BIOMET

OperatingSystem

User Guide

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1. General Information

1.1 System Overview

The Biomet Operating System (BiometOS) is a web-based application developed by Biomet to transform the orthopaedic delivery model and help surgeons, office administrators and patients experience the full benefits of pre-surgical planning. The BiometOS platform allows partners to collaborate amongst themselves, and with Biomet, through an intuitive interface.

Important notice: The user of the BiometOS system is bound by the terms and conditions in the End User License Agreement entered into and agreed to when registering for an account. The BiometOS User Agreement can be reviewed by clicking the following hyperlink: https://onepatient.biomet.com/ wps/portal/signature/signature/about

The information you supply through your use of this website will be used by Biomet or its affiliates in accordance with Biomet's privacy policy. You can access this by clicking the link to the Privacy Policy at the home page of onepatient.biomet.com

1.2 Contact Information

- Phone: 574.371.3710
- Email: biometos@zimmerbiomet.com

2. System Summary

2.1 High Level BiometOS Process

The BiometOS process is described below at a high level to illustrate the flow through which information will move for each case.

2.2 User Roles

The BiometOS operates with the following user roles. System instructions for each role may be found throughout this user guide:

> Surgeon
> Office Administrator
> Distributor
> Sales Representative

2.3 Compatible Internet Web Browsers

Supported web browsers must at a minimum meet the following requirements

- The Web browser shall be compatible with Khronos Group WebGL 1.0
- The Web browser shall be compatible with HTML v5.0
- The Web browser shall be compatible with CSS3
- The Web browser shall be compatible with Javascript V6.0
- The Web browser shall be compatible with WEBGL_depth_texture extension support
- Automatic updates must be disabled on all browsers

Supported iPad applications – (plan review tool). The iOS application is supported on Apple iPad devices with the following minimum capabilities

- The iPad shall have, at a minimum, iOS 6
- The iPad shall be compatible with OpenGL ES 1.1
- The iPad shall provide at a minimum a screen with 1024 X 768 pixel resolution at 132 PPI
- The iPad at a minimum shall have Dual Core A5X system chip

3. Getting Started with the BiometOS

3.1 Logging in to the BiometOS

The BiometOS is an invitation-only system. Invitations are managed via email and initiated by a Biomet Sales Representative (the invitation process is covered in detail in Section 4.4 pg. 21). Each email invitation contains a link to join the system by registering for an account.

Once registered, you may access the BiometOS directly via **onepatient.biomet.com**.

1. Type the web address into the browser search bar and hit Enter.
2. The BiometOS log in page will be displayed (Figure 1).
3. Enter your user ID and password and click the "Log in" button.
   a. If your user ID and/or password are invalid, you will receive an error message.

Figure 1 – Log in Page

4. Once you have been authenticated and logged in, the Case List within the Case Management area is displayed (Figure 2). You are now free to navigate through the system.

Figure 2 – Case List

3.2. BiometOS Navigation

The section below describes the navigational options available to each user. These navigation options are located at the top of each page and are based on each user's role and relationships within the system. (Figure 3).

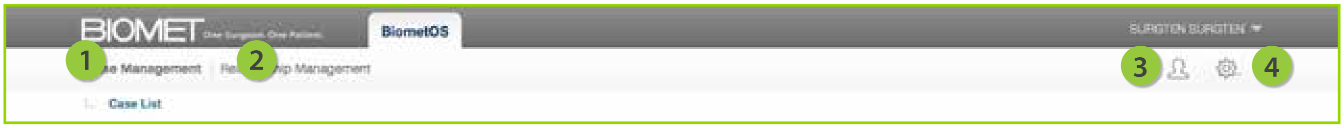

Figure 3 – Case Management

1. **Case Management** – The initial screen you will see when logged into the system. This screen contains two subsections, Case Action List and the Case Search.
2. **Relationship Management** – Allows you to view the relationships that you have with other users in the system and invite additional users.
3. **Invite User** – Begins the invitation process, allowing you to invite others to join the system. This option is only available to Distributors, Sales Representatives and Surgeon users.
4. **Manage Account** – Displays a menu with options for managing information within your user profile. Menu options are specific to each user's role.

3.3 Exiting the BiometOS

1. Click the down arrow to the right of your name in the header to display a menu.
2. Select the "Log Out" link (Figure 4).

Figure 4 – Log Out of BiometOS

3. The login page will be displayed and you will be logged out of the system.

4. Using the BiometOS

The following information highlights the core functionality available in the BiometOS and the steps to execute the desired actions. Some of the functionality within the system is specific to each user's role and relationships. Where applicable, users' role will be noted within this guide to indicate exactly who is able to perform a restricted function.

4.1 Managing Account - All Users

The Manage Account (All Users) section contains the information and options that are available for each user's account within the BiometOS. Options such as Personal Information, Notifications and Password are reviewed below. The system allows each user to update this information to ensure its accuracy.

4.1.1. Accessing the Manage Account Page

1. Click the Manage Account button in the navigation bar.
2. Review the available user account options and select the one from the list that you want to view and/or manage (Figure 5).

Figure 5 – Manage Account Menu

3. Once you have been redirected to the selected page, you can navigate through the additional options using the Manage Account tabs located at the top of the page (Figure 6).

Figure 6 – Manage Account Tabs

4.1.2. Personal Information Tab

The Personal Information tab within the Manage Account page contains information such as email address, name and phone number. This account option is available to all users for viewing and/or editing.

4.1.2.1. Editing Personal Information

1. Click the "Edit" button (Figure 7).

Figure 7 – Manage Account: Personal Information

2. Add or update information in the fields provided (Figure 8).

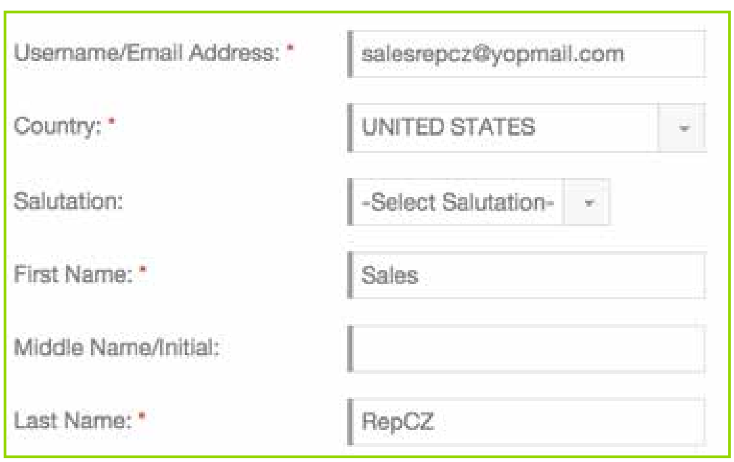

Figure 8 – Manage Account: Edit Personal Information

3. Click the "Save" button at the bottom of the tab to save your changes.
    a. The "Save" button will not be active unless there is a change made to one of the Personal Information fields.
    b. If the required fields are complete, you will receive a success message as confirmation of your changes.
    c. If any required fields are not complete, an error will be displayed and the changes will not be saved. You will need to correct any errors and save the changes.
4. Click the "Cancel" button at the bottom of the tab to discard your changes and return the fields back to their initial settings.

4.1.2.1.1. Uploading CV File to Personal Information

Within the Personal Information area, each user can upload a CV file to attach to their account. Only one file is allowed to be uploaded and stored at a time. Any current file would need to be removed prior to uploading a new version.

1. Click the "Edit" button to open the Personal Information fields.
2. Click the "Upload" button to display the Upload CV pop up (Figure 9).

