

PRECICE® EXTERNAL REMOTE CONTROL (ERC) 3P



Training Overview

Here's what will be covered:

- Objectives
- ERC 3P Buttons and Symbols
- ERC 3P Warnings
- Operating Room Use
- Programming the Prescription
- Reviewing Patient History
- Settings
- Patient Use
- Troubleshooting
- Technical Information
- ERC 3P Collateral



Objectives for Training

- Capable of explaining the features and benefits of the ERC 3P
- Become an expert in programming/navigating the ERC 3P in the following modes:
 - Operating room use
 - Patient use at home
 - Reviewing patient history
 - Settings and troubleshooting



ERC 3P WARNINGS

ERC 3P Warnings

WARNINGS



WARNING: DO NOT HAVE AN MRI PERFORMED. Avoid all places labeled as having a strong magnetic field. PRECICE implant is unsafe in Magnetic Resonance Imaging (MRI) environments.

You may see a written warning or the “magnet” symbol similar to the one below. The implant has not been tested for safety or compatibility in the MRI environment. An MRI environment may damage your implant.



Avoid areas with this symbol.



WARNING: REMOVE METAL ITEMS from your clothing, body and within 1 foot of you while using ERC. Metal items to be removed include: jewelry, knives, keys, credit cards, cell phones, tablets, computers, metal household items, electronic devices, etc. Non-magnetic zippers and buttons on clothing and shoes are ok.

Metal objects could be pulled very quickly to the magnets in the ERC and may injure you.

Credit cards, cell phones, or electronic devices that are within one foot of the ERC might get damaged.

If a metal object becomes attached to the ERC, shut off the ERC and remove the attached metal item.

ERC 3P Warnings (continued)



WARNING: Always follow the prescription and instructions from your doctor when using the ERC. If you do not follow your prescription, your bone could heal improperly or not at all.

- If you use the ERC less often than your doctor prescribes, your bone might harden too early. It will also stop getting longer before it has reached its target length. If this happens, you may need another surgery to make your bone the right length.
- If you use the ERC more than your doctor prescribes, you could lengthen the bone too quickly. This causes your bone to heal improperly or not at all. If this happens, you may need another surgery to treat the bone that will not heal.



WARNING: Make sure you always put the ERC on the skin right over the implanted device and in the correct direction. Placing the ERC in the wrong location on your leg could result in the bone not lengthening correctly. Your bone could harden too early if it is not lengthening correctly. You may need another surgery to make your bone the right length.



WARNING: Do not place the ERC on any open sore on your skin. The ERC may not be clean and you could get an infection. You may need medical intervention or surgery to treat an infection. An open sore is any cut on your skin.

ERC 3P Warnings (continued)



WARNING: Discuss any pain or discomfort you are having with your doctor. This treatment may cause some pain and discomfort. This could be a normal part of your treatment or a symptom of other issues. Your doctor may want to adjust your prescription during your treatment if you are experiencing pain or discomfort.



WARNING: DO NOT USE THE ERC ON OR BY PEOPLE WITH ACTIVE IMPLANTED DEVICES.

Persons with a pacemaker or a similar active implant should not handle or be exposed to the ERC. The strong magnetic fields can affect the operation of such devices.

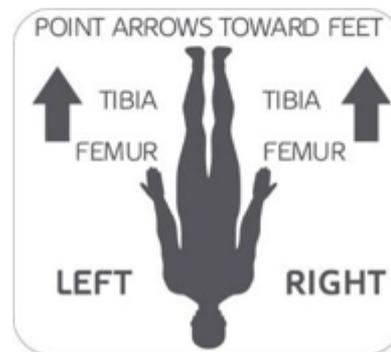


WARNING: If the ERC fails or stops running, move the ERC off of your leg. Disconnect the plug from the wall outlet. If you do not move the ERC, the motor may continue to run, and the implant may get too long. This could result in the need for another surgery.

ERC 3P Warnings (continued)

! **WARNING:** Do not attempt to open or repair the ERC. The ERC does not have any parts that you can service or adjust. You could damage the ERC or injure yourself. If you fail to follow this warning, you can electrocute or shock yourself. Also, it is recommended that you inspect the ERC upon first receipt for loose components. If there are loose components, cracks or exposed wires, contact your doctor for a replacement ERC.

! **WARNING:** Align the ERC toward the patient's feet as in the picture below. The Display screen should be facing you so it can be read. If the ERC is pointing in the wrong direction, the PRECICE device will not lengthen properly and may result in the need for another surgery. This figure shows the correct direction to point the ERC.



ERC 3P Warnings (continued)

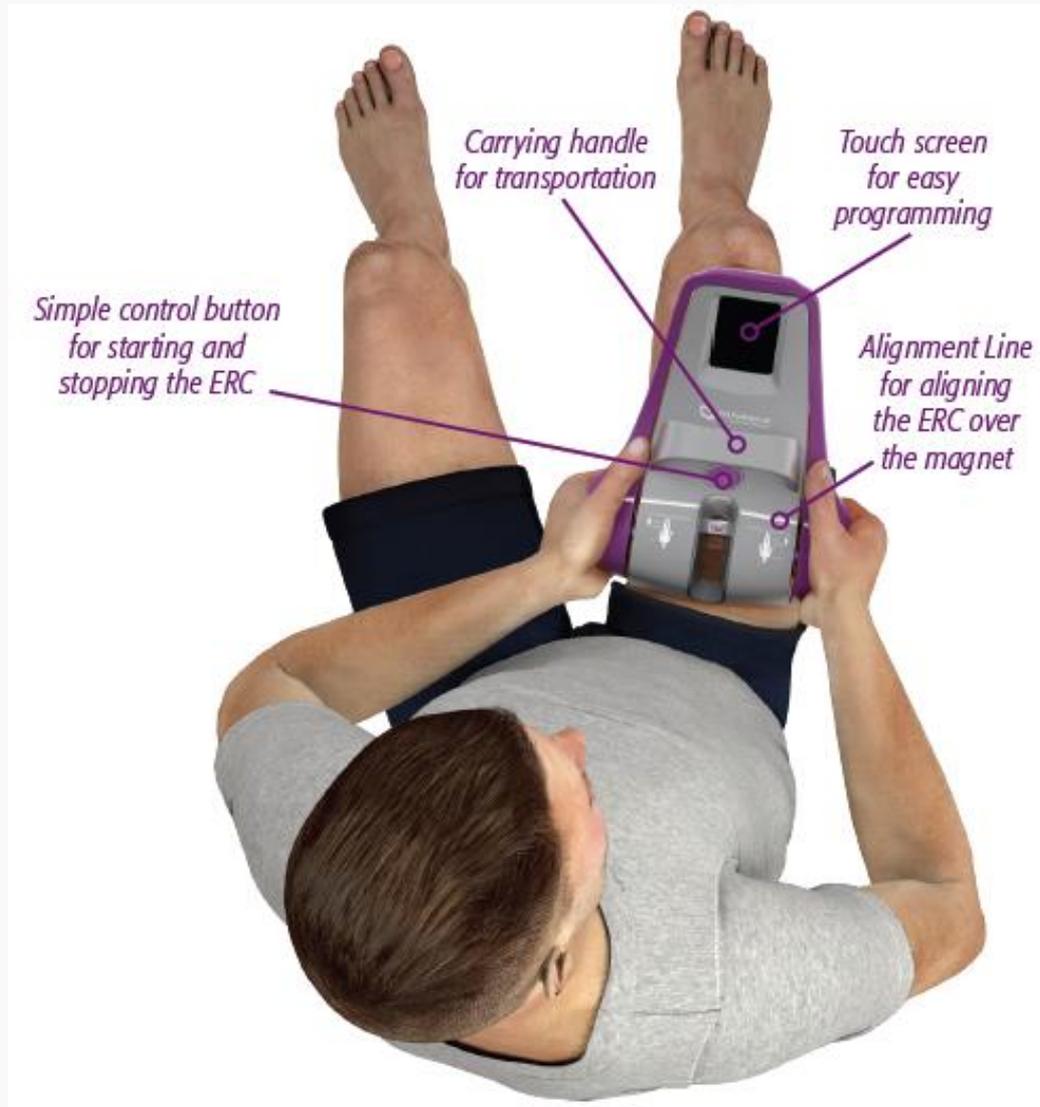
 **WARNING:** Before you use the ERC, make sure you receive training from your doctor or nurse. Improper use of the ERC could cause your bone to harden too soon or not at all. This could result in the need for another surgery.

