

ROSA[®] Hip

User Manual and Surgical Technique V1.1.1



Table of Contents

1. General Information	1
1.1 Conventions.....	1
1.2 ROSA Hip System Description.....	1
1.3 Contact.....	2
1.4 Training	2
1.5 Intended Use	2
1.6 Indications for Use	2
1.7 Contraindications	3
1.8 Complications.....	3
1.9 Restrictions for Use.....	3
1.10 Patents.....	3
2. About This Manual	4
2.1 Safety: Warnings, Cautions and Remarks	4
3. Description	7
3.1 Overview	7
3.2 Operating Principle	8
3.2.1 Case Information	8
3.2.2 ROSA Tablet and ROSA Communication Setup	8
3.2.3 Surgeon’s Preferences and Pre-operative Planning.....	8
3.2.4 Reference Fluoroscopic Images Acquisition	8
3.2.5 OR Setup.....	8
3.2.6 Acetabular Component Impaction.....	9
3.2.7 Trial and Validation	9
3.3 System Description.....	9
3.3.1 Robotic Unit.....	9
3.3.2 Optical Unit.....	12
3.3.3 ROSA Tablet	14
3.3.4 Instrumentation	15
3.4 Instrument Assembly.....	17
3.4.1 ROSA Quick Connect.....	17
3.4.2 ROSA Cup Inserter Assembly (Straight and Offset)	18
3.5 Instrument Installation on the Robotic Arm	21
3.5.1 ROSA Quick Connect on the Robotic Arm	21
3.5.2 Instrument Installation	21
3.5.3 Drapes	22

4. Installation	23
4.1 Warnings and Cautions About Robotic Unit Installation	23
4.2 Device Start Up.....	24
4.3 Emergency Procedure	24
4.3.1 Moving the Robotic Arm Away Using ROSA Application Interface.....	24
4.3.2 Moving the Robotic Arm Away if Application is Unresponsive ..	25
4.4 Reverting to Standard Instrumentation	25
4.5 Case Management Application	26
4.5.1 Case Management Application-Interface Overview	26
4.5.2 Starting a Case	26
5. ROSA Tablet Handling	27
5.1 Battery Charger Installation	27
5.2 Charging Procedure	28
5.3 ROSA Tablet Battery Removal/Installation Procedure	28
5.4 Turning ON the ROSA Tablet	29
5.5 Intra-operative Battery Swap	30
5.6 Turning OFF the ROSA Tablet	30
6. Intra-operative Guide/Surgery	31
6.1 Welcome Screen	31
6.2 ROSA Hip Application-User Interface Overview	31
6.2.1 Top Task Bar	31
6.2.2 Bottom Task Bar	31
6.3 Robotic Modes	34
6.4 Robotic Positions	35
6.5 Application Audible Notifications	35
6.6 Application Visual Notifications.....	35
7. ROSA Hip Application-MOBILE Panel	37
8. ROSA Hip Application-SURGEON Panel	38
9. ROSA Hip Application-SETUP Panel	39
9.1 Draping	39
9.2 Touchscreen Monitor Draping	40
9.3 Calibration of Sensor	41
9.4 Reference Images Acquisition	41
9.5 ROSA Positioning.....	46

10. ROSA Hip Application-IMPACTION Panel	48
10.1 Attach Instrument	48
10.2 Calibration Image Acquisition	49
10.3 Navigation Image Acquisition.....	51
10.4 Target Orientation.....	54
10.5 Impaction	54
10.6 Out	55
11. ROSA Hip Application-CUP VERIFICATION Panel	56
12. ROSA Hip Application-TRIAL and VALIDATION Panel	58
12.1 Trial Image Acquisition.....	58
12.2 Leg Length and Offset Change Computation.....	60
12.3 Final Image Acquisition	61
12.4 Current Implant System.....	63
12.5 Leg Length and Offset Change Computation.....	63
13. Robotic Errors	64
13.1 Collision Detection	64
13.2 Excessive Force on the Robotic Arm	64
13.3 Red EMERGENCY Button.....	65
13.4 Unknown Robotic Error	65
13.5 Drifting of the Robotic Arm	65
14. Post-operative Guide/Maintenance	66
14.1 Retrieval of Post-Surgical Log File	66
14.1.1 Surgeon Report	66
14.1.2 Investigation Logs.....	66
14.2 Shutdown	67
14.3 Cleaning, Disinfection and Sterilization	67
14.3.1 Cleaning the Robotic and Optical Units	67
14.3.2 Cleaning the ROSA Tablet.....	68
14.3.3 Cleaning the Optical Camera (if Optical Unit touchscreen was used).....	68
14.3.4 Instrument Reprocessing (Cleaning and Sterilization Methods)	68
14.3.4.1 ROSA Hip System Instrument Kit	69
14.3.4.2. ROSA Hip System Instrument Lifetime Expectancy ..	70
14.4 Storage and Transport	70
14.4.1 Storage and Protection	70
14.4.1.1 Device Storage and Protection	70
14.4.1.2 Instrument Storage and Protection	70
14.4.1.3 Care of Cables and Connectors.....	71
14.4.2 Device Transport.....	71
14.5 Maintenance Operations.....	71
14.5.1 Installation.....	71
14.5.2 Daily Checks.....	72
14.5.3 Periodic Maintenance.....	72
14.6 Troubleshooting.....	73

15. Technical Data	75
15.1 Labels and Symbols.....	75
15.1.1 Labels	75
15.1.2 Symbols on the Labels	76
15.1.3 Other Symbols on the Device.....	78
15.2 Technical Specifications	81
15.2.1 Robotic and Optical Units	
Environmental Specifications.....	81
15.2.2 ROSA Tablet and Battery	
Environmental Specifications.....	81
15.2.3 Device Dimensions.....	82
15.2.4 Robotic Arm Working Range	83
15.3 Safety Classification and Standards.....	83
15.3.1 Cable Lengths	85
15.4 Electromagnetic Compatibility	85
15.4.1 Electromagnetic (EM) Emissions	86
15.5 Electromagnetic Immunity	86
15.5.1 Electromagnetic and Magnetic Immunity	86
15.5.2 Electromagnetic Immunity and Portable and Mobile Radio	
Frequency (RF) Communication Equipment	88
15.5.3 Recommended Separation Distances.....	89
16. Application Licenses	90
16.1 Boost	90
16.2 Open SSL.....	90
16.3 OpenCV.....	92
16.4 JSON.....	92
16.5 Libgit2	93
17. Product Security Customer Control Considerations	94
17.1 Records Retention and Purging Historical Data	94
17.2 Cybersecurity.....	94
Appendix A: Implants Supported by the ROSA Hip System	95
Appendix B: Leg Length and Offset Measurements Method	102
Appendix C: Image Acquisition, Landmarking and Overlay Guidelines	104

1. General Information

1.1 Conventions

This document employs the following conventions:



WARNING: This symbol is present when a warning alerts you to a potential danger to health or life.



CAUTION: This symbol is present to prevent a risk of deterioration of the equipment in case of a handling error.



REMARK: This symbol is present to provide a general observation or information related to procedures, events or practices which are recommended or essential for a successful operation.

1.2 ROSA Hip System Description

The ROSA[®] Hip System (RHS) for use with the ROSA Recon Platform (PN 20-8020-100-01/17/26) is used to assist surgeons in performing Total Hip Arthroplasty (THA) with features to assist with the acetabular shell impaction for the direct anterior approach, as well as assessing the leg length change and the femoral offset.

The ROSA Hip System uses a Non-Device Medical Device Data System (MDDS) called the Zimmer Biomet Drive Portal, which manages the creation and tracking of surgical cases. The cases reside on the portal until they are uploaded to the ROSA Recon Platform before surgeries. The ROSA Hip System utilizes the Robotic Arm of the ROSA Recon Platform cleared in K182964, but does not add new stereotaxic or robotic components

The system uses fluoroscopic images to determine the instruments' orientation in relation to the patient anatomy and as a guide for acetabular component orientation. The system allows the surgeon to input the case's surgical pre-operative planning values and preview the acetabular component orientation intra-operatively. Throughout the surgical workflow, fluoroscopic images are acquired with a C-arm. Fluoroscopic images are then captured with the ROSA Tablet and transferred onto the ROSA Hip application. The current instruments' orientation is computed from the image capture and adjusted to match the surgeon's planning values using the Robotic Arm. The system provides pre-, intra- and post-operative measurements relative to patient anatomy and does not provide infrared-based stereotaxic navigation for implant placement. The Robotic Arm is maintained stationary to keep the instruments in a fixed orientation during acetabular component impaction. The system also provides component selection options based on leg length and offset change measurements.

The intra-operative workflow and surgical concepts implemented in the system remain close to the conventional THA direct anterior approach workflow. As such, at the time of the surgery, the system mainly assists the surgeon in (1) determining reference alignment axes and cup orientation using image-to-image and robotic registration, (2) precisely orienting the cup inserter relative to the desired orthopedic implant angle by using a Robotic Arm and (3) providing leg length and offset change measurements based on fluoroscopic image references.



CAUTION: Federal Law restricts this device to sale by or on the order of a physician.

1.3 Contact

Zimmer CAS
75 Queen Street, Suite 3300
Montreal (QC)
H3C 2N6, Canada
+1 514 396 5422
1 866 3D ORTHO
zimmerbiomet.com

1.4 Training

This device is a surgery assistance tool. It should only be used by authorized surgeons and healthcare professionals trained in the use of the device by Zimmer Biomet or by personnel authorized by Zimmer Biomet. It is not a replacement for the surgeon's expertise and experience.

1.5 Intended Use

The ROSA Hip System, for use with the ROSA Recon Platform, is intended to assist the surgeon in providing application-defined spatial boundaries for orientation and reference information to anatomical structures during hip orthopedic surgery procedures.



The device must only be used for its intended use.

1.6 Indications For Use

The ROSA Hip System, for use with the ROSA Recon Platform, is indicated as a fluoroscopic-guided system for total hip arthroplasty (THA). It is used to assist the surgeon in providing application-defined spatial boundaries for orientation and reference information to identifiable anatomical structures for the accurate placement of hip implant components provided that the points of interest can be identified from radiology images.

The intra-operative cup placement is performed relative to anatomical landmarks as recorded using the system intra-operatively and based on pre-operative planning values optionally determined using compatible X-ray-based surgical planning tools.

The ROSA Hip System is designed for use on a skeletally mature patient population. The targeted population has the same characteristics as the population that is suitable for the implants compatible with the ROSA Hip System. The ROSA Hip System is not for primary image interpretation and is applicable for the direct anterior approach.

The ROSA Hip System is to be used with the following hip replacement systems in accordance with their indications and contraindications: G7[®] Acetabular System, Avenir[®] Hip System, Avenir Complete[®] Hip System, Taperloc[®] Complete Hip System, Echo[®] Hip System.

1.7 Contraindications

The ROSA Hip System may not be suitable for use in case of:

- Hip pathology with significant bone loss (e.g. avascular necrosis of the femoral head with collapse, severe dysplasia of the femoral head or the acetabulum)
- Active infections of the hip joint area
- Hip replacement revision surgery
- Presence of undesirable radio-opaque element during intra-operative image acquisition
- Contraindications for the implant as given by the implant manufacturer
- Implants that are not compatible with the system

1.8 Complications

Possible complications associated with the use of the ROSA Hip System may include, but are not limited to the following: infection, implant misalignment.

1.9 Restrictions For Use

The ROSA Hip System described in this User Manual should not be used in combination with other products or components unless such other products or components are expressly recognized as compatible with the ROSA Hip System. The list of compatible instruments is provided in section 3.3.4.



MR Unsafe: Keep away from Magnetic Resonance Imaging (MRI) Equipment.

1.10 Patents

Patents available online at zimmerbiomet.com/patents










2. About This Manual

This User Manual provides detailed information about the ROSA Hip System. Further in this document, the ROSA Hip System can be referred to as “the device”. This manual is considered as the reference document for users. It is not a technical maintenance or service manual. For technical instructions about the device, please contact Zimmer Biomet’s Customer Service or one of its approved representatives. A troubleshooting guide is provided in section 14 of this manual: Post-operative Guide/Maintenance.



2.1 Safety: Warnings, Cautions and Remarks

The correct use of this equipment implies that the operating staff are familiar with these Instructions for Use. This manual must be carefully studied before using the device. Particular attention must be paid to the safety instructions related to people and the device.






Training, Use and Maintenance

-  The device must only be used after reading this User Manual and after having received the appropriate training. Please contact Zimmer Biomet’s Customer Service if unsure how to use the device.
-  The device must only be used for its intended use.
-  Do not open the device. In case of any issue or breakdown, do not intervene. Maintenance and service operations must only be carried out by Zimmer Biomet’s Customer Service or any of its approved representatives. Do not modify the device.
-  Never attempt to clean the device when it is connected to a power supply. To avoid electrical discharges, always unplug the device from the wall outlet before cleaning or disinfecting it.
-  Make sure the ROSA Tablet has sufficient battery charge before starting surgery.
-  Avoid dropping the ROSA Tablet. Damage to the ROSA Tablet can affect its proper function during surgery.
-  For Flat Panel Detectors, the image display must be set to a squircle.
-  Regarding C-arm compatibility, only Image Intensifiers of 9” or 12” diameter and *GE OEC Elite* and *GE OEC One* Flat Panel Detectors of 21x21cm or 31x31cm can be used.
-  When used in compliance with the indications for maintenance, the device can be run in permanent operation.

Electrical Safety








-  In order to avoid any risk of electric shock, the device must only be connected to an electric power network equipped with grounding. Device is class I, type BF.
-  Do not simultaneously touch the patient and any component of the device other than those attached to the electrical isolation interface part.

2.1 Safety: Warnings, Cautions and Remarks (cont.)





-  IPX0 Protection: Device without special protection against the penetration of liquids. Do not pour any liquid over the device.
-  Do not exceed the recommended input voltage for the device. Plugging the device into a higher voltage supply could damage the device.
-  In order to prevent accidental detachment of connectors, ensure the metallic ring is attached to the Robotic Unit's hook, if applicable.
-  Verify the metallic ring of the Optical Unit cable is attached to the hook on the Rear Panel of the Robotic Unit to ensure electromagnetic compatibility (EMC) protection, if applicable.
-  Do not connect any other elements to the Robotic Unit than those provided with the device.

Radiation Safety

Risks generated by laser beam exposure: The device uses a laser integrated into the navigation camera.





-  This laser is of class 2 (power inferior to 1 mW, eye protection by the palpebral reflex). Do not orient the laser beam to the eyes or to any light-reflecting surfaces (such as mirrors) to avoid any direct or indirect exposure to laser beam.
-  Do not orient the laser towards the patient's eyes, the user's eyes or anyone else's eyes.
-  MR Unsafe: Keep away from Magnetic Resonance Imaging (MRI) Equipment.
-  The device requires specific precautions regarding the EMC. It must be set up and initiated according to the EMC information provided in this User Manual.
-  Portable and mobile radio frequency communication devices might affect the operation of the device.
-  Usage of accessories, transducers and cables other than those specified in the User Manual, with the exception of the transducers and cables sold by Zimmer Biomet (as spare parts of internal components), might cause increased emissions or decreased immunity of the device.
-  The device must not be used adjacent to or stacked on top of any other equipment. If necessary, verify its correct operation in the corresponding configuration.

Risks Related to Transport and Immobilization






-  Ensure that the Robotic Unit is not moving once the immobilization system is locked.
-  Risk of pinching: Do not place fingers or feet under the stabilization feet before immobilization of the system.
-  Verify the position of the device and its environment when using the Robotic Unit immobilization system.
-  During transportation, the device can be immobilized by activating the Immobilization Pedal. Do not install the device on an inclined surface, unless stability is guaranteed.

2.1 Safety: Warnings, Cautions and Remarks (cont.)



Mechanical Safety

-  Ensure that the Foot Pedal is operating correctly before beginning a procedure. Visually inspect the device and perform a test for interruption/resumption of Robotic Arm movement.
-  Risk of collision: When the Robotic Unit is in Automatic mode, stay clear of the Robotic Arm and its path to the next position.
-  Risk of arm dropping-off: Do not lean on the Robotic Arm.
-  Risk of pinching: Do not place fingers in accessible parts of the plastic covers of the Robotic Arm.

Instruments

-  Before every surgery, the user must verify that all instruments are clean and sterilized as per instructions.
-  Verify the integrity of all instruments prior to each surgery. Visually inspect the instruments for damages.
-  Make sure that the Quick Connect Interface Screws are firmly tightened.
-  Handle instruments with care. Avoid dropping instruments. Damage to an instrument can have a significant effect on the function and accuracy of the procedure and consequently, on the post-operative surgical outcome. At the end of the procedure, instruments are placed in their tray for cleaning and sterilization.
-  Do not apply excessive torque on screws when installing an instrument. Do not use power tools.

Contamination

-  The device must be used with sterile drapes. These drapes must be installed in accordance with the instructions detailed in section 9.1 of this User Manual.
-  Verify the setup of the sterile drapes before beginning a surgery to ensure the asepsis of the surgical field.

Specific Warning for the United States of America

-  **CAUTION:** Federal Law restricts this device to sale by or on the order of a physician.

3. Description

3.1 Overview

The ROSA Hip System is an application that assists orthopedic surgeons with acetabular component impaction, inclination and version measurements, as well as assessing the leg length and offset changes based on fluoroscopic images acquired intra-operatively during a total hip arthroplasty. The ROSA Tablet is utilized to capture the fluoroscopic images and transfer data onto the robotic application. Pre-operative planning values related to implant positioning and sizing can be entered in the system as an option.

The device is composed of three units:

- Robotic Unit consisting of a compact Robotic Arm and Touchscreen
- Optical Unit and Touchscreen (optional)
- ROSA Tablet with Touchscreen

The intra-operative workflow and surgical concepts implemented in the system are aligned with the conventional THA direct anterior approach workflow. As such, at the time of the surgery and based on the surgical plan, the system assists the surgeon in determining the reference alignment axis in relation to anatomical landmarks, in positioning the corresponding instruments relative to the planned orthopedic implant orientation and in assessing the leg length and offset changes.

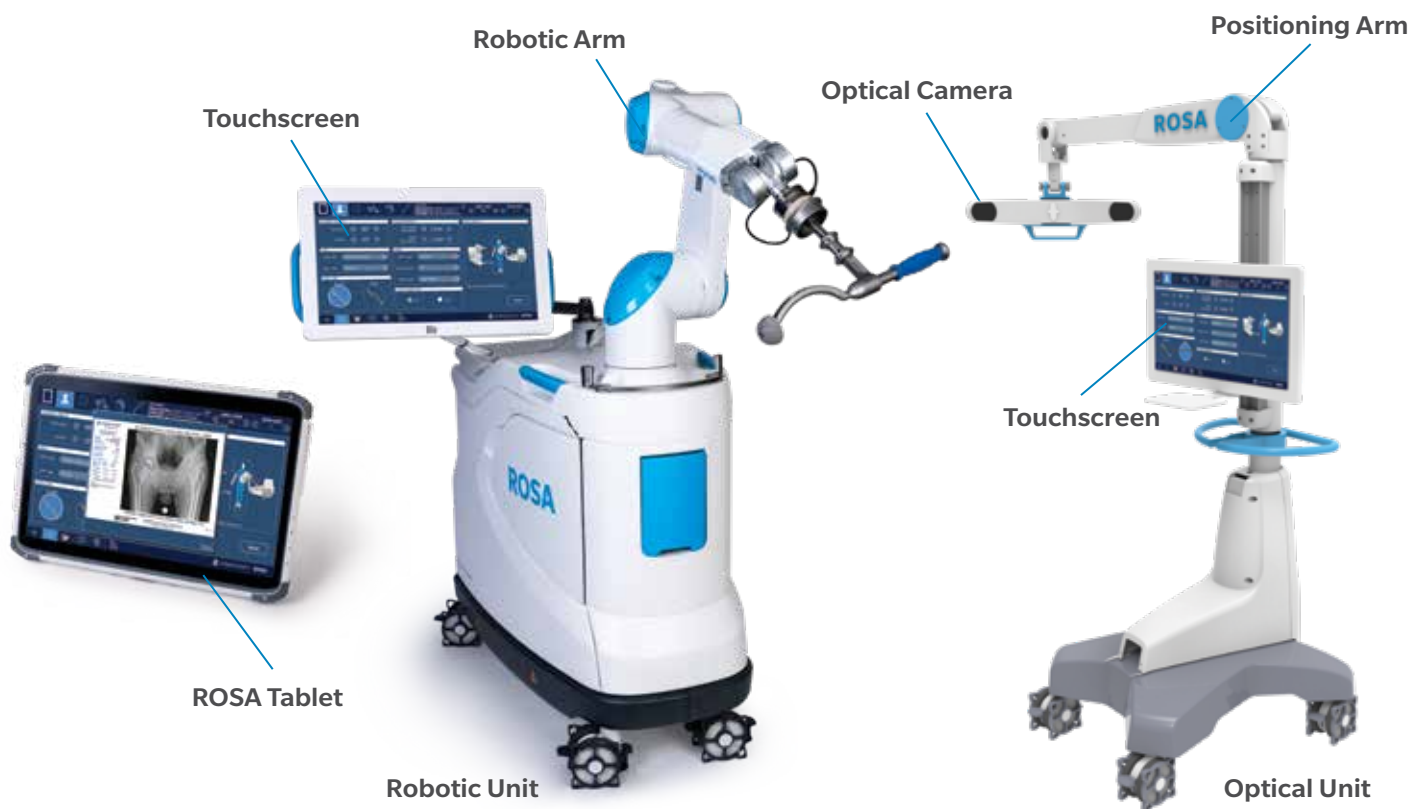


Figure 1: ROSA Hip System

3.2 Operating Principle

The operating principle for a total hip arthroplasty procedure is described below.

3.2.1 Case Information

The case is launched with a USB drive plugged into the Robotic Unit using the case management application. The welcome screen of the ROSA Hip application confirms the patient ID, procedure laterality and surgeon's name. Once the user has confirmed the information, the ROSA Hip application can be launched. The ROSA Hip application is launched on the ROSA Tablet directly without launching a specific case.

3.2.2 ROSA Tablet and ROSA Communication Setup

The communication between the ROSA Tablet and Robotic Unit can be established when the ROSA Hip application is launched on both devices and Wi-Fi is turned on. The ROSA Tablet is operated by a non-sterile operator and used to capture fluoroscopic images from the C-arm monitor and transfer them to the Robotic Unit. It can also be used to control the ROSA Hip application throughout the workflow.

3.2.3 Surgeon's Preferences and Pre-operative Planning

The surgeon's preferences are automatically selected when launching the ROSA Hip application if they were defined in the Zimmer Biomet Drive Case Management System (DCMS). The preferences can be modified intra-operatively in the ROSA Hip application.

Optional pre-operative planning values can be selected when launching the ROSA Hip application if pre-operative planning was performed with X-ray-based surgical planning tools. The implant sizing values and target values can be modified intra-operatively in the ROSA Hip application.

3.2.4 Reference Fluoroscopic Images Acquisition

Reference fluoroscopic images are acquired using the ROSA Tablet and transferred to the Robotic Unit through a wireless connection. The images are used to define the patient's reference axis in relation to anatomical landmarks and to determine the pre-operative leg length and offset measurements.

3.2.5 OR Setup

The patient is placed on the operating table in supine position. It is recommended to use standard OR stabilization devices to limit pelvis movement. The Robotic Unit is positioned on the operative side, at approximately the patient's hip level and approximately 90° relative to the operating table. The maximum height of the patient on the OR table should be 48 inches to ensure adequate Robotic Arm movement.



During the surgery, the surgeon must always stay on the same side as the Robotic Unit.



These recommendations are also applicable when the use of a traction table is preferred.

3.2.6 Acetabular Component Impaction

Acetabular component target angles can be modified prior to cup insertion. Based on the intra-operative planning values and intra-operative fluoroscopic images, the application provides live feedback on the instrument orientation to guide the acetabular component orientation during impaction.

Based on cadaveric testing, the system achieved cup placement accuracy within the Lewinnek and Callanan safe zones in 100% of cases for both inclination and version.



Risk of collision: When the Robotic Unit is in Automatic mode, stay clear of the Robotic Arm and its path to the next position.

3.2.7 Trial and Validation

Based on intra-operative fluoroscopic images, the ROSA Hip application will determine the intra-operative leg length and offset changes for the selected trial components and final implants. The ROSA Hip application also shows the projected leg length and offset values for compatible combination of components.

Based on cadaveric testing, the system achieved measurement accuracy of ± 5 mm of leg length change in 88% of cases and ± 5 mm of offset change in 87% of cases.

3.3 System Description

3.3.1 Robotic Unit

The Robotic Unit (PN 20-8020-110-01/17/26) is composed of the following main components:

- Robotic Arm
- Touchscreen for operating the device
- Immobilization System
- Foot Pedal
- Computer and Application

The Robotic Unit is equipped with swivel wheels and handles allowing the device to easily moved between operating rooms by a single person. The wheels are equipped with foot pressure brakes to lock the unit in place and cable pushers to avoid rolling on cables.