Figure 9 – Manage Account: Upload CV

3. Click the "Choose File" button to search your computer for the file that you want to upload.
4. Select the file and the filename will be displayed in the field.
5. Click the "Upload" button to initiate the upload of your file to your profile (Figure 10).
    a. You will receive a success message as confirmation of successful upload.
    b. Remember to save your profile after uploading or removing files.

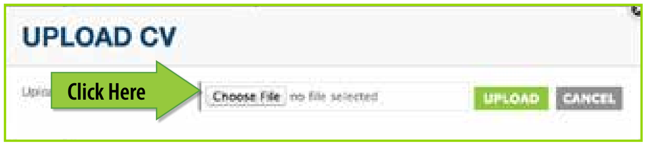

Figure 10 – Manage Account: Upload CV Pop-up

6. Click the "Cancel" button to discard the upload and close the upload window.

4.1.2.1.2. Downloading File from Personal Information

1. Click the "Download CV" link that is displayed in the Personal Information area (Figure 11).

Figure 11 – Manage Account: Download CV

2. A download window will open where you can select the location on your computer to save the file. This behavior will differ based on the web browser that you are using. You can open and view the file from its location once you complete the file download.

4.1.2.1.3. Removing File from Personal Information

1. Click the "Edit" button to open the Personal Information fields.
2. Click the "Remove" button next to the file to display the remove file pop-up (Figure 12).

Figure 12 – Manage Account: Remove CV

3. Click the "Remove" button on the confirmation pop-up (Figure 13).
   a. You will receive a success message as confirmation of successful file removal.
4. Click the "Cancel" button to close the pop-up and disregard your changes.

Figure 13 – Manage Account: Remove CV Pop-up

4.1.3. Notification Preferences Tab

The Notification Preferences tab within the Manage Account area allows you to manage the frequency with which you receive email notifications from the BiometOS. The Preferred Notification email default is your current email address, but can be changed from this page. (Please note that changing the email address here does not change your user ID for the system). Frequency of each notification type may be edited using the drop down menu. Options vary depending on the notification type.

> **Receive Immediately** – Receive a notification each time the associated action takes place within the system.

> **Receive Email Digest** – Collect all notifications that you would receive throughout the day and send them in one large notification each day.
> **Note: Notifications that are critical such as changes to your account, and other process related actions, are not eligible for this option.**

> **Never (Opt Out)** – Stop all notifications for the associated action. If this option is chosen, you will need to periodically check the system for notifications.
> **Note: Notifications that are critical such as changes to your account, and other process related actions, are not eligible for this option.**

4.1.3.1. Editing your Notification Preferences

1. Click the "Edit" button (Figure 14).

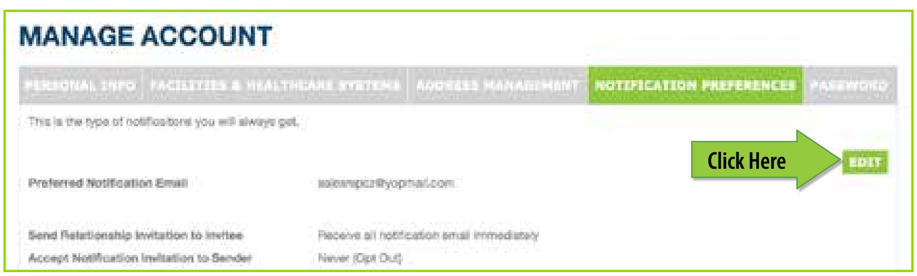

Figure 14 – Manage Account: Notification Preferences

2. The drop down field will open and allow you to update the frequency for each notification (Figure 15).

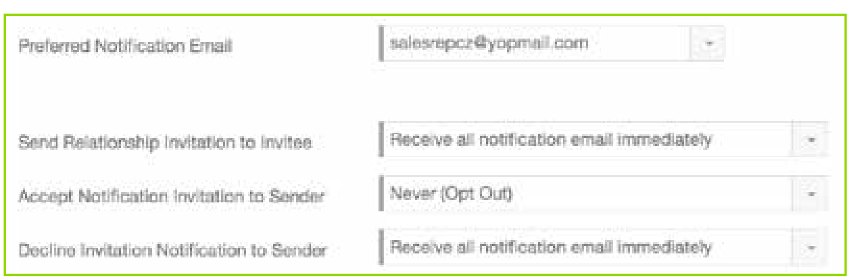

Figure 15 – Manage Account: Edit Notification Preferences

3. Click the "Save" button to update your preferences.

4. Click the "Cancel" to discard your changes.

4.1.4. Password Tab

The Password tab provides the ability to update your system password. Your password must meet the following requirements:

> 8 characters minimum
> At least one upper case character
> At least one lower case character
> At least one number or special character
> Cannot match user ID
> Cannot contain more than 2 of the same characters in a row (ex: dogggg! or 1111AA)
> Cannot be the same as previous passwords
> Cannot create new password within 2 minutes of each other

4.1.4.1. Changing Your Password

1. Enter your new password into the "New Password" field.
2. Re-enter your new password into the "Confirm Password" field.
   a. An error message will be displayed if the password entered does not meet the requirements listed above (Figure 16).

Figure 16 – Manage Account: Password

3. Click the "Submit" button to update your password (Figure 17).
   a. A confirmation message will be displayed.

Figure 17 – Manage Account: Password Changed

4. To cancel your changes, navigate away from the password tab without clicking the "Submit" button.

4.2 Managing Account – Distributors/ Sales Representatives

There are some options available within the Manage Account area that are specific to certain user roles. This section will highlight those options that are only available to the Distributor and Sales Representative roles.

4.2.1. Address Management Tab

The Address Management tab is where a Sales Representative can manage delivery addresses (Figure 18). A delivery address is an address that is associated to a Sales Representative or Surgeon and serves as the location that any Biomet instruments will be shipped to for a particular case.

Sales Representatives can setup a default delivery address, as well as additional delivery addresses, for their associated Surgeons. Setting a default delivery address ensures any cases that are planned will always have an address set for delivery.

When a case plan is approved, the system will assign the delivery address based on the addresses set up for the Surgeon and/or Sales Representative. The system will first check to see if the associated Surgeon has a delivery address assigned to their account. If there is no address assigned to the Surgeon, the system will use the default delivery address assigned to the associated Sales Representative.

If there is no default delivery address set for the Sales Representative, an email will be sent to the Sales Representative to inform him/her that a case has been approved with no address. To remedy this situation, the Sales Representative must log into the system, setup a delivery address and then manually add it to the case.

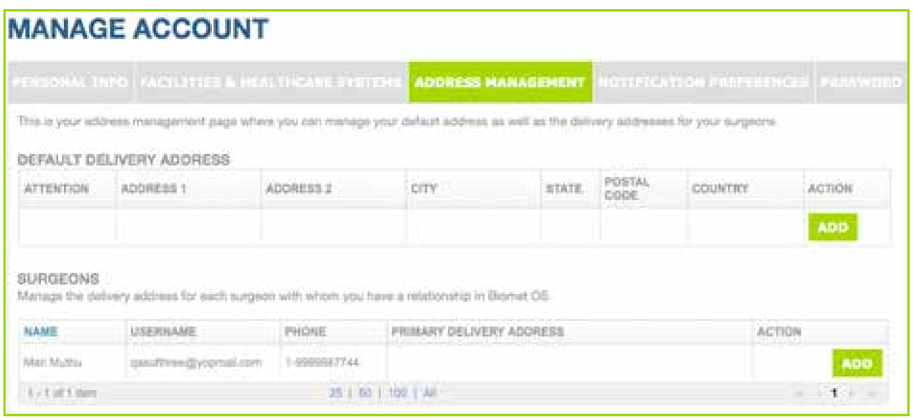

Figure 18 – Manage Account: Address Management

4.2.1.1. Adding a Default Delivery Address

Sales Representatives may add a default delivery address in the event that they do not currently have one associated with their account. This address will be available for the Sales Representative to assign as the delivery address for any of their associated Surgeons.