 **WARNING:** Follow the instructions your doctor gives to you about how much weight to put on your leg during your treatment. If you put more weight on your leg than your doctor recommends, the device could be damaged or break. This could result in the need for another surgery.

 **WARNING:** Do not leave the ERC unattended around children. The ERC is not intended to be used by anyone under the age of 18. Use of this device by anyone under the age of 18 may result in improper use, which may result in the need for another surgery.

For a full list of precautions, please refer to the Operator's Manual

Meet the ERC 3P



Illuminated viewing window



Contoured bottom that hugs the limb



Ergonomically friendly tibia handle

Meet the ERC 3P



NEW FEATURES

MAGNET DETECTION:

Assisting the user with more accurate alignment over the implant.

IMPLANT STALL DETECTION:

Alerting the user if the implant magnet is not rotating and cannot lengthen the implant.

ERC 3P BUTTONS AND SYMBOLS

ERC 3P Buttons and Symbols

	Continue Key: This is a touch screen key that provides a method to advance to the next screen or software state when it is displayed and pressed by the user.
	Go Back key: This is a touch screen key that provides a method to go back to a previous screen or software state when it is displayed and pressed by the user.
	Reset Value Key: When displayed, this touch screen key next to a value displayed allows the user to reset it when it is pressed.
	Clinical Key: This touchscreen key provides a method for a clinician to access software modes limited to non-patients. Accessing these modes requires a passcode.
	Control Button, Blinking Green: An external button is used by users to begin therapy, accept parameters entered, or advance to the software screen.
	Control Button, Solid Red: An external button is used by users to stop therapy at any time.
	Alignment Line: This line symbol labeled on the ERC 3P identifies the center of the ERC 3P magnet lengths. It can be used as method to align ERC magnets to implant magnets based on the lines or sutures located on the patient's limb.
	Alignment Area: This symbol is located within the Alignment Window over the center bar. It is used to identify that the location where the implant magnet must align with the ERC within the Alignment Window.

ERC 3P Buttons and Symbols (continued)

		IMPLANT STATUS ICONS	
1	→		One of the IMPLANT STATUS icons will be displayed when the following happens: the SENSOR ON feature is selected and the therapy session is in progress. The IMPLANT STATUS icons will be seen in the In-Progress, Uncoupled, or Stall screen.
2	→		1 UNCOUPLED: This icon means that the ERC has not sensed a magnet spinning during the session.
3	→		2 COUPLED: This icon means that the ERC has sensed a magnet is spinning during the session.
			3 STALL: This icon indicates that the ERC is not lengthening properly.

ERC 3P Buttons and Symbols (continued)

	<p>Initialization Button: This touchscreen button is displayed in Operating Room Mode when the unit is idle. Pressing it allows the user to begin the Initialization process for the ERC 3P at a time when it's convenient.</p>
	<p>Initialization Marker: Located on the Progress Bar in Operating Room Mode, they are used to indicate a point when therapy will be paused for required initialization. Green markers to the far right of the progress bar indicate that no initialization is required during the session.</p>

OPERATING ROOM

COMPLETED:
 0.00 mm

GOAL: 1.00 mm 

LENGTHEN  SENSOR ON 

 FEMUR | 8.5 | ANTE

OPERATING ROOM USE

Easy Operating Room Use!

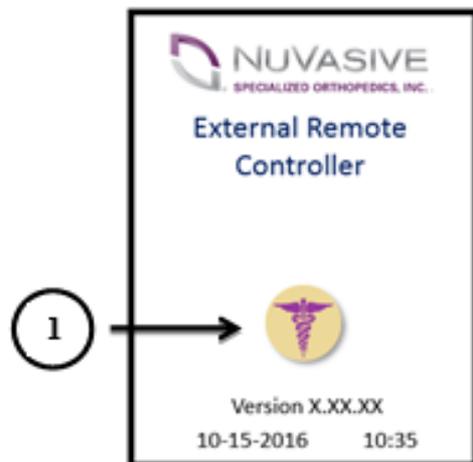
The ERC 3P is quick and simple to use in the operating room...

- 1) Turn on the ERC 3P and type in the physician passcode
- 2) Choose “Operating Mode” from menu
- 3) Select Femur or Tibia
- 4) Select Nail Size
- 5) Select Approach
- 6) Press the Controller Button when it is **Green!**



**Note: if the magnet detection feature is on, initialization will need to be performed before the lengthening session begins.*

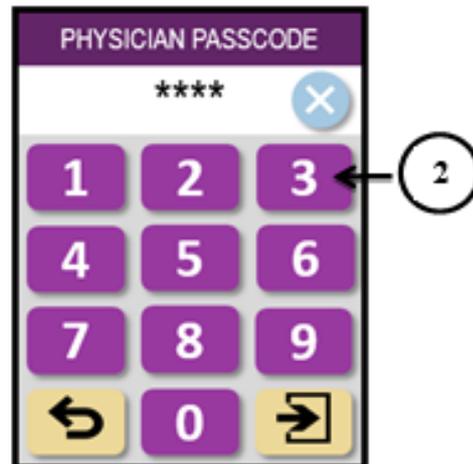
Operating Room Mode Entry



SPLASH SCREEN WITH CLINICAL BUTTON

When the ERC 3P is plugged in, the control panel will light up and the software will display the Splash Screen.