It has optional lateral openings and a sliding shelf that provides storage for various items.

The Robotic Unit is powered by the operating room power supply by plugging the Power Cable from the Rear Panel to a power plug compatible with the device characteristics.

The Foot Pedal is linked to the Robotic Unit by plugging the cable to the dedicated connector on the Rear Panel.

When not in use, the Robotic Unit Power Cable and Foot Pedal cable can be rolled around rollers on the Rear Panel. The Foot Pedal may also be stored in the storage area.



Figure 2: Front View of the ROSA Robotic Unit

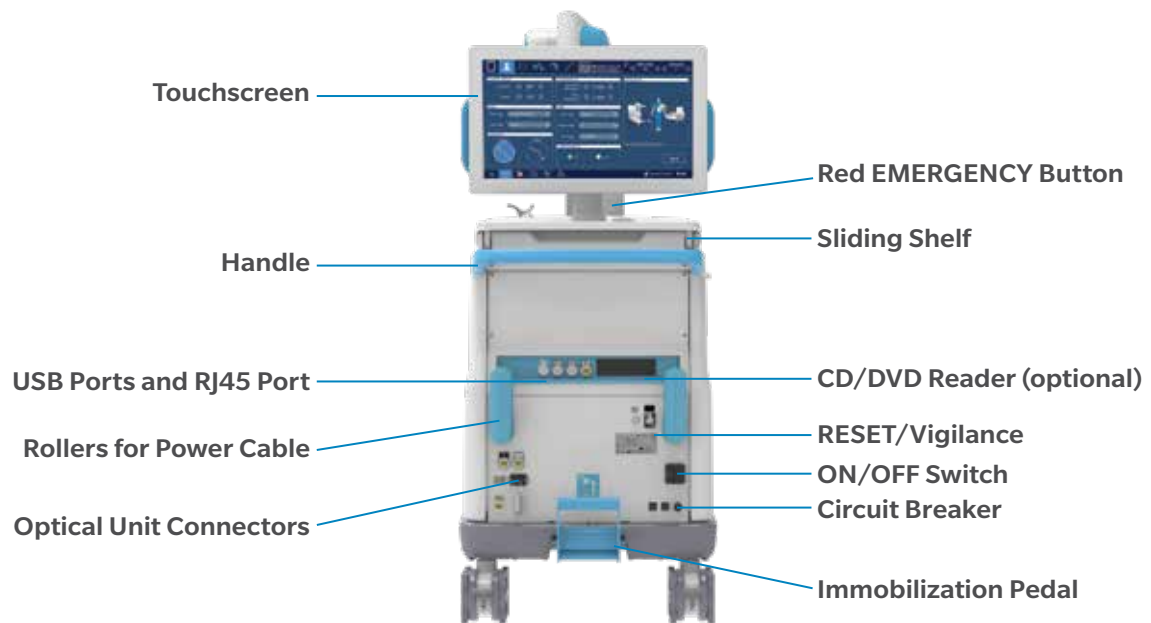




Figure 3: Rear Panel of the ROSA Robotic Unit


3.3.1 Robotic Unit (cont.)

The Rear Panel includes:

- Main ON/OFF switch to turn the device on and off
- RESET button to restart the computer
- CIRCUIT BREAKER button to restart the device after it has been turned off due to an overvoltage
- Connectors that plug in the Optical Unit and the Foot Pedal
- USB ports to import cases. One USB port is available in the storage area beneath the sliding shelf to connect a mouse
- CD/DVD reader (unplugged and non-functional)
- RJ45 port to connect the system to an intra-operative imaging system (deactivated)
- Controller servicing port (deactivated)
- Laser button (deactivated)

 Do not connect any other elements besides those provided with the device to the Robotic Unit.

 In order to prevent accidental detachment of connectors, ensure the metallic ring is attached to the Robotic Unit's hook, if applicable.

 Make sure the metallic ring of the Optical Unit cable is attached to the hook on the Rear Panel of the Robotic Unit in order to ensure EMC protection, if applicable.

3.3.1.1 Robotic Arm

The Robotic Unit is equipped with a Force Sensor in the Robotic Arm that allows it to be manually moved to the desired location by measurement of forces exerted at the end of the arm and a compensation principle, regardless of the instrument used.



3.3.1.2 Immobilization System


The Robotic Unit is equipped with a system immobilizing it to the ground. This system is composed of four stabilization feet, activated by a pedal. Two positions are available: the unit is immobilized when the pedal is down, the unit is mobile when the pedal is up. Additionally, each wheel of the Robotic Unit can be locked individually, activated by a pedal.




Immobilization Pedal in Down Position: Unit Immobilized



Immobilization Pedal in Up Position: Unit Mobile

 Risk of pinching: Do not place fingers or feet under the stabilization feet before immobilization of the system.


 Verify the position of the device and its environment when using the Robotic Unit immobilization system.
Make sure cables or wires are cleared from the area of the stabilization feet to prevent damage.

3.3.1.3 Vigilance Device (Foot Pedal)

The device is equipped with a Foot Pedal (PN RF 2PW-MED or MKF 2S-MED) for monitoring the Robotic Arm movements. The Robotic Arm will only move if the user presses down on the Foot Pedal. This operating principle applies to the SETUP and IMPACTION panels. The Robotic Arm movement is interrupted as soon as the user releases the Foot Pedal.



Figure 4: Vigilance Device (Foot Pedal)

 Ensure that the Foot Pedal is operating correctly before beginning a procedure. Visually inspect the device and perform a test for interruption/resumption of Robotic Arm movement.

3.3.2 Optical Unit

The Optical Unit (PN 20-8020-120-01) is composed of:

- Optical Camera
- Camera Positioning Arm
- Touchscreen

The Optical Camera is not used for the Direct Anterior approach with the ROSA Hip system since the system relies on fluoroscopic images. The Optical Unit can be optionally connected to the Robotic Unit for usage of the Touchscreen.

The Optical Unit is powered by the Robotic Unit by plugging the cable to the connector on the Robotic Unit Rear Panel. A roller is included to properly store the Optical Unit Cable. The Optical Unit is equipped with swivel wheels and a handle allowing the device to be easily moved between operating rooms by a single person. Each wheel has a brake and a cable pusher system. A laser is integrated into the camera but is not used with the ROSA Hip System.

3.3.2 Optical Unit (cont.)

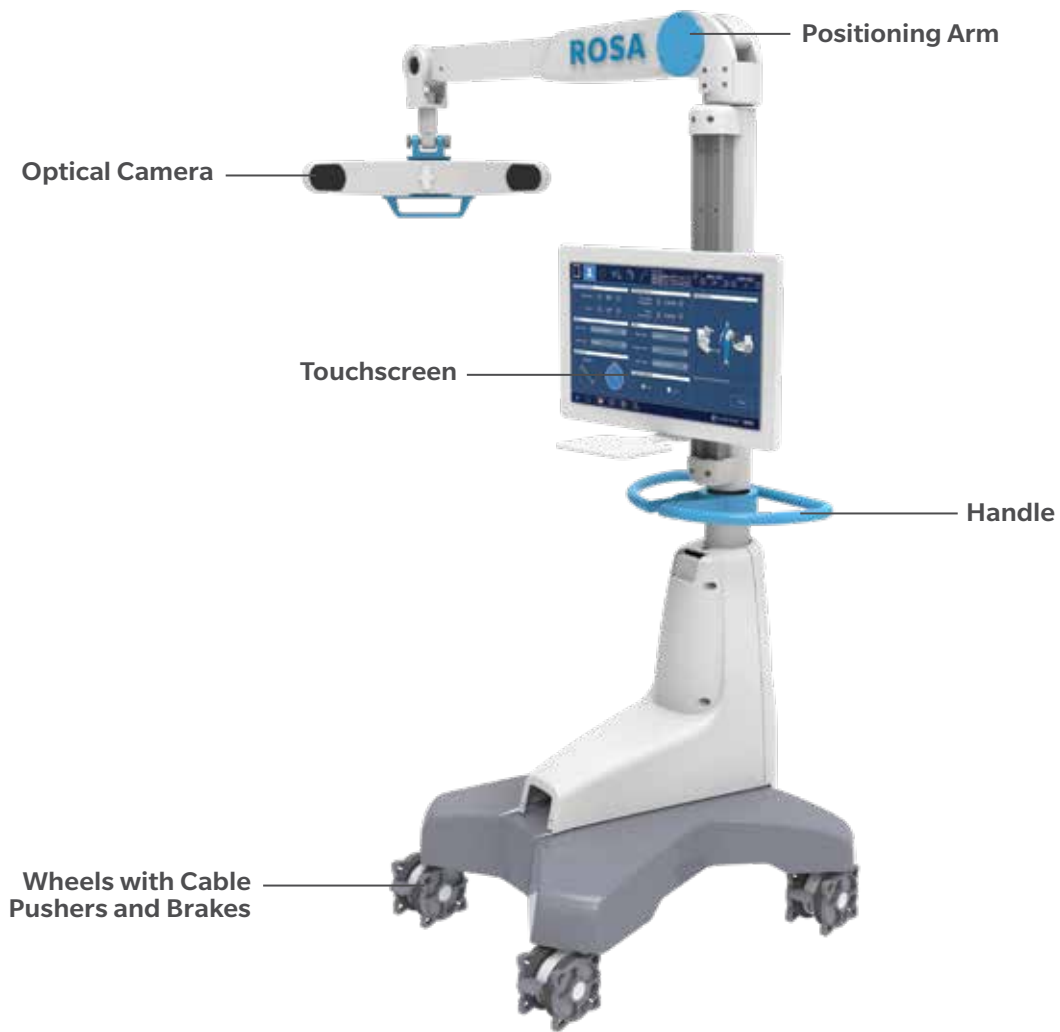




Figure 5: Optical Unit

-  Risks generated by laser beam exposure: The device uses a laser integrated into the Optical Camera. This laser is of class 2 (power inferior to 1 W, eye protection by the palpebral reflex). Do not orient the laser beam to the eyes or to any light-reflecting surfaces (such as mirrors) to avoid any direct or indirect exposure to laser beam.
-  Do not orient the laser towards the patient's eyes, the user's eyes or anyone else's eyes.

3.3.3 ROSA Tablet

The ROSA Tablet is a non-sterile digital tablet approved for use in a surgical environment. It is provided with the following non-sterile electronic accessories:

- Tablet Battery, corresponding to the battery of ROSA Tablet
- Battery Bay Charger, corresponding to the 6-slotted battery charger
- Power Cord, corresponding to the country-associated Power Cable for Battery Bay Charger

Two Tablet Batteries, one Battery Bay Charger and one Power Cord provided in the initial package with the ROSA Tablet.



The ROSA Tablet has a wireless connection to the Robotic Unit, established after the ROSA Hip application is launched.

 The Battery Bay Charger is not approved for use in a surgical environment.

3.3.4 Instrumentation

ROSA Instruments

All reusable instruments need to be sterilized before each use.

Component's Name	Part Number
ROSA Quick Connect Interface	20-8060-001-00
ROSA Quick Connect Sleeve	20-8060-002-00
ROSA Cup Inserter Handle	20-8060-301-00
ROSA STRT Cup Inserter Shaft	20-8060-302-00
ROSA OFFST Cup Inserter Shaft	20-8060-303-00
ROSA Cup Inserter Adaptor	20-8060-304-00
ROSA Cup Inserter Screw	20-8060-305-00
ROSA Hip Impaction Instrument Case	20-8060-306-00
Instrument Case Lid	110031221

Disposables

Component's Name	Part Number
ROSA Robotic Unit Drape (box of 20)	20-8020-080-00
Monitor Drape (box of 20)	ROSAS00056

ROSA Tablet

Component's Name	Part Number
ROSA Tablet	20-8060-400-00
Tablet Battery	20-8060-402-00
Tablet Battery Bay Charger	20-8060-403-00
Tablet Power Cord Type (I)	20-8060-400-02
Tablet Power Cord Type (B)	20-8060-400-03
Tablet Power Cord Type (G)	20-8060-400-04
Tablet Power Cord Type (L)	20-8060-400-05
Tablet Power Cord Type (M)	20-8060-400-06
Tablet Power Cord Type (J)	20-8060-400-07
Tablet Power Cord Type (H)	20-8060-400-08
Tablet Power Cord Type (N)	20-8060-400-09
Tablet Power Cord Type (E-F)	20-8060-400-10

3.3.4 Instrumentation (cont.)



The ROSA Hip System is not compatible with the older version Arm Drape (part number: ROSAS00055) and should not be used with this system. Use only the ROSA Robotic Unit Drape (part number: 20-8020-080-00).



Handle instruments with care. Avoid dropping instruments. Damage to an instrument can have a significant effect on the function and accuracy of the procedure and consequently, on the post-operative surgical outcome. At the end of the procedure, instruments are placed in their tray for cleaning and sterilization.

3.3.4.1 ROSA Quick Connect Interface and Sleeve

The ROSA Quick Connect Interface is attached to the Robotic Arm in sterile conditions using three captive screws. It enables maintaining sterile conditions when changing tools. This part must be cleaned and sterilized before each use.

The ROSA Quick Connect Sleeve slides on the interface connector and secures the connection of the instruments to the Robotic Arm.



Avoid touching the non-sterile part of the Robotic Arm during installation.

3.3.4.2 ROSA Cup Inserter Assembly (Straight Configuration)

The ROSA Cup Inserter Assembly (Straight Configuration) is attached to ROSA Quick Connect Interface by securing the ROSA Quick Connect Sleeve.



Figure 7: ROSA Cup Inserter Assembly (Straight Configuration)

3.3.4.3 ROSA Cup Inserter Assembly (Offset Configuration)

The ROSA Cup Inserter Assembly (Offset Configuration) is attached to ROSA Quick Connect Interface by securing the ROSA Quick Connect Sleeve.



Figure 8: ROSA Cup Inserter Assembly (Offset Configuration)

3.4 Instrument Assembly

The following instructions explain how to assemble ROSA Hip instruments.



Always verify the proper assembly of an instrument, installation of an instrument to the Robotic Unit or Robotic Arm by making sure screws are firmly tightened and ROSA Quick Connect sleeve is secured.

3.4.1 ROSA Quick Connect

ROSA Quick Connect Sleeve is inserted over ROSA Quick Connect Interface until it reaches the top surface (see Figure 9) and retractable, spring-loaded features are in contact with the ROSA Quick Connect Sleeve to hold it in place (see Figure 10).



Figure 9: ROSA Quick Connect Sleeve installation on ROSA Quick Connect Interface



Figure 10: ROSA Quick Connect Sleeve Installation on the Interface; Spring-loaded features and top surface are in contact with the sleeve

3.4.2 ROSA Cup Inserter Assembly (Straight and Offset)

The ROSA Cup Inserter Adaptor (PN 20-8060-304-00) assembles first onto the ROSA STRT Cup Inserter Shaft (PN 20-8060-302-00) or the ROSA OFFST Cup Inserter Shaft (PN 20-8060-303-00). The ROSA Cup Inserter Handle (PN 20-8060-301-00) is inserted into the ROSA Cup Inserter Adaptor and ROSA STRT (or OFFST) Cup Inserter Shaft assembly (see Figure 11).

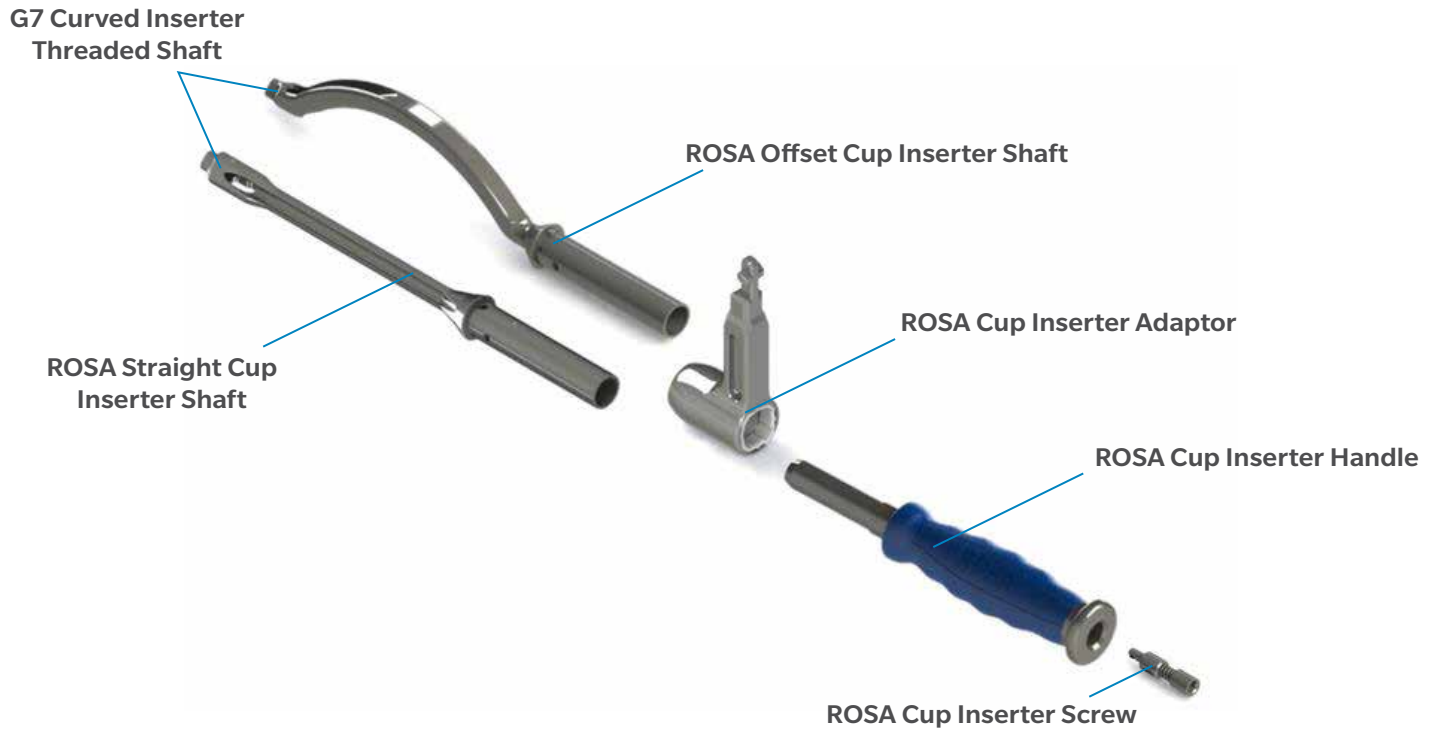


Figure 11: ROSA Cup Inserter Assembly Schematic

Then, the ROSA Cup Inserter Screw (PN 20-8060-305-00) must be inserted through the ROSA Cup Inserter Handle using the G7 Ball Hex Driver. Press and rotate the screw clockwise for half a turn until the physical stop is reached in order to secure the entire assembly (see Figure 12 (A) and (B)). The G7 Curved Inserter Threaded Shaft (PN 110003454) is inserted at the tip of the ROSA STRT Cup Inserter Shaft or the ROSA OFFST Cup Inserter Shaft. Using the G7 Ball Hex Driver, turn to advance the G7 Curved Inserter Threaded Shaft until the threads are exposed (see Figure 13 (A) and (B)).

3.4.2 ROSA Cup Inserter Assembly (Straight and Offset) (cont.)

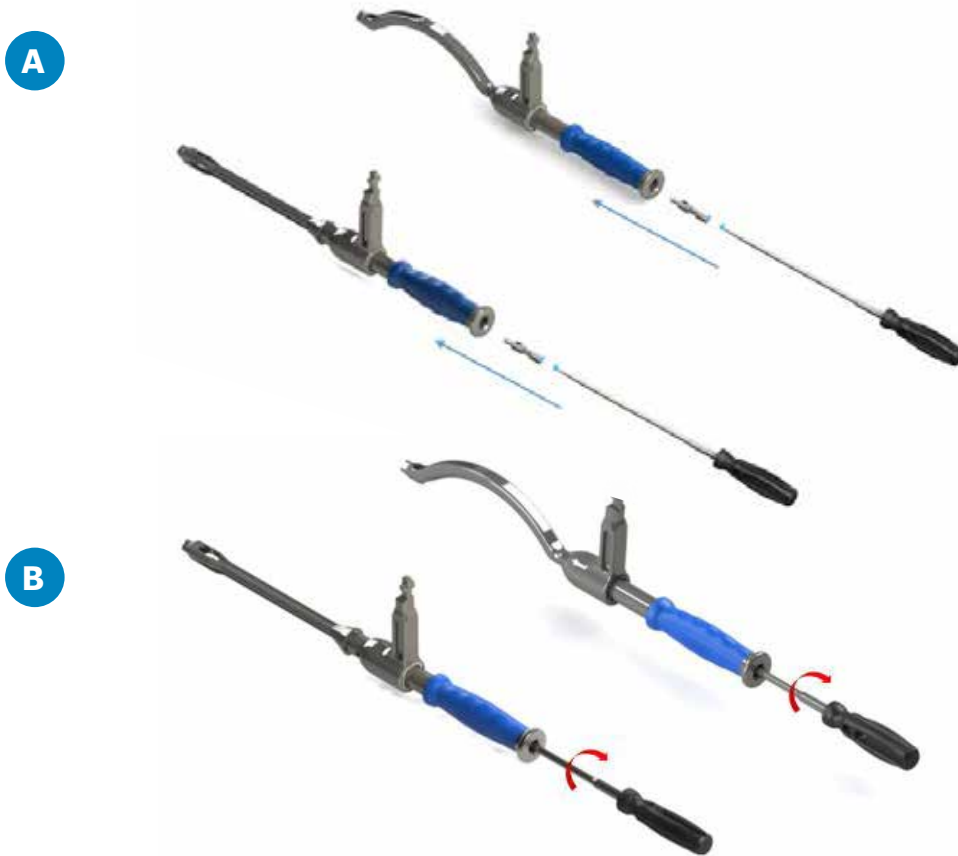


Figure 12: (A) Insertion of ROSA Cup Inserter Screw inside the unsecured assembly (see Figure 11) using the G7 Ball Hex Driver; (B) Ball hex driver pressing on the screw and rotating half a turn clockwise to secure the assembly

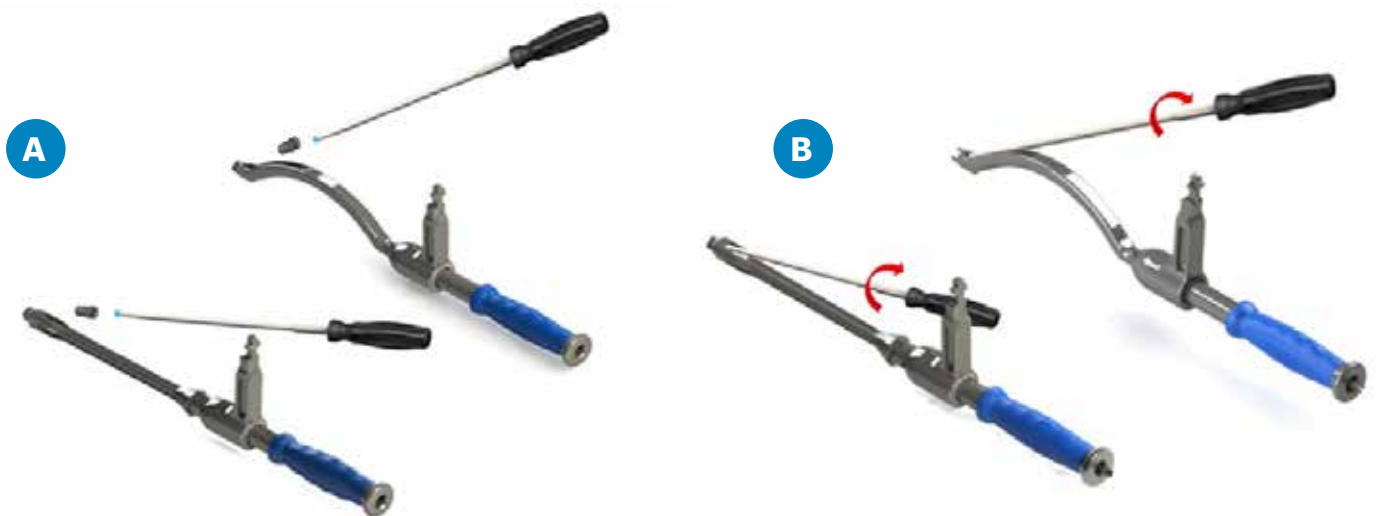


Figure 13: (A) Insertion of G7 Curved Inserter Threaded Shaft inside the tip of the ROSA STRT Cup Inserter Shaft or the ROSA OFFST Cup Inserter Shaft using the G7 Ball Hex Driver; (B) Ball hex driver pressing on the screw and rotating clockwise until the threads are exposed

3.4.2 ROSA Cup Inserter Assembly (Straight and Offset) (cont.)

ROSA Cup Inserter Adaptor is able to slide along the ROSA STRT (or OFFST) Cup Inserter Shaft (see Figure 13 (C)) and can also be maintained at a specific position to allow easy installation on the Robotic Arm and during Robotic Arm movements. ROSA Cup Inserter Adaptor must be locked on the shaft for all fluoroscopic images (see Figure 13 (D)). The ROSA Cup Inserter Adaptor is mechanically held into the specific position by a spring-loaded feature and there is a visual marking to further confirm the correct position.