1. Click the "Add" button in the action column to display the Add Default Address pop-up (Figure 19).

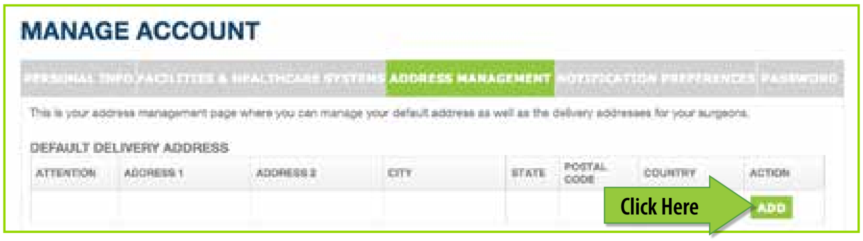

Figure 19 – Manage Account: Add Default Delivery Address

2. Enter the new default delivery address information into the required fields and click the "Save" button (Figure 20).
   a. An error message will display in the event that any required fields are incomplete.
   b. Click the "Cancel" button to close the pop-up and discard your changes.

Figure 20 – Manage Account: Add Default Delivery Address Pop-up

3. A success message will display once the default delivery address has been added to your account.

4.2.1.2. Editing a Default Delivery Address

Sales Representatives may edit the default delivery address associated with their account. Any changes to the address will only affect cases that have not yet been approved by a Surgeon. If there are cases that have already been approved and need a new address assigned, it will need to be done manually through the Case Details page. See section 4.2.2.1for how to manually edit the delivery information for a specific case.

Editing the default delivery address does not remove the previous default address from the system entirely. Therefore, this old address can continue to be used as the primary address for any surgeon associated with the users account.

1. Click the "Edit" button in the Action column to display the Edit Default Delivery Address pop-up (Figure 21).

Figure 21 – Manage Account: Edit Default Delivery Address

2. Edit the default delivery address fields and click the "Save" button (Figure 22).

Figure 22 – Manage Account: Edit Default Delivery Address Pop-up

   a. An error message will display if any required fields are incomplete.
   b. Click the "Cancel" button to discard your changes.

3. A success message will be displayed once the default delivery address has been saved to your account.

4.2.2. Adding a Surgeon Delivery Address

Sales Representatives may associate an existing or new delivery address to each Surgeon with which they are associated in the system. This includes a primary address along with the option for multiple secondary addresses. Once in the system, these addresses may also be used for other associated Surgeons as well.

1. Click the "Add" button in the Action column for the Surgeon you would like to add a delivery address for (Figure 23). The system will display the Add Delivery Address pop-up.

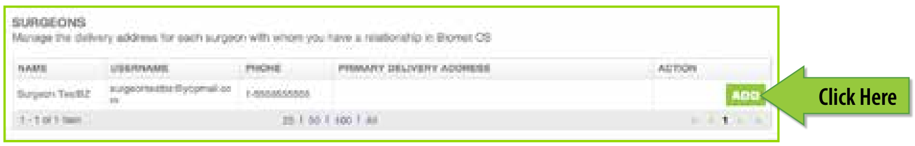

Figure 23 – Manage Account: Add Surgeon Delivery Address

2. Complete the address fields for the new address to be assigned.

Figure 24 – Manage Account: Add Surgeon Delivery Address Pop-up

1. **Primary Address** –Will determine if the delivery address being added will be set as a primary or secondary address for the Surgeon
2. **Existing Address Checkbox** –Will enable the Delivery Address drop down, which contains the Default Delivery address assigned to the Sales Representative and any Primary or Secondary addresses assigned to Surgeons associated with the Sales Representative's account. Selecting an address from here will populate the address fields.
3. **Attention Field** – The name entered here is important as it will serve as the contact person, at the delivery address, for any BiometOS shipments. In the event that a Sales Representative has more than one Surgeon at a single facility, the attention field can be used to differentiate between each Surgeon, even when the address assigned to them may be the same.

3. Complete the required address fields or select an existing address and click the "Save" button.
   a. An error message will display in the event that any required fields are incomplete.
   b. Click the "Cancel" button to discard your changes.
4. A success message will be displayed once the delivery address has been assigned to the Surgeon.

4.2.2.1. Editing a Surgeon Delivery Address

Sales Representatives may edit any addresses that are assigned to Surgeons associated with their account. This includes changing the current primary address.

1. Click the "Edit" button in the action column for the Surgeon whose address you would like to edit (Figure 25). The Edit Surgeon Delivery Address pop-up will appear.

Figure 25 – Manage Account: Edit Surgeon Delivery Address

2. Edit the address fields. Select any secondary addresses you would like to either edit or assign as the new primary.

3. Complete the required address fields and click the "Save" button (Figure 26).

   a. An error message will display in the event that any required fields are incomplete.
   b. Click the "Cancel" button to discard your changes.

Figure 26 – Manage Account: Edit Surgeon Delivery Address Pop-up

4. A success message will be displayed once the delivery address has been assigned to the Surgeon.

4.3 Managing Account – Surgeons

There are some options available within the Manage Account area that are specific to certain user roles. This section will highlight those options that are only available to the Surgeon user role.

4.3.1. Surgical Preferences Tab

Surgeons may manage their surgical plan preferences for use during the planning process and to be incorporated into the surgical plans created by the BiometOS for approval. Initial preferences will be setup with default values upon joining the BiometOS, but may be managed from the Surgical Preferences tab within Manage Account once active in the system (Figure 27).

Figure 27 – Manage Account: Surgical Preference

4.3.1.1. Editing Surgical Preferences

1. Preferences will be displayed with the option to edit (Figure 28). Click the "Edit" button next to the set of plan preferences you would like to edit.
   Note: You may not remove a primary set of preferences, which is why the Remove button will not be displayed for preferences marked as Primary.

Figure 28 – Manage Account: Edit Surgical Preferences

2. Edit the preferences. To reset all plan values back to default settings, you can click the "Reset All Values to Default" button (Figure 29).

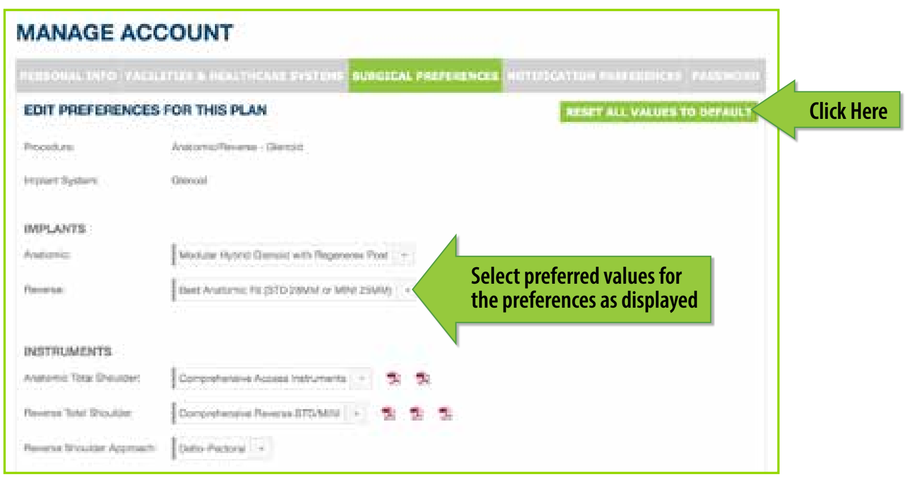

Figure 29 – Manage Account: Edit Surgical Preferences – Set Values

3. Complete the surgical preferences and click the "Save" button.
   a. An error message will display in the event that any preferences are incomplete.
   b. Click the "Cancel" button to discard your changes.
4. A success message will be displayed once the surgical preferences have been saved to your account.

