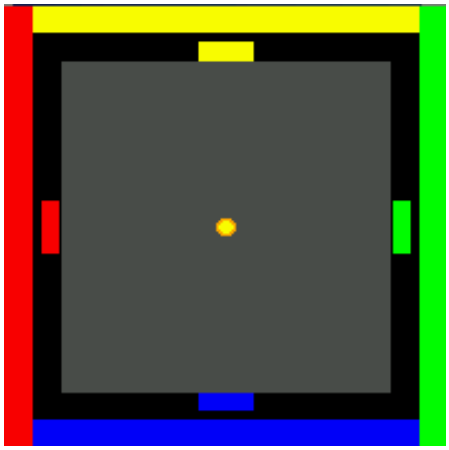


Figure 24 - 4-WAY PONG Therapy Activity

a. Patient Instructions

"There are 4 paddles that you control with the robot arm. You want to move the paddles to keep the yellow ball inside the gray box on the screen. If you go outside the box, you will lose points. You will gain points each time you keep the ball inside the box."

b. Activity Modifications

- Press ALT M to open menu
- The following variables can change the activity difficulty;

i. **Game Type**: The parameter "NSEW" represents the number and position of paddles (North, South, East, and West). The game can be played with one to four paddles; select paddle positions by adding or removing a representative letter.

ii. **Game Length:** How many movements/repetitions of the ball during the activity

iii. **Paddle Width**: The length/width of the colored paddles

iv. **Level (1-100)**: The speed of the ball during the activity. Higher numbers represent faster speeds.

v. The **paddle shape** can also be adjusted to Oval.

- Select New Game to activate modifications.

c. Activity Metrics

The following metrics provide feedback of activity performance;

- **Bounces:** how many ball bounces have been completed during the activity
- **Score**: each time the ball has been successfully kept within the gray square, the user will score 10 points. Each time the patient allows the ball to hit an outside wall, they will lose 10 points. This number represents the total score of the hits and misses.
- **Current Streak:** How many consecutive ball bounces the patient has saved from hitting the outside walls since the last hit.
- **Longest Streak:** The highest number of consecutive successful ball bounces.
- **Wall Hits:** How many times the patient has been unsuccessful in saving the ball from hitting the outside wall.
- **Paddle Hits:** How many times the patient has been successful in saving the ball from hitting the outside wall with a paddle throughout the duration of the activity. A measure of the number of patient movements.

Note: This information is not retained and cannot be viewed at a future date. The patient or therapist may wish to track their results.

5. Obstacle Training

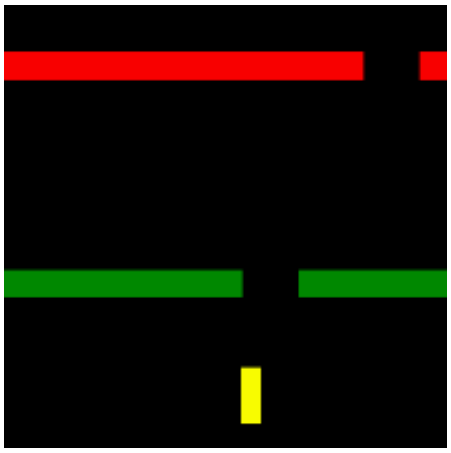


Figure 25 – Obstacle Training

a. Patient Instructions

"Pretend you are driving a yellow race car (yellow oval on screen). You must drive your car through the gates, avoiding crashing into walls. The robot may help you, but it will not prevent you from crashing, so you have to 'drive' the car."

b. Activity Modifications and Metrics

- The following variables can change the activity difficulty;
  - When you select this activity, choose to 'Send Forces' (robotic assistance)
  - The direction of the gates can then be selected (X=horizontal walls and side to side movements, Y=vertical walls and up and down movements)
  - Once the activity has started, press ALT M to open menu
  - **Horiz Motion:** Modify the direction (horizontal or vertical) of gates
  - **Game Width:** Change the width of the openings by adjusting the numbers in the text field up or down.
  - **Level (1-50)** We recommend that the speed/level is not set higher than 15.
  - Select New Game to activate modifications.
- The following metrics provide feedback of activity performance;
  - **Total Gates:** Number of walls/gates presented during the activity
  - **Through Gates:** Number of times the patient successfully passed through the 'gates'
  - **Hits Left/Right:** How many times the patient has hit one of the walls on the left or right

- **Score:** The patient gains 10 points every time they successfully pass through one of the gates, and then lose 10 points when they crash the yellow oval racer into one of the walls.
- **Current Streak:** How many consecutive gates the patient has successfully negotiated since the last hit.
- **Longest Streak:** The longest number of consecutive successful gates passed

Note: This information is not retained and cannot be viewed at a future date. The patient or therapist may wish to track their results.

7. Squeegee Therapy Activity

The Squeegee activity does not provide robot assistance. This activity is based on a window washing metaphor. The player moves the squeegee to remove the fog to reveal a clear image. The Squeegee activity can be used for several purposes:

Figure 26 – Squeegee Therapy Activity

- To orient the patient to the concept that movement of robot arm translates to movements on the screen.
- Assess visual neglect by asking patient to clear screen. Press ALT M to view percent filled
- To differentiate between visual neglect and motor impairments. Once a player has finished clearing the screen, ask them to use their unaffected arm to finish clearing the screen. Players that can clear the screen using their unaffected arm reflect a motor impairment rather than a visual impairment.

a. Patient Instructions

"Using your squeegee, you want to clear the screen to reveal a picture below. Try to clear the whole screen so we can see a complete picture".

b. Activity Modifications

Press:

i for a **Vertical Squeegee Tool**

- for a **Horizontal Tool**

o for a **Square Tool,**

n for a **New Image**

c to **Reveal the Image**

q to **Quit**

Press **ALT M** to **View Percentage of the Image Cleared**

c. Activity Modifications

The following metrics provide feedback of activity performance;

Time: Time taken to complete the activity

Percentage filled: total percentage of the picture colored/cleared

Percent left/right filled: percentage of the left or right side of the screen (respectively) colored/cleared during the activity.

12.5 Frequency and Duration of Therapy

A typical course of outpatient robot-assisted therapy is 18 sessions, consisting of a 1-hour treatment, 2 or 3 times per week, for a period of 6 to 8 weeks. A typical course of inpatient robot-assisted therapy is 20 sessions, consisting of a 1-hour treatment, 5 times per week for 4 weeks. A patient usually performs 1,024 movements per session (depending on the protocol selected). Many patients continue to make gains beyond the 6-8-week period tested during clinical trials, thus continuation of therapy may be as indicated by the patient's progress. Research does not tell us when a patient's recovery will plateau or end. Clinicians must assess each patient's progress and advocate for continuation of treatment when progress is being made.

12.6 Reports

Once a Patient ID has been selected, patient reports can be accessed in 3 ways;

- On the Home Page, select 'Reports and Analytics'
- On the Patient Dashboard, select 'View Reports'
- In the Therapy Session screen, select the Reports tab

Any of the above options will navigate to the screen below;

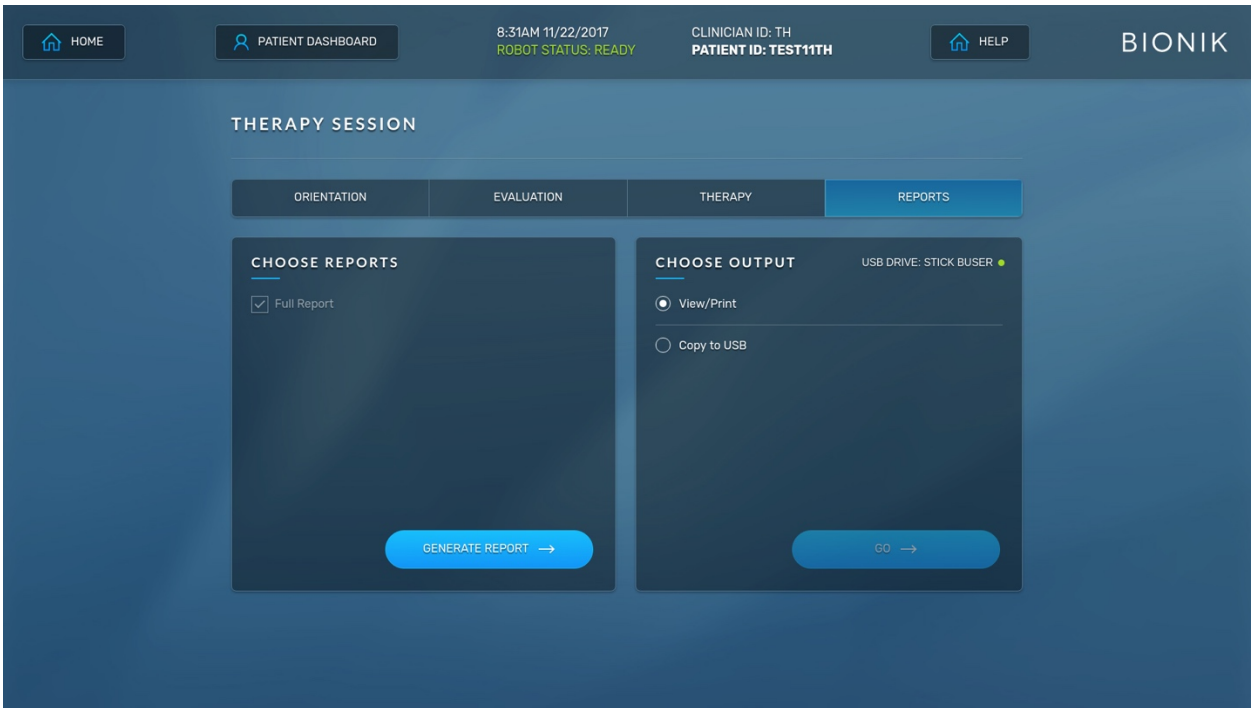


Figure 27 - Therapy Session, Reports Tab

Note: If the Evaluation tab is skipped during a patient's initial therapy session, the Clinician will be unable to generate this patient's report (and view the results of the Active Movement Test during their therapy). If even a single evaluation assessment has been completed, the Clinician will be able to generate a report and view the results of both the patient's subsequent Evaluation Assessments and Therapy Tests.