C



D



Figure 13: (C) ROSA Cup Inserter Adaptor sliding along the shaft; (D) ROSA Cup Inserter Adaptor locked on the shaft

3.5 Instrument Installation on the Robotic Arm

3.5.1 ROSA Quick Connect on the Robotic Arm

ROSA Quick Connect Interface is installed in a unique way on the Electrical Insulating Interface by aligning the index pin and central body (see Figure 14(A)). Captive screws in the ROSA Quick Connect Interface are used to tighten both components together (see Figure 14(B)).

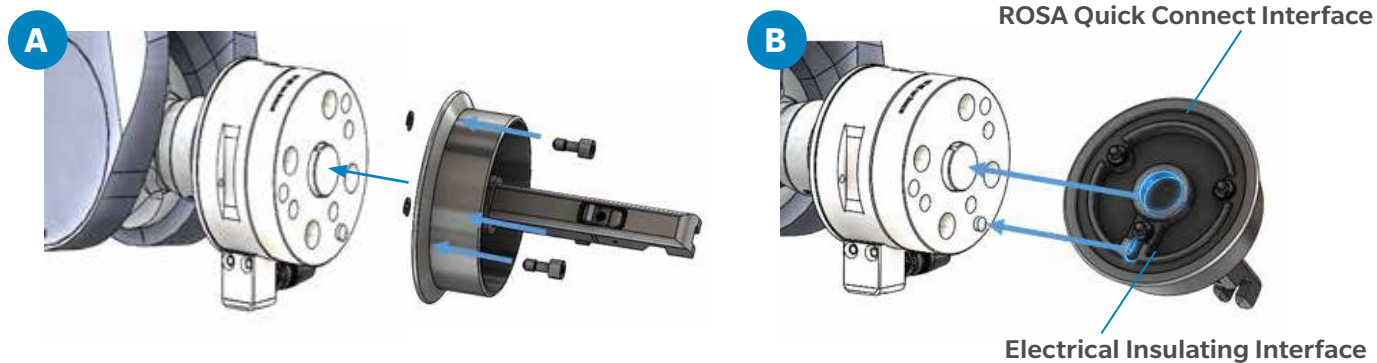



Figure 14: (A) ROSA Quick Connect Interface installation on the Electrical Insulating Interface of the Robotic Arm; (B) Captive screws are used to tighten both components

 Avoid touching the non-sterile part of the Robotic Unit.

 Do not apply excessive torque on screws when installing an instrument. Do not use power tools.

3.5.2 Instrument Installation

The selected configuration of ROSA Cup Inserter Assembly can be installed on the ROSA Quick Connect Interface (see Figure 15). The ROSA Quick Connect Sleeve slides along the interface until it comes to a complete stop to fully secure the assembly (see Figure 16). These are the visual indicators to show that the ROSA Quick Connect Sleeve is secured:

- Faceted portion of the ROSA Cup Inserter Adaptor is completely covered
- Retractable spring-loaded feature is fully extended on the opposite end Retractable



Figure 15: Cup Inserter installation on the ROSA Quick Connect Interface with the ROSA Quick Connect Sleeve in the unlocked position

3.5.2 Instrument Installation (cont.)



Figure 16: ROSA Quick Connect Sleeve sliding along the interface to lock the installation

3.5.3 Drapes

Drapes for the Robotic Unit and Touchscreens are required prior to starting the surgery. Instructions on how to install the drapes are provided in section 9.1 of this User Manual.















Never use a torn drape. In case of a tear, or when concerned that the sterility is compromised, discard the drape and use a new one.



Never use damaged tape for taping the ROSA Arm Drape to the ROSA Arm Instrument Interface at the end of the Robotic Arm.

4. Installation

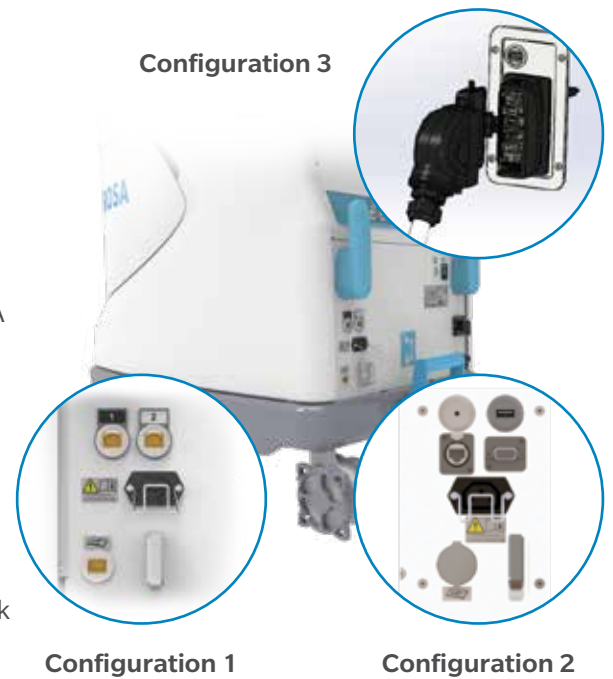
4.1 Warnings and Cautions About Robotic Unit Installation






-  Ensure that the Robotic Unit is not moving once the immobilization system is locked.
 -  Risk of pinching: Do not place fingers in accessible parts of the plastic covers of the Robotic Arm.
 -  Risk of pinching: Do not place fingers or feet under the stabilization feet before immobilization of the system.
 -  In order to avoid any risk of electric shock, the device must only be connected to an electric power network equipped with grounding. Device is Class I, type BF.
 -  Do not simultaneously touch the patient and any component of the device other than those attached to the electrical isolation interface part.
 -  Ensure that the Foot Pedal is operating correctly before beginning a procedure. Visually inspect the device and perform a test for interruption/resumption of a Robotic Arm movement.
 -  The operating table must not be moved once an instrument guided by the Robotic Unit is inserted into the patient anatomy.
- Risks generated by laser beam exposure: the device uses a laser integrated into the optical camera.
-  This laser is of class 2 (power inferior to 1 mW, eye protection by the palpebral reflex). Do not orient the laser beam to anyone's eyes or to any light-reflecting surfaces, such as mirrors, to avoid any direct or indirect exposure to laser beam.
 -  Verify the position of the device and its environment when using the Robotic Unit immobilization system.
 -  During transportation, the device can be immobilized by activating the immobilization pedal. Do not install the device on an inclined surface, unless its stability is guaranteed.
 -  IPX0 Protection: Device without special protection against the penetration of liquids. Do not pour any liquids over the device.
 -  Do not connect any other elements besides those provided with the device to the Robotic Unit.

4.2 Device Start Up

Turning the device ON:

1. Place the Robotic Unit on one side of the operating table and the Optical Unit on the opposite side. Plug the Optical Unit into the Robotic Unit.
 - For Configuration 1 only: Plug the white and black cables into the corresponding white and black ports
 - For Configuration 2 only: Plug the USB, Ethernet, Jack and VGA cables into the corresponding ports
 - For Configuration 3 only: Plug the single connector into its socket and secure the connection
2. Plug the Power Supply Cable into a power source of appropriate voltage.
3. For Configuration 1 and 2 only: Attach the metallic ring of the Optical Unit cable to the hook on the Robotic Unit Rear Panel. Lock the connector in place using the metallic clip.
4. Turn the robot ON.



-  In order to prevent unit damage, ensure the Power Supply Cable is plugged into an appropriate-voltage power source.
-  In order to prevent accidental detachment of connectors, ensure the metallic ring is attached to the Robotic Unit's hook. Lock the connector in place using the metallic clip, if applicable.
-  Make sure the metallic ring of the Optical Unit cable is attached to the hook on the Rear Panel of the Robotic Unit in order to ensure EMC protection, if applicable.
-  If the screen remains black at start up: Check that the Touchscreen is powered ON (button on the right side of the screen) and/or restart the computer by pushing the button located on the Rear Panel of the device.
-  To restart the device, wait at least 10 seconds after shutting down and for the RESTART button light to go off before powering back on.

4.3 Emergency Procedure

In case of emergency or device failure requiring a fast removal of the device to access the patient, follow one of the procedures described below. The user may choose to move the device away from the operating table partially or completely, depending on the procedure that is needed to cope with the device failure or emergency.

4.3.1 Moving the Robotic Arm Away using ROSA Application Interface

Partial Removal—Moving the Robotic Arm Away

This procedure can be performed by one sterile operator.

1. Press the ROSA HOME button in the bottom task bar.
2. Press on the Foot Pedal to release the assembly from any residual forces and remove any instruments that are linking the patient to the Robotic Unit.
3. Send the Robotic Arm to the ROSA HOME position to free space around the patient's hip.



ROSA HOME button

4.3.1 Moving the Robotic Arm Away using ROSA Application Interface (cont.)

Full Removal–Moving the Robotic Unit Away

This procedure requires one sterile operator and one non-sterile operator.

1. Complete the steps of Section 4.3.1 - Partial Removal–Moving the Robotic Arm Away.
2. Deactivate the Robotic Unit immobilization system (one main pedal and four wheels).
3. Move the Robotic Unit away to free up space around the patient.
4. If necessary, move the Optical Unit away after releasing the wheel brakes.
5. After a full removal of the Robotic Unit, revert to standard instrumentation.

4.3.2 Moving the Robotic Arm Away if Application is Unresponsive

This procedure requires one sterile operator and one non-sterile operator.

1. Unlock the ROSA Quick Connect Sleeve by sliding the sleeve towards the Quick Connect Interface.

If forces are exerted on the connected instrument, it may be difficult to slide the Quick Connect Sleeve.



If the Quick Connect Sleeve cannot be unlocked, disconnect the cup from the Cup Inserter to release the assembly from any residual forces.

1. Remove any instruments that are linking the patient to the Robotic Unit.
2. Deactivate the Robotic Unit immobilization system (one main pedal and four wheels).
3. Move the Robotic Unit away to free up space around the patient.
4. If necessary, move the Optical Unit away after releasing the wheel brakes.
5. After a full removal of the Robotic Unit, revert to standard instrumentation.



If there was a full removal of the Robotic Unit or if there was a problem with ROSA instrumentation that could lead to inaccuracy, the surgeon must revert back to standard instrumentation. The ROSA Hip System can still be used for leg length and offset measurement.

4.4 Reverting to Standard Instrumentation

A full set of the implant system's standard instrumentation is needed to perform a surgery in conjunction with the ROSA Hip System in case the ROSA Hip System cannot be used. It is mandatory to revert to standard instrumentation for impaction in case of:

- Full removal of the Robotic Unit
- Problem(s) with the ROSA instrumentation that could lead to inaccuracy

For any other problem encountered at any time during the surgical flow, it is always possible to revert to standard instrumentation by pressing the ROSA HOME button in the bottom task bar of the ROSA Hip application and following the displayed instructions summarized below:

1. Press the ROSA HOME button in the bottom task bar.
2. If instruments are connected to the robot:
 - Press on the Foot Pedal to release the assembly from any residual forces and remove any instruments that are linking the patient to the Robotic Unit using the Quick Connect
3. Send the Robotic Arm to the ROSA HOME position to free space around the patient's hip.
4. Continue surgery using standard instrumentation.



ROSA HOME button

4.5 Case Management Application

4.5.1 Case Management Application–Interface Overview

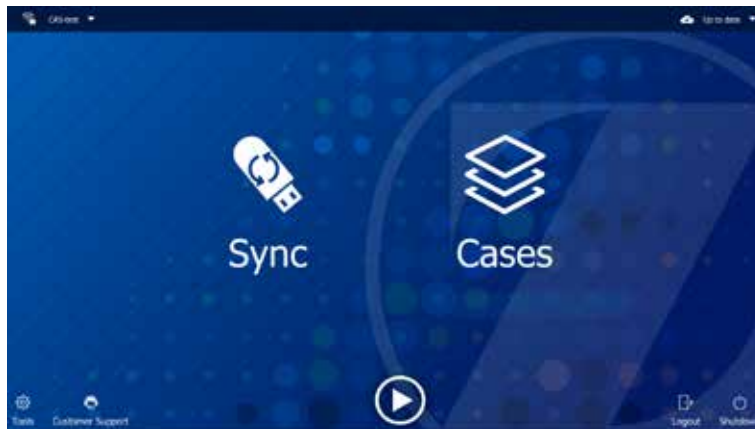


Figure 17: Case Management Application - Interface Overview

Case Management Application Functions

SYNC: This function decrypts the case(s) from a USB drive and syncs them with the ROSA Clinical Computer.

CASES: This function lists the cases that were uploaded using the SYNC function. When selecting a case, a PIN will be required to load the case and launch the welcome screen of the ROSA Surgery application.

LOGOUT: This function exits the case management application and should only be used by authorized personnel to access the maintenance mode.

SHUTDOWN: This function shutdowns the system.

4.5.2 Starting a Case

The Case Management application will start upon powering up the system.

1. Insert a USB drive containing the encrypted case(s) in a USB port.
2. Use the SYNC function to upload the case(s) to the ROSA Clinical Computer.
3. Use the CASES function to search for the case to be launched (at least three letters).
4. Select the appropriate case and click LAUNCH.
5. Type in the PIN for the selected case.

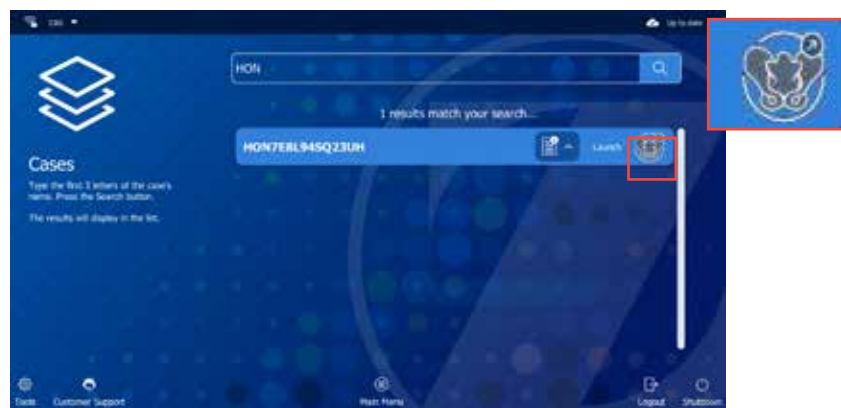


Figure 17A: Case Management - Starting a Case

5. ROSA Tablet Handling





5.1 Battery Charger Installation

To power on the Battery Bay Charger, ensure the following steps have been completed:

1. Assemble the items for the Battery Bay Charger: connect the Power Adaptor to the charger. Ensure the connector is fully inserted.
2. Plug the Power Cord into the Power Adaptor of the Battery Bay Charger. Ensure the connector is fully inserted.
3. Plug the Tablet Power Cord into an AC power outlet. Ensure the light indicator on the power adaptor is illuminated.



Figure 18: Battery Bay Charger Installation

-  Only use the Power Adaptor that is provided with your charger.
-  In order to prevent unit damage, ensure the appropriate Supply Cable is plugged into a power source of appropriate voltage.
-  The Power Adaptor, charger and batteries may become hot during normal use. Allow for proper ventilation around the devices.
-  The Tablet Battery Bay Charger is not approved for use in a surgical environment and should not be installed and used within the operating room.

5.2 Charging Procedure




The ROSA Tablet Battery should be fully charged before use of the ROSA Tablet. A Battery Bay Charger is provided for this purpose. Since this charger has been successfully installed using the instructions in section 5.1, the batteries can be charged.

The charger is designed with six charging slots or bays. Each bay will charge one Tablet Battery, allowing charging for up to six Tablet Batteries simultaneously. A Tablet Battery may be inserted into any bay and several batteries may be inserted in any order. Charging will begin when the first Tablet Battery is inserted into a bay. Make sure the connector pins on the battery line up properly with the pins in the bay. An orange indicator light on the top of each slot will indicate the Tablet Battery is charging. The color will change to blue once the charge is complete.

5.2 Charging Procedure (cont.)



Figure 19: Charging Battery in Battery Bay Charger

-  This charger must only be used with the specific Tablet Battery models for which it is designed. Failure to do so may result in battery or charger damage or personal injury.
-  Never force a Tablet Battery inside the Tablet Battery Bay.
-  In order to avoid an unexpected shutdown of the ROSA Tablet during a procedure, charge the Tablet Battery as soon as the ROSA Tablet displays a notification that the battery level is equal to 20%.

5.3 ROSA Tablet Battery Removal/Installation Procedure

For performance purposes, a battery should always be plugged into the Battery Bay Charger, while another is used in the ROSA Tablet. The removal and installation operations should happen during the swapping out battery procedure.

To remove the battery from the ROSA Tablet:

1. Shut down the ROSA Tablet by pressing the SHUTDOWN button from the App Launcher portal.
2. Remove the hand strap on the back side of the ROSA Tablet by releasing the keyholes in the corners.
3. Unlock the grey lock button located on the left of the battery by pushing the notch to the left direction.



Lock/Unlock Button

5.3 ROSA Tablet Battery Removal/Installation Procedure (cont.)

4. Removal: Slide the lock button down and remove the battery.



To install a battery in the ROSA Tablet:

1. Ensure that the lock button is unlocked.
2. Position the battery in the ROSA Tablet's battery compartment. Ensure the shape of the battery matches the shape of the ROSA Tablet's battery compartment and push down on the battery until a locking sound is heard.



3. Ensure the battery is fully seated and slide the lock button into the lock position.
4. Install the hand strap on the back side of the ROSA Tablet.



Never leave the ROSA Tablet with the battery compartment empty. A tablet left without a battery in its compartment for several minutes may need to be replaced. There should be a battery installed in the ROSA Tablet at all times.

5.4 Turning ON the ROSA Tablet

Ensure a battery is installed in the ROSA Tablet. To start the ROSA Tablet, press and hold the power button for two seconds. The power button is located on the outer edge of the ROSA Tablet, bottom right corner (see image at right). The screen will then display the App Launcher Portal. Select the ROSA Hip Launcher to launch the ROSA Hip application.



5.5 Intra-operative Battery Swap

The ROSA Tablet Battery can be changed during a surgical procedure.



Do not quit the application workflow when following this procedure.

To change the ROSA Tablet Battery during a surgical procedure:

1. Remove the battery from ROSA Tablet (refer to section 5.3).
2. Install a charged battery in the ROSA Tablet (refer to section 5.3).
3. Turn on the ROSA Tablet (refer to section 5.4).
4. Launch the ROSA Hip application on the ROSA Tablet.
5. Select the MOBILE CONNECTION panel on the ROSA Tablet and press the Wi-Fi button.
6. Select the currently in-use ROSA Tablet from the list of available devices on the robot and reestablish communication.

5.6 Turning OFF the ROSA Tablet

The ROSA Tablet can be turned OFF using the application. After exiting the ROSA Hip application, the ROSA Tablet's user interface will return to the App Launcher portal. Click SHUTDOWN to turn off the device.

6. Intra-operative Guide/Surgery

6.1 Welcome Screen

Upon launching a case, a welcome screen will appear where the user can confirm the patient ID, procedure laterality and surgeon's name. Once the user has confirmed that the information is correct, the ROSA Hip application can be launched. If the information is incorrect, the user can quit and relaunch the correct case.



Figure 20: ROSA Application Welcome Screen

6.2 ROSA Hip Application-User Interface Overview

The ROSA Hip user interface consists of two task bars: one at the top containing the main panels of the ROSA Hip application and one at the bottom of the screen that contains features accessible in any panel. The middle of the user interface displays instructions for navigating the application workflow.

6.2.1 Top Task Bar

6.2.1.1 Panel Buttons

The panel buttons allow direct access to a specific panel. An icon featuring a light blue background indicates the currently active panel. Icons featuring white outlines indicate that the panel(s) are directly accessible. Greyed out icons indicate that these panels are not accessible at that time. Inaccessible panels will become accessible once all necessary preceding tasks have been completed.



6.2.1.1 Panel Buttons (cont.)

List of Panel Buttons



MOBILE CONNECTION



IMPACTION



SURGEON



CUP VERIFICATION



SETUP



TRIAL and VALIDATION

6.2.1.2 Case Information

The case information displays the following details:

- Procedure laterality
- Implant selection
(acetabular implant brand
and femoral implant brand)
- Patient ID



By activating the PENCIL button, you can modify:

- Femoral implant brand
- Femoral implant type
- Acetabular implant type

Press the APPLY button to apply the change or press CANCEL to discard changes.

Implant component sizes are displayed directly on the user interface. All supported implants are shown in Appendix A of this document.



Case information will be transferred to the ROSA Tablet once communication is established.

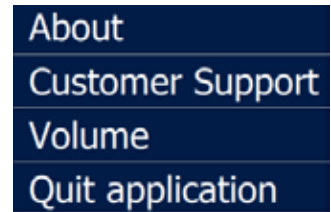
6.2.2 Bottom Task Bar



6.2.2.1 Menu

The MENU button is accessible during the procedure in the bottom task bar, and consists of these four options:

- **About:** Information about the ROSA Hip application
- **Customer Support:** Customer service details
- **Volume:** Adjustment of the volume of all sounds of the ROSA Hip application on the Robotic and Optical Units
- **Quit Application:** Quit with an option to send the Robotic Arm to PARK position



6.2.2.2 Snapshot

The SNAPSHOT button allows the user to take a screenshot of the ROSA screen. The SNAPSHOT button is accessible during the procedure in the bottom task bar. Snapshots can be downloaded along with the Surgeon Report.



SNAPSHOT Button

6.2.2.3 ROSA HOME

Sends the Robotic Arm to HOME position. Going to HOME position makes the application skip the impaction steps so no robotic steps can be performed. However, CUP VERIFICATION and the TRIAL and VALIDATION panels are still available after the Robotic Arm has been sent to HOME position.



HOME Button

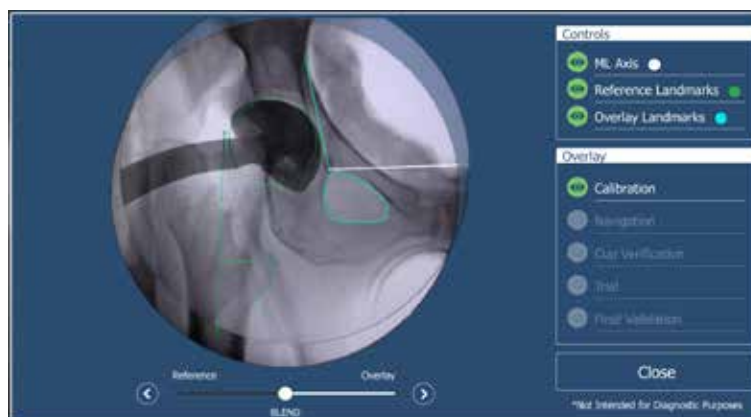
6.2.2.4 Registration Overlay

The REGISTRATION OVERLAY button displays a selected image overlaid on the reference image to show the results of image registration. Options to increase or lower the overlaid image opacity and to show or hide image elements are available. The REGISTRATION OVERLAY button is accessible during the procedure once reference images are completed. The Registration Overlay display can be used to visually confirm adequate registration to the reference image.



REGISTRATION OVERLAY Button

- ML axis will be displayed in white
- Reference landmarks will be displayed in green
- Overlay landmarks will be displayed in blue



6.2.2.5 Pre-operative Plan

Displays a view of the pre-operative plan if ONE Planner[®] Hip was used to template the case.



PRE-OPERATIVE PLAN Button

6.2.2.6 Connection Status

Status of the connection between the ROSA Tablet and the Robotic Unit is displayed at all times.



Disconnected



Connected

6.3 Robotic Modes

Three robotic modes are programmed to dictate the behavior of the Robotic Arm at two distinct steps: SETUP and IMPACTION panels. To trigger any of these robotic modes, the Foot Pedal must be pressed down. Then, the interface will inform the user about the current mode of the Robotic Unit with a color frame around the main panel.

Automatic (Orange Color Frame)

The Robotic Arm will move to a pre-determined position.



In this mode only, press down the pedal, no other action is required by the user.

Collaborative (Green Color Frame)

The Robotic Arm will move if the surgeon applies a gentle force at the end of the Robotic Arm to move it to a desired position.

The Robotic Arm will move at a slow speed to connect the instrument to the ROSA Quick Connect Interface and to change the instrument orientation inside the incision.