4.4 Inviting Others to Join the BiometOS

Existing BiometOS users may invite others to join the BiometOS at any time. Invitation rules are based on the inviting user's role and will determine the role of those whom they invite and/or establish a relationship with.

> **Distributors** can invite Sales Representatives and Surgeons to join.

> **Sales Representatives** can invite Surgeons to join.

> **Surgeons** can invite Office Administrators (Office Admin) to join.

• Office Admin users are beneficial to Surgeons when it comes to managing the interaction between the Surgeon office and Biomet. They are able to provide detailed information, on behalf of the Surgeon, that will be used to process orders in a timely fashion.

4.4.1. Creating a New Invitation

Invitations may be created from two locations within the BiometOS.

4.4.1.1. Creating Invitation from Relationship Management

1. Click on the "Relationship Management" link in the main system navigation
2. Click the "Invite User" button (Figure 30).

Figure 30 – Relationship Management: Invite User

4.4.1.2. Creating Invitation from Navigation Header

1. Click on the "Invite User" button in the main system navigation (Figure 31).

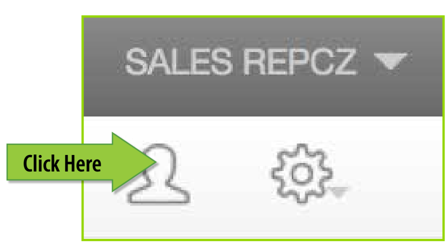

Figure 31 – BiometOS Navigation: Invite User

4.4.1.3. Selecting User Type – (Distributors Only)

Distributors also have Sales Representative authority, so they can invite both Sales Representatives and Surgeons to join the system. When they click the "Invite User" button, they will first have to specify the role of the invitee.

1. Click the appropriate button for the role of the invitee (Figure 32).

Figure 32 – Invite: Select User Type

4.4.1.4. Completing the User Invitation Form

To complete the invitation, enter the required information (Figures 33-35):

1. Invitee's first name
2. Invitee's last name
3. Enter and confirm the invitee's email address
4. Invitee's country
5. Confirm that inviting user role and name are correct
6. Click the "Continue" button
   a. An error message will be displayed if any required fields do not contain acceptable data and your changes will not be saved.
   b. An error message will also be displayed if the email entered already exists in the system.

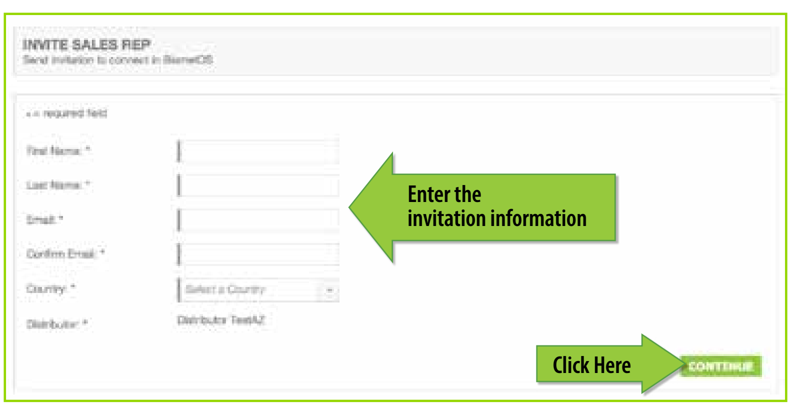

Figure 33 – Invite: Distributor Invites Sales Rep

4.4.1.5. Verifying Registration Information

1. Review the registration information and ensure that it is correct. This will be used to support the invitee if they accept the invitation and register with the BiometOS (Figure 36).
2. Click the "Send Invitation" button to send the invitation.
3. Click the "Revise" button to return to the previous screen and update any necessary invitation information.

Figure 36 – Invite: Verify Registration Information

4. A success message will be displayed when the invitation has been sent and you will be redirected to the Relationship Management page where the pending invitation within your Permanent Relationships table can be viewed (Figure 37).

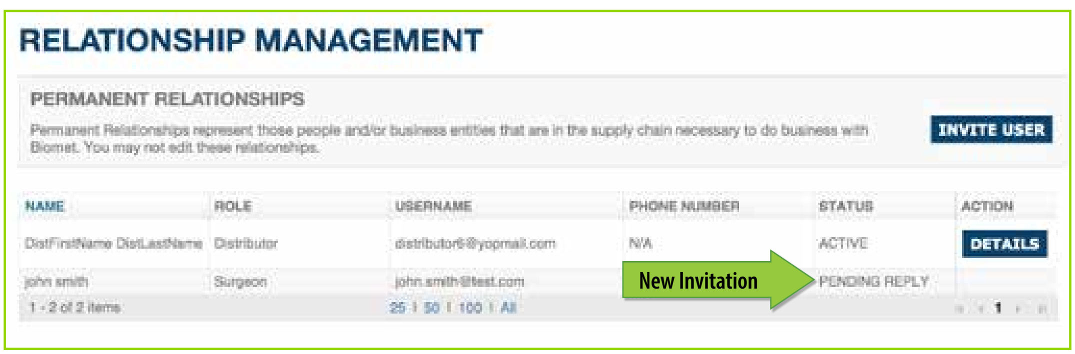

Figure 37 – Invite: View Pending Invitation

5. The invitee will receive an email notification of the invitation, which will include a link to respond. The invitation will be in pending status until the recipient accepts or declines the invitation. You will receive a notification if the invitee does not respond within 30 days or declines the invitation.

4.5. Relationship Management

Existing users may view contact information and established BiometOS relationships via the Relationship Management portion of the system.

4.5.1. Viewing Relationships

1. Click on the "Relationship Management" link in the navigational header.
2. The Relationship Management page is displayed along with any active or pending relationships with other users (Figure 38).

Figure 38 – Invite: View Relationships

3. Click the "Details" button to display a pop-up containing the associated user's contact information (Figure 39).

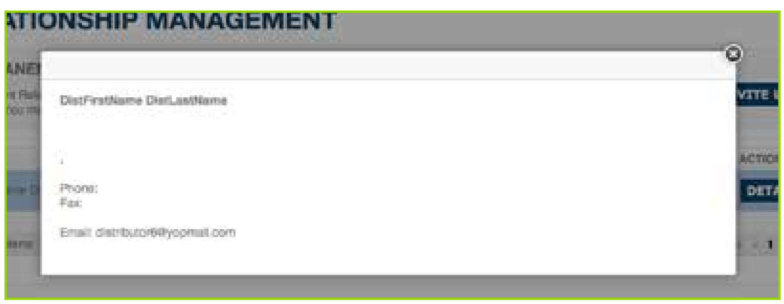

Figure 39 – Invite: View User Information

5. Case Management

The Case Management area is where cases associated with each user are displayed. This is the default screen upon login and is also accessible by clicking the "Case Management" link in the main system navigation.

The Case Management area consists of two subpages: Case Action List and Case Search (Figure 40).

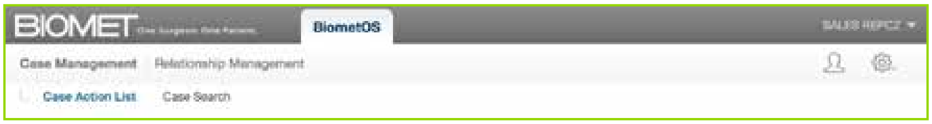

Figure 40 – Case Management: Navigation

5.1. Case List

The Case List table displays a list of cases that a user has access to. A user can view open, closed, or a combination of open and closed cases in their Case List.