12.6.1 Generating Reports

1. To calculate and generate a report, first select the type of report under the 'Choose Report.' Refer to Section 9 for details regarding the different report types.
2. Then click 'Generate Report'
3. The time to calculate each report depends on how many evaluation sessions are recorded, and the amount of data collected for each evaluation task. For the standard Active-Assisted protocol, each report takes about 100 seconds per therapy session to calculate. If a patient has 3 evaluation sessions, that's about 5 minutes (300 seconds).

12.6.2 View and Print Reports

1. Once a report has been generated, select View/Print in the Choose Output Menu, then click 'Go' (see screen above for more detail.).
2. This will open a separate Firefox window with a PDF version of the patient's report
3. In this window, you can view the patient's report on screen or click on the printer icon in the top right of the Firefox window to print with a compatible printer.

12.6.3 Copy to Removable Media

- Insert your USB drive into the USB port at the rear of the robot (see figure 2)
- In the Choose Output Menu, select 'Copy to USB' and click 'Go'
- The Robot will copy the PDF file to your USB. Click 'OK' on the confirmation message popup.

13 Patient Dashboard

13.1 Patient Dashboard

The patient dashboard provides tools to aid with certain administrative tasks associated with the currently logged-in patient.

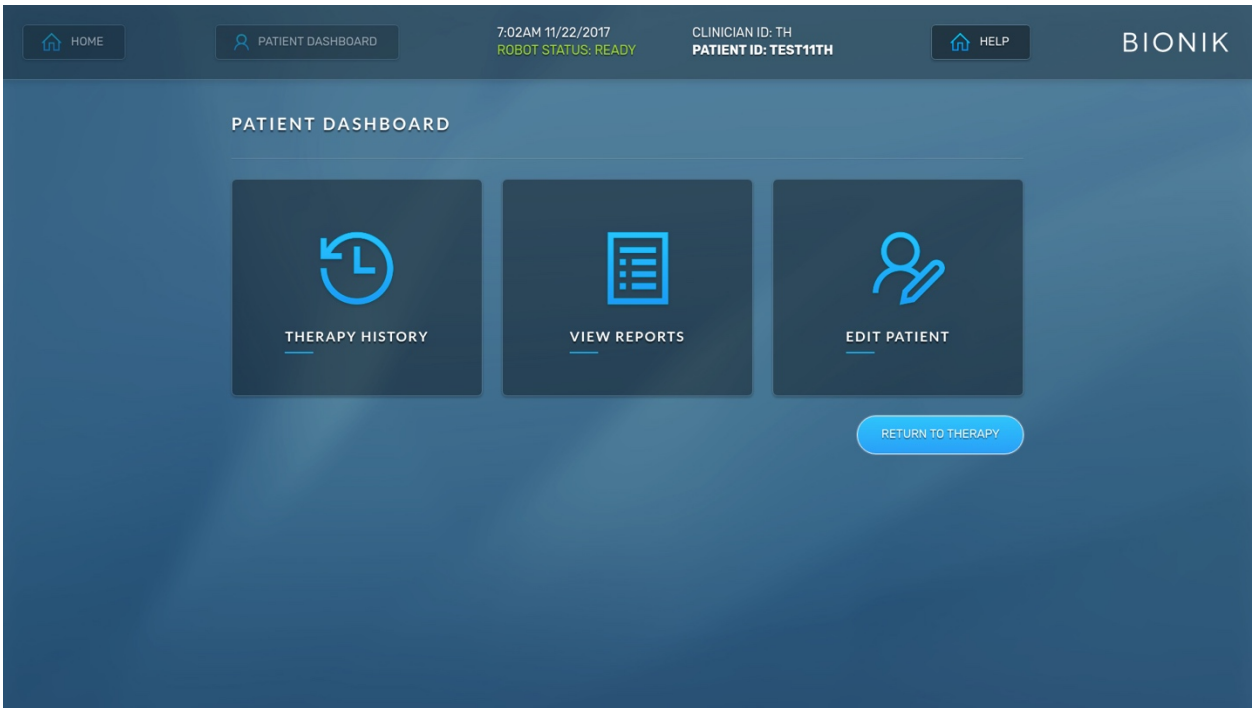


Figure 28 - Patient Dashboard

13.2 Therapy History

- The InMotion ARM records a history of therapy sessions in chronological order for each patient.
- To view the therapy history for the currently logged in patient, click on the Therapy History button.
- Once the patient's therapy history has appeared, each previous session may be viewed by clicking on the View button associated with the session date and time.

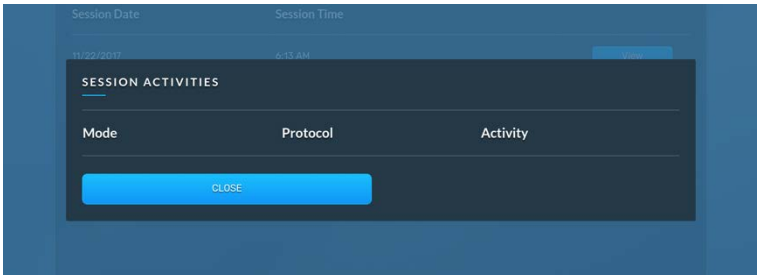


Figure 29 - Therapy History

13.3 View Reports

- Refer to Section 6.6 for details on generating, viewing, and printing reports
- Refer to Section 9 for details regarding the different types of reports.

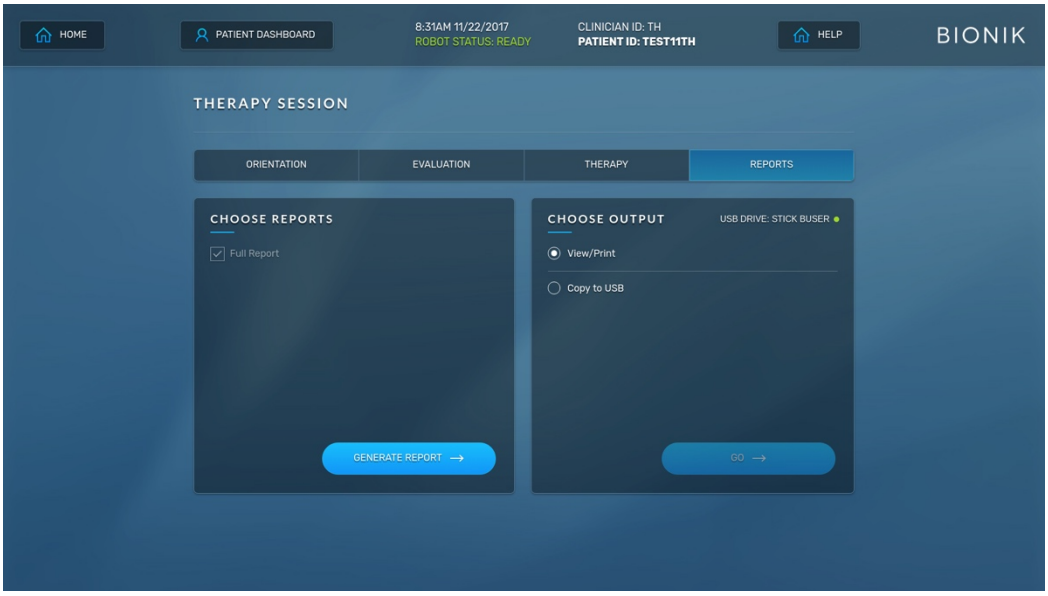


Figure 30 - Reports

13.4 Edit Patient

- To update a patient's information, click on the Edit patient button,
- The EDIT PATIENT screen will appear for the current patient.
- Click on any field to activate editing for that field.