- 1 Press the **Clinical Button** to begin using ERC 3P clinically.

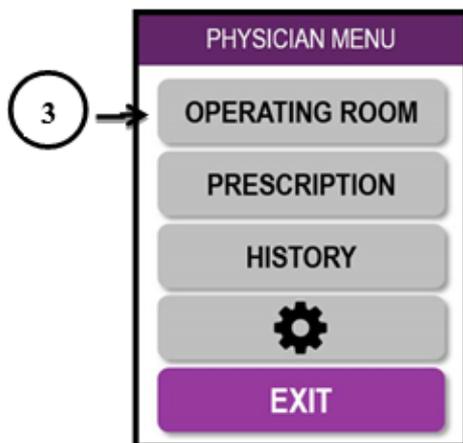


PHYSICIAN PASSCODE SCREEN

The physician will then enter in the passcode to gain clinical access to the unit. The passcode will always be "333".

- 2 Enter the passcode "333" and press the continue key

Operating Room Mode Entry (continued)

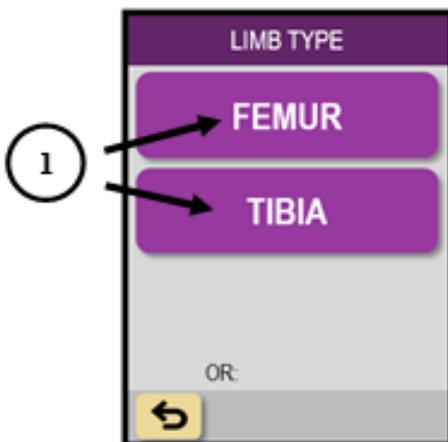


PHYSICIAN MENU SCREEN

After the correct physician passcode has been entered, the physician is given a menu of options.

- 3 Press the "OPERATING ROOM" key

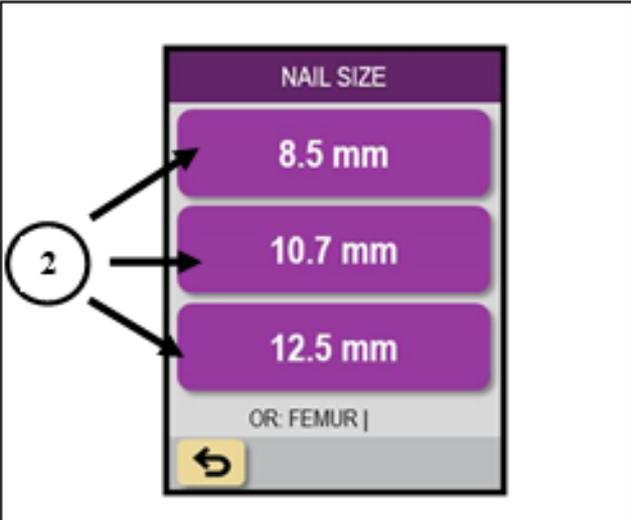
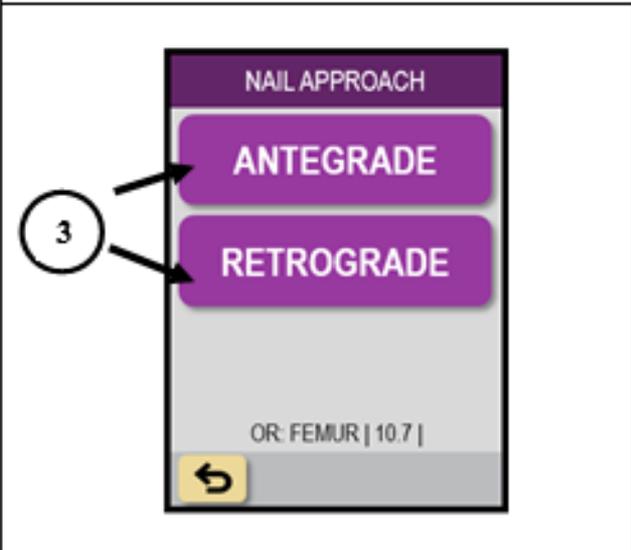
Implant Selection



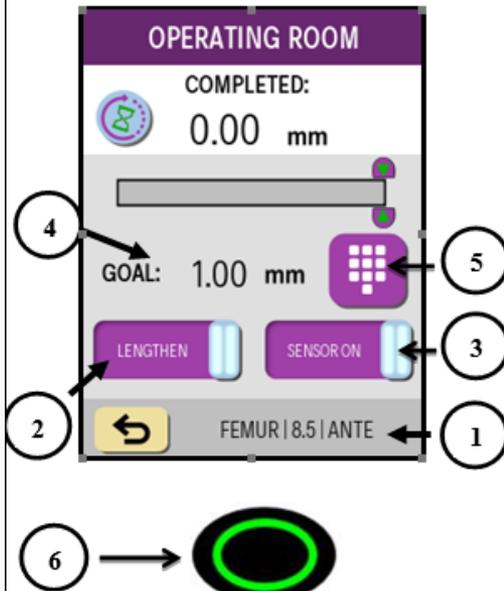
LIMB TYPE SCREEN

After selecting OPERATING ROOM option, the ERC 3P needs to know information about the implant being used.

- 1 Select either the **FEMUR** or **TIBIA** option depending on what limb the implant is used for.

	<p style="text-align: center;">NAIL SIZE SCREEN</p> <p>2 Select either 8.5 NAIL, 10.7 NAIL, or 12.5 NAIL depending on the size of the implant used.</p>
	<p style="text-align: center;">NAIL APPROACH SCREEN</p> <p>3 Select ANTEGRADE or RETROGRADE depending on the approach that was used to install the implant.</p>

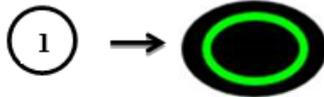
Operating Room Mode Set Up



OPERATING ROOM MODE SCREEN

- 1 IMPLANT SELECTED STRING:** This indicates the selection that was made for the implant that therapy will be provided. Press the **GO BACK** key if this information is incorrect.
- 2 LENGTHEN/SHORTEN KEY:** Lengthen will distract the implant and Shorten will retract the implant. Pressing this key will switch between these two options.
- 3 SENSOR ON/OFF KEY:** Sensor On enables the detection feedback technology for the implant magnet. Sensor Off disables this technology. Pressing this key will switch between these two options.
- 4 GOAL (TARGET) LENGTH:** The length displayed indicates when the ERC 3P will automatically stop when the implant length has achieved this value during therapy.
- 5 ADJUST GOAL LENGTH KEY:** Press this key if the desired target length needs to be different than what is displayed. This will prompt a keypad to be displayed
- 6** Press the **blinking green GO** button on the ERC 3P to begin initialization for therapy.