Area to Touch During Collaborative Mode

ROSA Quick Connect Interface



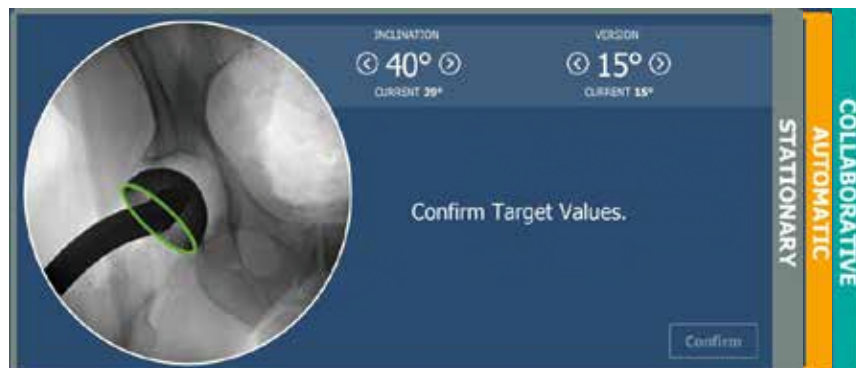
Instrument Handle



The Robotic Arm should not be manipulated by the Quick Connect Sleeve.

Stationary (Grey Color Frame)

The Robotic Arm will not move.



6.4 Robotic Positions

At various points during the ROSA Hip System surgical flow, the Robotic Arm is sent to a known position:

HOME

- Goes to this position after DRAPING and remains there until the Robotic Unit is ready to be positioned next to the operating table
- Goes back to this position when the impaction is completed
- Goes to this position when the ROSA HOME function is selected

PARK

- Position for transportation of the robot
- When the robot is turned on, it will be in PARK position
- After completing the surgery and undrapping the robot, the robot will be sent to PARK position and then the robot can be shut down

SETUP

- Goes to this position before IMPACTION panel to position the Robotic Unit for surgery

DRAPING

- Goes to this position in the beginning of SETUP panel to install ROSA Hip Quick Connect and the ROSA Robotic Unit Drape

INSTRUMENT ATTACHMENT

- Goes to this position to attach the Impactor to perform the impaction

6.5 Application Audible Notifications

The application has audible notifications for the following cases:

- Robotic Arm is in Automatic mode and moving to a predetermined location
- Successful force-torque (F/T) sensor calibration
- Target instrument orientation achieved
- Foot Pedal is released while in Collaborative mode
- Minor or major notification
- Snapshot of the current screen

6.6 Application Visual Notifications

Foot Pedal

- Press and hold down the Foot Pedal to move the Robotic Arm
- Further directions on the screen will describe the current action

6.6 Application Visual Notifications (cont.)

Landmark Acquisition

After any fluoroscopic image acquisition, required landmarks will display in landmarks list with three colors:

- **White:** Upcoming landmark points to be positioned
- **Yellow:** Current selected landmark points to be positioned
- **Green:** Landmark points successfully positioned

Remaining number of points required for landmarks is displayed in associated circle.

After the reference image acquisition step, all subsequent landmark placement will have automatic landmarking. Following the placement of the teardrop and trochanter



apex point (if applicable), the automatic landmarking provides an initial placement of the remaining landmarks. The placement of those landmarks should always be compared to the reference image and modified if necessary.

LANDMARKS	
✓	Teardrop
✓	Brin line
2	Obturator Foramen major
2	Obturator Foramen minor
1	Lesser Trochanter apex
2	Lesser Trochanter base
2	Shaft medial
2	Shaft lateral
4	Femoral Head Center ✕

7. ROSA Hip Application- MOBILE Panel

In the MOBILE panel of ROSA Hip application, the user establishes the connection between the Robotic Unit and the ROSA Tablet by following these steps:

1. On the ROSA Tablet, click the **TURN Wi-Fi ON** button.
2. On the Robotic Unit screen, click the **TURN Wi-Fi ON** button.
3. On the Robotic Unit screen, choose the device that matches the tablet name (as displayed on the tablet screen) from the device list.
4. On the Robotic Unit screen, click the OK button to confirm connection to the selected tablet device.
5. If the chosen tablet is not the previously connected device on this Robotic Unit, confirm connection by entering on the ROSA tablet the PIN displayed on the Robotic Unit screen.
6. Ensure connection is established (Wi-Fi symbol is displayed in the bottom taskbar when a connection is established) and click **NEXT**.



Stay within 20 feet (6 meters) of the robot to maintain the connection between the ROSA Tablet and the Robotic Unit.



If the connection is interrupted, a notification will appear on the screen. The user should re-establish the connection between the Robotic Unit and the ROSA Tablet by following these steps below.

To re-establish connection with the same ROSA Tablet device:

1. On the ROSA Tablet, click on **SAME DEVICE** button.
2. On the Robotic Unit screen, click on **SAME DEVICE** button.


To establish connection with other ROSA Tablet device:

1. On the Robotic Unit screen, click on **OTHER DEVICE** button.
2. Perform steps described above to connect Robotic Unit and the ROSA Tablet.


8. ROSA Hip Application- SURGEON Panel

In the SURGEON panel of the ROSA Hip application, the user can review pre-operative plan values, if a plan was completed, and select certain surgical parameters. The following categories are displayed:

- Planned Angles
- Operative Side Targets
- Shell and Stem Type
- Impactor
- C-arm Type and Size

 Regarding C-arm compatibility, only Image Intensifiers of 9" or 12" diameter and GE OEC Elite and GE OEC One Flat Panel Detectors of 21x21cm or 31x31cm can be used.

 For Flat Panel Detectors, the image display must be set to a squircle.

 Selecting the wrong C-arm type and size will lead to inaccurate leg length and offset measurements and could cause malposition of the implant.

A green checkmark means the option is selected.

When all surgical parameters have been selected, click NEXT to proceed to the SETUP panel.



NEXT Button

9. ROSA Hip Application- SETUP Panel

9.1 Draping

The ROSA Robotic Unit can be draped using the ROSA Robotic Unit Drape.

Move the Robotic Arm to DRAPING Position

1. In the SETUP panel, press and hold the Foot Pedal to move the Robotic Arm to DRAPING position.

Install the ROSA Quick Connect Interface

1. Once the Robotic Arm is in DRAPING position, install the ROSA Quick Connect Interface by firmly tightening the three captive screws using the 3.5 mm hexagonal screwdriver.



During this step, ensure that the sterile operator does not come in contact with the non-sterile parts of the Robotic Arm.

Install ROSA Robotic Unit Drape

The ROSA Robotic Unit Drape part number is: 20-8020-080-00. To drape the ROSA Robotic Unit, follow the below steps:

1. With the help of a non-sterile user, drape the Robotic Unit by following the instructions on the user interface and in the IFU provided with the drape.
2. Install the blue integral elastic at the end of the sterile drape on the ROSA Quick Connect Interface, ensuring the elastic does not go beyond the end of the ROSA Quick Connect Interface.
3. Ensure the blue stripe on the ROSA Robotic Unit Drape is aligned on top of the Robotic Arm.
4. Ensure the blue circle stickers are aligned with the elbow joint of the Robotic Arm.
5. Ensure the green square stickers are aligned with the posts of the ROSA Base Reference Bar.



- ⚠ Do not apply excessive torque on screws when installing an instrument. Do not use power tools.
- ⚠ Ensure the ROSA Robotic Unit Drape is not installed too tightly so that the Robotic Arm can move freely without pulling on the drape.
- ⚠ Verify the setup of the sterile drapes before beginning a surgery to ensure asepsis of the surgical field.
- ⚠ The sterile drape extremity should not go beyond the end of the ROSA Quick Connect Interface.
- ⚠ Ensure that no excessive force is applied to the Force and Torque Sensor Cable when installing and removing the drape.

9.2 Touchscreen Monitor Draping

To drape the Touchscreen Monitor on the robot, follow the below steps:

1. Slide the monitor drape over the screen from top to bottom.
2. Fully unfold the drape over the screen.
3. If also draping the Camera Stand Monitor, cover the mouse and its support with the lower part of the drape.
4. Stretch the drape around the screen and tape it at the back of the screen.



9.3 Calibration of Sensor

Install the ROSA Quick Connect Sleeve:

1. Once the Robotic Arm is draped, install the ROSA Quick Connect Sleeve on the ROSA Quick Connect Interface.
2. Click NEXT when the ROSA Quick Connect Sleeve is installed.

Calibrate the Force Sensor:

1. Confirm that each of the shown statements is true by clicking to add a checkmark to each statement:
 - ✓ The ROSA Quick Connect Sleeve is installed on the ROSA Quick Connect Interface
 - ✓ No other instrument is installed
 - ✓ The ROSA Robotic Arm is free of any force
2. Click CALIBRATE.
3. If unsuccessful, perform calibration again, making sure no instruments are installed and no force is applied on the ROSA Robotic Arm.
4. If successful, click NEXT to move ROSA to HOME position.



Do not touch the Robotic Arm. Only the ROSA Quick Connect Interface and the ROSA Quick Connect Sleeve should be installed on the Robotic Arm.



9.4 Reference Images Acquisition

Position the C-arm for Fluoroscopic Image Acquisition:

1. Move the C-arm to align the field of view over the pelvis.
2. If pre-operative imaging was performed, orient the C-arm so the fluoroscopic image matches the pre-operative X-ray of the patient's pelvic tilt and rotation. The obturator foramens on the pre-operative X-ray can be used as references to adjust the C-arm orientation to match the fluoroscopic image to the pre-operative X-ray image.
 - If pre-operative imaging was not performed, orient the C-arm to reach the desired image reference plane. Ensure that the pelvis is in a neutral position throughout the surgery to keep imaging consistent
 - Adjust the tilt of the C-arm to achieve good visibility of the obturator foramens (i.e. the contour of the feature is clearly visible and not too thin) and desired reference plane is reached
 - Adjust the rainbow of the C-arm until the obturator foramens are symmetrical
3. Lock the C-arm axis (tilt and rainbow) and click NEXT.

9.4 Reference Images Acquisition (cont.)

- ❗ Regarding C-arm compatibility, only Image Intensifiers of 9" or 12" diameter and *GE OEC Elite* and *GE OEC One* Flat Panel Detectors of 21x21cm or 31x31cm can be used.
- ❗ Matching pelvic tilt and rotation to the pre-operative X-ray establishes this view as the reference for all orientation and radiographic measurements.



AP Pelvis Image Acquisition:

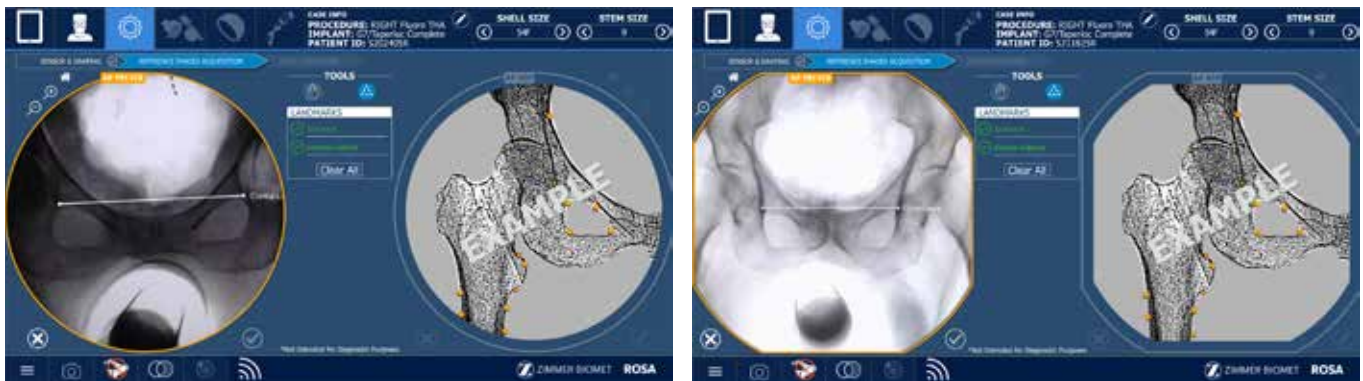
1. Acquire a fluoroscopic image of the patient's pelvis with the C-arm matching the field of view of the displayed Example image. Operative teardrop, non-operative teardrop and both obturator foramens should be visible on the image.
2. Capture a photo of the C-arm image displayed on its monitor with the ROSA Tablet, while ensuring the entire fluoroscopic image circle or squircle is captured. Automatic detection of C-arm image area is framed in the camera view. Ensure ROSA Tablet is not too far or at too much of an angle in relation to the C-arm monitor and wait for the camera to auto-focus.
3. If necessary, adjust the Region of Interest on the ROSA Tablet screen to contain only the fluoroscopic image, making sure not to exclude any part of the circle or squircle and click NEXT. Verify that:
 - ✓ Both teardrops are visible
 - ✓ Both obturator foramens are shown completely and match the orientation of the pre-operative X-ray if pre-operative imaging was performed
 - ✓ Coccyx alignment matches the orientation of the pre-operative X-ray if pre-operative imaging was performed
 - ✓ The image orientation is representative of an AP X-ray, i.e. antero-posterior

- ❗ Make sure to take good quality images (i.e. the contour of the image and all the features are clearly visible) with good contrast. Contrast may need to be adjusted on the C-arm monitor. Avoid using blurry images, as they are likely to lead to inaccurate landmark positioning and might affect system performance.
- ❗ The distortion normally present on the edges of the fluoroscopic image is not compensated.
- ❗ Only use the ROSA Tablet for image acquisition of the C-arm fluoroscopic images.

9.4 Reference Images Acquisition (cont.)


- Position the landmarks according to the landmarks list:
 - ✓ Ipsilateral: Place one point on the ipsilateral reference point of the medio-lateral reference line, e.g. ipsilateral (operative) teardrop
 - ✓ Contra-Lateral: Place one point on the contralateral reference point of the medio-lateral reference line, e.g. contralateral (non-operative) teardrop
- Click the CHECKMARK button to accept the landmarks positioning.
If the landmarks need to be repositioned, click the CLEAR ALL button to remove all positioned landmarks on the image. The specific landmark can also be selected and dragged on the image to be repositioned. If an image needs to be retaken, click the DISCARD button to go back to the image acquisition step and reacquire the image with the ROSA Tablet.


 Zoom landmark feature is displayed when adjusting landmark position to facilitate placement.




AP Hip Image Acquisition:

- Move the C-arm to align the field of view over the operative hip matching the field of view of the displayed Example image. Operative teardrop, acetabulum, femoral shaft and trochanters should be visible on the image.

 Do not rotate the C-arm orientation between AP Pelvis and AP Hip images. Only use C-arm in/out slider for adjustment. The system does not compensate for C-arm movement, other than translational, between these two reference images.

 Do not move the patient or table between AP Pelvis and AP Hip image acquisitions. If the patient is moved between the two acquisitions, acquired images should be discarded and taken again. The system does not compensate for patient movement between these reference images.

 The leg position (internal/external rotation and abduction/adduction) in the AP Hip image should be replicated during the trial and final image acquisitions of the workflow. The system does not compensate for internal/external rotation discrepancies between images.

- Acquire a fluoroscopic image of the operative hip.

9.4 Reference Images Acquisition (cont.)

3. Capture a photo of the C-arm image displayed on its monitor with the ROSA Tablet, while ensuring the entire fluoroscopic image circle or squircle is captured. Automatic detection of C-arm image area is framed in the camera view. Ensure the ROSA Tablet is not too far or at too much of an angle in relation to the C-arm monitor and wait for the camera to auto-focus.

If necessary, adjust the Region of Interest to contain only the fluoroscopic image making sure not to exclude any part of the circle or squircle and click NEXT. Verify that:

- ✓ Teardrop of the operative side is visible
- ✓ Acetabulum is centered in the image
- ✓ Proximal third of the femoral shaft is present
- ✓ Trochanters are visible

Make sure to take a good quality image (i.e. the contour of the image and all the features are clearly visible) with good contrast. Contrast may need to be adjusted on the C-arm monitor. Avoid using blurry images, as they are likely to lead to inaccurate landmark positioning and might affect system performance.



The distortion normally present at the edges of the fluoroscopic image is not compensated.



Only use the ROSA Tablet for image acquisition of the C-arm fluoroscopic images.

4. Position the landmarks according to the landmarks list.

- ✓ Teardrop: Place one point on the teardrop
- ✓ Brim line: Place one point on anterior pelvic brim to create line from teardrop tangential to pelvic brim
- ✓ Obturator foramen major: Place two points at each edge of the long axis of the foramen. The long axis and short axis must intersect
- ✓ Obturator foramen minor: Place two points at each edge of the short axis of the foramen. The long axis and short axis must intersect
- ✓ Trochanter apex: Place one point on the reference trochanter apex
- ✓ Trochanter base: Place two points, one on either side of the trochanter apex point
- ✓ Shaft medial: Place two points on the medial side of the lower femoral shaft. The medial shaft points should be distal to lesser trochanter by more than 2 mm
- ✓ Shaft lateral: Place two points on the lateral side of the lower femoral shaft. The lateral shaft points should be distal to lesser trochanter by more than 2 mm
- ✓ Femoral head center: Place four points spread out around the contour of the femoral head, so as to draw a circle that surrounds the femoral head

Femoral axis can be adjusted manually after positioning shaft medial and shaft lateral landmarks.

The obturator foramen major and minor axis landmarks are used to generate an obturator foramen outline.

This outline, displayed in **green** on the image, is recalculated when the obturator foramen landmarks are modified. This obturator foramen outline is used throughout the workflow for the image registration process.



Therefore, it is important to confirm that the obturator foramen outline generated by the application is accurate and consistent throughout the workflow to generate accurate image registrations.

9.4 Reference Images Acquisition (cont.)

- Click the CHECKMARK button to accept the landmarks positioning.

If the landmarks need to be repositioned, click the CLEAR ALL button to remove all positioned landmarks on the image. The specific landmark can also be selected and dragged on the image to be repositioned. If an image needs to be retaken, click the DISCARD button to go back to the image acquisition step and reacquire the image with the ROSA Tablet.



Zoom landmark feature is displayed when adjusting landmark position to facilitate placement.



Once AP Pelvis and AP Hip reference images have been acquired, C-arm adjustments (tilt, rainbow, relative patient-detector distance) should only be modified to match newly acquired images to the reference Hip image. Altering these parameters for other reasons during the procedure could affect the system's radiographic measurements accuracy, as it does not compensate for such image modifications.



Femoral Head Resection and Reaming:

- Complete femoral head resection and reaming using conventional instrumentation and click NEXT when ready to proceed to impaction.




9.5 ROSA Positioning

During a ROSA Hip procedure, it is mandatory for the Robotic Unit to be on the side of the operative hip and for the surgeon to stand on the same side as the Robotic Unit.

Move the Robotic Arm to SETUP Position:


1. Press and hold the Foot Pedal down to move the Robotic Arm to the SETUP position.




 Risk of collision: When the Robotic Unit is in Automatic mode, stay clear of the Robotic Arm and its path to the next position.

Position the Robotic Unit:

1. Move the Robotic Unit and align the ROSA Quick Connect with the operative hip.
2. Align the ROSA Quick Connect Interface with the edge of the table.
3. Align the Robotic Arm approximately 90° relative to the surgery table.
4. Click NEXT to proceed to Robotic Unit immobilization.

 To move the Robotic Unit, use the handle at the back of the robot only.

 The Robotic Unit should be at approximately 90° angle to the operating table, as described in section 3.2.5 OR Setup.



9.5 ROSA Positioning (cont.)

Lock the Robotic Unit:

1. Lock the four wheels of the Robotic Unit by pressing down the pedal on each wheel.
2. Activate the immobilization system by pressing down the main lever at the back of the Robotic Unit.
3. Click NEXT when the Robotic Unit is locked.



10. ROSA Hip Application- IMPACTION Panel

10.1 Attach Instrument

Move the Robotic Arm to INSTRUMENT ATTACHMENT Position:

1. Press and hold the Foot Pedal down to move the Robotic Arm to the INSTRUMENT ATTACHMENT position.
2. Insert the Cup Inserter with the cup loaded onto it into the joint space ensuring the cup is in contact with the bone. Ensure that the cup is centered in the acetabulum and remains movable in the joint space. In this step, the instrument and Robotic Arm are not attached.
3. Click NEXT.




Attach Instrument:

1. Press the Foot Pedal to move the Robotic Arm (in Collaborative mode) to align with the Cup Inserter and attach to the Quick Connect Interface, sliding the Quick Connect Sleeve to lock.
2. Confirm cup size and type displayed on the screen.
3. Click NEXT.



10.1 Attach Instrument (cont.)

 Selecting the wrong cup size and type will cause inaccurate implant positioning.

Calibrate the Instrument:

1. Confirm that each of the shown statements is true by clicking to add a checkmark to each statement:
 - ✓ Impactor is installed
 - ✓ No external force is applied on Robotic Arm (other than those exerted by the patient anatomy on the instrument)
2. Click CALIBRATE:
 - ✓ If unsuccessful, perform calibration again (refer to previous section for steps on how to attach instrument)
3. If successful, click NEXT

If instrument calibration is unsuccessful (refer to section 14.6 Troubleshooting):

Option 1:

1. Remove any force applied to the F/T sensor.
2. Execute instrument calibration again.

Option 2:

1. Use the BACK TO ATTACH INSTRUMENT button.
2. Press Foot Pedal to disconnect the instrument.
3. Perform attach instrument steps described above.




10.2 Calibration Image Acquisition

1. Press Foot Pedal and gently press on the Robotic Arm to move the cup to the approximate angles recommended on the screen.
2. Before proceeding to the next step, acknowledge that the sliding adaptor is at indicated position.
3. Click NEXT.



10.2 Calibration Image Acquisition (cont.)




-  To ensure that the sliding adaptor is at the indicated position, verify that the laser marking on the Cup Inserter Shaft aligns with the adaptor and the spring-loaded feature is engaged. If they are not aligned, press the Foot Pedal and adjust the Robotic Arm until the adaptor is fully down.



Calibration Image Acquisition:

1. Move the C-arm to align the field of view over the operative hip to match the field of view of the displayed Example image. Operative teardrop and acetabulum should be visible on the image and cup must be centered.
2. Adjust the C-arm to match the orientation of the reference image shown on the screen in case the patient has moved.
3. Acquire a fluoroscopic image of the operative side showing the Cup Inserter instrument inside the incision. Capture a photo of the C-arm image displayed on its monitor with the ROSA Tablet, while ensuring the entire fluoroscopic image circle or squircle is captured. Automatic detection of C-arm image area is framed in the camera view. Ensure the ROSA Tablet is not too far or at too much of an angle in relation to the C-arm monitor and wait for the camera to auto-focus. Verify that:
 - ✓ Teardrop of the operative side is visible
 - ✓ Acetabulum and acetabular component are centered in the image
 - ✓ Obturator foramen shape matches its shape on the reference image shown to the left of the screen

The calibration image is the first of two images used by the application to interpret the current inclination and version of the Cup Inserter relative to the Robotic Arm position. This shows updated values of instrument orientation as the Robotic Arm is moved. The second image needed by the application is the Navigation image which is described in the next step.

-  Make sure to take a good quality image (i.e. the contour of the image and all the features are clearly visible) with good contrast. Contrast may need to be adjusted on the C-arm monitor. Avoid using blurry images, as they are likely to lead to inaccurate landmark positioning and might affect system performance.
-  The distortion normally present at the edges of the fluoroscopic image is not compensated.
-  Only use the ROSA Tablet for image acquisition of the C-arm fluoroscopic images.

If necessary, adjust the Region of Interest to contain only the fluoroscopic image making sure not to exclude any part of the circle or squircle and click NEXT.

10.2 Calibration Image Acquisition (cont.)

- Adjust the ellipse to match the opening of the cup, if needed, and confirm. Position teardrop landmark and adjust automatic landmarks, if necessary. Click the CHECKMARK button to accept the landmark positioning.

If the landmarks need to be repositioned, click the CLEAR ALL button to remove all positioned landmarks. The specific landmark can also be selected and dragged on the image to be repositioned. If the calibration image needs to be retaken, click the DISCARD button to go back to Collaborative mode to adjust instrument orientation and reacquire the image.

If manual landmark placement is needed, position the landmarks according to the landmarks list.

- ✓ Teardrop: Place one point on the teardrop
- ✓ Brim line: Place one point on anterior pelvic brim to create line from teardrop tangential to pelvic brim
- ✓ Obturator foramen major: Place two points at each edge of the long axis of the foramen
- ✓ Obturator foramen minor: Place two points at each edge of the short axis of the foramen. The long axis and short axis must intersect



Place landmarks based on the landmark positions of the reference image displayed.



Zoom landmark feature is displayed when adjusting landmark position to facilitate placement.



The displayed version angles are calculated by assuming that the cup is in anteversion with the C-arm projection plane.



The registration adjusts only the rotation in the projection plane of the C-arm and does not correct for tilt, rainbow or patient movement between two images. Use the Overlay Tool to verify that the projection plane is constant by making sure that the obturator foramen outlines and brim lines are accurately superimposed and have the same scaling. Any discrepancy between the overlaid landmarks could affect the system's radiographic measurement accuracy.