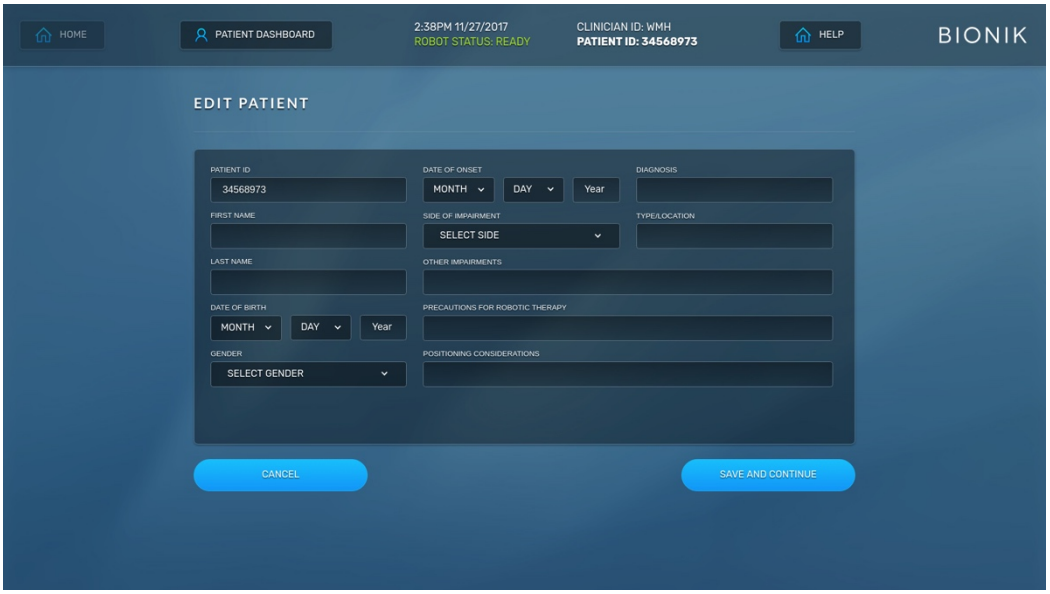


Figure 31 - Edit Patient

14 Admin

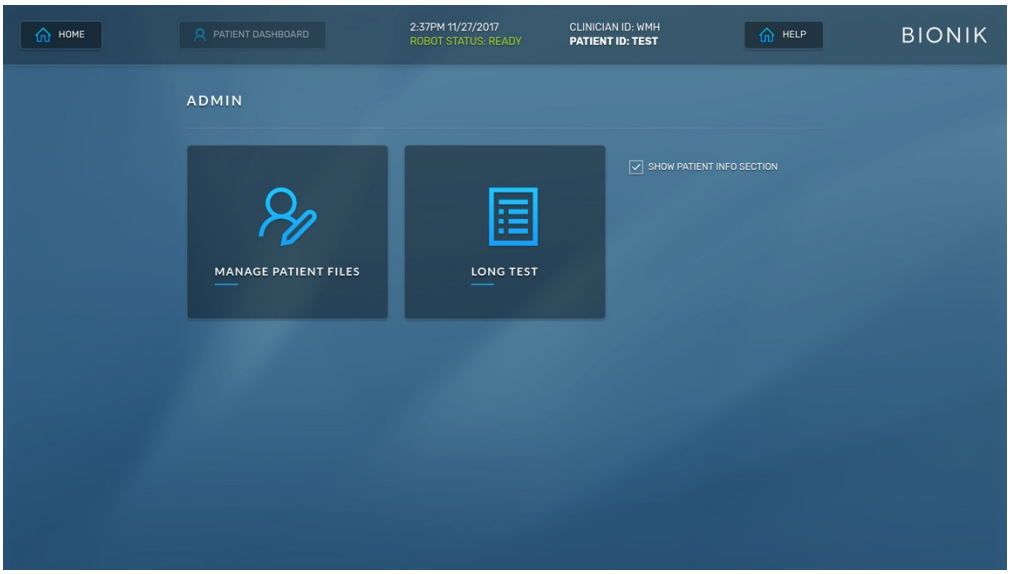


Figure 33 - Admin

14.1 Manage Patient Files

1. **COPY TO USB**

   Connect a USB Flash Drive to the USB port located at rear panel of the InMotion ARM Robot.

   Select a patient by clicking on the circle to the left of the desired Patient ID Code.

   Click on the COPY TO USB button

   When prompted, check the patient ID is the desired one to Copy and click YES.

2. **DELETE**

   Select a patient by clicking on the circle to the left of the desired Patient ID Code.

   - Click on the DELETE Files button
   - When prompted, check the Patient ID (s) are the correct file(s) to delete and click YES.

   Caution: Files deleted in this manner are permanently deleted and cannot be recovered.

Disk capacity: When the computer's hard disk starts to fill up, a warning will be displayed every time a game task is run. When the disk gets nearly full, the games will refuse to run. To check current disk usage, open a terminal window (click the rectangular

1. **Terminal button at the bottom right of the screen), type "df -h /home" and press Enter. For example:**
2. **$ df -h /home**
   Filesystem Size Used Avail Use% Mounted on
   /dev/sda2 23G 12G 11G 51% /home
   $

14.2 Long Test

The LONG TEST is a diagnostic tool that runs the robot through a 50,000 cycle test of the green circle passive movement task. It is not used in therapy, only for testing and troubleshooting.

14.3 Show Patient Info Section

a. SHOW PATIENT INFO SECTION is a setting that enables data fields to be used in addition to the Patient ID Code. These fields include: First & Last Name, Data of Birth, Gender, Date of Onset, Diagnosis etc.

b. These fields can be enabled in order to track usage of the robot and report on trends such as patient outcomes over time.

15 Performance Metrics in Adaptive Therapy

Note: These performance metrics are based on the Active Assisted Therapy activities. This is a repetitive activity that takes about 15 minutes for the patient to complete. The goal of this activity is therapy, not evaluation. The patient should be instructed that the Active Assisted therapy is not an evaluation task, and the task is too long for the patient to be careful enough to provide good evaluation data. For this reason, these performance metrics should not be considered as an evaluation of the patient's ability. The assessments provided in the Evaluation tab should be used for evaluation and formal documentation of performance.

The Robot senses position, direction, and velocity during Active Assisted Therapy activities. At completion of every 80 movements (5 rotations around clock) a Performance Feedback window appears displaying 5 quality movement metrics. These metrics provide performance feedback that can be used to coach patients.

For each metric, 0 is the optimum score. A lower score indicates better performance.

Figure 34 - Performance metrics

After 320 movements, a summary bar graph for each metric will appear on the screen. See figure 35. This summary bar graph provides an opportunity to review the patient's performance

[Placeholder]

Figure 35 - Performance Metrics Summary

15.1 ARM Robot Performance Metrics

1. Robot Initiate

Metric: The number of times the Robot initiated movement out of 80 attempts. Ideal score is 0, indicating the patient initiated all 80 movements.

Score: Number of Robot initiations out of 80. Ideal score=0

2. Distance from Target

Metric: How close did the patient come to the target? The distance from center to target is either 14 cm or 10cm for the Active-assisted Protocols. To calculate this metric, the distance from the target is determined: 14 cm - distance traveled towards target. = distance from target.

Score: Distance in millimeters from the target, average over 80 movements. Ideal score=0. Trials with healthy controls indicates a score of 0-2 is attainable without neurological impairment.

3. Robot Power

Metric: How much moving power was provided by the robot, rather than by the patient? Measures amount of work the robot does to assist, averaged over 80 movements. It reflects patient's effort, tone and resistance to movement.

- Active: low score (below 70). The patient is actively moving; the robot is guiding.
- Flaccid: higher scores (70 to 120) Robot carries weight of arm, the patient is largely passive.
- High Tone: very high scores (+120) Patient resists robot either actively or due to hypertonia.

Score: Average milliwatts of power, average per slot. Ideal score=0 indicating no assistance was required to complete the task.

4. Motion Jerk

Metric: How smooth was the patient's motion? Measures change in acceleration or smoothness of movement. Jerky movement is similar to the experience of a person learning to drive a manual transmission car. The ideal score is zero, indicating a smooth or fluid acceleration and deceleration.

Score: Average meters (not millimeters) per second cubed, average per slot. Trials with healthy controls indicate a score of 100 (for the V2 model, this result may vary depending on the robot model and batch) is attainable without upper extremity impairment.

5. Distance from Straight Line

Metric: How far did the patient stray from the intended straight movement pathway between targets?

Score: Average distance in millimeters from the path, average per slot. Trials with healthy controls indicates a score of 2-4 is attainable without neurological impairment.

6. Helpful Hints

These 5 performance metrics are designed so that 0 is the best score. Motion errors will cause the scores to become greater than 0. The scores all measure real quantities, but because they are single numbers that summarize a set of 80 movements, they present information of a general nature as feedback for the patient during the therapy sessions. Therapists can use the data files generated by the protocol's evaluation tasks and reports for a more specific indication of the patient's progress.

Performance metric data is only collected between the time of motion initiation and the time when the pointer would hit the target if the patient does not resist the robot motor force.