Initialization (Only if "Sensor On" is selected)



INITIALIZATION SET UP SCREEN

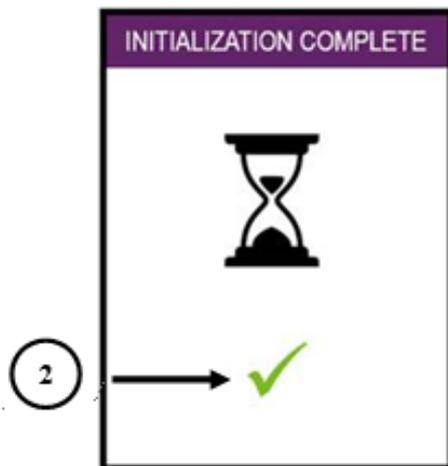
After pressing the **blinking green GO** button to begin therapy and if the SENSOR ON is selected, the ERC 3P should be placed into its storage case. This will ensure that there are no metal objects around it during the initialization process

- 1 Once the ERC 3P has been placed into its storage case, press the **blinking green GO** button again to begin initialization.

INITIALIZATION IN-PROGRESS/COMPLETE SCREEN

Once initialization has begun, the ERC 3P will display this screen during initialization.

- 2 If initialization has successfully completed, this icon will be displayed.



The ERC 3P is now ready for operating room use!

PROGRAMMING THE PRESCRIPTION

Easy Prescription Entry!

The software will guide the user effortlessly through prescription programming...

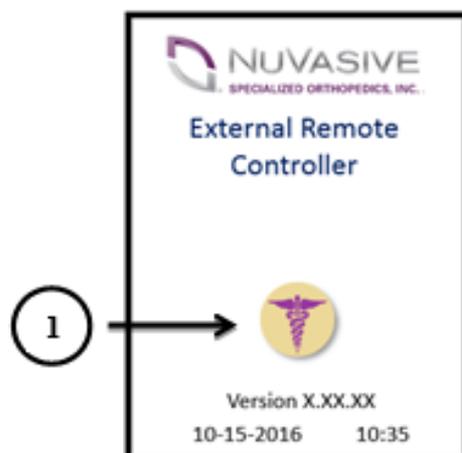
- 1) Turn on the ERC 3P and type in the physician passcode
- 2) Choose the “Prescription” from the menu
- 3) Select prescription 1 (or 2 if bi-lateral)
- 4) Input prescription information
- 5) Review and confirm the prescription

The prescription has been entered!



How to Program Prescriptions into an ERC

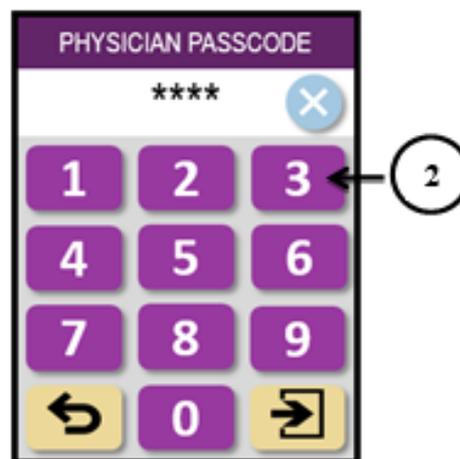
Prescription Programming Entry



SPLASH SCREEN WITH CLINICAL BUTTON

When the ERC 3P is plugged in, the control panel will light up and the software will display the Splash Screen.

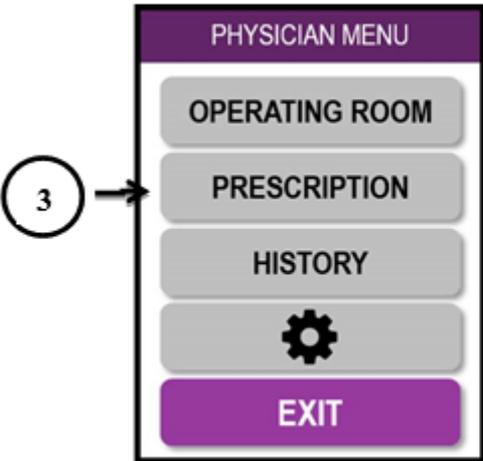
- 1 Press the **Clinical Button** to begin using ERC 3P clinically.

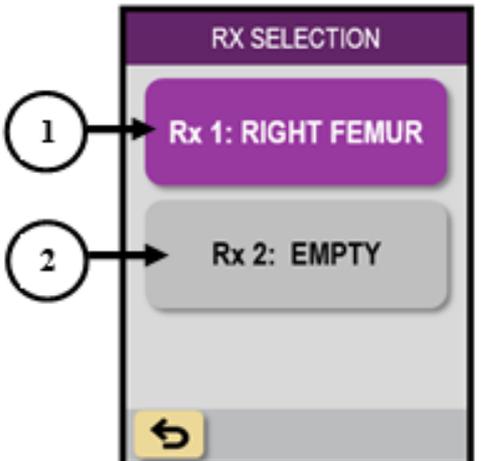


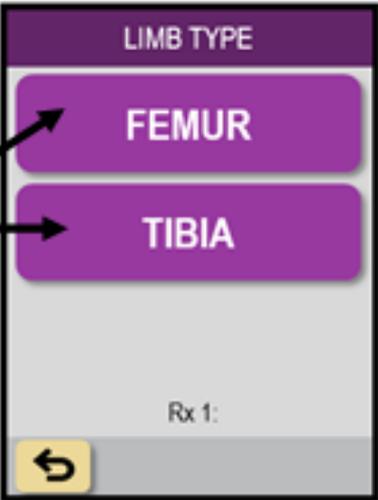
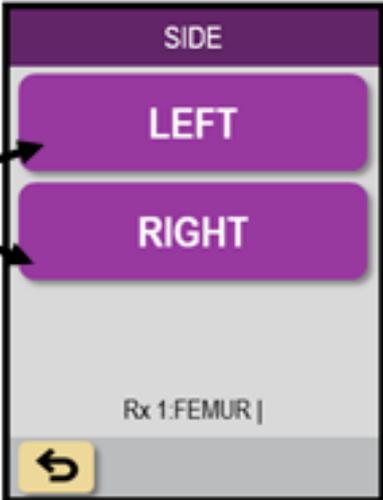
PHYSICIAN PASSCODE SCREEN

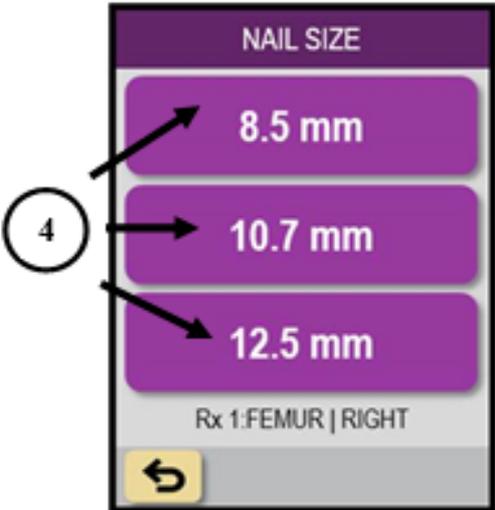
The physician will then enter in the passcode to gain clinical access to the unit. The passcode will always be "333".