Figure 41 – Case Management: Case List Table

5.1.1. Case List Tabs

- **Open Cases:** This is the default tab that opens and displays a list of all open cases when first logging into BiometOS.
- **Closed Cases:** This tab displays all Closed Cases.
- **All Cases:** This tab displays all Open and Closed Cases.
- **Search:** Each column can be searched by clicking the blank box underneath the column header. Once three characters are typed, a drop down list or free form text field will appear. Multiple fields can be searched at one time. Once the desired information is entered in a field(s), click the Search button to filter the results in the Case List.
- **Clear Search:** Clears the current search and displays unfiltered list of cases.
- **Advanced Sort:** Provides the capability to sort by any column.
- **Show/Hide Column(s):** Provides the capability to display only the columns a user wishes to see.

5.1.2. Column Headers

- **Case Created:** Is the date that a Patient Code is created for a case.
- **Patient Code:** Is the unique code that is assigned to the case.
- **Side:** Is the side of the body upon which the procedure is being performed.
- **Procedure Type:** Is the type of procedure being performed - Shoulder, Knee or Hip.
- **Tracking Number:** Is the shipping tracking number for the case.
- **Patient Name:** Is the Patient's name associated with the case.
- **Surgeon Name:** Is the Surgeon's name associated with the case.
- **Case Status:** Shows the current progress of the case.
- **Surgery Date:** Is the projected surgery date for the case.
- **Delivery Date:** The projected date for the kit to be delivered.
- **Plan:** This field displays two icons – a bone icon to launch the Plan Review Tool and a PDF icon to launch the 2D plan in PDF format.
- **Task Name:** Is the specific action to be completed, if the action is not associated to the user's role as a Surgeon, Office Administrator, Sales Representative, or Distributor then this will show as blank.
- **Action:** Displays a button labeled REVIEW for Surgeons, or CLAIM for Office Administrators, Sales Representatives, or Distributors.

5.1.3. Claiming and Completing an "Enter Missing Case Data" Action

1. Review the Case Action List table.
2. Click the "Claim" button for the case you would like to complete the action for (Figure 42).

Figure 42 – Case Management: Case List – Missing Data

3. The system will open the case and display instructions for completion (Figure 43).
4. Complete the required information and click the "Complete" button to submit the information and allow the system to continue processing the case.
5. In the event that the missing information is not available and will need to be added later, you can click the "Release" button to return the action to the Case Action List.

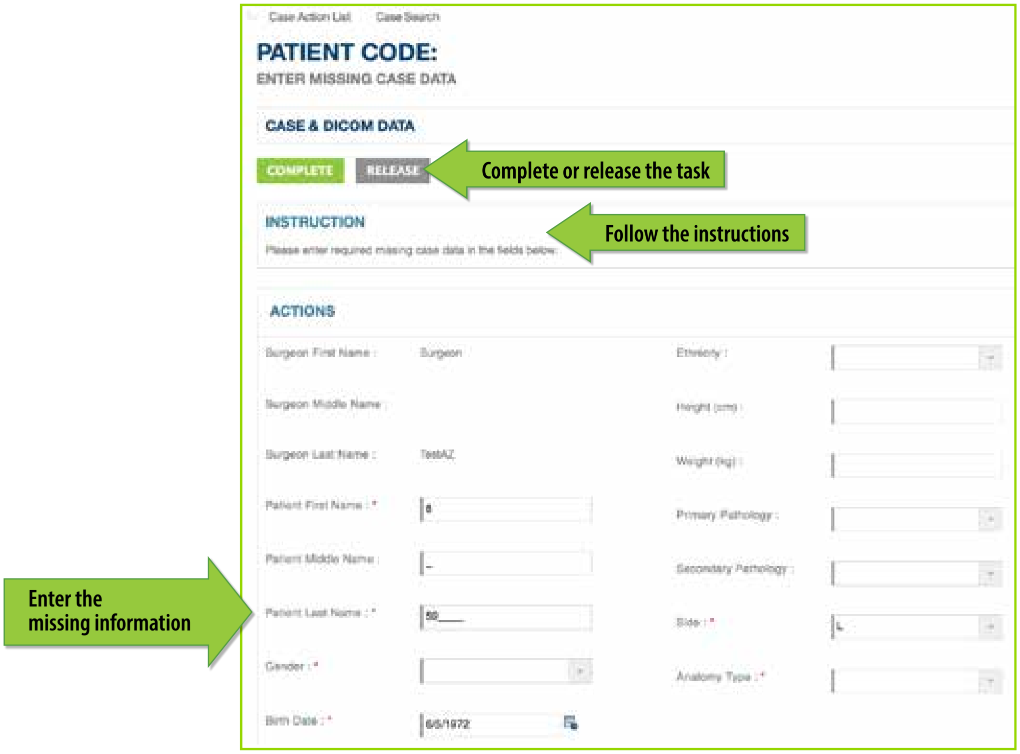

Figure 43 – Case Management: Enter Missing Case Data

5.2. Cases Awaiting Approval (Surgeons)

The Cases Awaiting Approval table is only displayed for Surgeon users and will display all open cases associated with each surgeon. Each case listed is ready to be reviewed and/or approved.

1. Review the Cases Awaiting Approval List.

2. Click the "Review" button for the case and plan you would like to review in the 3D Planning Tool (Figure 44). Reviewing and approving plans will be detailed in Section 6 pg. 30.

Figure 44 – Case Management: Cases Awaiting Approval

5.2.1. Viewing Case Details

Users may view the Case Details page for any case with which they are associated.

1. View the Case List page or Case Search page to find a specific case (Figure 45).
2. Click the "Patient Code" hyperlink for the case you would like to view in more detail.

Figure 45 – Case Management: Open Case Details

3. Case details are arranged in separate detail boxes across the Case Details page. The boxes can be expanded and collapsed using the corner arrow buttons or the "Expand/Collapse All" buttons at the top. (Figure 46)

Figure 46 – Case Management: Open Case Details

5.2.2. Editing Case Details (Sales Representatives, Surgeons, Office Admins)

Users with the appropriate role may edit information that is displayed within the case detail boxes.

5.2.2.1. Editing Patient Information

1. Click the "Edit" button inside the patient information box to display the Edit Patient Information pop-up (Figure 47).
2. Edit the information.
3. Click the "Save" button to close the pop-up and update the information.
   a. An error message will be displayed if any of the required fields are incomplete and changes will not be saved.
4. Click the "Cancel" button to close the pop-up and cancel your changes.

Figure 47 – Case Details: Edit Patient Information

5.2.2.2. Editing Delivery Information

1. Click the "Edit" button inside the delivery information box to display the Edit Delivery Information pop-up.

2. Edit the information (Figure 48).

   > **Delivery Date** – system generated date based upon the date the images are received into the system. This date includes turnaround times for each step in the process.

   - Due to the time required for process completion, the delivery date can only be changed to an earlier date based upon the system constrained time frame. This will be determined according to where the case is in the process at the time of editing.

   > **Surgery Date** – The anticipated date the surgery will be performed.

   > **Delivery Address** – The default delivery address, as well as any other delivery address associated with the Surgeon.

   - The delivery address is set for each case once Surgeon Approval is complete.
     – If the Sales Representative does not have a delivery or default address set for the Surgeon, an email notification will be sent to update this information. (See 4.2.1 Address Management Tab pg. 11)

     – Once updated in address management, the address may be assigned to the case by selecting it in the Delivery Date drop down. This can be updated up until the case is ready to be shipped.
   - After Surgeon approval, the address can be updated using the drop down until the case is ready to be shipped.

3. Click the "Save" button to close the pop-up and save the delivery information.

   a. An error message will be displayed if any required fields do not contain acceptable data and the changes will not be saved.