The performance metrics are critical to the success the therapy. During the first three training sessions, it is important to review procedures and assess the level of understanding for each patient. A description of each performance metric with the score should be provided. Upon demonstration of competency and understanding by the patient, feedback is only provided when display changes. Verbal encouragement and environmental distraction should be kept to a minimum and feedback in general should be kept to a minimum (except for the performance metrics display).

For patients with minimal movement, encourage as much movement as possible and focus on motion initiation. For patients with significant movement, use the performance metrics indicating the patient's speed, accuracy, and smoothness. Frequently patients need to be told to slow down to be more accurate. There are “hide” and “show” buttons on each of the metric displays that may help the patient focus on the most relevant metric.

16 Patient Reports

The InMotion system produces the following reports that can be viewed on screen, printed or downloaded in PDF format.

- InMotion Log Data Report
- InMotion Evaluation Report
- InMotion Progress Report
- InMotion Utilization Report
- InMotion Daily Therapy Report
- InMotion Notes Record

16.1 Log Data report

The InMotion Log Data report shows the number of tests that were completed during the evaluation sessions compared to number of tests in a standard evaluation.

The Log Data Report displays Patient ID and session number at top of the page. The date, time, Patient ID and session are displayed at bottom of each page. The length of the report varies based on the number of sessions. This report shows a tally of tests measured during evaluation session. Each session is a separate table and each test is on a separate line. The Count column shows number of trials. If a test has an incorrect number of trials, the test is count is in bold. The number in the "Count Should Be" column represents the trials that should have occurred if the full treatment and evaluation protocols were followed.

16.2 Evaluation Report

The evaluation reports display findings for 9 evaluation measures that are calculated from Circle, Point-to-Point, Stabilization, and Resistance assessments. In addition to graphic representations, the evaluation reports quantify performance by providing an objective numeric value. The Evaluation report is a 1-page report providing graphs and motor control measures for each of the 4 evaluation tests.

At top of page 1 the Patient ID, Clinician ID, and the session data and time are recorded. Information about the side (left or right) tested can be added to the report by the clinician once printed or added in Edit Patient. See section 11.4.

If more than one evaluation has been conducted the session will display Session 1/ 2 evaluation sessions. Information will only be displayed for tests that were conducted. For example, if during the first session the patient did not perform circle tests, then results for circle tests would not be displayed.

At the bottom of page 1, the date and time of evaluation, type of report, patient ID and page number is printed.

Within the Evaluation Report, there are 4 graphs with the corresponding Evaluation Metrics displayed below each graph.

The following points briefly describe each evaluation metric:

1. Point to Point Assessment Metrics

The Point to Point graph and metrics indicate the patient's active range of motion and motor control in the horizontal plane. This assessment requires 80 movements or 5 rotations around the green circle.

The metrics produced by this assessment include:

a. Smoothness

This is mean velocity / max velocity. Movement following a minimum-jerk speed profile for reaching movements would have a smoothness result of 0.533. If motions are

accurate (if path and reach error are low and the graph looks correctly formed), a larger number indicates a better score.

b. Reach Error

This shows how close the patient moved to each target, measured in meters. 0.01 means the patient moved to within 1 cm of each target, on average. If a patient did not move from the initial position, the result would be 0.14 m (14 cm) from the destination target. A smaller number indicates a better score.

c. Mean Velocity

The mean velocity of each path movement is calculated, then the mean of these 80 means is calculated. If movements are accurate, a larger number indicates a better score.

d. Max Velocity

The maximum velocity of each movement is calculated, then the mean of these 80 movements is calculated. If movements are accurate, a larger number indicates a better score.

e. Path Error

The mean distance from the intended straight line movement pathway is calculated. The mean of these 80 measures is then calculated. A smaller number indicates a better score.

2. Circle Assessment Metrics

The Circle graph measures Movement Coordination in the horizontal plane. The patient is asked to draw 20 circles, in 4 sets of 5. The measurement scales for this graph are:

a. Size

A single ellipse is fit to the set of circle trials drawn by the patient. The area of the fitted ellipse is calculated in square meters. An 8 cm (0.08 m) radius circle would have an area of 0.0201 m^2. A greater result indicates a better score.

b. Independence

Independence is the ratio of the minor axis of the fitted ellipse to the major axis. A perfect circle would have a ratio of 1.0; a flat line would have a ratio of 0.0. A greater result indicates a better score.

3. Stabilization Assessment Metrics

The patient is asked to hold the robot handle still on the center target, while the robot applies force in different directions around the green circle.

An ideal trial would hold the yellow circle pointer steady in the center, with no motion. A trial with a patient with no upper limb motor activation will show a star-shaped graph, similar to the Point to Point assessment graph.

The metrics produced by this assessment include:

Hold Deviation

Deviation shows motion away from the center, in meters. A mean deviation and results for the 8 compass points are shown. A lesser result indicates a better score.

4. **Resistance Assessment Metrics**

   The Resistance assessment determines movement against resistance in the horizontal plane. The patient attempts 16 movements against graded resistance.

   An ideal assessment graph would show movement similar to the Point to Point star-shaped graph. A trial with a patient with no upper limb motor activation will show no movement away from the center target.

   The metrics produced by this assessment include:

   Displacement

   Displacement shows distance traveled from the center target, in meters. A mean displacement and results for the 8 compass points are shown. A larger number indicates a better score.

   A detailed explanation of the interpretation of the evaluation measures is outline of the scope of this user manual. This content will be covered in your Clinical Training schedule. For more information, please contact **support@bioniklabs.com**.

16.3 Progress Report

Throughout the course of treatment, a clinician may evaluate a patient's performance several times. The Progress report trends a patient's performance metrics across sessions.

The Progress Report is two pages and contains 9 bar graphs and Evaluation metrics. If 2 evaluations have been performed, then 2 bars per graph will be displayed. If 3 evaluations have been performed, then 3 bars per graph will be displayed for each measure, representing the result for the first, second and third evaluations.

This report records patient progress using sensitive, objective, and reliable kinematic measures of motor control. For patients with a severe to moderately impaired upper extremity, small changes in motor control may not immediately translate to function; however, the robot provides more sensitive measures of motor control recovery and progress than traditional tools.

Therapists are required to document patient progress. The Progress reports show the results

of intensive interactive robotic therapy. It can also be used to document progress with other treatment approaches or interventions. Objective progress comparisons can be used to justify continuation of treatment (when progress is occurring) and to support and engage patients in the recovery process

At top of the first page the report lists patient ID and first and last date of evaluations. At the bottom of both pages is current evaluation data and time, name of report, patient ID and page number.

Each graph has bars corresponding to number of evaluations. From left to right, the bar represents results from the most recent evaluation on the left.

The titles indicate test and measure type. At top of each bar graph next to name of measure there is a symbol indicating whether higher or lower values are better. For example, in the first bar graph: smoothness= [⋀]. The [⋀] symbol indicates that a higher number is better. For reach error the formula is y [⋁]. The [⋁] symbol indicates that less is better.

- A horizontal dotted line in each bar graph represents a typical value for an individual without upper extremity impairments.
- If the result is within range the bar graph will be fully enclosed by a black line.
- If the result is very large the bar will not have a back bar at top to indicate the value exceeds y-axis scale.
- If the result is very small the bar will not have a surrounding black line.
- If the result is missing from the data set the bar chart will show a short bar that drops below the zero line.

16.4 Utilization Report

The Utilization Report provides details about each therapy session including session date, number of therapeutic activities, and time spent with each activity. It also includes a summary of total number of sessions, total activities and total patient participation time.

16.5 Daily Therapy Report

The Daily Therapy Report provides a graphical representation of each Active Movement Test performed during a treatment session. The graph is accompanied by 6 objective performance metrics. Typically, 4 Active Movement Tests are performed during a treatment session, thus 4 graphs and their associated metrics appear on the report.

The 6 performance metrics include movement smoothness; reach error, mean velocity, max velocity, path error and initiation time. These metrics are the same as those produced on the Evaluation Report for the Pont-to-Point Assessment. The performance metrics in the

Daily Therapy Report are likely to differ from those displayed on the screen every 80 movements in the Active-Assisted Therapy protocols because the metrics displayed on the screen reflect the adaptations or adjustments in the algorithms that are happening in the background. The metrics in the Daily Therapy Report reflect actual performance without the influence of the robot adaptation and are therefore the most consistent metrics to use for daily treatment documentation and to track a patient's performance within a session.

It is normal for performance to vary within and across sessions, however it is most common to see a positive trend in performance over time. Therapists should not modify treatment protocol as a result of normal performance variation.