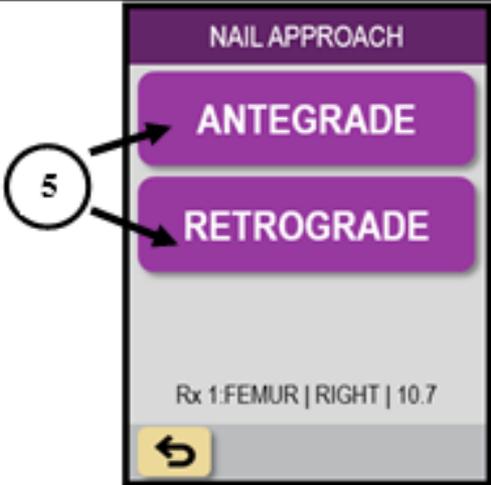
- 2 Enter the passcode "333" and press the continue key

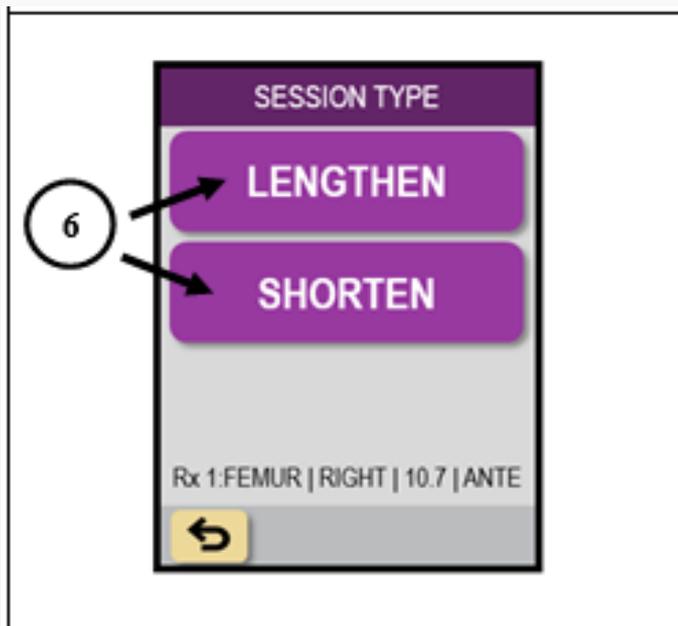
 <p>The image shows a vertical menu titled "PHYSICIAN MENU". It contains five buttons: "OPERATING ROOM", "PRESCRIPTION", "HISTORY", a gear icon, and "EXIT". The "EXIT" button is highlighted in purple. A circled number "3" with an arrow points to the "PRESCRIPTION" button.</p>	<h3>PHYSICIAN MENU SCREEN</h3> <p>After the correct physician passcode has been entered, the physician is given a menu of options.</p> <p>3 Press the "PRESCRIPTION" key</p>
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Prescription Programming	
 <p>The image shows a screen titled "RX SELECTION". It has two main buttons: "Rx 1: RIGHT FEMUR" (highlighted in purple) and "Rx 2: EMPTY". At the bottom left, there is a yellow button with a left-pointing arrow. A circled number "1" with an arrow points to "Rx 1: RIGHT FEMUR", and a circled number "2" with an arrow points to "Rx 2: EMPTY".</p>	<h3>PRESCRIPTION SELECTION SCREEN</h3> <p>After selecting PRESCRIPTION option, the ERC 3P appropriate prescription can be selected.</p> <p>1 FIRST PRESCRIPTION: Select Rx 1 to create or change the first prescription for therapy.</p> <p>2 SECOND PRESCRIPTION: Select Rx 2 to create or change the second prescription for therapy. This option cannot be selected if a first prescription has not been created.</p>

	<p>LIMB TYPE SCREEN</p> <p>2 Select either FEMUR or TIBIA option depending on the implant.</p>
	<p>LIMB SIDE SCREEN</p> <p>3 Select LEFT or RIGHT depending on which side of the patient the implant was installed.</p>

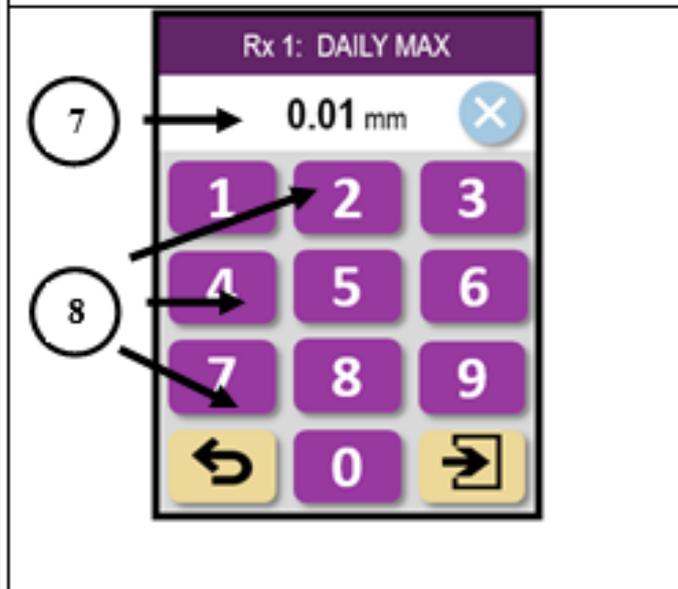
	<h3>NAIL SIZE SCREEN</h3> <p>4 Select either 8.5 NAIL, 10.7 NAIL, or 12.5 NAIL depending on the size of the implant.</p>
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	<h3>NAIL APPROACH SCREEN</h3> <p>5 Select ANTEGRADE or RETROGRADE depending on the approach that was used to install the implant.</p>
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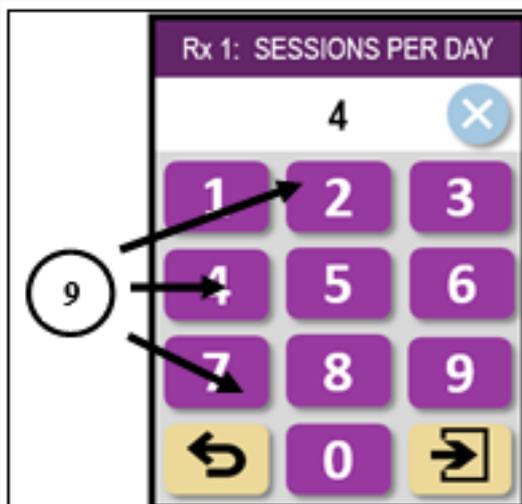
SESSION TYPE SCREEN

- 6 Select **LENGTHEN** or **SHORTEN** depending on the type of therapy that is required.