4. Click the "Cancel" button to close the pop-up and discard the changes.

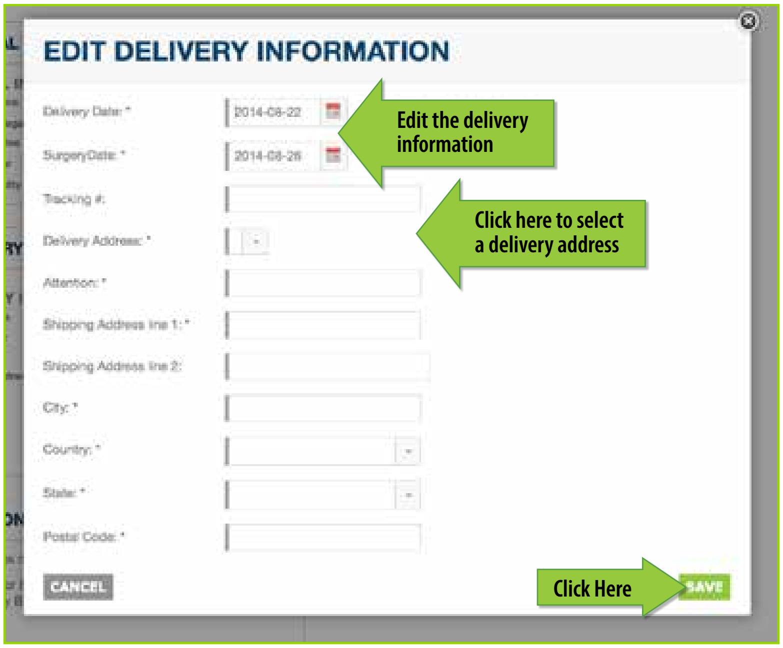

Figure 48 – Case Details: Edit Delivery Information

5.2.2.3. Viewing Plan Information

The plan information box contains information related to the approved plan for each case (Figure 49). Prior to approval, some of the information will be left blank. This box also contains a link to view the plan in the 3D Planning Tool. If a plan has not yet been created for the case, the box will display a message informing the user.

Figure 49 – Case Details: View Plan Information

5.2.3. Viewing Related Cases

The Related Cases box contains a link to any other cases that are related to the same patient and surgeon.

1. Click the "Patient Code" hyperlink to display the case details page for a related case (Figure 50).

Figure 50 – Case Details: Edit Patient Information

6. 3D Planning Tool

Once a plan has been created for a case, it will be available for review by the associated Sales Representative, Surgeon and Office Admin users.

> When a plan is created, users associated with the case will receive a notification (based on that user's notification preferences) that the plan is ready for review/approval.

> The amount of time to approve the plan is determined by the plan type. This review time is set as a Surgical Preference for each plan type and can be managed within the Surgical Preferences tab for a Surgeon.

> During review/approval all users are able to manipulate and edit the plan. However, only changes made by the Surgeon will be saved to the plan.

> Only the Surgeon, with Approval Authority, is able to approve a plan.

> Once the plan is approved, all associated users will still have the ability to view the plan.

6.1. 3D Planning Tool (Browser-based)

Plan review/approval occurs within the 3D Planning Tool. There are two versions of this tool that can be used: a browser-based application and an iPad specific application. Both versions of the 3D Planning Tool require an internet connection in order to review a case.

The browser-based application is accessed directly through the BiometOS system. This version of the 3D Planning Tool is designed to run on PCs (i.e. Windows and Mac machines) that support any of the approved system browsers as outlined in section 2.3.

Plans can be accessed in several different ways. Surgeons can access the plan review tool through the Cases Awaiting Approval flow section (5.1.3) or via the "3D Planning Tool" link bone icon in the Plan Information box on the Case List page. Sales Representative and Office Admin Users can access the plan review tool via the Case Details page and the Case List page only.

> Click the "Review" button for a case in the Cases Awaiting Approval table (Figure 52).

> Click the "3D Planning Tool" link in the Plan Information box on the Case Details page (Figure 53).

Figure 52 – Cases Awaiting Approval

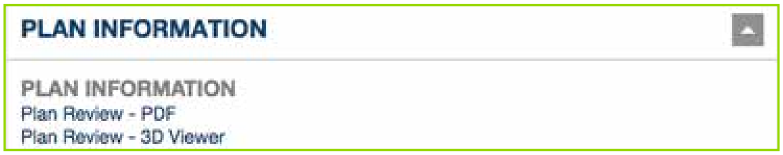

Figure 53 – Case Details : Plan Information

The iPad application was specifically designed for the iOS environment to allow for a more mobile planning experience. Both applications function the same, however some of the user interactions are slightly different. Sections 8 & 9 outline how each specific application works.

6. 3D Planning Tool

6.1.1. Main Screen

Once a case is accessed, the 3D Planning Tool will be launched and the selected case will be loaded. When fully loaded, the case should appear similar to the image below (Figure 54).

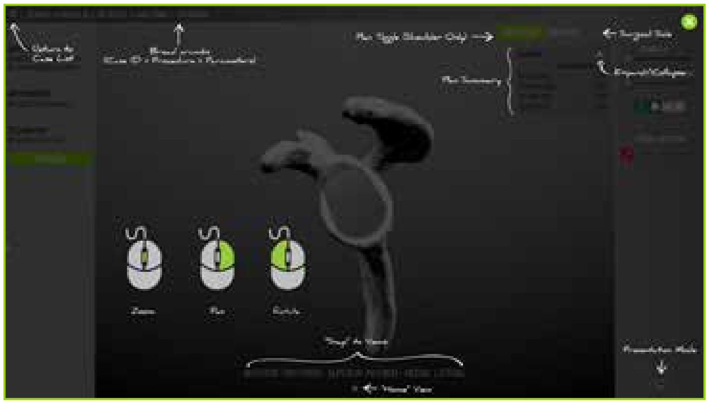

Figure 54 – 3D Planning Tool (Browser Based) : Main Screen

> **Return to Case List Button –** Returns you to the case list where you can select a different case to load.

> **Breadcrumbs –** Consist of the Case ID, Procedure and Parameters related to the current plan. Selecting a breadcrumb will display the appropriate panel on the left column depending on the value that you select in the breadcrumb.

> **Plan Toggle –** Plans are created for both Anatomic and Reverse components. This button allows you to switch between the two procedures.

> **Surgical Side** – Represents the side of the body on which the surgery will be performed.

> **Plan Summary** – Contains a summary of the parameter values that were used in the planning process. You can collapse/expand this menu by clicking the arrow in the upper right corner.

> **Zoom/Pan/Rotate** – Mouse functions that allow you to directly manipulate the view of the bone and implant.

> **Snap To Views** – Allow you to quickly change the view of the bone and implant based on the selection.

> **Home View –** Returns the bone and implant to the default view.

> **Presentation Mode** – Toggles the view to presentation mode, where the top bar and left columns are hidden. In presentation mode all visibility controls remain active. However, the ability to edit the plan parameters is removed. This view is ideal for reviewing the plan with a patient.

6.1.2. Visibility Controls

Buttons/controls located on the right hand panel allow the user to control visibility of the bone and implant(s) (Figure 55).

Figure 55 – 3D Planning Tool (Browser-Based) : Visibility Controls

> **Visibility and Transparency Sliders –** Adjust the visibility of the bone and the implants that are being incorporated as part of the surgical plan. The eye buttons will toggle the visibility of the bone/implant itself on and off within the 3D image. The slider will adjust transparency of the bone/implant. Setting the slider all the way to the right makes the item solid and if set all the way to the left the item will be invisible.