Cup version angle should be greater than 10°.

10.3 Navigation Image Acquisition

- Press Foot Pedal and gently press on the Robotic Arm to move the cup to the approximate angles recommended on the screen.
- Before proceeding, to the next step, acknowledge that the sliding feature is at indicated position.
- Click NEXT.



10.3 Navigation Image Acquisition (cont.)






-  To ensure that the sliding feature of the adaptor is at the indicated position, verify that the laser marking on the Cup Inserter Shaft aligns with the adaptor. If they are not aligned, press the Foot Pedal and adjust the Robotic Arm until the adaptor is fully down.



Navigation Image Acquisition:

-  Robot base, patient, table and C-arm must not move between calibration and navigation images.
 -  Do not change tilt or rainbow between calibration and navigation images.
1. Without moving the C-arm between calibration and navigation images, acquire a fluoroscopic image of the operative side showing the Cup Inserter instrument inside the incision.
 2. Capture a photo of the C-arm image displayed on its monitor with the ROSA Tablet while ensuring the entire fluoroscopic image circle or squircle is captured. Automatic detection of C-arm image area is framed in the camera view. Ensure the ROSA Tablet is not too far or at too much of an angle in relation to the C-arm monitor and wait for the camera to auto-focus. Verify that:
 - ✓ Teardrop of the operative side is visible
 - ✓ Acetabulum and acetabular component are centered in the image
 - ✓ Obturator foramen shape matches its shape on the reference image shown to the left of the screen
 - ✓ The cup is centered on the image

The Navigation image is the second of two images used by the application to be able to interpret the current inclination and version of the Cup Inserter relative to the Robotic Arm position. With both images acquired (i.e. Calibration image and Navigation image), the application is able to determine the current instrument orientation based off the total movement of the Robotic Arm.

-  Make sure to take good quality images (i.e. the contour of the image and all the features are clearly visible) with good contrast. Contrast may need to be adjusted on the C-arm monitor. Avoid using blurry images, as they are likely to lead to inaccurate landmark positioning and might affect system performance.
-  The distortion normally present on the edges of the fluoroscopic image is not compensated.
-  Only use the ROSA Tablet for image acquisition of the C-arm fluoroscopic images.

10.3 Navigation Image Acquisition (cont.)

If necessary, adjust the Region of Interest to contain only the fluoroscopic image making sure not to exclude any part of the circle or squircle and click NEXT.


- Adjust the ellipse to match the opening of the cup, if needed, and confirm. Position teardrop landmark and adjust automatic landmarks, if necessary. Click the CHECKMARK button to accept the landmark positioning.


If the landmarks need to be repositioned, click the CLEAR ALL button to remove all positioned landmarks on the image. The specific landmark can also be selected and dragged on the image to be repositioned.


If the navigation image needs to be retaken, click the DISCARD button to go back to the image acquisition step and reacquire the image with the ROSA Tablet.

If manual landmark placement is needed, position the landmarks according to the landmarks list.

- ✓ Teardrop: Place one point on the teardrop
- ✓ Brim line: Place one point on anterior pelvic brim to create line from teardrop tangential to pelvic brim
- ✓ Obturator foramen major: Place two points at each edge of the long axis of the foramen
- ✓ Obturator foramen minor: Place two points at each edge of the short axis of the foramen. The long axis and short axis must intersect


 Place landmarks based on the landmark positions of the reference image displayed.


 Zoom landmark feature is displayed when adjusting landmark position to facilitate placement.

 The displayed version angles are calculated by assuming that the cup is in anteversion with the C-arm projection plane.



The registration adjusts only the rotation in the projection plane of the C-arm and does not correct for tilt, rainbow or patient movement between two images. Use the Overlay Tool to verify that the projection

 plane is constant by making sure that the obturator foramen outlines, brim lines and pelvis are accurately superimposed over one another. Any discrepancy between the overlaid landmarks could affect the system's radiographic measurements accuracy.

 Cup version angle should be greater than 10°.


10.4 Target Orientation

Target Values:

1. Change target inclination angle value, if necessary.
2. Change target version angle value, if necessary.
3. Click CONFIRM.

Move the Robotic Arm to Planned Orientation:

1. Press and hold Foot Pedal and lightly press on Robotic Arm to move it to planned orientation.
2. Current inclination and version values will be displayed in:
 - Red when they are over $\pm 5^\circ$ of the target value
 - Yellow when they are within $\pm 5^\circ$ of the target value
 - Green when they are within $\pm 2^\circ$ of the target value
3. Click NEXT when satisfied with version and inclination values.


 Computed cup angles assume the use of C-arm with 1 m (meter) distance between the detector and the source.



10.5 Impaction




1. Impact the cup until it is fully seated. The Robotic Arm maintains the target orientation while you impact.
2. Use fluoroscopy to confirm that cup is fully seated (no image transfer to ROSA needed).
3. If cup is not fully seated, continue to impact.
4. Click NEXT when impaction is done.

 Do not move the Robotic Unit during impaction.

 Impaction must be done only in the dedicated panel. If you need to re-impact after clicking NEXT, impaction must be done without the use of the Robotic Arm.

10.5 Impaction



-  Do not impact the Robotic Unit, only impact instrument handle.
-  As with any impaction instrumentation, it is recommended to impact along the axis of the instrument to optimize the impaction.
-  Processed images must not be modified (rotated) during impaction flow.

10.6 Out

Move Robotic Arm Out to Disconnect Impaction Tool:

1. Press and hold Foot Pedal and disconnect the Robotic Arm from the Cup Inserter Adaptor after unlocking the ROSA Quick Connect Sleeve (step 1 on the screen).
2. Detach the impacted cup from the Cup Inserter using the grooves along the instrument shaft to correctly position the G7 Ball Hex Driver against the screw (step 2 on the screen).
3. Click NEXT.



Move Robotic Arm to HOME Position

1. Press and hold Foot Pedal to move the Robotic Arm to the HOME position.

11. ROSA Hip Application- CUP VERIFICATION Panel

Verification Image Acquisition:

1. Move the C-arm to align the field of view over the operative hip to match the field of view of the displayed Example image. Operative teardrop and acetabulum should be visible on the image and cup must be centered.
2. Adjust C-arm to match the orientation of the reference image shown on the screen in case the patient has moved.
3. Acquire a fluoroscopic image of the operative side showing the impacted acetabular component with the C-arm.
4. Capture a photo of the C-arm image displayed on its monitor with the ROSA Tablet, while ensuring the entire fluoroscopic image circle or squircle is captured. Automatic detection of C-arm image area is framed in the camera view.

Ensure the ROSA Tablet is not too far or at too much of an angle in relation to the C-arm monitor and wait for the camera to auto-focus. Verify that:

- ✓ Teardrop of the operative side is visible
- ✓ Acetabulum and acetabular component are centered in the image
- ✓ Obturator foramen shape matches its shape on the reference image shown to the left of the screen

Make sure to take good quality images (i.e. the contour of the image and all the features are clearly visible)



with good contrast. Contrast may need to be adjusted on the C-arm monitor. Avoid using blurry images, as they are likely to lead to inaccurate landmark positioning and might affect system performance.



The distortion normally present at the edges of the fluoroscopic image is not compensated.



Only use the ROSA Tablet for image acquisition of the C-arm fluoroscopic images.

If necessary, adjust the Region of Interest to contain only the fluoroscopic image making sure not to exclude any part of the circle or squircle and click NEXT.

5. Adjust the ellipse to match the opening of the cup, if needed, and confirm.
6. Position teardrop landmark and adjust automatic landmarks, if necessary.
7. Click on the CHECKMARK button to accept the landmark positioning.

If the landmarks need to be repositioned, click the CLEAR ALL button to remove all positioned landmarks on the image. The specific landmark can also be selected and dragged on the image to be repositioned. If an image needs to be retaken, click the DISCARD button to go back to the Image Acquisition step and reacquire the image with the ROSA Tablet.

If manual landmark placement is needed, position the landmarks according to the landmarks list.

- ✓ Teardrop: Place one point on the teardrop
- ✓ Brim line: Place one point on the anterior pelvic brim to create a line from teardrop tangential to the pelvic brim
- ✓ Obturator foramen major: Place two points at each edge of the long axis of the foramen
- ✓ Obturator foramen minor: Place two points at each edge of the short axis of the foramen. The long axis and short axis must intersect

11. ROSA Hip Application-CUP VERIFICATION Panel (cont.)

- ⚠ Place landmarks based on the landmark positions of the reference image displayed.
- ! Zoom landmark feature is displayed when adjusting landmark position to facilitate landmark placement.



- ! Cup version angle should be greater than 10°.

The registration adjusts only the rotation in the projection plane of the C-arm and does not correct for tilt, rainbow or patient movement between two images. Use the Overlay Tool to verify that the projection

- ! plane is constant by making sure that the obturator foramen outlines, brim lines and pelvis are accurately superimposed over one another. Any discrepancy between the overlaid landmarks could affect the system's radiographic measurements accuracy.

The CUP VERIFICATION panel can be accessed and repeated at other points of the ROSA Hip procedure to verify cup orientation. This feature can be used to verify reamer orientation in the reaming step, as well as to verify acetabular cup orientation any number of times during or after impaction. The panel can be accessed by clicking on the CUP VERIFICATION panel icon on the top bar.


12. ROSA Hip Application- TRIAL & VALIDATION Panel

Proceed with preparing the femoral canal using conventional instrumentation. When you are ready for trial reduction, click NEXT to move to the trial step to measure leg length and offset changes.



12.1 Trial Image Acquisition




1. Move the C-arm to align the field of view over the operative hip to match the field of view of the AP Hip reference image. Operative teardrop, acetabulum, proximal femoral shaft and trochanters should be visible on the image and positioned so that all of these regions of interest are centered in the field of view.
2. Adjust the C-arm to match the orientation of the reference image shown on the screen in case the patient has moved.

 The registration adjusts only the rotation in the projection plane of the C-arm and does not correct for tilt, rainbow or patient movement between two images. Use the Overlay Tool to verify that the projection plane is constant by making sure that the obturator foramen outlines, brim lines and pelvis are accurately superimposed over one another.

The AP Hip image leg position should be replicated in trial and final image acquisitions. The system does not compensate for internal/external rotation of the leg. If the leg is not repositioned to match the AP Hip reference image, it could affect system measurement results. The lesser and greater trochanter X-ray projections can be used as references to adjust the leg rotation to match the fluoroscopic image to the AP Hip reference image.

3. Acquire a fluoroscopic image of the operative hip.
4. Capture a photo of the C-arm image displayed on its monitor with the ROSA Tablet while ensuring the entire fluoroscopic image circle or squircle is captured. Automatic detection of C-arm image area is framed in the camera view. Ensure ROSA Tablet is not too far or at too much of an angle in relation to the C-arm monitor and wait for the camera to auto-focus. Verify that:
 - ✓ Teardrop of the operative side is visible
 - ✓ Acetabular component is centered in the image
 - ✓ Proximal third of the femoral shaft is visible
 - ✓ Trochanters are visible

12.1 Trial Image Acquisition (cont.)

-  Make sure to take good quality images (i.e. the contour of the image and all the features are clearly visible) with good contrast. Contrast may need to be adjusted on the C-arm monitor. Avoid using blurry images, as they are likely to lead to inaccurate landmark positioning and might affect system performance.
-  The distortion normally present on the edges of the fluoroscopic image is not compensated.
-  Only use the ROSA Tablet for image acquisition of the C-arm fluoroscopic images.




If necessary, adjust the Region of Interest to contain only the fluoroscopic image making sure not to exclude any part of the circle or squircle and click NEXT.

5. Adjust the ellipse to match the opening of the cup, if needed, and confirm.
6. Position teardrop and trochanter landmarks and adjust automatic landmarks, if necessary.
7. Click the CHECKMARK button to accept the landmark positioning. If the landmarks need to be repositioned, click the CLEAR ALL button to remove all positioned landmarks on the image. The specific landmark can also be selected and dragged on the image to be repositioned. If an image needs to be retaken, click the DISCARD button to go back to the image acquisition step and reacquire the image with the ROSA Tablet.

If manual landmark placement is needed, position the landmarks according to the landmarks list.

- ✓ Teardrop: Place one point on the teardrop
- ✓ Brim line: Place one point on the anterior pelvic brim to create a line from the teardrop tangential to the pelvic brim
- ✓ Obturator foramen major: Place two points at each edge of the long axis of the foramen
- ✓ Obturator foramen minor: Place two points at each edge of the short axis of the foramen. The long axis and short axis must intersect
- ✓ Trochanter apex: Place one point on the reference trochanter apex
- ✓ Trochanter base: Place two points, one on either side of the trochanter apex point
- ✓ Shaft medial: Place two points on the medial side of the lower femoral shaft. The medial shaft points should be distal to lesser trochanter by more than 2 mm
- ✓ Shaft lateral: Place two points on the lateral side of the lower femoral shaft. The lateral shaft points should be distal to lesser trochanter by more than 2 mm
- ✓ Cup center: Adjust position and size of cup center circle

Femoral axis can be adjusted manually after positioning shaft medial and shaft lateral landmarks by dragging the proximal and/or distal points of the femoral axis.

-  Place landmarks based on the landmark positions of the reference image displayed.
-  Zoom landmark feature is displayed when adjusting landmark position to facilitate landmark placement.
-  Cup version angle on image should be greater than 10°.


12.1 Trial Image Acquisition (cont.)



Current Implant System:

Select the current components from the drop-down list:

- Stem Brand
- Stem Type
- Head Length
- Neck Type
- Liner Type
- Shell Type

 Cup size and stem size can be accessed in the upper menu.

12.2 Leg Length and Offset Change Computation


Upon confirmation, current leg length and offset change measurements are shown for the current selected components and projected leg length and offset change values for a subset of available combinations of Trial Head Offset using the currently selected Neck Type.

Option buttons allow displaying the Offset Value as Global or Femoral Offset. (See Appendix B for the method used to calculate leg length and offset change values).

The SHOW MORE button can be used to display leg length and offset change values for all compatible component combinations.

If other trial components are inserted and need to be assessed, the NEW IMAGE button allows for reacquiring a Trial image.

Otherwise, select NEXT to proceed to Final Components Validation.

 The values of Horizontal Offset (HO) and Vertical Offset (VO) used to calculate projected leg length and offset measurements for all supported hip component systems implemented in the ROSA Hip application are the same as the values listed in the surgical techniques, ordering information and/or sizing guide documents for each implant brand.

12.2 Leg Length and Offset Change Computation (cont.)



12.3 Final Image Acquisition

1. Move the C-arm to align the field of view over the operative hip to match the field of view of the AP Hip reference image. Operative teardrop, acetabulum, proximal femoral shaft and trochanters should be visible on the image and cup must be centered.
2. Adjust C-arm to match the orientation of the reference image shown on the screen in case the patient has moved.



The registration adjusts only the rotation in the projection plane of the C-arm and does not correct for tilt, rainbow or patient movement between two images. Use the Overlay Tool to verify that the projection plane is constant by making sure that the obturator foramen outlines and brim lines are accurately superimposed over one another.



The AP Hip image leg position should be replicated in trial and final image acquisitions. The system does not compensate for internal/external rotation and abduction/adduction of the leg. If the leg is not repositioned to match the AP Hip reference image, it could affect system measurement results. The lesser and greater trochanter X-ray projections can be used as references to adjust the leg rotation to match the fluoroscopic image to AP Hip reference image.

3. Acquire a fluoroscopic image of the operative hip. Capture a photo of the C-arm image displayed on its monitor with the ROSA Tablet, while ensuring the entire fluoroscopic image circle or squircle is captured. Automatic detection of C-arm image area is framed in the camera view. Ensure the ROSA Tablet is not too far or at too much of an angle in relation to the C-arm monitor and wait for the camera to auto-focus. Verify that:
 - ✓ Teardrop of the operative side is visible
 - ✓ Acetabular component is centered in the image
 - ✓ Proximal third of the femoral shaft is visible
 - ✓ Trochanters are visible



Place landmarks based on the landmark positions of the reference image displayed.



Zoom landmark feature is displayed when adjusting landmark position to facilitate landmark placement.



Cup version angle on image should be greater than 10°.

12.3 Final Image Acquisition (cont.)

- ! Make sure to take good quality images (i.e. the contour of the image and all the features are clearly visible) with good contrast. Contrast may need to be adjusted on the C-arm monitor. Avoid using blurry images, as they are likely to lead to inaccurate landmark positioning and might affect system performance.
- ! The distortion normally present at the edges of the fluoroscopic image is not compensated.
- ! Only use the ROSA Tablet for image acquisition of the C-arm fluoroscopic images.

If necessary, adjust the Region of Interest to contain only the fluoroscopic image making sure not to exclude any part of the circle or squircle and click NEXT.

- Adjust the ellipse to match the opening of the cup, if needed, and confirm. Position teardrop and trochanter apex landmarks and adjust automatic landmarks, if necessary.
- Click the CHECKMARK button to accept the landmark positioning.

If the landmarks need to be repositioned, click the CLEAR ALL button to remove all positioned landmarks on the image. The specific landmark can also be selected and dragged on the image to be repositioned. If an image needs to be retaken, click the DISCARD button to go back to the image acquisition step and reacquire the image with the ROSA Tablet.

If manual landmark placement is needed, position the landmarks according to the landmarks list.

- ✓ Teardrop: Place one point on the teardrop
- ✓ Brim line: Place one point on the anterior pelvic brim to create a line from the teardrop tangential to the pelvic brim
- ✓ Obturator foramen major: Place two points at each edge of the long axis of the foramen
- ✓ Obturator foramen minor: Place two points at each edge of the short axis of the foramen. The long axis and short axis must intersect
- ✓ Trochanter apex: Place one point on the reference trochanter apex
- ✓ Trochanter base: Place two points, one on either side of the trochanter apex point
- ✓ Shaft medial: Place two points on the medial side of the lower femoral shaft. The medial shaft points should be distal to lesser trochanter by more than 2 mm
- ✓ Shaft lateral: Place two points on the lateral side of the lower femoral shaft. The lateral shaft points should be distal to lesser trochanter by more than 2 mm
- ✓ Cup center: Adjust position and size of cup center circle

Femoral axis may be adjusted manually after positioning shaft medial and shaft lateral landmarks.

- ! Place landmarks based on the landmark positions of the reference image displayed.

- ! Zoom landmark feature is displayed when adjusting landmark position to facilitate landmark placement.


- ! Image version angle should be greater than 10°.



12.4 Current Implant System

Select the current components from the drop-down list:

- Stem Brand
- Stem Type
- Head Length
- Neck Type
- Liner Type
- Shell Type

 Cup size and stem size can be assessed in the upper menu.

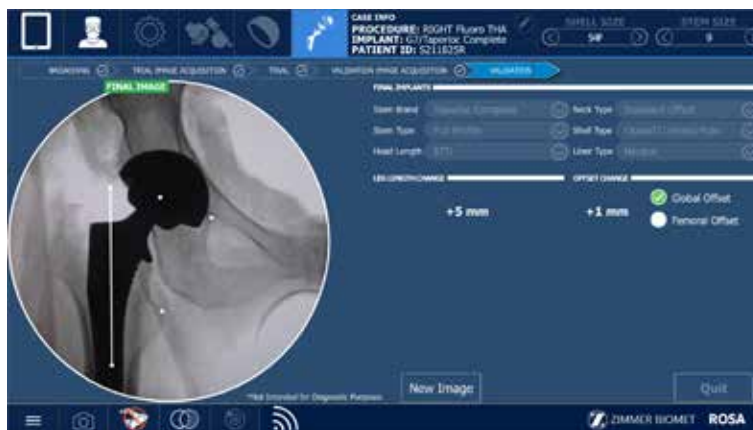
12.5 Leg Length and Offset Change Computation

Upon confirmation, current leg length and offset change measurements are shown for the current selected components.

Option buttons allow displaying the Offset Value as Global or Femoral offset. (See Appendix B for the method used to calculate Leg Length and Offset change values).

If other final components are inserted and need to be assessed, the NEW IMAGE button allows reacquiring a Final image.

Otherwise, click QUIT to send the Robotic Arm to PARK position.



13. Robotic Errors

13.1 Collision Detection

If a collision is detected in Automatic mode, the Robotic Arm will automatically stop, switch to Stationary mode and a notification will appear on the user interface.



CONTINUE: If there are no more obstacles, click CONTINUE to return to Automatic mode.

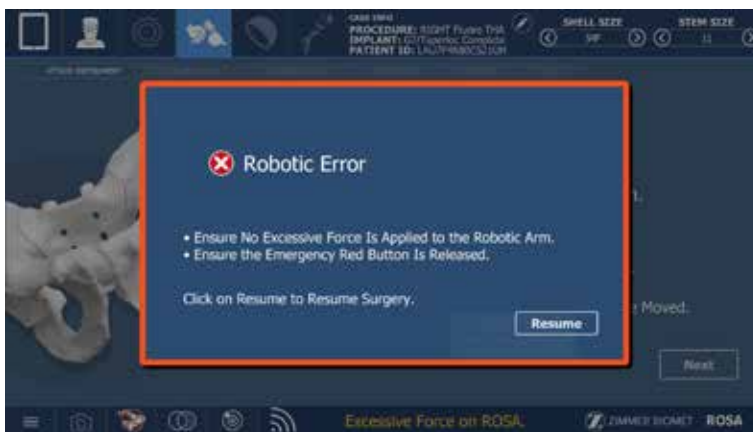
13.2 Excessive Force on the Robotic Arm

In case of excessive force on the Robotic Arm, a notification will appear on the user interface:

- Excessive Force on ROSA (shown on bottom task bar): Force applied does not exceed the joint load limit, and the surgical flow will not be interrupted



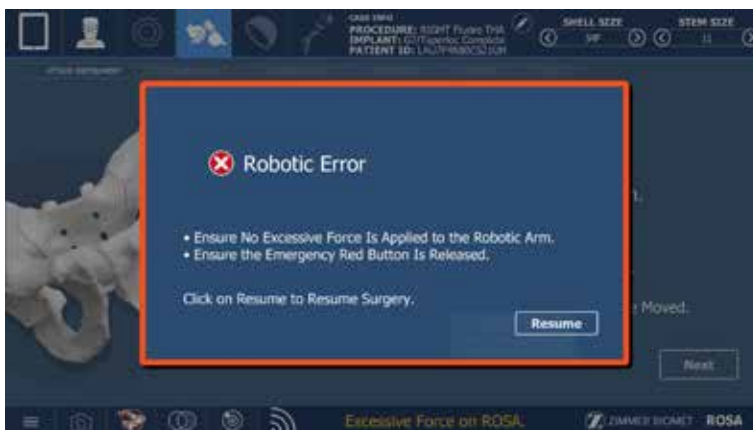
- ROBOTIC or UNKNOWN ROBOTIC ERROR (pop-up window): Force applied exceeds the load limit, the flow is interrupted and a procedure needs to be followed (see below in section 13.4 - Unknown Robotic Error)



13.3 Red EMERGENCY Button

To stop the Robotic Arm at any time, press down on the red EMERGENCY button. The EMERGENCY button is located on the Robotic Unit near the base of the Robotic Arm.

1. Press down to activate.
2. Turn clockwise to release.
3. Upon the release of the EMERGENCY button, follow the Unknown Robotic Error procedure (section 13.4 below).



13.4 Unknown Robotic Error

An unknown robotic error notification will appear if excessive force is applied to the Robotic Arm or if the EMERGENCY button is pressed.

1. Ensure no excessive force is applied to the Robotic Arm.
2. Ensure the EMERGENCY button is released.
3. Click RESUME to resume the surgery.



13.5 Drifting of the Robotic Arm

Although the system cannot detect drifting (no notification), it is very easy to recognize. With the Foot Pedal pressed in Collaborative mode, the Robotic Arm will move without applying any force on it. Please verify:

- Draping: make sure the draping is not pulling at the end of the Robotic Arm where the Force Sensor is located
- That calibration was done according to instructions. If available, use the BACK TO ATTACHMENT button to reattach the instrument and perform the calibration again (refer to section 10.1)

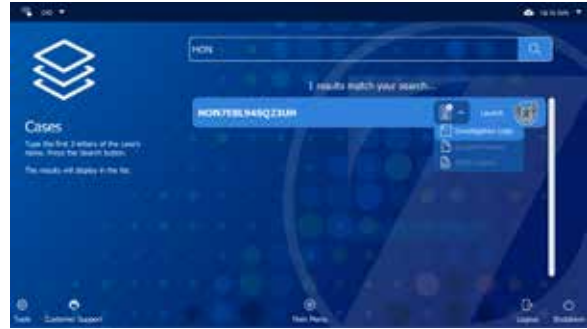
14. Post-operative Guide/Maintenance

14.1 Retrieval of Post-Surgical Log File

14.1.1 Surgeon Report

The Surgeon Report is intended for research purposes and can only be requested by the surgeon. This report is generated by the ROSA Hip application for each procedure and contains the following information:

- Surgeon name and surgery date
- Case ID and procedure
- Patient gender and last two digits of the birth year
- Time spent on each surgical step
- Pre-operative plan
- Pelvic data
- Acetabular component target and final angles
- Each set of trial components inserted and analyzed with leg length and offset change measurements
- Final implant selection with final leg length and offset change measurement
- Any snapshots of the screen taken during the flow



The Surgeon Report is transferred to a USB drive provided by the surgeon. To get the Surgeon Report once the surgery is completed:

1. Close the application.
2. Click the SURGEON REPORT button associated with the case for which the report is requested.
3. Insert a USB drive in any of the Robotic Unit's USB ports.
4. Acknowledge that you are the surgeon responsible for this case and click NEXT.
5. Enter the PIN associated with the case.
6. Click GENERATE.