17 Completing a patient session

17.1 Logout

To Log out:

1. Click on the HOME icon in the upper left corner of the screen.
2. Select LOGOUT on the Home screen and select YES at the ARE YOU SURE prompt.
3. When the Home login screen appears, click on LOGOUT SYSTEM and select YES at the ARE YOU SURE prompt. These steps will secure patient data and return the user to the system login **page.**

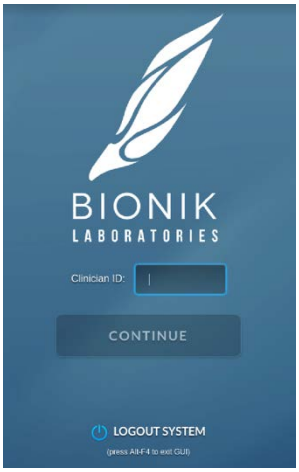


Figure 36 – Logout Prompt

17.2 Disconnecting the Robot from the Patient

1. Press the spacebar to pause the motion of the robot.
2. Stop any games in progress and close all open windows on the computer by pressing 'q' or using the window close 'x' button.
3. Release the Velcro straps on the forearm pads to free the patient's arm from the robot.
4. Move the patient away from the robot.

17.3 Cleaning the ARM Robot

The robot, and particularly the portion in contact with the patient, must be kept clean. Each site is responsible for setting hygiene procedures appropriate for its circumstances.

At a minimum, the Forearm Support and Arm Handle must be cleaned after every use by a patient. They should first be taken off the system, so they can be cleaned without the possibility of cleaning liquid getting into motors or electrical equipment.

The materials used can tolerate Isopropyl alcohol. Wipes should be used instead of bottles or spray bottles, again, to prevent liquid from getting into motors or electrical equipment.

At a minimum, after each patient, clean the:

- Arm Robot Handle
- Forearm Pad and Elbow Pad
- Wrist Support

Note: the above listed parts can all be removed from the system.

17.4 Cleaning the Logitech K400+ Wireless Keyboard

If you have a **Logitech Wireless** keyboard, before you clean your device:

- Make sure it's turned off.
- Remove the batteries.
- Keep liquids away from your device, and don't use solvents or abrasives.

To clean your Touchpad, and other touch-sensitive and gesture-capable devices:

- Use lens cleaner to lightly moisten a soft, lint-free cloth and gently wipe down your device.

To clean your keyboard:

- Use compressed air to remove any loose debris and dust between the keys. To clean the keys, use water to lightly moisten a soft, lint-free cloth and gently wipe down the keys.

In most cases, you can use isopropyl alcohol (rubbing alcohol) and anti-bacterial wipes. Before using rubbing alcohol or wipes, we suggest you test it first in an inconspicuous area to make sure it doesn't cause discoloration or remove the lettering from the keys.

For instructions on replacing the Logitech K400+ Wireless Keyboard batteries, see: Maintaining the Logitech K400+ Wireless Keyboard.

17.5 Powering the Robot Off

Warning: Except in an emergency, do not turn off power to the system using the main power switch without following the procedure outlined below.

1. Stop any games in progress and close all open windows on the computer by pressing 'q' or using the window close 'x' button.
2. Ensure that you logout of the current patient session. See section 13.1, Logout.
3. Logout of the system by clicking on the words "Logout System" on the Login screen.

4. Click the shutdown button [icon] in the upper right corner of the computer screen, then click “OK”. Wait for system to shut down.
5. Turn off the Main Power Switch by pressing on the bottom half of the rocker switch labeled ◯. See figure 3.

Notes:

- **Do not turn off the LCD Monitor.**
- **It is recommended that the rehabilitation robots be turned off at night.**
- **A logout or lock screen option is not available.**

18 Accessing the User Manual

1. Click on the HELP button in the Navigation Bar to display the onboard user manual.

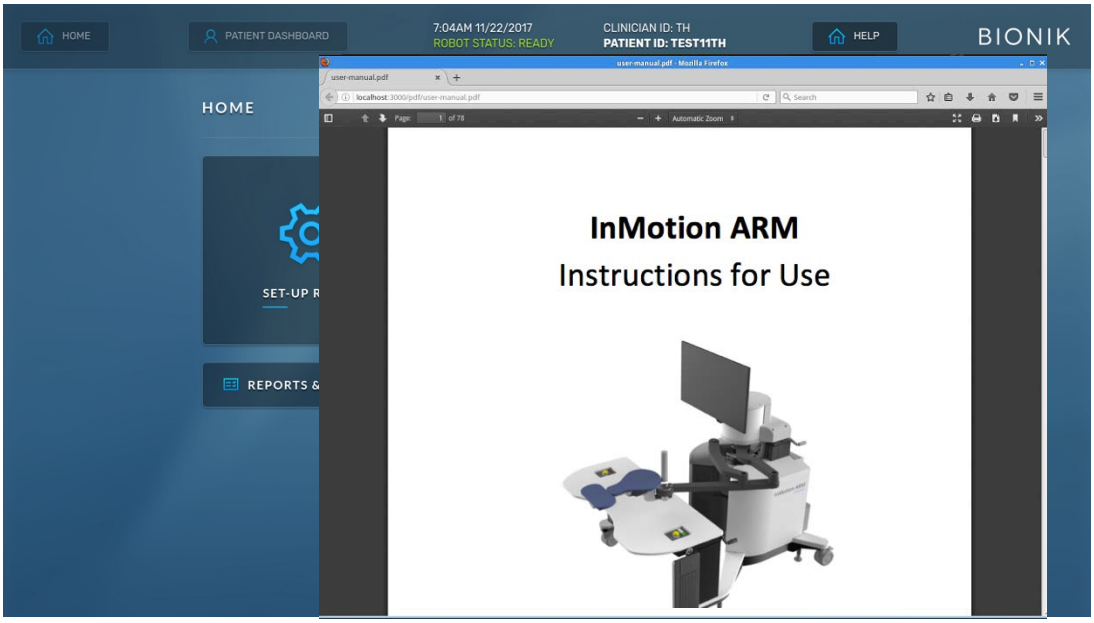


Figure 38 - Onboard User Manual

2. Or online via: **http://eng.interactive-motion.com/usermanual/arm.html**

19 InMotion Nomenclature Guide - Old vs. New

Robot Process	Old Nomenclature	New Nomenclature	Screen Location
Calibration	Calibration	Robot Set-up/Set-up	HOME
Add a new patient	New	Add a patient	HOME ADD A NEW PATIENT
Find an existing patient	Select	Find a patient	HOME FIND A PATIENT
Operation of Activities	Run	Start (Therapy Session, Orientation etc.)	ALL THERAPY SCREENS
Orientation	Test	Passive movement test	THERAPY SESSION - ORIENTATION Tab
	One-way record	Active movement test	THERAPY SESSION - ORIENTATION Tab (does not collect data) - THERAPY Tab (collects data)
Evaluation	Circle Clockwise…	Circle assessment clockwise…	THERAPY SESSION - EVALUATION Tab
	Circle Counter clockwise	Circle assessment counter clockwise	
	Point to Point	Point to point assessment	
	Playback Static	Stabilization assessment	
	Round Dynamic	Resistance assessment	
Therapy	Planar adaptive	Active-assisted (AA) 14 therapy	THERAPY SESSION - THERAPY Tab
	Planar adaptive10cm	Active-assisted (AA) 10 therapy	
	Planar random	AA 14 random therapy	
	Planar k1012/ku10 adaptive	AA 10 Graphical Therapy A/B	
	Planar k1012/ku10 random	AA 10 Random Graphical Therapy A/B	
	Adaptive Fan North/South	AA 14 Fan North/South/East/West therapy	
	Strength 50/100/150/200	Resistance 50/100/150/200 Therapy	
	Static 50/100/150/200	Stabilization 50/200/150/200 Therapy	
	Orthogonal Gain 2/3/4	Error Augmentation 2/3/4 Therapy	
	Curl 12/24 CW	Curl Perturbation CW 12/24 Therapy	
	Curl 12/24 CCW	Curl Perturbation CCW 12/24 Therapy	
Games	Games	Additional Activities	
	Cretan Square Maze	Maze	
	Pong	4-way pong	
	Race/Slalom	Obstacle training	
	Squeegee	Squeegee	
Reporting	Calculate	Generate Report	THERAPY SESSION - REPORT Tab PATIENT DASHBOARD REPORTS AND ANALYTICS
	Show	View/Print	
File Management	Tools	Admin	ADMIN

Figure 37 - InMotion Nomenclature Guide - Old vs. New

20 Printer

Notes: To print patient reports see section 14.

The robot computer system supports the HP M402dw Wireless printer. The system does not support other printer models.

20.1 Setting up Wireless Printing

This is usually done at the BIONIK factory. These instructions should only be needed to set up a new printer. The printer needs to be set up first, then the InMotion Robot system is set up afterwards.