> **Landmarks Button –** Will toggle on and off the landmarks

> **Resection Buttons –** Allow you to manage the display of the resections on the 3D image. You can only select one of these three options at a time:

- **Full Circle** – Displays the entire bone without any cuts.
- **Colored Circle** – Displays the entire bone; however, sections of bone that will be resected during the procedure are shaded by color.
- **Button** – Displays the bone as it will appear with all resection areas removed. This provides an indication of the bone that will remain after the surgical procedure.

> **Cross-Section Tool** – Allows you to view a cross-section of the bone/implant within the 3D image. This tool is useful to see where the implant will be located inside the bone.

- **Cross-Section Toggle** – Will toggle on and off the Cross-Section Tool.
- **Cross-Section Slider** – Controls the depth of the cross-section cut in the 3D image. The cut will always be parallel to the viewing angle, no matter the position of the bone/implant within the 3D image.

6.1.3. Panel Navigation

A series of expanding/collapsing panels located on the left side of the screen allow the user to navigate to different areas of the tool to make adjustments to the plan or switch between different cases (Figure 56).

Figure 56 – 3D Planning Tool (Browser-Based) : Panel Navigation

> **Close/Open Panel Buttons –** Arrows which open or close a respective panel. Panels move left as they are collapsed, exposing more of the 3D image.

> **Case List Panel –** Displays cases that require approval ("To Approve") or have already been approved ("Approved").

> **Case Search** – Allows user to search their case list by patient code. To remove search, either delete the text or click the "x" button on the right hand side of the search field.

> **Selected Case** – Loaded case will be highlighted.

> **Load Progress Bar** – When selecting a new case, the progress bar below the patient code indicates how much of the case data has been loaded.

> **Procedure Panel** – Displays all the plans and parameter panel options for a given case. Also indicates the actively selected plan and parameter panel.

> **Procedure Selection** – Allows the user to switch between multiple plans that were created for the case.

> **Parameter Panel Selection** – Allows the user to switch between the different parameter panels.

> **Parameter Panel**– Displays different options (Planning, Notes, Approval) for adjustments that can be made to the loaded plan.

6.1.4. Edit Planning Parameters

Users may make a variety of edits to a given plan via the planning parameters panel (Figure 57).

Figure 57 – 3D Planning Tool (Browser-Based) – Edit Parameters

> **Reset Parameters Button** – Will reset all editable parameters back to the originally planned values.

> **Implant Selector** – Allows the user to change both the type and size of the implant components used in the plan. Options are limited based on the geography of the Surgeon with whom the case is associated.

> **Adjustable Parameters** – Allows the user to edit each listed planning parameter. To adjust values the user must click the "+" or "-" buttons next to each value. As values are changed, the implant position within the 3D image will update.

Note: If a surgeon user utilizes Internet Explorer (IE) for case review and makes adjustments without approving the plan before exiting the 3D planning tool, the adjustments will not be saved and will need to be made again upon the next log in.

6.1.5. Notes

Users may use the Notes function to review any system notifications associated with a case. In addition, Surgeons have the ability to add notes specific to a case (Figure 58).

Figure 58 – 3D Planning Tool (Browser-Based) : Notes

- > **Unread Notes –** Indicator that displays the number of system notifications that have not been read.
- > **System Notifications –** Notifications generated by the BiometOS during planning that should be considered prior to approval.
- > **Mark as Read** – Clicking on a notification will mark it as read. Unread notifications remain in bold text. Selecting a notification will also expand it, if it is too long to fit allowable space.
- > **Scroll** – If enough system notifications are present, a scroll bar will show up allowing users to access additional notifications.
- > **Surgeon Notes –** This area allows Surgeon users to enter any notes they wish to have associated with the case. Notes added to this section are for the Surgeon's personal use only. Notes entered by other users will not be saved. Biomet will not review, respond to, or otherwise take any action based on these notes.
- > **Add Notes** – Allows Surgeon users to type in a new note. Notes are displayed in reverse chronological order.
- > **Delete Notes** – Hover the mouse over a note and then click the trash can icon to remove a note from a case.

6.1.6. Presentation Mode

A presentation mode is available and ideal for reviewing a plan with the patient. When using this mode, all plan adjustment controls and panel navigation are removed from view. Visibility Controls remain active, as previously described (Figure 59).

Figure 59 – 3D Planning Tool (Browser-Based) : Presentation Mode

> **Exit Presentation Mode –** Returns the view mode to normal to allow for editing of the plan.

6.1.7. Approval

Case Summary Details and plan Approval may be performed via the Approval panel (Figure 60).

Figure 60 – 3D Planning Tool (Browser-Based) : Approval

> **Case Summary Details –** Displays the Implant, Instrument, and Technology details for the selected case.

> **Open Approval Pop-up Box Button –** Opens the Approval Pop-up Box to allow users to enter their credentials.

> **Enter Credentials** – Allows user to enter username and password.

> **Approve Button** – Validates credentials and approves case.

> **Exit Approval Pop-up Box** – To exit the approval pop-up click anywhere outside the box.

6. 3D Planning Tool

6.2. 3D Planning Tool (iPad App)

6.2.1. Downloading

The BiometOS application is available for download from the App Store.

6.2.2. Requirements

The iOS application is supported on Apple iPad devices capable of running an iOS that conforms with section 2.3 requirements.

6.2.3. Hardware

iPad 2, Wi-Fi or Wi-Fi+3G, 1024×768 pixel resolution
iPad 3rd generation, Wi-Fi or Wi-Fi+4G, 2048×1536 pixel resolution (Retina display)
iPad 4th generation, Wi-Fi or Wi-Fi+4G, 2048×1536 pixel resolution (Retina display)

6.2.4. Accessing a Plan

Unlike the browser-based 3D Planning Tool, where the user can directly launch a specific case, the 3D Planning Tool iPad app is a standalone application. To access a plan for review/approval the user must first launch the app and login with valid BiometOS credentials. Once logged in, the user must select a case from the case list to load the plan in the tool. The case list displayed in the app will be specific to the user that is logged in.

1. Launch the BiometOS 3D Planning Tool app and enter credentials (Figures 61 & 62).

Figure 61

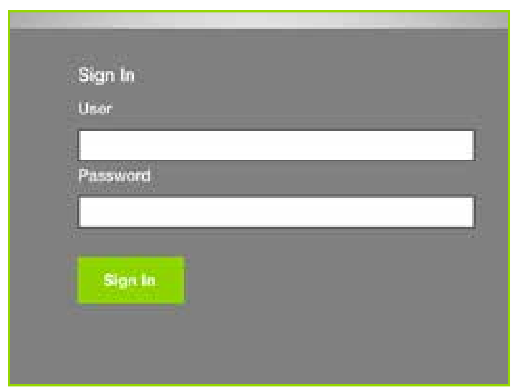

Figure 62

3. Select the desired case from the case list on the left side of the screen (Figure 63).

Figure 63 – 3D Planning Tool (iPad App) : Case List Select Screen

6.2.5. Main Screen

Once a case is accessed, the 3D Planning Tool will be launched and the selected case will be loaded. When fully loaded, the case should appear similar to the image below (Figure 64).

Figure 64 – 3D Planning Tool (iPad App) : Main Screen

> **Return to Case List Button –** Returns user to the case list where he/she can select a different case to load.

> **Breadcrumbs –** Consist of the Case ID, Procedure and Parameters related to the current plan. Selecting a breadcrumb will display the appropriate panel on the left column depending on the value .

> **Plan Toggle –** Plans are created for both Anatomic and Reverse components. This button allows users to switch between the two procedures.

> **Surgical Side –** Represents the side of the body on which the surgery will be performed.

> **Plan Summary –** Contains a summary of the parameter values that were used in the planning process. You can collapse/expand this menu by tapping the arrow in the upper right corner.