14.1.2 Investigation Logs

Investigation Logs are intended for the assessment of a specific adverse event or product complaint and can only be requested by a Zimmer Biomet Complaint Handler on behalf of the hospital or surgical team. This report is generated by the ROSA Hip application to provide the entire application logs specific to a patient case under investigation and contains only case specific logs. The Investigation Logs file is securely encrypted and can therefore be transferred to a standard USB flash drive. To access the Investigation Logs once the surgery is completed:

1. Close the application.
2. Click the INVESTIGATION LOGS button associated with the case for which the report is requested.
3. Insert a USB drive in any of the Robotic Unit's USB ports.
4. Acknowledge that the download is related to a specific adverse event or product complaint and click NEXT.
5. Enter the PIN associated with the case.
6. Click GENERATE.

14.2 Shutdown

Click the MENU button on the left of the bottom task bar. Selecting QUIT gives access to the following three options:

- Quit and send Robotic Arm to the PARK position
- Quit only
- Cancel

The QUIT button is also available in the TRIAL and VALIDATION panel at the end of the workflow.



Risk of collision: When the Robotic Unit is in Automatic mode, stay clear of the Robotic Arm and its path to the next position.

By quitting the ROSA Hip application, the user interface returns to the case management application (refer to section 4.5. Case Management Application). Click SHUTDOWN to power down the device.



Wait 10 seconds after the extinction of the Touchscreen to turn the power switch of the device to “0” for the operating system to shut down properly. Turn the power switch to the “0” position. Remove the ROSA Quick Connect Interface from the Robotic Arm.



To restart the device, wait at least 10 seconds after shutting down and for the RESET button light to turn off completely.

1. Remove the Power Cable from the power supply plug.
2. Disconnect the Optical Unit from the Robotic Unit if it was used.
3. Clean the Robotic and Optical Units (refer to section 14.3 - Cleaning, Disinfection and Sterilization).



All wastes and residues must follow the hospital recycling guidelines.

After each surgery, completely power down the ROSA Tablet. For instructions, refer to section 5.6.

14.3 Cleaning, Disinfection and Sterilization

14.3.1 Cleaning the Robotic and Optical Units

Make sure the device is turned off and unplugged before cleaning. After each use, clean the covers, panels and the Robotic Arm with a damp cloth.

Use a mild alkaline detergent, if necessary, to remove scuffs and stains. Do not use any solvents that may damage or discolor paint finishes or plastic components. Read the labels of cleaning products carefully. Both the cloth and cleaning product must be approved for use in an operating room.

Robotic and Optical Units are not waterproof. Be careful not to spill or splash liquids where they can enter electronic assemblies.



Never attempt to clean the device when it is connected to the power supply. To avoid electrical discharges, always unplug the device from the wall outlet before cleaning or disinfecting it.



IPX0 protection: Device without special protection against the penetration of liquids. Do not pour any liquid over the device.

14.3.2 Cleaning the ROSA Tablet

Screens and bezels should be cleaned with a soft, dampened, lint-free cloth. Cleaning cloth should be sprayed first to avoid fluid entering the venting area.

Cleaner Ingredient Options:

- Up to 70% Ethanol
- Rubbing alcohol
- Up to 5% bleach and water solution
- Diversey™ Virox® TM/MC Disinfecting Wipes
- Glass cleaner, such as Windex®

Cleaning Products to Avoid:

Never use acidic or alkaline cleaners or organic chemicals, such as acetone, toluene, xylene or kerosene. Do not use solutions containing heavy non-diluted bleaches or other corrosive substances, as they will eventually damage plastic surfaces.



Use of incorrect cleaners can result in optical impairment of touch panel and/or damage to functionality.

Cleaning Directions:

1. Shut down the ROSA Tablet before cleaning with a soft, lint-free cloth.
2. Wipe the surface gently; if there is a directional surface texture, wipe in the same direction as the texture.
3. Take a dry cloth and wipe the ROSA Tablet dry. Avoid having liquids seep into the internal components and areas of the monitor's display unit.

14.3.3 Cleaning the Optical Camera (if Optical Unit Touchscreen was used)

Camera Housing

Clean the camera housing only if required. Clean the whole surface of the camera using a soft, lint-free cloth dampened with a non-abrasive and mild detergent.

Illuminator Filters and Lenses

Clean the illuminator filters and lenses only if required. Carefully wipe them using a cloth that is suitable for optical glasses. Remove fingerprints and pay attention not to cause damage or scratches.

14.3.4 Instrument Reprocessing (Cleaning and Sterilization Methods)



Before every surgery, the user must verify that all instruments are clean and sterilized as per instructions.

For reusable instruments, also refer to:

- Zimmer Biomet Instrument Care, Cleaning, Maintenance and Sterilization Instructions (97-5000-170-00)



- Reusable Instrument Lifespan Manual (1219)
- Surgical Instrument Package Insert (803.029)
- Tray Instructions for Use (87-6203-999-88)






Section 14.3.4.1 describes the sterilization methods recommended for the instruments. Reusable instruments must be cleaned after use before sterilization. They should not be sterilized in the protective bag or packaging supplied with them. All sterilizations should be performed using standard and regularly maintained equipment.

The instrument type-dependent instructions are indicated in section 14.3.4.1 - ROSA Hip System Instrument Kit as applicable to each instrument.



14.3.4.1 ROSA Hip System Instrument Kit

Additional specific cleaning instructions as defined in the text are indicated as applicable to each instrument as follows:

- A. Requires disassembly
- B. Requires water jet to flush difficult to access areas
- C. Screw/unscrew components or activate mechanism while flushing the area
- D. Screws/mechanisms should be checked and lubricated with a medical grade surgical lubricant after each cleaning as determined upon inspection

Part Number	Description	Sterilization and Specific Cleaning Instructions	Instrument
20-8060-001-00	ROSA Quick Connect Interface	Autoclave additional specific cleaning requirements: B C D	 A circular metal component with a central shaft. Callouts '3x D' and 'B-C-D' point to specific features.
20-8060-002-00	ROSA Quick Connect Sleeve	Autoclave	 A cylindrical metal sleeve with a flange on one end.
20-8060-301-00	ROSA Cup Inserter Handle	Autoclave additional specific cleaning requirements: B	 A blue-handled metal shaft with a threaded end. Callout 'B' points to the handle.
20-8060-302-00	ROSA STRT Cup Inserter Shaft	Autoclave additional specific cleaning requirements: B D Note: Disassemble the G7 curved inserter threaded shaft (P/N: 110003454) for cleaning.	 A long, thin metal shaft with a threaded end. Callout 'B-D' points to the shaft.
20-8060-303-00	ROSA OFFST Cup Inserter Shaft	Autoclave additional specific cleaning requirements: B C D Note: Disassemble the G7 curved inserter threaded shaft (P/N: 110003454) for cleaning	 A long, thin metal shaft with a curved section and a threaded end. Callout 'B-C-D' points to the shaft.

14.3.4.1 ROSA Hip System Instrument Kit (cont.)

Part Number	Description	Sterilization and Specific Cleaning Instructions	Instrument
20-8060-304-00	ROSA Cup Inserter Adaptor	Autoclave additional specific cleaning requirements: B	
20-8060-305-00	ROSA Cup Inserter Screw	Autoclave additional specific cleaning requirements: B C D	

14.3.4.2. ROSA Hip System Instrument Lifetime Expectancy

The reusable instruments for the ROSA Hip System have a lifetime of five years under normal use, estimated at 480 surgeries over five years. For disposal of reusable instruments, please refer to the Reusable Instrument Lifespan Manual (1219).

The ROSA Tablet has a lifetime of two years under normal use.

14.4 Storage and Transport

14.4.1 Storage and Protection

14.4.1.1 Device Storage and Protection

At the end of each procedure, the device and mobile tablet should be shutdown and stored in an area fulfilling the storage conditions defined in the Technical Specifications. Store the device, mobile tablet and battery according to their storage temperature specifications (refer to section 15.2 Technical Specifications).

In order to preserve the device, it should be stored in an area where there is no traffic and where it is not exposed to fluids. The device must not be placed on sloping ground without the assurance of its stability.

The immobilization system may be used during storage. During storage, ensure that the Touchscreen is folded above the Robotic Unit so it is protected in the event of a collision.

14.4.1.2 Instrument Storage and Protection

The instruments shall remain protected from all impacts during handling and storage. Special care should be taken of all instruments because any damage whatsoever may directly affect the registration and positioning accuracy of instruments on a planned trajectory.

14.4.1.3 Care of Cables and Connectors

To avoid damage to cables, make sure they are not bent at sharp angles. Handle the connectors with care, paying particular attention to the following points:

- Pull connections apart by gripping the connector. Do not pull them apart by tugging on the cable as this can damage the connecting cable and connector pins
- Do not leave cable connectors where they may get damaged, particularly on the floor, where they may easily be stepped on or rolled over by heavy equipment
- Do not put heavy objects on cables or cable connectors
- Never force a connection



Do not connect any elements other than those provided with the device to the Robotic Unit.



In order to prevent accidental detachment of connector and to ensure EMC protection, make sure that the metallic ring of the Optical Unit Cable is attached to the hook on the Rear Panel of the Robotic Unit, if applicable.



For safety reasons and to ensure proper functioning of the device, do not use any cables other than those distributed by Zimmer Biomet.

14.4.2 Device Transport

When transporting the Robotic Unit, ensure the Touchscreen is folded above the Robotic Unit so that it is protected in the event of a collision.



When transporting the Optical Unit, ensure that the camera is folded following the indications below, so that it is protected in the event of a collision.

Transporting the device from one site (building) to another is performed only under the responsibility of the user. Any damages or malfunctions eventually caused during transportation are not covered by Zimmer Biomet.



During transportation, the device can be immobilized by activating the immobilization pedal. Do not install the device on an inclined surface, unless its stability is guaranteed.



Activate all wheel brakes of the Optical Unit to ensure its immobilization.



Transportation or displacement of the device can be handled by one person.

14.5 Maintenance Operations

14.5.1 Installation

The device is installed on site by Zimmer Biomet personnel or its approved representatives only. The installation requires expert knowledge of the device.

14.5.2 Daily Checks

Regularly perform a safety check of the device. Inspect the device to ensure no defects appear on the:

- Robotic Unit, including the Robotic Arm
- Optical Unit
- Optical Camera (not used for ROSA Hip System)
- Force Sensor Connector
- Immobilization system and locks of Robotic Unit
- Foot Pedal
- Instruments
- ROSA Tablet

These safety checks are recommended to be done each day of use. Check the physical condition of the instruments to ensure no defects are present. Never use a distorted or damaged component.

14.5.3 Periodic Maintenance

A maintenance agreement is established between the customer and Zimmer Biomet. It covers the frequency of the preventive maintenances and lists the different checks and tests performed. Maintenance plays a preventive role in possible issues that may arise with product use.

The Zimmer Biomet Customer Service team is committed to dealing with any operation faults that may appear on the device.

Zimmer Biomet will provide on-demand, schematic diagrams, calibration information and other information necessary to perform maintenance technical tasks that are identified as being able to be performed by service personnel.



Do not open the device. In case of any issue or breakdown, do not intervene. Maintenance and service operations must only be carried out by Zimmer Biomet's Customer Service or any of its approved representatives. Do not modify the device.



When used in compliance with the indications for maintenance, the device can be run in permanent operation.





14.6 Troubleshooting

Issue	Cause	Solution
The device does not turn on	The Power Cable is unplugged	Check that the Power Cable is connected
	The ON/OFF switch is turned to OFF	Turn the switch located on the back panel of the device to ON
	Electric current is cut off by an external circuit breaker	Press the CIRCUIT BREAKER button to reset it
	Electric current is cut off by an internal circuit breaker	Contact Zimmer Biomet Customer Service
The touchscreen does not work	The screen is off	Turn the Touchscreen on by pressing the button to the right side of the screen
	The screen Power Cable is unplugged	Ensure that the power, video and USB Touchscreen cables are connected
	The video cable is unplugged	
	The USB cable is unplugged	
	The screen displays the message “No video input” and then goes black. The RESET button indicator located on the Rear Panel of the device is red	Press the RESET button on the Rear Panel of the device and check that the RESET button indicator is blue
	The actions of the application do not correspond to the buttons activated. The touchscreen is not calibrated	Contact Zimmer Biomet Customer Service
	The touchscreen behavior is sporadic, i.e. some touches on the screen are not working	Contact Zimmer Biomet Customer Service
The CD/DVD reader does not operate	CD/DVD is unplugged and non-functional	CD/DVD cannot be used
A USB port does not work	USB port faulty	Try another USB port. Inform Zimmer Biomet Customer Service
	Connection problem with the USB port	
Case data cannot be uploaded with the flash drive	Case data is corrupted	Download the case data on the USB drive and sync again with the device
	USB drive is faulty	Download the case data on a new USB drive and sync again with the device
The Robotic Unit immobilization system does not work	The immobilization pedal cannot go through its full range down to its locked position	Check that there is no obstacle under the stabilization feet

14.6 Troubleshooting (cont.)

Issue	Cause	Solution
The Robotic Arm movement is interrupted	The device indicates detection of a collision. An unsuitable tool is installed on the Robotic Arm. The tool does not correspond to the current stage in the procedure	Ensure that the tool installed corresponds to the current stage in the procedure. Restart the movement
	The device indicates that the user interrupted the movement. The Foot Pedal is turned off	Check that the Foot Pedal is connected to the Rear Panel of the device
	The light on the RESET button on the rear panel of the device is off and the Foot Pedal doesn't work	Contact Zimmer Biomet Customer Service
The Robotic Arm drifts slowly in Collaborative Mode	An unsuitable tool is installed on the Robotic Arm. The tool does not correspond to the current stage in the procedure	Stop the Collaborative mode. Check that the tool installed corresponds to the current stage of the procedure. Launch Collaborative mode once again
	The tool is in contact with an object	Ensure that the elements secured to the Robotic Arm are not in contact with an external object
The interface displays a communication error message with the Robotic Unit	The Force Sensor Cable is unplugged	Connect the cable to the Force Sensor. Restart the device
	The red EMERGENCY button has been activated and the Robotic Unit remains off	Deactivate the red EMERGENCY button and restart the device
The red EMERGENCY button light is on	The red EMERGENCY button has been activated	Release the red EMERGENCY button and restart the device
	The redundancy check of the Foot Pedal triggered an error	Shut down the device and restart
Robotic error is detected	The red EMERGENCY button has been activated	Release the red EMERGENCY button and resume the surgery
	Excessive force applied to the Robotic Arm	Remove any force applied to the Robotic Arm and resume the surgery
Instrument calibration is unsuccessful	An external force is applied on the Robotic Arm during the calibration of the Quick Connect Interface	Remove any force applied to the F/T sensor and execute instrument calibration again
	The instrument is under high pressure from the pelvis (during calibration of the Cup Inserter in the IMPACTION panel)	Disconnect the instrument by clicking the BACK TO ATTACH INSTRUMENT button. Reassemble instrument in the incision. Execute instrument calibration again



15. Technical Data

-  The device requires specific precautions regarding the EMC. It must be installed and operated according to the EMC information provided in the User Manual.
-  Portable and mobile radio frequency communication devices might affect the operation of the device.
-  Usage of accessories, transducers and cables other than those specified in the User Manual, with the exception of the transducers and cables sold by Zimmer Biomet (as spare parts of internal components), might cause increased emissions or decrease immunity of the device.
-  The device must not be used adjacent to or stacked on top of any other equipment. If this cannot be avoided, verify its perfect operation in the corresponding configuration.

15.1 Labels and Symbols

15.1.1 Labels

The device labels affixed on the device components are detailed below. Bar codes and 2D Matrix are examples only.

System	Countries	Robotic Unit Label Example
110V	US	 <p>Advantech:</p>  <p>Or</p> <p>Onlogic:</p> 

15.1.1 Labels (cont.)

Optical Unit Label Example



ROSA Tablet Label Example



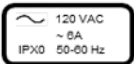











Refurbished and Loaner Units

Platforms	Units
20-8020-200-01 ROSA RECON PLATFORM 110V REFURB	20-8020-210-01 - ROSA RECON ROBOTIC UNIT 110V REFURB 20-8020-220-01 - ROSA RECON OPTICAL UNIT REFURB
20-8020-300-01 ROSA RECON PLATFORM 110V LOANER	20-8020-310-01 - ROSA RECON ROBOTIC UNIT 110V LOANER 20-8020-320-01 - ROSA RECON OPTICAL UNIT LOANER









15.1.2 Symbols on the Labels

Label	Description
	Caution
	Refer to instruction manual/booklet
	Power supply specifications for concerned countries (ex: Germany, France) IPX0: No protection against liquids



15.1.2 Symbols on the Labels (cont.)

Label	Description
	Power supply specifications for concerned countries (ex: USA, Canada) IPX0: No protection against liquids
	Power supply specifications for concerned countries (Japan) IPX0: No protection against liquids
	BF type device
	MR Unsafe: Keep away from Magnetic Resonance Imaging (MRI) equipment
	Federal law restricts this device to sale by or on the order of a physician
	Non sterile
	Do not immerse in any liquid
	Consult Instructions for Use
	Attention: Read all warnings and precautions in Instructions for Use
	European market authorization
	Bureau Veritas/Curtis-Straus nationally recognized testing laboratories mark, with "US" and "C" identifiers, for USA and Canada
	Regulatory Compliance Mark (RCM) for Australia and New Zealand










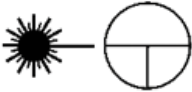
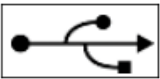
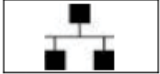
15.1.2 Symbols on the Labels (cont.)

Label	Description
	Manufacturer's name and address
	Manufacturing date
	Authorized representative in the European Community
	Product reference
	Serial number
	Lot number
	Device weight
	The equipment should not be disposed of in the normal waste stream








15.1.3 Other Symbols on the Device

Label	Location	Description
	Bottom of Robotic Unit Rear Panel	OFF – Switch off the device
	Bottom of Robotic Unit Rear Panel	ON – Switch on the device

15.1.3 Other Symbols on the Device (cont.)

Label	Location	Description
	Bottom of Robotic Unit Rear Panel	Central unit RESTART button
	Bottom of Robotic Unit Rear Panel	Foot Pedal socket
	Bottom of Robotic Unit Rear Panel	Socket for black RJ45 cable of Optical Unit wiring
	Bottom of Robotic Unit Rear Panel	Socket for white RJ45 cable of Optical Unit wiring
	Bottom of Robotic Unit Rear Panel	Socket for Optical Unit main cord
	Bottom of Robotic Unit Rear Panel	Controller servicing port (deactivated)
	Bottom of Robotic Unit Rear Panel	Robotic Unit immobilization system Move lever up/down to unlock/lock
	Bottom cover of Robotic Unit, above stabilization feet	Risk of foot crushing
	Middle of Robotic Unit Rear Panel	Distance sensor on/off symbol Not applicable for Hip application (deactivated)
	Camera handle on Optical Unit	Optical sensor laser pointer ON/OFF symbol OFF is a stable position, while the ON position only remains during the time the button is depressed
	Middle of Robotic Unit Rear Panel	USB port
	Middle of Robotic Unit Rear Panel	Ethernet socket symbol Not applicable for Hip application (deactivated)

15.1.3 Other Symbols on the Device (cont.)

Label	Location	Description
	Middle of Robotic Unit Rear Panel	Do not use USB ports for charging a cell phone. Connection for USB drive, keyboard and mouse only
	Middle of Robotic Unit Rear Panel	Do not use USB ports for connecting a wireless device. Connection for USB flash drive, keyboard and mouse only
	Top cover of Robotic Unit	Emergency stop
	Rear of Touchscreen on Robotic Unit	Stored energy hazard
	Optical Unit	Lock Optical Unit in place using the brake on all four wheels
	Optical Unit	Fold the camera arm for transportation
	Rear of camera on the right	Laser beam – Never look directly at the laser beam – Class II laser

15.2 Technical Specifications

15.2.1 Robotic and Optical Units Environmental Specifications

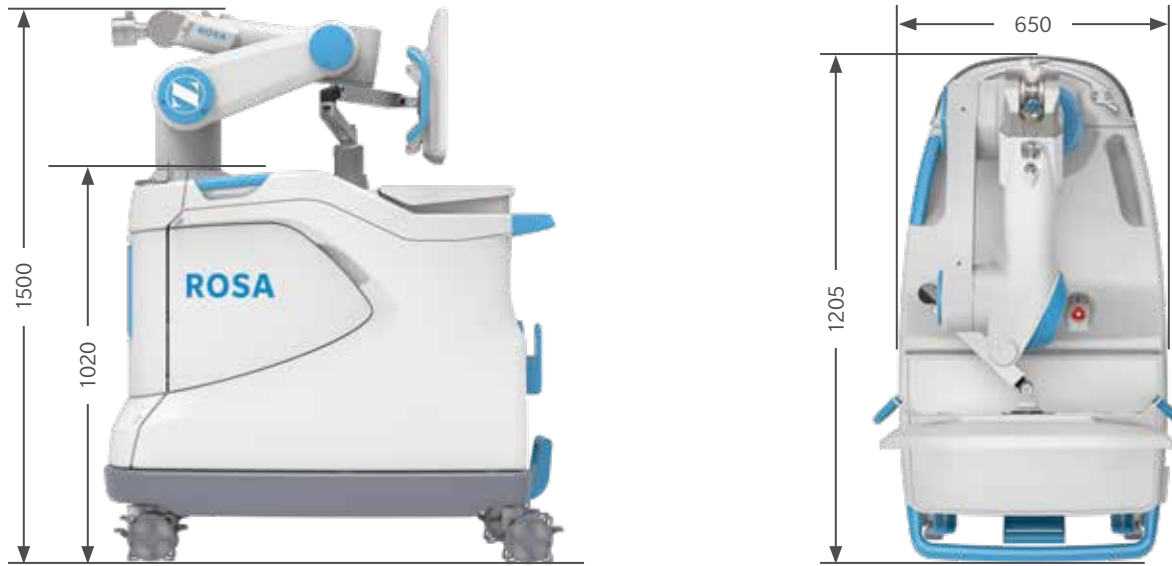
Environment	Storage and Transportation	Operating
Temperature	0°C to 50°C	15°C to 35°C
Relative Humidity	8% to 93% (without condensation)	8% to 75% (without condensation)
Air Pressure	800 hPa to 1060 hPa	800 hPa to 1060 hPa

15.2.2 ROSA Tablet and Battery Environmental Specifications

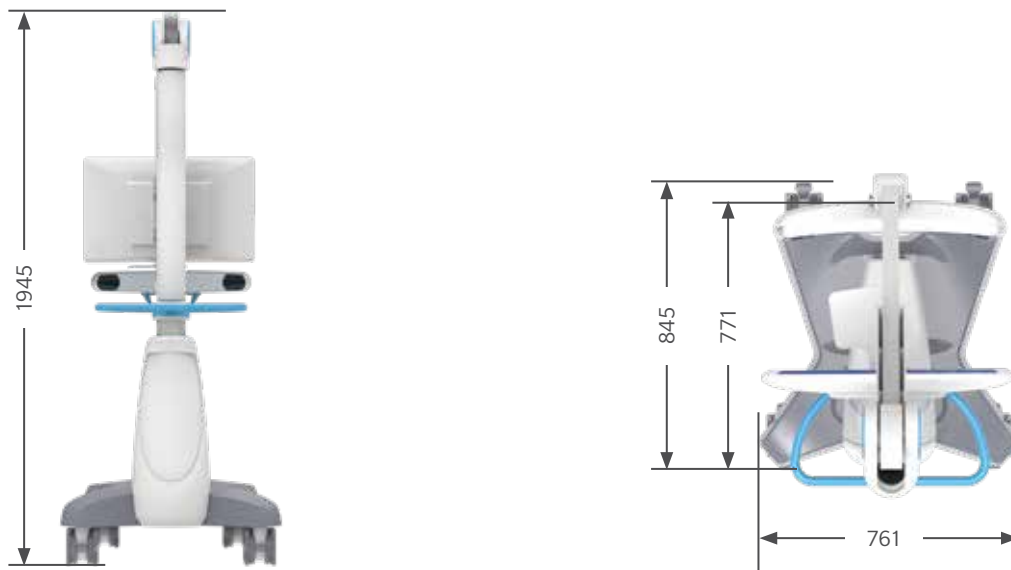
Environment	Storage and Transportation	Operating
Temperature	-55° to 70° Celsius	AC mode: -20° to 60° Celsius Battery mode: -20° to 45° Celsius
Relative Humidity	0% to 93% (without condensation)	0% to 90% (without condensation)

15.2.3 Device Dimensions

The device has the following exterior dimensions in millimeters:



Robotic Unit Dimensions



Optical Unit Dimensions

15.2.3 Device Dimensions (cont.)



Mobile Tablet Dimensions (mm)

Robotic Unit weight: Approximately 320kg (705 lb)
 Optical Unit weight: Approximately 140 kg (309 lb)
 Mobile Tablet weight: Approximately 1.8kg (3.97 lb)

15.2.4 Robotic Arm Working Range

ROSA Hip is equipped with a Stäubli 6-axis Robotic Arm and has 6° of freedom.