20.1.1 HP M402dw Printer Control Interface

1. Control Panel Display
2. Attention light - blinks when the printer requires user attention
3. Ready light (green) - On when the printer is ready to print. It blinks when the printer is receiving print data, or when the printer is in sleep mode
4. Left arrow button - use to navigate through the selections within a menu
5. Back arrow button - use to exit from a sub-menu, or to exit from a selection without making a change
6. Wireless button - blinks when wireless is enabled. Press as a shortcut to the Wireless menu
7. Right arrow button - use to navigate through the selections within a menu

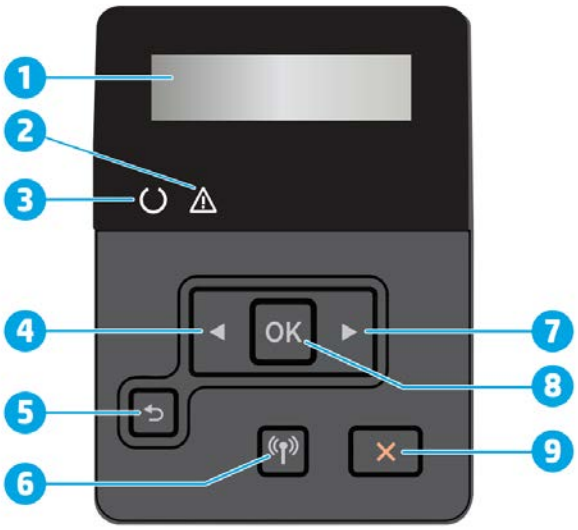


Figure 29 - Printer Control Interface

8. OK button - use to enter a sub-menu, or to select a displayed menu item
9. Cancel (X) button - use to cancel a print job, or to exit from using the Control panel

20.1.2 Setting up HP M402dw Printer

1. Turn printer on using the power switch on the front of the printer. Wait until display says: "Ready."
2. Start by pressing the Cancel (X) button and then the OK button to bring you to the top "Setup Menu".
3. Use the right and left arrow buttons to navigate through the choices until you find "Network Setup" (it will display under "Setup Menu") and press OK. You're now within the "Network Setup" submenu.
4. Press the right and left arrow buttons until you find "Wi-Fi Direct", and press OK. (Do NOT select "Wireless Menu".)
5. Within the "Wi-Fi Direct" submenu, find "On/Off", press OK, use the right and left arrow buttons to find "On", and press OK.
6. Use the right and left arrow buttons to find "Wi-Fi Direct Password" and press OK.
7. Use the right and left arrow buttons to find "View" and press OK.
8. Write down the password shown, you'll need it later (it's an 8 digit number). Also note - later, when we're setting up the InMotion Robot, the software will refer to this password as the "Key".
9. Press the Cancel (X) button to exit from Setup and bring you back to Ready.
10. If the Wireless button is blinking blue, that means Wireless is enabled, which we don't want. (If not, skip the rest of 9). Here's how to disable it.
    a. Press the Wireless button, which will bring you to "Turn Wireless On/Off".
    b. Press OK.
    c. If "On" is shown, press the right arrow button to bring you to "Off", and then press OK.
    d. Press the Cancel (X) button to exit.
11. Note that powering the printer off and on will not change the WiFi password.

20.1.3 addpri: Configure Wireless Printer Connection on Robot Computer

The remaining steps run as part of the addpri (add printer) script. The addpri script will

- remove an old printer configuration, if any,
- configure the wireless network,
- add a new wireless printer configuration
- send a test page to the newly configured printer

Text in the Robot Terminal Window are shown in fixed width text panes:

```
Example text in a fixed width text pane
```

Type the commands and inputs shows in bold in a Terminal Window. When <Enter> is indicated, type the Enter key on the keyboard. Type the bold text in the text panes only. Non-bold text in the text panes is printed by the software. Do not type the $. When it asks for password for imt, type your imt login password.

Change to printer setup directory and run addpri script.

If you get lost or something seems wrong, hit control-C in the Terminal Window several times to exit from script.

Open a Terminal Window (Control-Alt-T) and type this text shown in bold.

```
$ cd /opt/imt/distro/hp-printer-wifi <Enter>
$ ./addpri <Enter>
```

This addpri script will run all the setup commands. You will need to enter information as directed. This script will run several steps automatically, pausing only to ask for keyboard input, then it will pause to run the printer configuration.

addpri: Remove old printer setup, if any.

You must type the imt password when prompted.

```
Running sudo ./rmpri
[sudo] password for imt: (type password, then <Enter>)
Removing all old printer configs...
Remove all printers from network
Turning PC WiFi Direct off
rmpri done.
```

addpri: Turn on wifi and set up printer.

You must type the 8 digit WiFi printer password when prompted (where it shows NNNNNNNN).

```
Running sudo ./setpw
Setting up HP wireless printer...
Printer WiFi Direct mode must already be on!


Turning PC WiFi Direct on...

Searching network for HP M402 printer
'DIRECT-98-HP-M402-LaserJet' NN:NN:NN:NN:NN:NN 94

Found 1 M402 printer(s).

Script will wait to connect after you enter 8-digit WiFi Key.

Enter 8-digit WiFi Key from Printer LCD display: NNNNNNNN <Enter>
setpw done.
```

addpri: Run Printer Configuration Tool

You must follow instructions here when prompted. Bold text will tell you to click with the mouse. Windowing error messages may appear on the Terminal Window during this set of steps, ignore these messages.

```
Running system-config-printer
```

A Printer configuration program window will appear. Do the following commands in this window.

1. The heading will show: There are no printers configured yet.

2. Click +Add. A New Printer Window will appear. There will be two +Add buttons, use the lower one.

3. The window label will show Select Device.

4. The system responds slowly during this section. Wait for it.

5. Click Network Printer

6. After a few seconds, a list of printers will appear.

7. Find HP Laserjet M402dw

8. Click it and wait. it will take several seconds to select.

9. In right-side pane, Click IPP network printer via DNS-SD. (It may already be selected.) Do not select LPD network printer.

10. Click Forward

11. A popup will show: Searching for Drivers… wait for it to disappear.

12. The window label will show Choose Driver.

13. Ignore the bottom pane asking to select printer from database.

14. Click Provide PPD file.

15. Click the file selector, it should say: (None)

16. A Select a File popup will appear.

17. Select: imt-hp-m402-ps.ppd
18. Click Open.
19. imt-hp-m402-ps.ppd will show in the select button
20. Click Forward
21. The window label will show: Installable options
22. Click forward.
23. The window label will show: Describe Printer - keep these settings
24. Click Apply.
25. A popup will show: would you like a test page?
26. Click Cancel.
27. Display will show that the printer is configured.
28. Click X to close system-config-printer window.

addpri: Print a test page.

```
Running firefox checkmark.pdf
```

A test page will show a large checkmark.

- From the firefox menu, click the printer icon to print this page as a test page.
- Click X to close firefox.
- If the printer configuration works, it should print a black checkmark. No checkmark or a gray checkmark indicates a problem.

If there are multiple HP Laserjet M402dw wireless printer present, it should choose the closest one. If not, then turn off other similar printers during this process and try again.

21 Software Notes

The InMotion Robot uses a version of Ubuntu Linux that has been modified for this purpose. The installed applications have not been stripped down to a minimum, but please do not consider this a general purpose PC for office use. Please do not reconfigure the computer's operating system as this could interfere with robot operation.

21.1 Software Updates

Software updates are distributed by BIONIK. Follow installation instructions that accompany the update media.

22 Maintenance

If there are problems with the operation of your InMotion Robot, please call BIONIK at **+1 617-926-4800** or e-mail **support@bioniklabs.com**.

22.1 User Maintenance

The robot needs specific cleaning, both on a regular basis and after every patient. See the section on Cleaning the Robot, and consult your institution's infection control policies.

- Check the fan inlets for dust accumulation. To clean them, unplug the power cord, and then vacuum out the dust from them.
- If data is backed up, periodically verify that the backups are successful.
- Check that the cables at the power inlet and outlet have not become loose.
- Check that the external power cords have not been damaged.

22.2 Maintaining the Logitech K400+ Wireless Keyboard

Figure 30 - Logitech K400+ Wireless Keyboard

1. The **Logitech** wireless keyboard has a power switch at the top edge.

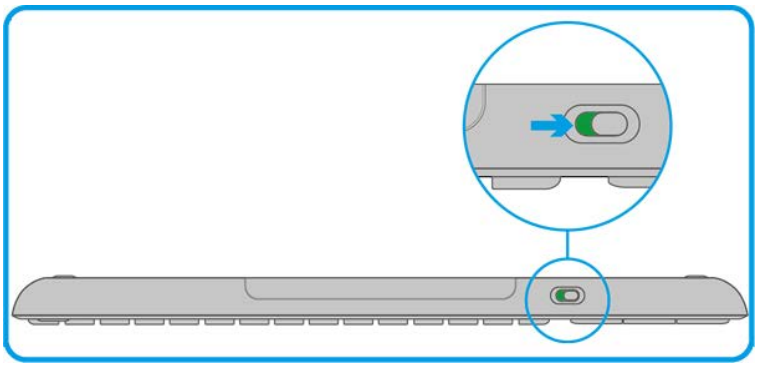


Figure 31 - Logitech K400+ Wireless Keyboard Power Switch

2. The Logitech keyboard has a battery compartment. We recommend replacing the keyboard batteries annually.

Warnings

- **Do not try to recharge the keyboard batteries.**
- **BOTH batteries must be replaced at the same time.**
- **Only use two (2) 1.5 volt AA (LR6) Alkaline batteries that meet IEC 60086-5 or UL 2054. (Both Eveready and Duracell state their Alkaline batteries meet IEC 60086-5.)**
- **Be sure to install the batteries with the + and - terminals facing in the direction indicated in the battery compartment. Failure to follow these instructions carries the risk of fire or rupture.**
- **If a battery is leaking, take care not to touch the chemicals and electrolyte in batteries directly. Since alkaline solution is used in this battery system, there are risks of not only damage to cloth or skin due to adhesion of the solution, but of loss of eyesight if the solution gets into the eye.**
- **In such an emergency case that the solution gets into an eye, wash it immediately with plenty of water and receive medical treatment from a doctor.**
- **When the solution adheres to the skin and/or clothes, wash it with water and consult a doctor.**