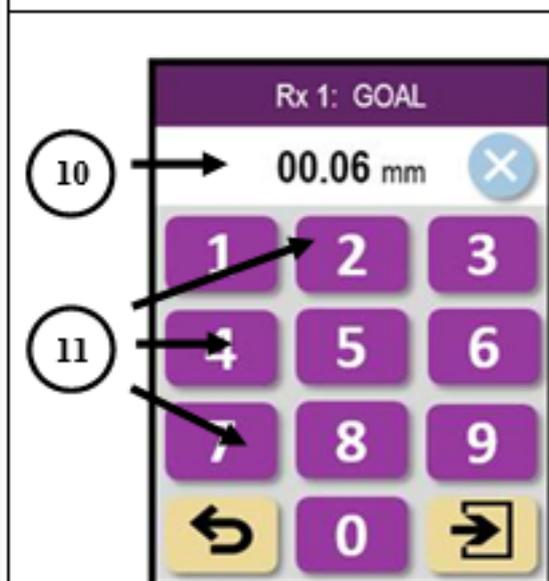
DAILY MAXIMUM SCREEN

- 7 This value displayed indicates the prescribed daily maximum length of adjustment for the implant.
- 8 Enter daily max value desired in mm into keypad. Numbers will move from right to the left. Press **CONTINUE**.



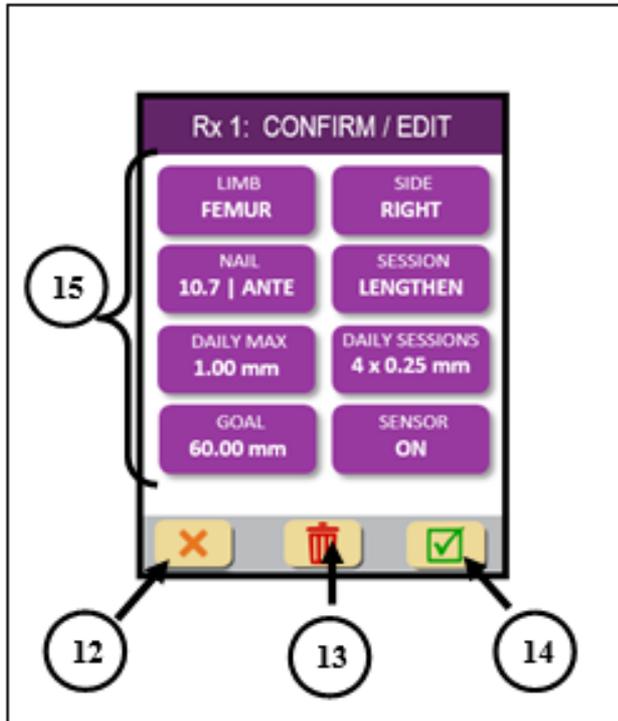
DAILY SESSIONS SCREEN

- 9 Using the keypad, enter the prescribed number of sessions per day. Press **CONTINUE**.



PRESCRIPTION GOAL SCREEN

- 10 This value displayed indicates the overall therapy length for the prescription of the implant.
- 11 Enter the therapy goal value desired in mm into keypad. Numbers will move from right to the left. Press **CONTINUE**.



PRESCRIPTION CONFIRMATION SCREEN

Once the prescription has been entered, the prescription must be confirmed before it is saved.

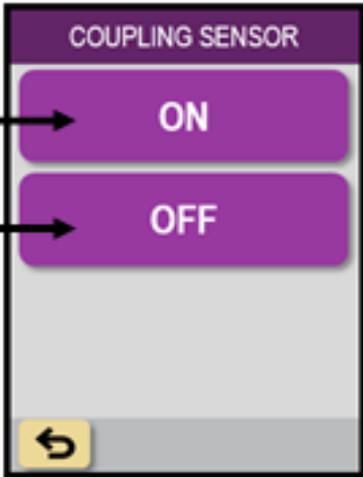
- 12 **CANCEL:** Press this key to cancel prescription being programmed.
- 13 **DELETE:** Press this key to delete the prescription and exit Prescription Programming.
- 14 **ACCEPT:** Press this key to accept the prescription.
- 15 **CHANGE:** Press any parameter key to make specific changes to the parameter.



PRESCRIPTION SAVED SCREEN

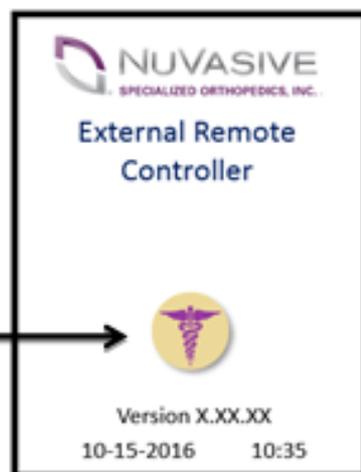
After the ACCEPT key is pressed. This screen will appear when the prescription has been successfully saved.

The prescription entered into the ERC 3P has now been saved!

 <p>DELETE Rx 1?</p> <p>ARE YOU SURE YOU WANT TO DELETE Rx 1: RIGHT FEMUR?</p> <p>16 → YES</p> <p>17 → NO</p>	<h3>PREScription DELETION SCREEN</h3> <p>After the DELETE key is pressed. This screen will appear to confirm the deletion of the prescription.</p> <p>16 YES: Press this key to continue to delete the prescription.</p> <p>17 NO: Press this key to go back to the Prescription Confirmation screen.</p>
 <p>COUPLING SENSOR</p> <p>18 → ON</p> <p>19 → OFF</p> <p>←</p>	<h3>PREScription COUPLING SENSOR SCREEN</h3> <p>While in the Prescription Confirmation Screen, if the Sensor parameter key is pressed, this screen will appear.</p> <p>18 ON: Press this key to turn the detection sensors on during patient use.</p> <p>19 OFF: Press this key to turn the detection sensors off during patient use.</p>

REVIEWING PATIENT HISTORY

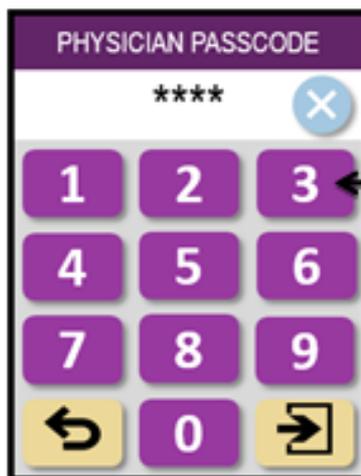
Patient Use History Review Entry



SPLASH SCREEN WITH CLINICAL BUTTON

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- 1 Press the **Clinical Button** to begin using ERC 3P clinically.