Dimension	Storage and Transportation
Maximum radius between joint 1 and 5 (R.M) 850 mm	850 mm
Minimum radius between joint 1 and 5 (R.m1) 209 mm	209 mm
Minimum radius between joint 2 and 4 (R.m2) 208 mm	208 mm
Minimum radius between joint 3 and 5 (R.b) 540 mm	540 mm

15.3 Safety Classification and Standards

Navigation camera = Class 2	Type Classification
Protection against electric shock	Class 1 Patient protection = type BF applied part
Protection against ingress of fluids	Robotic Unit = IPX0 Optical Unit = IPX0 Footswitch = IP68
Protection against laser beam	Navigation camera = Class 2

15.3 Safety Classification and Standards (cont.)

Standard Classification	Standard Description
IEC 60601-1 Ed. 3.1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performances
IEC 60601-1-2 Ed. 4.0	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performances – Collateral Standard: Electromagnetic Compatibility
IEC 60601-1-6 Ed. 3.1	Medical devices - Part 1-6: General requirement for basic safety and essential performance – Usability
IEC 62366-1	Medical devices – Part 1: Application of usability engineering to medical devices
ISO 17664:2017	Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices
ISO 17665-1:2006	Sterilization of healthcare products-Moist heat-Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
IEC 62304 Ed. 1.0	Medical device application – Application life cycle process
IEC 60825-1 Ed. 3.0	Safety of laser products – Part 1: Equipment classification and requirements

15.3.1 Cable Lengths

Cable and Accessories	Maximum Length	Type of Tests	In Accordance with
Power Cable Foot Pedal Cable	>3m	RF Emissions	CISPR, Class A
	>3m	Harmonic current	IEC 61000-3-2
		Voltage fluctuations/ Flicker	IEC 61000-3-3
Optical Unit Main Cord Force Sensor Cable	>3m	Electrostatic discharge immunity	IEC 61000-4-2
	>3m		
		Radiated immunity – electromagnetic fields	IEC 61000-4-3
		Electrical fast transient/ burst immunity test	IEC 61000-4-4
		Surge immunity test	IEC 61000-4-5
ISO 17665-1:2006		Conducted immunity - Conducted RF	IEC 61000-4-6
ISO 10993-1:2018		Radiated immunity - Magnetic field	The electromagnetic field strengths of fixed radio frequency transmitters
IEC 62304 Ed. 1.0		Downtimes, dips and variation of the power supply voltage	The electromagnetic field strengths of fixed radio frequency transmitters

15.4 Electromagnetic Compatibility

All the information below is based on the normative requirements manufacturers of Electrical Medical devices are subjected to, in regards with IEC60601-1-2. The medical device complies with applicable electromagnetic compatibility standards, however, the user will ensure that any electromagnetic interference does not create an additional hazard, such as radio frequency transmitters or other electronic devices. In this section, you will find the information necessary to ensure the installation and commissioning of your medical device under the best conditions in terms of electromagnetic compatibility.

The different cords of the medical device must be separated from each other. Certain types of mobile telecommunication devices, such as mobile phones, are likely to interfere with the medical device. The separation distances recommended in this chapter must therefore be strictly observed. The medical device must not be used near or on another device. If this cannot be avoided, it must be checked for proper operation under the conditions of use before use. The use of accessories other than those specified or sold by Zimmer CAS as replacement parts, may result in an increase in the emission or a reduction of the immunity of the medical device.

15.4.1 Electromagnetic (EM) Emissions

The device has been designed for use in an electromagnetic environment as specified below. The user must ensure that it operates in this type of environment.

Cable and Accessories	Maximum Length	Type of Tests In Accordance with
RF emissions CISPR 11(1)	Group 1	The ROSA Recon Platform is part of CISPR11 group 1. The ROSA Recon Platform uses RF energy as below: Wi-Fi in the 2.4 GHz band (2400 to 2483,5MHz) or in the 5.0GHz band (5150 to 5250MHz; 5250 to 5350MHz and 5470 to 5725MHz) as a mean of radio communication (5GHz band being restricted to indoor use only). Emission powers in the 2.4GHz band do not exceed 19.92dBm, compliant with ETSI EN 300 328. Emission powers in the 5.0GHz band do not exceed 21.18dBm, compliant with ETSI EN 301 893. The device uses 2 dipole antennas.
RF emissions CISPR 11(1)	Class A	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 own expense.

(1)The emission characteristics of this device make it suitable for use in industrial areas and hospitals (Class A defined in CISPR 11). When used in a residential environment (for which Class B defined in CISPR 11 is normally required), this device may not provide adequate protection for radio frequency communications services. The user may need to take mitigation measures, such as relocating or reorienting the device.



BE	LU	NL	FR	DE
IT	DK	IE	UK	EL
ES	PT	AT	FI	SE
CY	EE	HU	LV	LT
MT	PL	SI	SK	CZ
BG	RO	HR		
NO	CH	IS	LI	

Ensuring that the system operates in the above environment will maintain basic safety and essential performance with regard to electromagnetic disturbances for the expected service life.

Reference	Performance Specification	If Lost or Degraded Due to EM Disturbances
Essential Performance 1	Accurate instrument positioning	Instrument positioning not accurate
Essential Performance 2	Accurate instrument displayed	Information displayed not accurate
Essential Performance 3	Accurate mobile connection	Instrument positioning not accurate
Basic Safety 1	Unwanted robot motion	Unwanted robot motion could occur
Basic Safety 1	Robot arm collision	Collision detection feature affected

Using the ROSA Hip System with other products or components, unless such other products or components are expressly recognized as compatible with ROSA Hip System, could affect basic safety and essential performance in terms of EM disturbances.

15.5 Electromagnetic Immunity

15.5.1 Electromagnetic and Magnetic Immunity

Electromagnetic Immunity

ROSA Hip System is intended for use in a professional healthcare facility environment. The user of ROSA Hip System should ensure that it is used in such an environment.

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level of ROSA Hip	Electromagnetic Environment Guide
Electrostatic discharge (ESD) EN 61000-4-2	±8 kV contact (direct, indirect horizontal, indirect vertical) ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Main power quality should be that of a professional healthcare facility environment
Electrical fast transient/burst Signal input/output parts PORT (L> 3m) IEC 61000-4-4	± 1 kV/100 Hz	± 1 kV/100 Hz	Main power quality should be that of a professional healthcare facility environment
Electrical fast transient/burst Input a.c power PORT IEC 61000-4-4	± 2 kV/ 100 Hz	± 2 kV/ 100 Hz	
Surge Input a.c power PORT IEC 61000-4-5	± 0,5 kV, ±1 kV line to line ± 0,5 kV, ±1 kV, ± 2 kV line to ground	± 0,5 kV, ±1 kV line to line ± 0,5 kV, ±1 kV, ± 2 kV line to ground	Main power quality should be that of a professional healthcare facility environment
Voltage dips Input a.c power PORT EN 61000-4-11	0% UT for 0.5 cycles At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT for 1 cycles and 70% UT for 25\30 cycles (500ms) Single phase: at 0°	0% UT for 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<5% UT (>95% dip in UT) for 0,5 cycle 0% UT for 1 cycle and 70% UT for 25/30 cycles (500ms) Single phase: at 0°	Main power quality should be that of a professional healthcare facility environment. If the user of the device requires continued operation during power outages, it is recommended that the device be powered from an uninterruptible power supply or a battery
Voltage interruptions EN 61000-4-11	0 % UT For 250\300 cycles	0 % UT For 250\300 cycles	
RATED power frequency (50\60 Hz) magnetic field Enclosure port IEC61000-4-8	30 A/ma 50 Hz and 60 Hz	30 A/ma 50 Hz and 60 Hz	Power frequency magnetic fields should be at levels characteristic of a professional healthcare facility environment

Note: UT is the a.c. main voltage prior to application of the test level using a minimum distance of 15 cm between the ROSA Hip device and source of power frequency magnetic field.

15.5.2 Electromagnetic Immunity and Portable and Mobile Radio Frequency (RF) Communication Equipment

Electromagnetic Immunity Conducted and Radiated RF

ROSA Hip is intended for use in a professional healthcare facility environment. The user of ROSA Hip should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level of ROSA Hip	Electromagnetic Environment Guide
Conducted disturbances induced by RF fields Signal input/output parts PORT (L > 0m) IEC 61000-4-6	3 V 150 kHz to 80 MHz 6V in ISM band and band between 0.15MHz and 80MHz including amateur radio band 80% MA at 1KHz	3 V 150 kHz to 80 MHz 6V in ISM band and band between 0.15MHz and 80MHz including amateur radio band 80% MA at 1KHz	Main power quality should be that of a professional healthcare facility environment Warning: Portable and mobile RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ROSA Hip System device, including cables specified by the manufacturer
Conducted disturbances induced by RF fields Input a.c power PORT IEC 61000-4-6	3 V 150 kHz to 80 MHz 6V in ISM band and band between 0.15MHz and 80MHz including amateur radio band 80% MA at 1KHz	3 V 150 kHz to 80 MHz 6V in ISM band and band between 0.15MHz and 80MHz including amateur radio band 80% MA at 1KHz	Otherwise, degradation of the performance of this equipment could result
Radiated RF electromagnetic field IMMUNITY Enclosure port IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	
IMMUNITY to proximity fields from RF wireless communications equipment Enclosure port IEC 61000-4-3	385MHz/ 27V/m 450 MHz/ 28V/m 710 MHz/ 9V/m 745 MHz/ 9V/m 780 MHz/ 9V/m 810 MHz/ 28V/m 870 MHz/ 28V/m 930 MHz/ 28V/m 1720 MHz/ 28V/m 1845 MHz/ 28V/m 1970 MHz/ 28V/m 2450 MHz/ 28V/m 5240 MHz/ 9V/m 5500 MHz/ 9V/m 5785 MHz/ 9V/m	385 MHz/ 27V/m 450 MHz/ 28V/m 710 MHz/ 9V/m 745 MHz/ 9V/m 780 MHz/ 9V/m 810 MHz/ 28V/m 870 MHz/ 28V/m 930 MHz/ 28V/m 1720 MHz/ 28V/m 1845 MHz/ 28V/m 1970 MHz/ 28V/m 2450 MHz/ 28V/m 5240 MHz/ 9V/m 5500 MHz/ 9V/m 5785 MHz/ 9V/m	

15.5.2 Electromagnetic Immunity and Portable and Mobile Radio Frequency (RF) Communication Equipment (cont.)

The ISM (Industrial Scientific and Medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

15.5.3 Recommended Separation Distances

The ROSA Hip System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user or installer of the medical device can help to avoid electromagnetic interference by maintaining a minimum distance, depending on the maximum power of the radio frequency transmission equipment. RF portable communications equipment (including peripherals such as antenna cables and external antennas) should not be used closer than 30 cm (12 inches) to any part of the ROSA Hip device, including the cables specified by the manufacturer. Otherwise, the performance of these devices may be impaired.

16. Application Licenses (U.S. Launch)

16.1 Boost

Boost Application License (U.S. launch) - Version 1.0 - August 17th, 2003

Permission is hereby granted, free of charge, to any person or organization obtaining a copy of the application and accompanying documentation covered by this License (the “Application”) to use, reproduce, display, distribute, execute, and transmit the application, and to prepare derivative works of the application, and to permit third-parties to whom the application is furnished to do so, all subject to the following: The copyright notices in the application and this entire statement, including the above License grant, this restriction and the following disclaimer, must be included in all copies of the application, in whole or in part, and all derivative works of the application, unless such copies or derivative works are solely in the form of machine-executable object code generated by a source language processor.

THE APPLICATION IS PROVIDED “AS IS”, WITHOUT WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO THE WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TITLE AND NONINFRINGEMENT. IN NO EVENT SHALL THE COPYRIGHT HOLDERS OR ANYONE DISTRIBUTING THE APPLICATION BE LIABLE FOR ANY DAMAGES OR OTHER LIABILITY, WHETHER IN CONTRACT, TORT OR OTHERWISE, ARISING FROM, OUT OF OR IN CONNECTION WITH THE APPLICATION OR THE USE OR OTHER DEALINGS IN THE APPLICATION

16.2 Open SSL

Copyright © 1998-2008 The OpenSSL Project. All rights reserved.

Redistribution and use in source and binary forms, with or without modification, are permitted provided that the following conditions are met:

1. Redistributions of source code must retain the above copyright notice, this list of conditions and the following disclaimer.
2. Redistributions in binary form must reproduce the above copyright notice, this list of conditions and the following disclaimer in the documentation and/or other materials provided with the distribution.
3. All advertising materials mentioning features or use of this application must display the following acknowledgment: “This product includes application developed by the OpenSSL Project for use in the OpenSSL Toolkit. (<http://www.openssl.org/>)”
4. The names “OpenSSL Toolkit” and “OpenSSL Project” must not be used to endorse or promote products derived from this application without prior written permission. For written permission, please contact openssl-core@openssl.org.
5. Products derived from this application may not be called “OpenSSL” nor may “OpenSSL” appear in their names without prior written permission of the OpenSSL Project.
6. Redistributions of any form whatsoever must retain the following acknowledgment: “This product includes application developed by the OpenSSL Project for use in the OpenSSL Toolkit (<http://www.openssl.org/>)”

16.2 Open SSL (cont.)

THIS APPLICATION IS PROVIDED BY THE OpenSSL PROJECT ``AS IS'' AND ANY EXPRESSED OR IMPLIED WARRANTIES, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE ARE DISCLAIMED. IN NO EVENT SHALL THE OpenSSL PROJECT OR ITS CONTRIBUTORS BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY, OR CONSEQUENTIAL DAMAGES (INCLUDING, BUT NOT LIMITED TO, PROCUREMENT OF SUBSTITUTE GOODS OR SERVICES; LOSS OF USE, DATA, OR PROFITS; OR BUSINESS INTERRUPTION) HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, STRICT LIABILITY, OR TORT (INCLUDING NEGLIGENCE OR OTHERWISE) ARISING IN ANY WAY OUT OF THE USE OF THIS APPLICATION, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.

Copyright © 1995-1998 Eric Young (eay@cryptsoft.com)

All rights reserved.

This package is an SSL implementation written by Eric Young (eay@cryptsoft.com).

The implementation was written so as to conform with Netscapes SSL.

This library is free for commercial and non-commercial use as long as the following conditions are adhered to. The following conditions apply to all code found in this distribution, be it the RC4, RSA, lhash, DES, etc., code; not just the SSL code. The SSL documentation included with this distribution is covered by the same copyright terms except that the holder is Tim Hudson (tjh@cryptsoft.com).

Copyright remains Eric Young's, and as such any Copyright notices in the code are not to be removed.

If this package is used in a product, Eric Young should be given attribution as the author of the parts of the library used.

This can be in the form of a textual message at program startup or in documentation (online or textual) provided with the package.

Redistribution and use in source and binary forms, with or without modification, are permitted provided that the following conditions are met:

1. Redistributions of source code must retain the copyright notice, this list of conditions and the following disclaimer.
2. Redistributions in binary form must reproduce the above copyright notice, this list of conditions and the following disclaimer in the documentation and/or other materials provided with the distribution.
3. All advertising materials mentioning features or use of this application must display the following acknowledgment: "This product includes cryptographic application written by Eric Young (eay@cryptsoft.com)" The word 'cryptographic' can be left out if the routines from the library being used are not cryptographic related.
4. If you include any Windows specific code (or a derivative thereof) from the apps directory (application code) you must include an acknowledgment: "This product includes application written by Tim Hudson (tjh@cryptsoft.com)"

THIS APPLICATION IS PROVIDED BY ERIC YOUNG ``AS IS'' AND ANY EXPRESS OR IMPLIED WARRANTIES, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE ARE DISCLAIMED. IN NO EVENT SHALL THE AUTHOR OR CONTRIBUTORS BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY, OR CONSEQUENTIAL DAMAGES (INCLUDING, BUT NOT LIMITED TO, PROCUREMENT OF SUBSTITUTE GOODS OR SERVICES; LOSS OF USE, DATA, OR PROFITS; OR BUSINESS INTERRUPTION) HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, STRICT LIABILITY, OR TORT (INCLUDING NEGLIGENCE OR OTHERWISE) ARISING IN ANY WAY OUT OF THE USE OF THIS APPLICATION, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.

16.2 Open SSL (cont.)

The License and distribution terms for any publicly available version or derivative of this code cannot be changed. i.e. this code cannot simply be copied and put under another distribution License [including the GNU Public License.]

16.3 OpenCV

License Agreement

For Open Source Computer Vision Library

(3-clause BSD License)

Copyright © 2000-2020, Intel Corporation, all rights reserved.

Copyright © 2009-2011, Willow Garage Inc., all rights reserved.

Copyright © 2009-2016, NVIDIA Corporation, all rights reserved.

Copyright © 2010-2013, Advanced Micro Devices, Inc., all rights reserved.

Copyright © 2015-2016, OpenCV Foundation, all rights reserved.

Copyright © 2015-2016, Itseez Inc., all rights reserved.

Copyright © 2019-2020, Xperience AI, all rights reserved.

Third-party copyrights are property of their respective owners.

1. Redistributions of source code must retain the above copyright notice, this list of conditions and the following disclaimer.
2. Redistributions in binary form must reproduce the above copyright notice, this list of conditions and the following disclaimer in the documentation and/or other materials provided with the distribution.
3. Neither the names of the copyright holders nor the names of the contributors may be used to endorse or promote products derived from this application without specific prior written permission.

This application is provided by the copyright holders and contributors “as is” and any express or implied warranties, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose are disclaimed. In no event shall copyright holders or contributors be liable for any direct, indirect, incidental, special, exemplary, or consequential damages (including, but not limited to, procurement of substitute goods or services; loss of use, data, or profits; or business interruption) however caused and on any theory of liability, whether in contract, strict liability, or tort (including negligence or otherwise) arising in any way out of the use of this application, even if advised of the possibility of such damage.

16.4 JSON

MIT License

Copyright © 2013-2019 Niels Lohmann

Permission is hereby granted, free of charge, to any person obtaining a copy of this application and associated documentation files (the “Application”), to deal in the application without restriction, including without limitation the rights to use, copy, modify, merge, publish, distribute, sublicense, and/or sell copies of the application, and to permit persons to whom the application is furnished to do so, subject to the following conditions:

16.4 JSON (cont.)

The above copyright notice and this permission notice shall be included in all copies or substantial portions of the application.

THE APPLICATION IS PROVIDED "AS IS", WITHOUT WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO THE WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT. IN NO EVENT SHALL THE AUTHORS OR COPYRIGHT HOLDERS BE LIABLE FOR ANY CLAIM, DAMAGES OR OTHER LIABILITY, WHETHER IN AN ACTION OF CONTRACT, TORT OR OTHERWISE, ARISING FROM, OUT OF OR IN CONNECTION WITH THE APPLICATION OR THE USE OR OTHER DEALINGS IN THE APPLICATION.

16.5 Libgit2

For Libgit2 integral License description, please refer to: <https://github.com/libgit2/libgit2/blob/main/COPYING>

17. Product Security Customer Control Considerations

17.1 Records Retention and Purging Historical Data

The ROSA Recon Platform will be located at the Healthcare Delivery Organization (HDO) facility and is subject to the regulatory requirements and records retention period. After this period and upon request by the HDO, Zimmer Biomet field service engineers will assist the HDO with purging historical data from the ROSA Recon Platform.

The ROSA Recon Platform will be located at the Healthcare Delivery Organization (HDO) facility and is subject to the HDO's physical and environmental safeguards to mitigate the risks of loss, theft and physical tampering. The ROSA Recon Platform should be stored in a location at the HDO with physical access control to authorized personnel only when not in use.

17.2 Cybersecurity

It is strongly recommended that users protect against malicious application by installing an up-to-date, reputable antivirus protection and firewall product. Zimmer Biomet takes no responsibility for malicious activity that may result from lack of current, appropriate IT security practices.

APPENDIX A: Implants Supported by the ROSA Hip System

CAUTION: Verify regional availability of implants prior to selection in the Implant Selection (including sizing).

The following table contains the hip implant systems (Stem Brand) and associated available stem type, broach/stem sizes, neck types as well as head offset.

Hip Implant System (Stem Brand)	Stem Type	Broach/Stem Size	Neck Type	Head Length	
Taperloc® Complete	Full Profile	4	Standard Offset XR 123°	-6	
		5	Standard Offset	-3	
		6	High Offset	STD	
		7	XR 123°	+3	
		8		+6	
		9	Standard Offset	+9	
		10	High Offset	+12	
		11			
		12			
		13			
		14			
		15			
		16			
		17			
		18			
		Reduced Distal	9	Standard Offset	
			10	High Offset	
			11	XR 123°	
	12				
	13				
14					
	20	Standard Offset			
	22	High Offset			
	24				

APPENDIX A: Implants Supported by the ROSA Hip System (cont.)

Hip Implant System (Stem Brand)	Stem Type	Broach/Stem Size	Neck Type	Head Length
Taperloc® Complete	Microplasty	4	Standard Offset XR 123°	-6
		5	Standard Offset High Offset XR 123°	-3
		6		STD
		7		+3
		8		+6
		9		+9
		10		+12
		11		
		12		
		13		
		14		
		15		
		16		
		17		
		18		
				20
		22		
		24		
Echo® Bi-Metric®	Full Proximal Profile	7	Standard Offset	-6
		8	Lateralized Offset	-3
		9		STD
		10		+3
		11		+6
		12		+9
		13		+12
		14		
		15		
		16		
		17		
		18		
		19		
		20		
21				

APPENDIX A: Implants Supported by the ROSA Hip System (cont.)

Hip Implant System (Stem Brand)	Stem Type	Broach/Stem Size	Neck Type	Head Length
Echo® Bi-Metric®	Reduced Proximal Profile	7	Standard Offset	-6
		8	Lateralized Offset	-3
		9		STD
		10		+3
		11		+6
		12		+9
		13		+12
		14		
		15		
		16		
		17		
		18		
		19		
		20		
	21			
	Microplasty® Full Proximal Profile	7	Standard Offset	
		8	High Offset	
		9		
		10		
		11		
		12		
13				
14				
15				
16				
17				
Microplasty® Reduced Proximal Profile	7	Standard Offset		
	8	High Offset		

APPENDIX A: Implants Supported by the ROSA Hip System (cont.)

Hip Implant System (Stem Brand)	Stem Type	Broach/Stem Size	Neck Type	Head Length
Avenir Complete®	Collared	0	Standard Offset High Offset	-3.5 0
		1	Standard Offset High Offset Coxa Vara	+3.5
		2		+7
		3		+10.5
		4		
		5		
		6		
		6.5		
		7		
		7.5		
	8			
	8.5			
	9			
	Collarless	0	Standard Offset High Offset	
		1	Standard Offset High Offset Coxa Vara	
		2		
		3		
		4		
		5		
		6		
6.5				
7				
7.5				
8				
8.5				
9				

APPENDIX A: Implants Supported by the ROSA Hip System (cont.)

Hip Implant System (Stem Brand)	Stem Type	Broach/Stem Size	Neck Type	Head Length
Avenir®	Cementless	1	Standard Offset Lateral Offset	-3.5 0 +3.5 +7 +10.5
		2		
		3		
		4		
		5		
		6		
		7		
		8		
		9		
	Cemented	1	Standard Offset Lateral Offset	
		2		
		3		
		4		
		5		
		6		
		7		
		8		
		9		

The following table contains the acetabular component types from G7® and associated available sizes.

Shell Type	Shell Size
PPS® Limited Hole	42A
	44A
	46B
	48C
	50D
	52E
	54F
	56F
	58G
	60G
	62H
	64H
	66I
	68I

APPENDIX A: Implants Supported by the ROSA Hip System (cont.)

Shell Type	Shell Size
PPS Finned Limited Hole	42A
	44A
	46B
	48C
	50D
	52E
	54F
	56F
	58G
	60G
	62H
	64H
	66I
68I	
OsseoTi® Limited Hole	42A
	44A
	46B
	48C
	50D
	52E
	54F
	56F
	58G
	60G
	62H
	64H
	66I
68I	

APPENDIX A: Implants Supported by the ROSA Hip System (cont.)