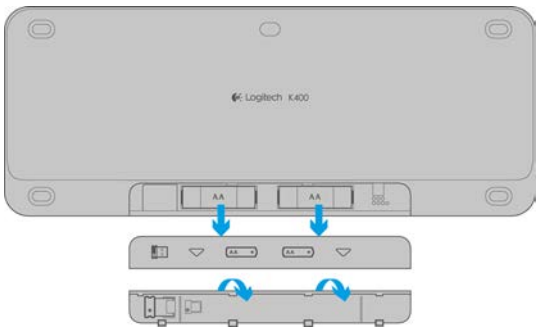


Figure 32 - Logitech K400+ Wireless Keyboard Battery Compartment

22.3 BIONIK Maintenance

BIONIK and its world-wide distributors offer maintenance services, including service life extension. Contact BIONIK for more information.

BIONIK will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist Service Personnel to repair those parts of ME Equipment that are designated by BIONIK as repairable by Service Personnel.

23 Troubleshooting

23.1 LCD Character Display Status

23.1.1 Boot

At boot, the microcontroller first checks that the software was compiled with the correct i2c speed. If it was not, the LCD displays; BUILD ERROR! I2C FREQ NOT 400 kHz Otherwise, the LCD displays (C) 2014 BIONIK dmd trb sps cjj for 3.5 seconds, and then displays waiting for the computer to boot.

This indicates that the microcontroller is waiting for the computer to upload the configuration file, which will tell it minimum and maximum sensor values and which sensors to enable and disable. The robot power (57V) cannot be enabled until that configuration file has been uploaded; this is part of the computer's boot process.

23.1.2 LCD Display

Once that file has been received, the screen enters its normal state, which might look something like this:

no 57V - 24C 3%
(sam2_temp)

23.1.3 Top line

The top line of the LCD display always shows four pieces of information.

1. **The first piece of information can be in one of five states:**

Display	Meaning
no 57V	robot power is off
57V ON	robot power is on
ACTIVE	robot power is on and a game is running
STOP	Stop button is pressed
STOP-FAIL	Stop button is half-pressed, i.e., contact failure

2. **The second piece can be a - or a C ; this indicates whether the robot is calibrated.**

3. **The third piece is the electrical box distribution board temperature.**

4. **The fourth piece is the fan speed. Note that to keep it within 2 characters, if the fan is running at 100%, it will display as 99%.**

23.1.4 Bottom line

The second line of the LCD display shows the fault status.

ACTIVE C 24C 3% no 57V - 25C 3% E-STOP - 25C 3%
motor power on (sam2_temp) status_es0

When the robot is running, the bottom line will display motor power on. Otherwise, if the power if off:

- If no fault is present, the most recent fault that caused the power to be removed will be displayed in parenthesis.
- If a fault is currently present - i.e., it is currently not possible to start the robot - the first fault found will be displayed, alternating with the word “FAULT!”. (If there are multiple faults, only the first one found will be displayed.)

23.2 Potential Troubleshooting Scenarios

23.2.1 Power lamp  does not light

If you cannot hear fans turning, check the rocker switch on the Electrical Box. If that is on, check if there is power available at the outlet. Unplug the Electrical Box and plug in a known good piece of equipment. If power is available, contact BIONIK.

If you can hear fans turning, check the fans by holding a piece of paper by them and seeing if air is drawn towards the Electrical Box. If so, power is likely OK and the problem may be a faulty Power lamp. If the robot otherwise works properly, it's OK to use the robot until a replacement lamp can be installed. Contact BIONIK for the replacement.

23.2.2 The center Start button’s lamp  does not light after you press it

If the robot functions properly other than the Ready lamp, then the likely cause is a burnt-out Ready lamp. The intended state of the Ready lamp can be read from the computer in a terminal window by typing: $CROB_HOME/tools/check-uc

- Check the reading of the LCD character display.
- Next, check that all Emergency Stop buttons are released. Do this by pressing each in, and then releasing it.
- Next, check if the connections for the two remote Emergency Stop boxes to the Electrical Box are loose (see Figure 1).
- Next, try power-cycling. First turn off the system via software. Then remove power from the system via the Electrical Box’s rocker switch or by unplugging it. Wait at least 30 seconds with the power off.
- If the above does not resolve the problem, contact BIONIK.

23.2.3 The center Start button's lamp  shuts off and operation stops immediately after the robot starts moving

Check for loose connections on the cables between the motors and the Electrical Box.

Check the reading of the LCD character display.

For those who have a technical background, power down the system, and then check inside the motor cases to see if either encoder's set screw is loose (more difficult).

23.2.4 The center Start button's lamp  and operation stops after operating for a while

Check for loose connections on the cables between that motor and the Electrical Box.

Check the reading of the LCD character display.

Check if, after a wait of a few minutes, the panel will turn back on. If so, there may be an overheating problem. Check the two lower fan inlets (on the lamps and buttons side) are sucking in air. Check that none of the inlets or outlets is blocked.

For those who have a technical background, power down the system, and then check inside the motor cases to see if either encoder's set screw is loose (more difficult).

23.2.5 Computer reports that it has not been calibrated

Robot needs to be calibrated. See section 6.7 , Calibrating and Selecting Robot Type.

23.2.6 Calibration fails

Repeat calibration and watch if the robot-arm is obstructed, preventing it from hitting the built-in stops.

Make sure the software is set for proper robot type, i.e. if there is a HAND Robot connected, make sure the software robot-type is set to "Planarhand"; if there is no HAND Robot, make sure it's set to "Planar" (ARM Robot).

23.2.7 After Calibration, handle is not centered

Check that the bottom cables at the Electrical Box are attached to the bottom motor, and the top cables to the top motor.

23.2.8 Internal computer does not start up, even though the Power lamp  is lit

If there has been too rapid a power cycle, the internal computer may not automatically restart on power-on. Shut off power to the Electrical Box for at least 30 seconds before restoring it.

Check the reading of the LCD character display.

23.2.9 One motor does not work

Check for loose connections on the cables between that motor and the Electrical Box.

Check if the output circuit breaker for that motor has tripped (normal condition has the handle all the way up; if tripped, lower the handle and then raise it.)

Check the text on the LCD character display.

With the power disconnected, open the Electrical Box and check for loose connections.

23.2.10 Everything works but the HAND Robot

Check the top of the "Games Console". If the Protocol is "planar adaptive", you need to change the robot type to Planarhand- in this User Manual, see section 6.7.

23.2.11 Intermittent Operation

Check for loose connections on the cables between the motors and the Electrical Box.

Check the reading of the LCD character display.

23.3 Fuses

No Power at the LCD Monitor

There are two Littelfuse 0215.800HXP fuses at reference designators F1 and F2 on the Power PCB that are in series with the AC Outlet Power. If you suspect one or both have failed, contact BIONIK. The reason they have failed should be determined before replacing them.

F5

There is a Littelfuse 0215010.MXP fuse at reference designator F5 on the Power PCB that is in series with the power supply for the servoamps. If you suspect it has failed, contact BIONIK. The reason it has failed should be determined before replacing it.

23.3.1 Failure of computer CMOS battery

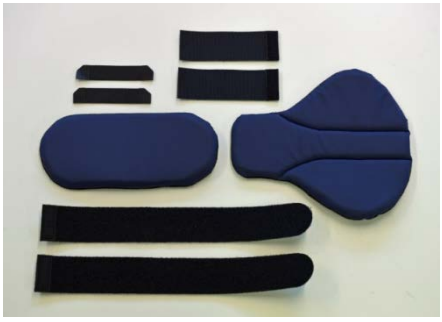
If the software indicates a failure of the CMOS battery, contact BIONIK.

> **Warning: There are dangers of fire or explosion with battery misuse. Do not attempt to recharge, force open, or heat the battery. Do not install it backwards. Because of these dangers, only BIONIK trained personnel should replace a failed battery and they should do so only with a brand certified for safety.**

As of the writing of this manual, only the Energizer ECR2032 and Duracell DL2032 were known to have such certifications. Also note, after battery replacement the BIOS settings may have to be reprogrammed.

25 Replacement Parts

The following parts and accessories are available for purchase form BIONIK. Please consult your BIONIK Regional Sales Manager for pricing and terms.