> **Zoom/Pan/Rotate –** Finger gestures that allow you to directly manipulate the view of the bone and implant.

> **Snap to Views –** Quickly changes the view of the bone and implant based on the selection.

> **Home View –** Returns the bone and implant to the default view.

> **Presentation Mode –** Toggles the view to presentation mode, where the top bar and left columns are hidden. In presentation mode, all visibility controls remain active. However, the ability to edit the plan parameters is removed. This view is ideal for reviewing the plan with a patient.

6.2.6. Visibility Controls

Buttons/controls located on the right hand panel allow the user to control visibility for the bone and implant (Figure 65).

Figure 65 – 3D Planning Tool (iPad App) : Visibility Controls

> **Visibility and Transparency Sliders –** Adjust the visibility of the bone and the implants that are being incorporated as part of the surgical plan. The eye buttons will toggle the visibility of the bone/implant itself on and off within the 3D image. The slider will adjust transparency of the bone/implant. Setting the slider all the way to the right makes the item solid and, if set all the way to the left, the item will be invisible.

> **Landmarks Button –** Will toggle on and off the landmark points/lines associated with either the bone or implant that are displayed within the 3D image.

> **Resection Buttons –** Allow you to manage the display of the resections on the 3D image. You can only select one of these three options at a time:

- **Full Circle** – Will toggle on and off the Cross-Section Tool.
- **Colored Circle** – Displays the entire bone, with sections of bone that will be resected during the procedure shaded by color.
- **Square** – Displays the bone as it will appear with all resection areas removed. This provides an indication of the bone that will remain after the surgical procedure.

> **Cross-Section Tool –** Displays a cross-section of the bone/implant within the 3D image. This tool is useful to see where the implant will be located inside the bone.

• **Cross-Section Toggle** – Will toggle on and off the Cross-Section Tool.

• **Cross-Section Slider** – Controls the depth of the cross-section cut in the 3D image. The cut will always be parallel to the viewing angle, no matter the position of the bone/implant within the 3D image.

6.2.7. Panel Navigation

A series of expanding/collapsing panels located on the left side allows users to navigate to different areas of the tool to make adjustments to the plan or switch between different cases (Figure 66).

Figure 66 – 3D Planning Tool (iPad App) : Panel Navigation

> **Close/Open Panel –** Swipe right to open and left to close within a given panel. Panels move left as they are collapsed, exposing more of the 3D image.

> **Case List Panel –** Displays cases that require approval ("To Approve") or have already been approved ("Approved").

• **Case Search** – Allows user to search their case list by patient code. To remove search, either delete the text or tap the "x" button on the right hand side of the search field.

• **Selected Case** – Loaded case will be highlighted.

• **Load Progress Bar** – When selecting a new case the progress bar below the patient code indicates how much of the case data has been loaded.

> **Procedural Panel –** Displays all the plans and parameter panel options for a given case. Also indicates the actively selected plan and parameter panel.

- **Procedure Selection** – Allows user to switch between multiple plans that were created for the case.

- **Parameter Panel Selection** – Allows the user to switch between the different parameter panels.

> **Parameter Panel –** Displays different options (Planning, Notes, Approval) for adjustments that can be made to the loaded plan.

6.2.8. Edit Planning Parameters

Users may make a variety of edits to a given plan via the planning parameters panel (Figure 67).

Figure 67 – 3D Planning Tool (iPad App) : Edit Parameters

> **Reset Parameters Button –** Resets all editable parameters back to the originally planned values.

> **Case List Panel –** Allows the user to change both the Type and Size of the implant components used in the plan. Options are limited based on the geography of the Surgeon to whom the case is associated.

> **Adjustable Parameters –** Allows the user to edit each listed planning parameter. To adjust values the user must tap on the "+" or "-" buttons next to each value. As values are changed, the implant position within the 3D image will update.

6.2.9. Notes

Users may use the Notes function to review any system notifications associated with a case. In addition, Surgeons have the ability to add notes specific to a case (Figure 68).

Figure 68 – 3D Planning Tool (iPad App) : Notes

> **Unread Notes –** Indicator that displays the number of system notifications that have not been read.

> **System Notifications –** Notifications generated by the BiometOS during planning that should be considered prior to approval.

- **Procedure Selection** – Tapping on a notification will mark it as read. Unread notifications remain in bold text. Selecting a notification will also expand it, if it is too long to fit allowable space.
- **Scroll** – Swipe up/down to scroll.

> **Surgeon Notes –** This area allows Surgeon users to enter any notes they wish to have associated with the case. Notes added to this section are for the Surgeon's personal use only. Notes entered by other users will not be saved. Biomet will not review, respond to, or otherwise take any action based on these notes.

- **Add Notes** – Allows Surgeon user to type in a new note. Notes are displayed in reverse chronological order.
- **Delete Notes** – Swipe within a note to the right to access the trash can icon, then tap the trash can to delete the note.

6.2.10. Presentation Mode

A presentation mode is available and ideal for reviewing a plan with a patient. When using this mode, all plan adjustment controls and panel navigation are removed from view. Visibility Controls remain active, as previously described (Figure 69).

Figure 69 – 3D Planning Tool (iPad App) – Presentation Mode

> **Exit Presentation Mode –** Returns the view mode to normal to allow for editing of the plan.

6.2.11. Approval

Case Summary Details and plan Approval may be performed via the Approval panel (Figure 70).

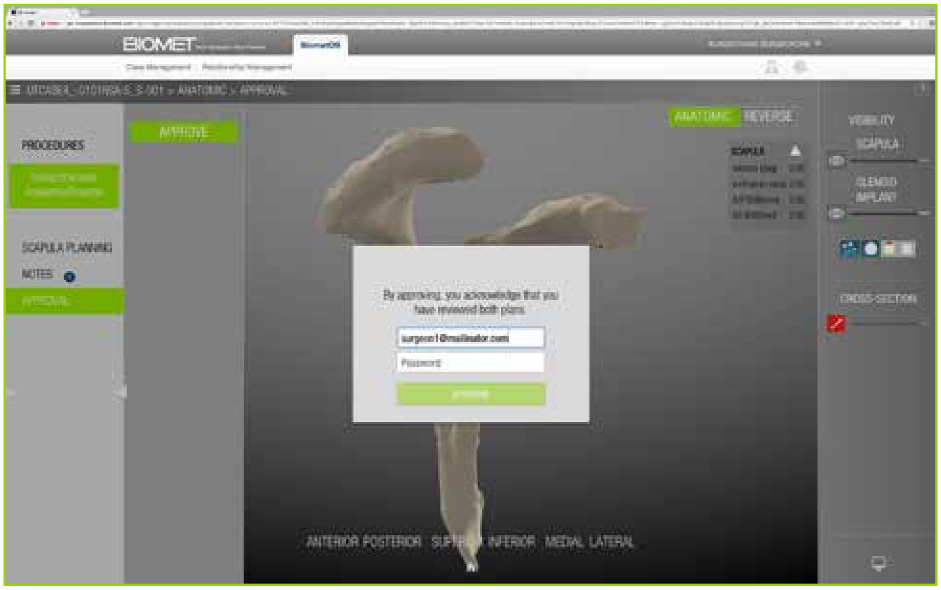

Figure 70 – 3D Planning Tool (iPad App) : Approval

> **Case Summary Details –** Displays the Implant, Instrument, and Technology details for the selected case.

> **Open Approval Pop-up Box Button –** Opens the Approval Pop-up Box to allow users to enter their credentials.

- **Enter Credentials** – Allows user to enter username and password.
- **Approve Button** – Validates credentials and approves case.
- **Exit Approval Pop-up Box** – To exit the approval pop-up, tap anywhere outside the box.