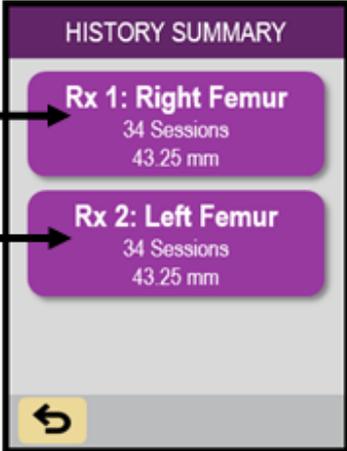
PHYSICIAN PASSCODE SCREEN

The physician will then enter in the passcode to gain clinical access to the unit. The passcode will always be "333".

- 2 Enter the passcode "333" and press the continue key

 <p>The image shows a vertical menu titled "PHYSICIAN MENU". It contains five buttons: "OPERATING ROOM", "PRESCRIPTION", "HISTORY", a gear icon, and "EXIT". The "EXIT" button is highlighted in purple. A circled number "3" with an arrow points to the "HISTORY" button.</p>	<h3>PHYSICIAN MENU SCREEN</h3> <p>After the correct physician passcode has been entered, the physician is given a menu of options.</p> <p>3 Press the "HISTORY" key</p>
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History Summary and Selection

 <p>The image shows a screen titled "HISTORY SUMMARY". It displays two prescription entries: "Rx 1: Right Femur" and "Rx 2: Left Femur". Each entry shows "34 Sessions" and "43.25 mm". A circled number "1" with an arrow points to the "Rx 1" entry, and a circled number "2" with an arrow points to the "Rx 2" entry. A back arrow icon is visible at the bottom left.</p>	<h3>HISTORY SUMMARY SCREEN</h3> <p>After selecting HISTORY option, a summary of patient use history is displayed for each prescription. (Note: Small font numbers represent total number of sessions completed and total length completed)</p> <p>1 Select this key to view history details of Prescription 1.</p> <p>2 Select this key to view history details of Prescription 2.</p>
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DATE	TIME	+/- mm	TOTAL mm
10-03-2016	18:25	+0.25	56.50
10-02-2016	11:32	+0.25	56.25
10-02-2016	18:25	+0.25	56.00
10-01-2016	10:42	+0.25	55.75
10-01-2016	17:05	+0.25	55.50
09-30-2016	9:22	+0.25	55.25

DETAILED HISTORY SCREEN

Each session performed by the patient will be listed for the prescription selected.

3 **SCROLL UP:** Pressing this key will view more recent entries.

4 **SCROLL DOWN:** Pressing this key will view less recent entries.

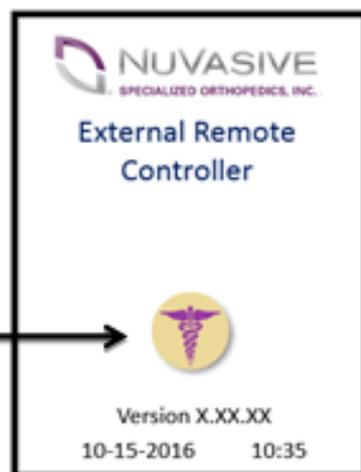
5 **RETURN:** Pressing this key will go back to the History Summary screen.

Key:

- Red: lengthening stopped due to stall
- Yellow: lengthening stopped due to uncoupling

SETTINGS

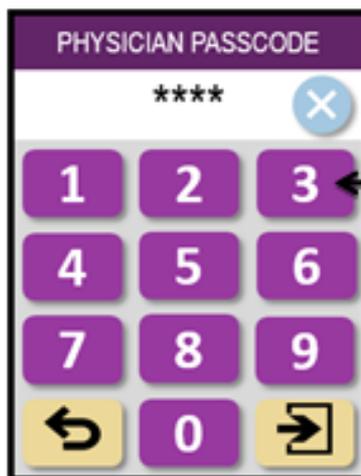
Patient Use History Review Entry



SPLASH SCREEN WITH CLINICAL BUTTON

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- 1 Press the **Clinical Button** to begin using ERC 3P clinically.



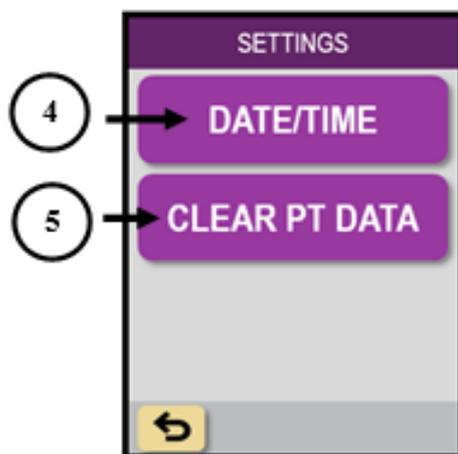
PHYSICIAN PASSCODE SCREEN

The physician will then enter in the passcode to gain clinical access to the unit. The passcode will always be "333".

- 2 Enter the passcode "333" and press the continue key

 <p>The diagram shows a vertical menu titled "PHYSICIAN MENU" with a purple header. Below the header are five buttons: "OPERATING ROOM", "PRESCRIPTION", "HISTORY", "SETTINGS" (represented by a gear icon), and "EXIT" (represented by a purple button). A circled number "3" with an arrow points to the "SETTINGS" button.</p>	<h3>PHYSICIAN MENU SCREEN</h3> <p>After the correct physician passcode has been entered, the physician is given a menu of options.</p> <p>3 Press the "SETTINGS" key</p>
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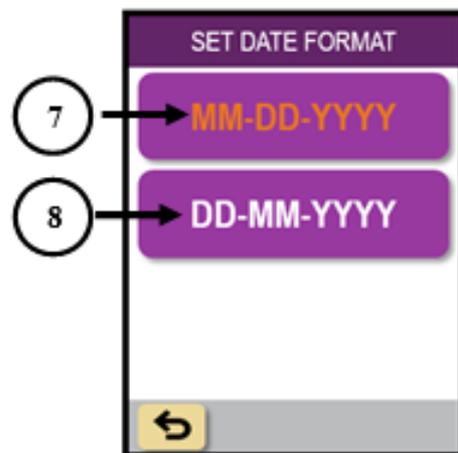
Settings Options: Date/Time



SETTINGS MENU SCREEN

After selecting SETTINGS option, a menu of options to change ERC 3P settings is available.