Shell Type	Shell Size
OsseoTi® Multi Hole	42A
	44A
	46B
	48C
	50D
	52E
	54F
	56F
	58G
	60G
	62H
	64H
	66I
	68I
	70I
	72I
	74J
76J	
78J	
80J	

The following table summarizes the liner types available in the ROSA Hip application.

Liner Types
Neutral
High Wall
+5 mm
10° Face Changing
Dual Mobility

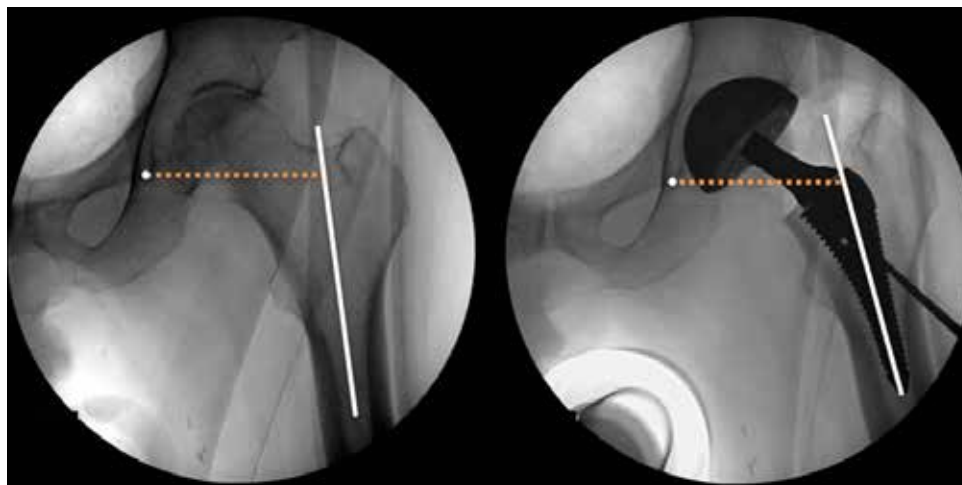
For the complete list of liner types compatible with the ROSA Hip System, contact your Zimmer Biomet sales representative.

APPENDIX B: Leg Length and Offset Measurements Method

The Leg Length is measured as the perpendicular distance from the trochanter apex to the medio-lateral axis aligned on the teardrop point. Leg Length change is calculated as the difference between the Leg Length measured on the Trial or Final Validation image and the Leg Length measured on the AP Hip reference image.

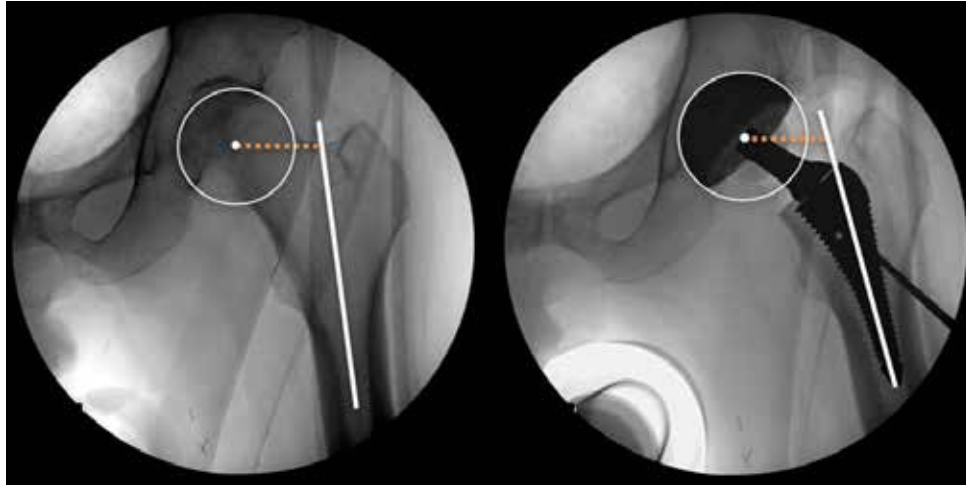


The Global Offset is measured as the distance from the teardrop point to the intersection point on the femoral axis. Global Offset change is calculated as the difference between the Global Offset measured on the Trial or Final Validation image and the Global Offset measured on the AP Hip reference image.



APPENDIX B: Leg Length and Offset Measurements Method (cont.)

The Femoral Offset is measured as the distance from the femoral head center point to the intersection with the femoral axis. Femoral Offset change is calculated as the difference between the Femoral Offset measured on the Trial or Final Validation image and the Femoral Offset measured on the AP Hip image corrected for leg abduction/adduction.



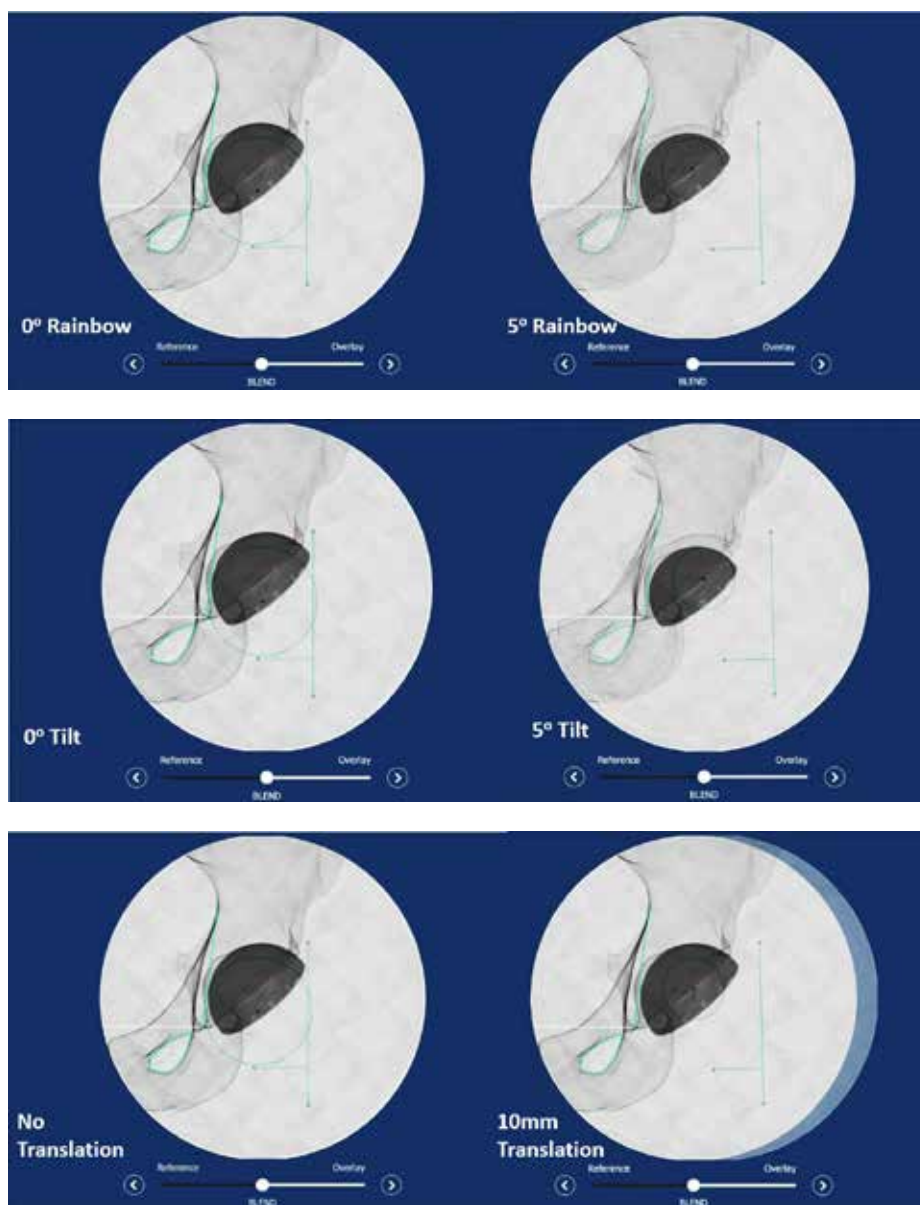
APPENDIX C: Image Acquisition, Landmarking and Overlay Guidelines

This section provides insight on considerations to take into account when acquiring fluoroscopic images, positioning landmarks and verifying image registration overlays to ensure optimal system performance. These guidelines should be followed for all image acquisitions throughout the workflow when applicable.

Fluoroscopic Image Field Of View (FOV)

The C-arm Field Of View (FOV) for hip images should be consistent throughout the procedure in order to ensure best image registration accuracy. Changes in the FOV from one hip image to the next increases the amount of processing required to register images in a common coordinate system. This additional processing can increase the margin of error of the system's radiographic measurement results. Therefore, a consistent FOV should be maintained for all hip images throughout the workflow by ensuring that images show the same Regions of Interest (ROI), centered on the same point, with the same projection view.

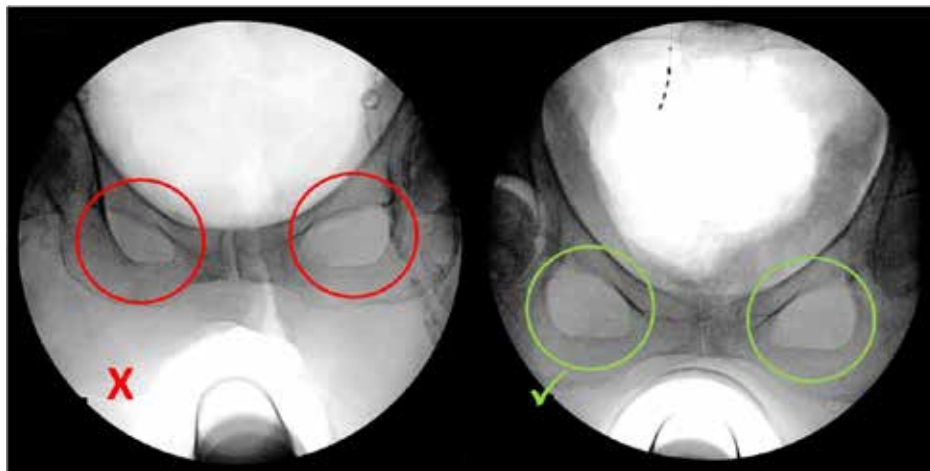
Furthermore, the rainbow and tilt discrepancy of the C-arm should be limited to a maximum of $\pm 5^\circ$ between the AP Hip reference image and any subsequent image. As for the translation of the C-arm, it should be limited to a maximum of $\pm 10\text{mm}$ between the AP Hip reference image and any subsequent image. (Translation can be observed in the overlay feature where the contour of the circles or squircles are not aligned. See example below).



APPENDIX C: Image Acquisition, Landmarking and Overlay Guidelines (cont.)

Pelvis Neutral Position

For the reference image acquisition, the pelvis should be placed in a neutral position. The pelvis neutrality is deemed acceptable when the obturator foramen are symmetrical.



APPENDIX C: Image Acquisition, Landmarking and Overlay Guidelines (cont.)

Landmarking Consistency

It is critical that landmark placement is consistent and reproducible between each image during the procedure. The landmarks are the reference points used by the system to register different images together and compute measurements in the TRIAL and VALIDATION panel. Discrepancies between respective landmark positions from one image to another will induce errors and lead to inaccurate radiographic measurements by the system.

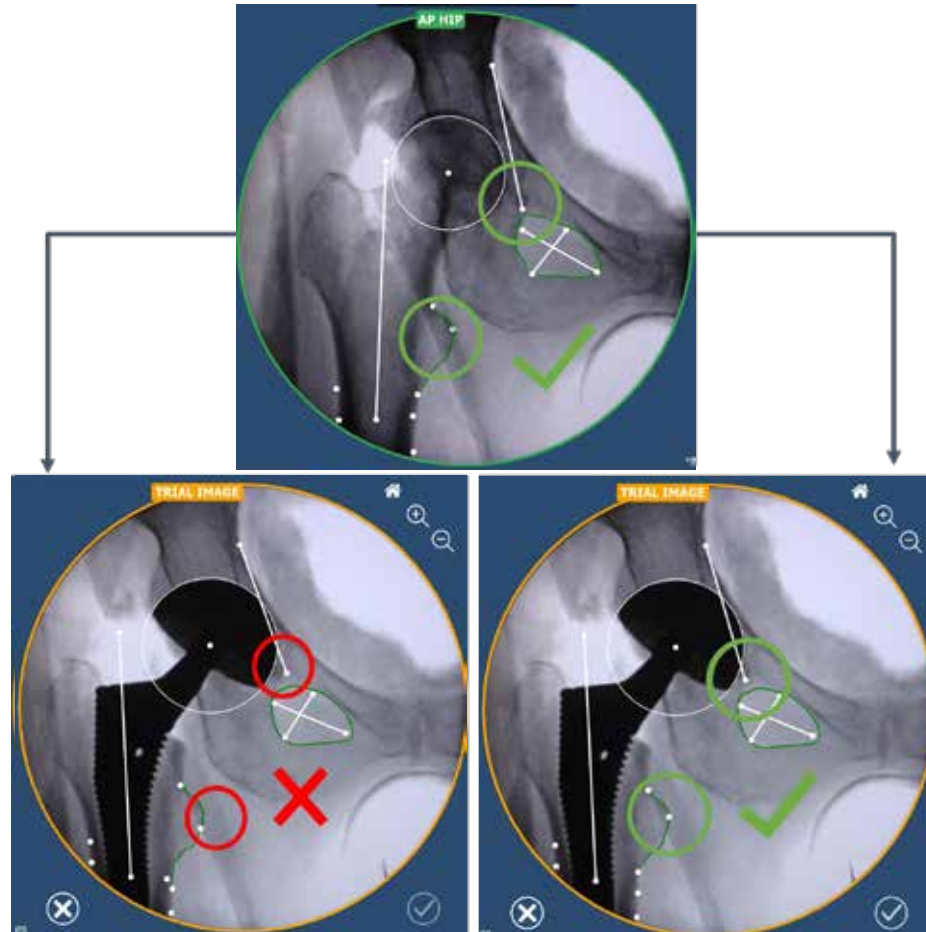


Image Registration Overlay Accuracy

Image registration accuracy is evaluated using the registration Overlay Tool immediately after acquiring and processing the landmarks of each image. If the registration overlay is visually unsatisfactory, close the registration Overlay Tool and discard the current image. If necessary, adjust the C-arm position. Then, acquire a new image and reposition the landmarks. The AP Hip image on the left of the screen should be used as a reference to position landmarks and match the field of view. Details on how to assess image registration quality are presented in the sections below.

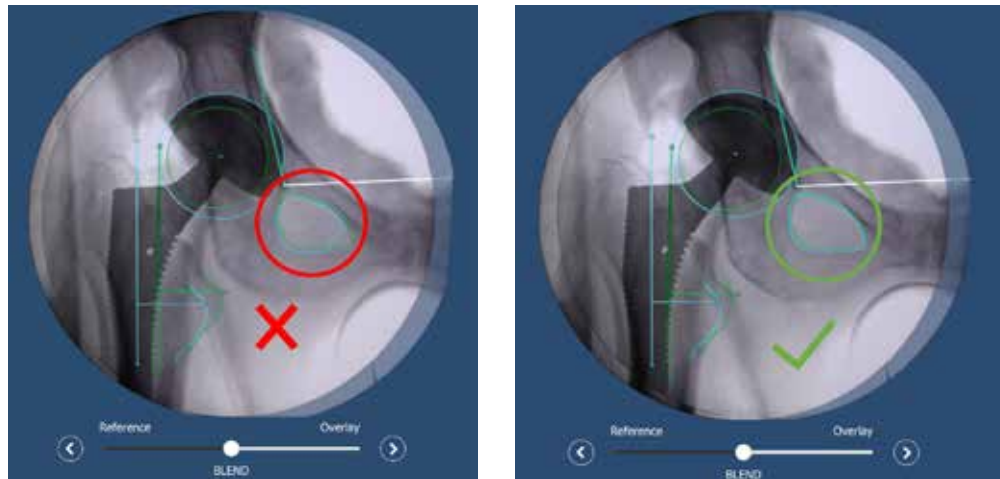
Obturator Foramen Landmarking

The obturator foramen outline is used throughout the workflow for the image registration process. This obturator foramen outline is generated by the system based on the major and minor axis landmarks. It is important to confirm that the obturator foramen outline generated by the application is accurate and consistent throughout the workflow to ensure accurate image registrations. This verification can be done using the registration Overlay Tool. Inconsistent obturator foramen outlines between images can induce errors in the registration, which can lead to incorrect scaling or rotation of images. Any noticeable discrepancy between the current image obturator foramen outline and the AP Hip obturator foramen outline will induce errors in the image registration and, therefore, negatively affect system radiographic measurements. Incorrect scaling of the image registrations can be prevented by verifying that the obturator foramen outlines during landmarking are consistent in size and shape.

APPENDIX C: Image Acquisition, Landmarking and Overlay Guidelines (cont.)

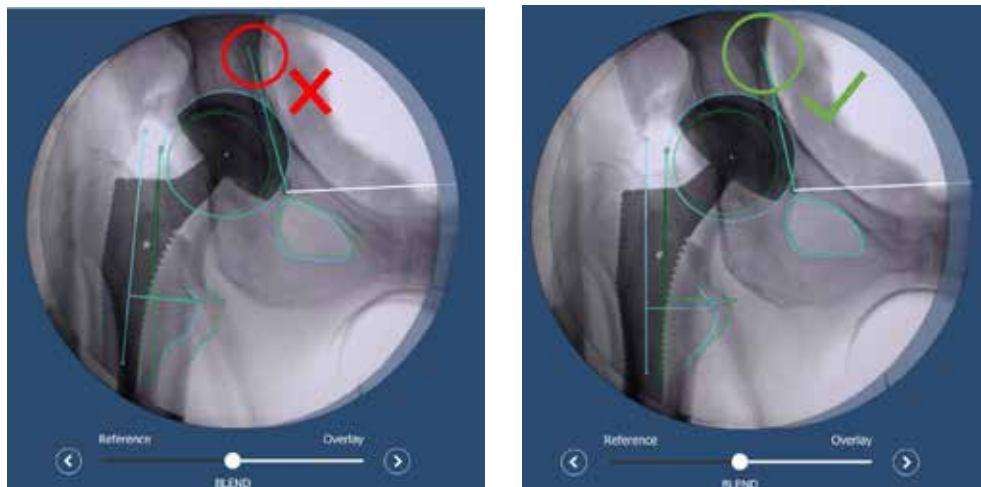
The obturator foramen outline can be modified by moving one of the obturator foramen landmarks of the major or minor axis. The obturator foramen outline will be updated instantly when one of these markers is moved.

If the obturator foramen outline shape is inconsistent when compared to the obturator foramen outline in the AP Hip reference image, it may be the result of a significant change in patient's orientation relative to the C-arm. Adjustments of the C-arm to match the AP Hip reference image obturator foramen outline may be required. Alternatively, if possible, the patient (or operating table) can be slightly repositioned to match the AP Hip reference image obturator foramen outline.



Brim Line

The brim line position plays an important role in the registration process as it helps to determine the relative rotation of the images in reference to the AP Hip reference image. Variations in the brim line orientation can lead to inaccurate image registration rotations, leading to inaccurate radiographic measurements. When placing the teardrop and brim line landmarks, ensure that the brim line orientation is consistent throughout the images of the procedure. The registration Overlay Tool should be used to ensure brim lines are placed as identically as possible throughout the images of the workflow.



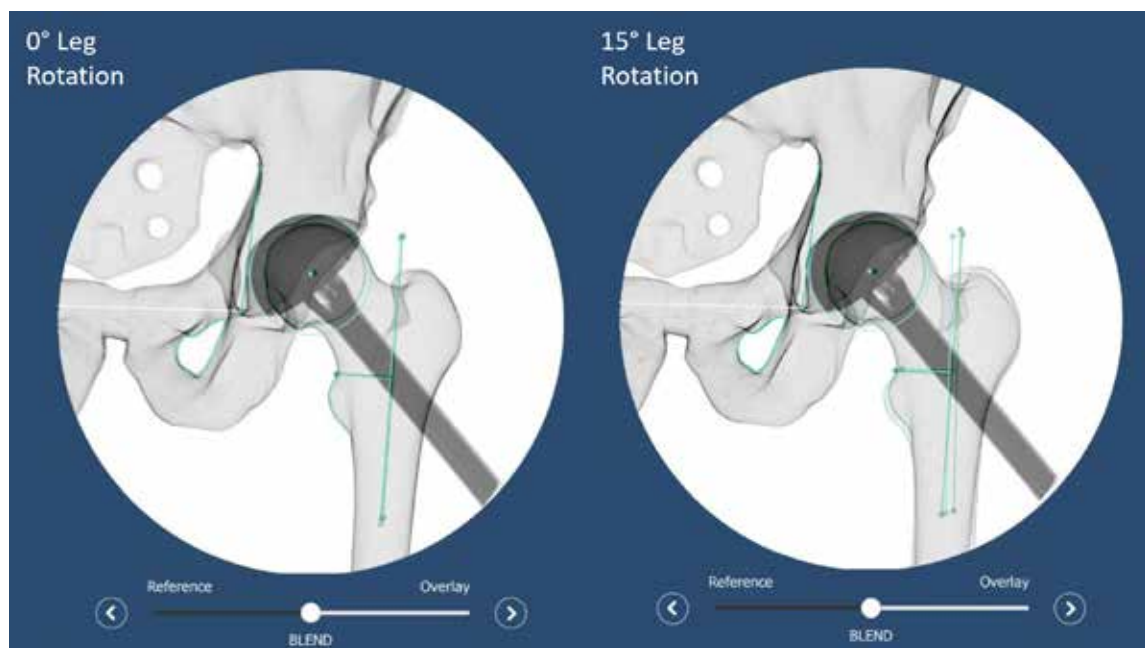
APPENDIX C: Image Acquisition, Landmarking and Overlay Guidelines (cont.)

Leg Abduction/Adduction

The femoral head landmarks are used by the system to generate a circle that approximates the femoral head projection. The center of this circle is used by the system for femoral offset computation, but also as the rotation point to compensate for leg abduction/adduction in comparison to the Trial/Final image leg position. This correction is performed to realign the AP Hip femoral axis with the trial and final hip femoral axis to allow for leg length and offset change measurements. Therefore, it is critical that the generated circle, which approximates the femoral head, is positioned accurately to allow the system to correctly compute the femoral axis rotation around the femoral head center. If the femoral head center is not positioned accurately, image corrections may be inaccurate and may lead to inaccurate measurements. Depending on the patient's hip condition, it may be difficult to identify the femoral head perimeter. In such cases, the femoral head landmarks should be positioned to approximate the femoral head center of rotation.

Leg Rotation

The AP Hip image leg rotation should be replicated in the Trial and Final image acquisitions to ensure system measurement accuracy. The system's registration algorithm does not compensate for changes in internal/external rotation of the leg. Any discrepancy between the leg rotation in the AP Hip reference image and Trial/Final image, Trial or Final can lead to inaccurate radiographic measurements of the Global and Femoral offsets values.



To ensure proper matching of the leg rotation, the leg should be repositioned as closely as possible to match its original rotation in the AP Hip reference image. To this end, the lesser and greater trochanter projections in the AP Hip reference image should be used as a reference to match the trial or final image leg rotation.

If the leg is not repositioned to match the AP Hip reference image, it could affect system measurement results.

The leg rotation differences between the AP Hip reference image and the Trial/Final image should not be more than $\pm 15^\circ$.

Please visit [ZimmerBiomet.com/ROSAHip](https://www.zimmerbiomet.com/ROSAHip) for additional information.

Zimmer Biomet does not practice medicine. This technique was developed in conjunction with health care professionals. This document is intended for surgeons and is not intended for laypersons. Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training surgeons have received.

As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as the best treatment for each patient. Results will vary based on health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure. Caution: Federal (USA) law restricts this device to sale by or on the order of a surgeon. Rx only.

All content herein is protected by copyright, trademarks and other intellectual property rights, as applicable, owned by or licensed to Zimmer Biomet or its affiliates unless otherwise indicated, and must not be redistributed, duplicated or disclosed, in whole or in part, without the express written consent of Zimmer Biomet.

This material is intended for health care professionals. Distribution to any other recipient is prohibited.

For indications, contraindications, warnings, precautions, potential adverse effects and patient counseling information, see the package insert or contact your local representative; visit www.zimmerbiomet.com for additional product information.

Check for country product clearance and reference product specific instructions for use. Not for distribution in France.

©2022, 2023 Zimmer Biomet



Legal Manufacturer

Zimmer CAS
75 Queen Street, Suite 3300
Montreal (QC)
H3C 2N6, Canada
+1 514 396 5422
1 866 3D ORTHO

[zimmerbiomet.com](https://www.zimmerbiomet.com)