Part Number	Description	Illustration / Photo	Notes (all Qty = 1, unless noted)
IMT-5-AS-0616	**Arm Pad Kit, InMotion ARM, InMotion ARMw/HAND**		**Consists of:** **1. IMT-5-ME-0577, Forearm Pad** **2. IMT-5-ME-0599, Webbing Bridge, Qty 2** **3. IMT-5-ME-0578, Elbow Pad** **4. IMT-5-ME-0590, Long Strap, Qty 2** **5. IMT-5-ME-0591, Short Strap, Qty 2**
IMT-5-ME-0589	**Hand Rest**		

26 Disposal

Disposal of the computer's lithium CMOS battery in the Electrical Box must be done according to government regulations, ideally via recycling. Regulations can vary by municipality, state and country.

BIONIK only uses lithium CMOS batteries with IEC 60086-4 (Safety of lithium batteries) compliance, minimizing risks associated with these batteries.

Disposal of the keyboard's alkaline batteries must be done according to government regulations, ideally via recycling. Regulations can vary by municipality, state and country.

The Computer Screen is produced by ASUS, which has a recycling and takeback program. See http://csr.asus.com/english/Takeback.htm.

The WEEE symbol indicates that the product (electrical, electronic equipment) should not be treated as conventional waste in Europe. Please check local regulations for disposal of electronic products.

27 Specifications

27.1 Operating Environmental

Temperature:

30 C

0 C

WARNING: Allow time for the equipment to acclimate to the environment before operation - specifically, do not use the equipment while there is possible condensation.

Relative Humidity:

85 %, non-condensing, non-icing

35 %

Atmospheric Pressure:

101.3 kPa

80 kPa

27.2 Storage/Transportation Environmental

Temperature:

60 C

-10 C

Relative Humidity:

85 %, non-condensing, non-icing

35 %

Atmospheric Pressure:

27.3 Power

WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

100 — 230 V ac, 50/60 Hz, automatic. <900 VA. IEC 60320 C14 connector.

Computer Screen Power Port voltage is the same as the input voltage. Its current is limited to 0.8 A. It should be used to power the Computer Screen.

27.4 Mechanical

The Arm Robot and the robot support legs and base support at least 320 N (32 kg) of downward force and 213 N (22 kg) of upward force in the robot's worst-case position.

If your Arm Robot has a force transducer, to keep from damaging it, you should not push on the handle in any direction with a force greater than 65 N (6.6 kg).

The Arm Robot, the handle components, and the robot support table support at least 266 N (27 kg) of radially outward load.

Endpoint friction is less than 4.5 N.

Nominal peak motor torque is 16 Nm per motor.

Mass of uncrated Arm Robot system: 136 kg (300 lb)

Arm Robot dimensions:

Width 96.5 cm (38 in)

Depth 128.4 cm (50.6 in) - not including patient chair

Height 96.2 cm (37.9 in) - at lowest height, not including the monitor

27.5 Position, Velocity and Force Data Accuracy

- By design, InMotion ARM Robot position data are accurate to within 1 mm
- By design, InMotion ARM Robot velocity data are accurate to within 1 mm per second
- By design, InMotion ARM Robot force data are accurate to within 1 newton

27.6 Product Label

27.6.1 Product Label

The Arm Robot's Product Label is located on the back of the system, on the right side.

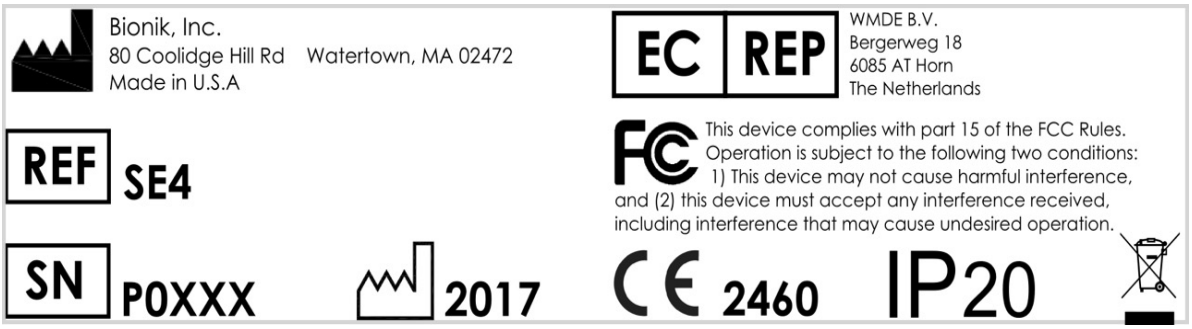


Figure 12 - Product Label

27.6.2 Product Label Symbols

Symbol	*Name / Use*
	Manufacturer (from EN ISO 15223)
REF	Model Number
SN	Serial Number
	Date of Manufacture (from EN ISO 15223)
EC REP	European Community Authorized Representative
	FCC Radio Frequency Interference Rules Notice FCC: Class B digital device, pursuant to Part 15 of the FCC Rules.
CE	European Community Notified Body Number
IP20	Ingress Protection (from IEC 60529). Protected against solid foreign objects of 12.5mm diameter and greater; Not protected against liquids
	WEEE – indicates separate collection for electrical and electronic equipment

Figure 13 - Product Label Symbols

27.7 Special Precautions regarding EMC

Medical Electrical Equipment needs special precautions regarding EMC (Electromagnetic Compatibility) and needs to be installed and put into service according to the EMC information provided.

Portable and mobile RF (Radio Frequency) communications equipment can affect Medical Electrical Equipment.

Only accessories, transducers and cables supplied by BIONIK may be used with the robot. Use of other accessories, transducers and cables may result in increased emissions or decreased immunity of the robot.

The robot should not be used adjacent to or stacked with other equipment. If such use is necessary, the robot should be observed to verify normal operation in the configuration in which it will be used.

27.8 Guidance and manufacturer's declaration — electromagnetic emissions

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

Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The robot 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 robot 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. The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Table 7 - Guidance, Electromagnetic Emissions

27.9 Guidance and manufacturer's declaration — electromagnetic immunity

The robot is intended for use in the electromagnetic environment specified below. The customer or the user of the robot 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	± 8 kV contact	Complies	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
	± 15 kV air	Complies	
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines	Complies	Mains power quality should be that of a typical commercial or hospital environment.
	± 1 kV for input/output lines	Complies	
Surge IEC 61000-4-5	± 1 kV line(s) to line(s)	Complies	Mains power quality should be that of a typical commercial or hospital environment.
	± 2 kV line(s) to earth	Complies	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0Vrms for 0,5 cycle	Complies - Pass by Crit. A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the robot requires continued operation during power mains interruptions, it is recommended that the robot be powered from an uninterruptible power supply or a battery.
	0Vrms for 1 cycle	Complies - Pass by Crit. A	
	70Vrms for 25 cycles	Complies - Pass by Crit. A	
	0Vrms for 5 s	Complies - Pass by Crit. C	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	Complies	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 8 - Guidance, Electromagnetic Immunity

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 robot, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** d = 1.17 √P d = 1.17 √P 80 MHz to 800 MHz d = 2.33 √P 800 MHz to 2.3 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[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	

Table 8 - Guidance, Electromagnetic Immunity (continued)

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.
[a] 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 robot is used exceeds the applicable RF compliance level above, the robot should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the robot. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 8 - Guidance, Electromagnetic Immunity (continued)

27.10 Logitech K400+ Wireless Keyboard

The Logitech K400+ Wireless keyboard operates at 2.4GHz, transmitting 0 dBm (1mW) power.

27.11 Other

Ingress Protection: IP20 (protected against objects > 12.5 mm in size, not protected against ingress of liquids).

Essential Performance: None

Expected Service Life: 3 years without maintenance

Mode of operation: Continuous

Applied Part classification: Type B

Protection against electric shock: Class 1 ME Equipment

A-weighted emission sound pressure level at the workstation: less than 70 dB(A)

Transportability: Stationary (Use of leveling feet is mandatory)

28 Training

BIONIK provides hands-on training at the customer site with all sales of the system. We recommend training for clinicians who will be using the system. Contact BIONIK Support <support@bioniklabs.com> for scheduling.

29 In Case of Emergency

1. Press a Stop button  to stop motion of the robot.
2. Pull the straps on the Forearm Support and Shoulder Harness to free the user's arm and trunk from the machine.
3. Safely transport the patient away from the machine.
4. If there is an equipment malfunction, pull the power plug.
5. Place a “Do Not Use” sign clearly visible on the robot until the malfunction has been resolved.

30 BIONIK Device Tracking

BIONIK would like to know the location of all its systems to facilitate possible recalls or advisory notices.

Accordingly, upon a transfer (whether through purchase or other type of acquisition) of an InMotion system, BIONIK requests the following information:

- New contact name, address, telephone number, email address
- Device serial number
- Date the device was received
- From whom the device was received

Please send this information to:

BIONIK Inc.
Support Department
80 Coolidge Hill Road
Watertown, MA, 02472

Or email: support@bioniklabs.com

31 BIONIK Contact Details

USA Office:

BIONIK Inc.
80 Coolidge Hill Road
Watertown, MA, 02472
+1 617-926-4800
www.bioniklabs.com

Support:
+1 617 926 4800 x4814
support@bioniklabs.com

Information and Feedback:
+1 617 926 4800
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