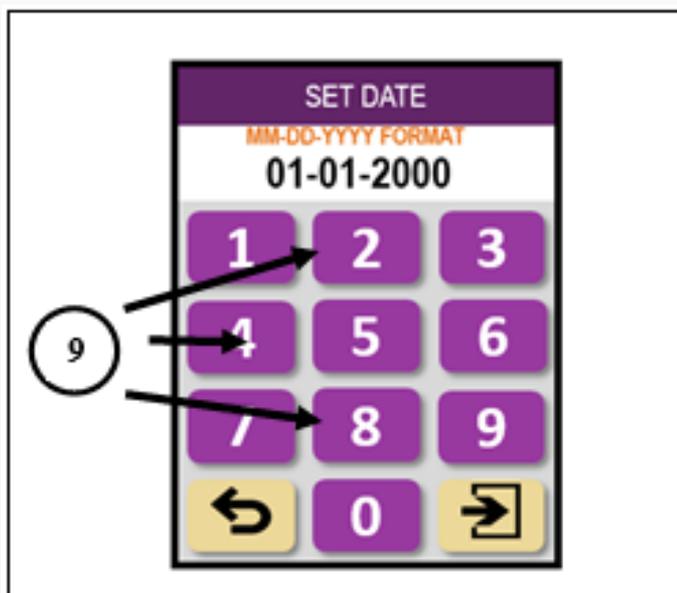
- 4 **DATE/TIME:** Press this key to change the date, date format, or time.
- 5 **CLEAR PATIENT DATA:** Press this key to clear all patient data from the ERC 3P.



SET DATE FORMAT SCREEN

If the Date/Time option is selected from the Settings Menu screen, the date format is reviewed. Selected format is highlighted in red.

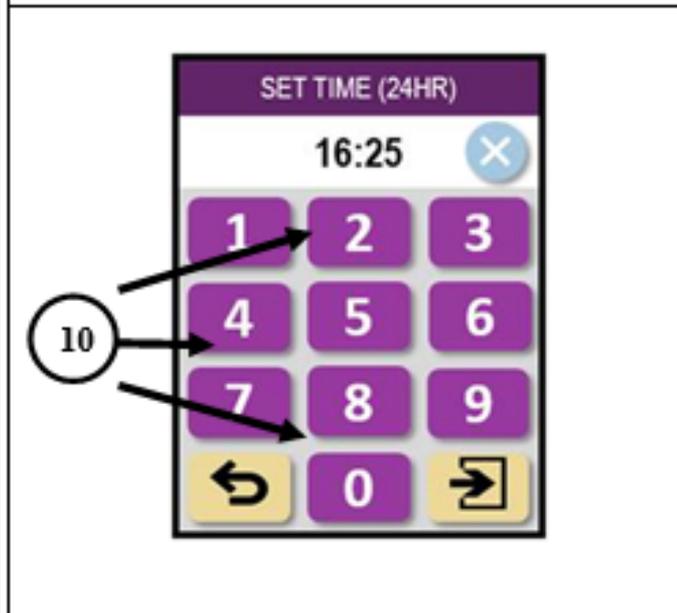
- 7 **MM-DD-YYYY:** Press this key to highlight the format that will be used to display and log the date.
- 8 **DD-MM-YYYY:** Press this key to highlight the format that will be used to display and log the date.



SET DATE SCREEN

9

Using the keypad, enter the date that is to be changed in the format identified. Use two digits for the day and month and four digits for the year. The values entered will move from right to left with each key press. Press **CONTINUE**.

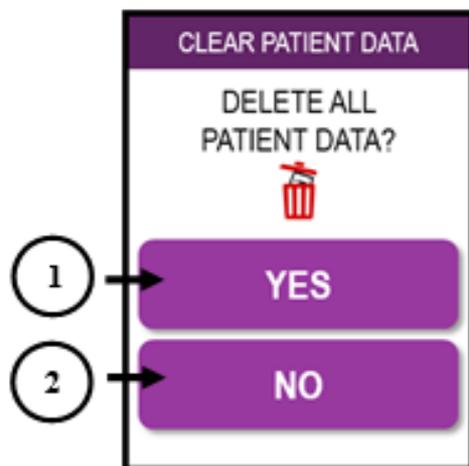


SET TIME SCREEN

10

Using the keypad, enter the time that is to be changed in the 24 hour format. The values entered will move from right to left with each key press. Press **CONTINUE** to go back to the Settings Menu screen.

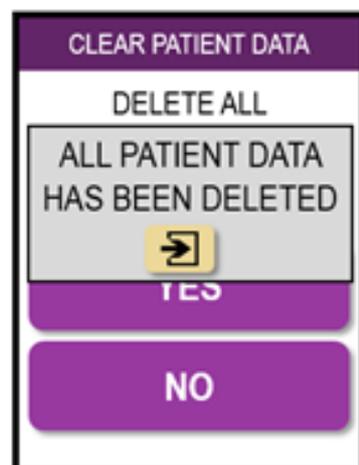
Settings Options: Clear Patient Data



CLEAR PATIENT DATA SCREEN

If the Clear Patient Data option is selected from the Settings Menu screen, the ERC 3P requests confirmation that all patient data will be deleted.

- 1 **YES:** Press this key to delete all patient data from the ERC 3P.
- 2 **NO:** Press this key to go back to the Settings Menu screen.



DELETED PATIENT DATA CONFIRMED SCREEN

If the Patient Data has been confirmed to be deleted, a pop up will occur to indicate the data has been deleted. Press **CONTINUE** to go back to the Physician Menu screen.

PATIENT USE

Easy for the Patient to Use!

The ERC 3P is extremely easy for the patient to navigate...

- 1) Turn on the ERC 3P
- 2) Review the summary screen
- 3) Align the ERC of the magnet in the implant
- 4) Press the **Green Go** button!

**Note: if the magnet detection feature is on, initialization will need to be performed before the lengthening session begins.*



Choose the location where you will be doing the treatment.



- Check that there is an electrical outlet close to the ERC.
- Make sure there are no electronic devices within one foot of the ERC. These electronic devices could get damaged.

Remove all loose metal from your treatment area.

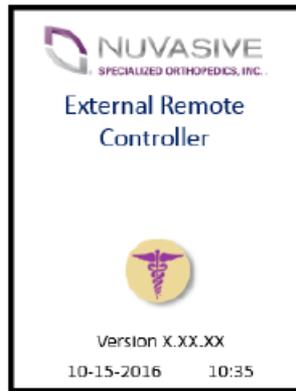


- Remove metal items from your clothing and body.
- Remove unattached metal items from the area (jewelry, knives, keys, etc.). Zippers and buttons on clothing and shoes are ok.
- Do not use the ERC within one foot of metal objects. Metal objects could be pulled very quickly to the magnets in the ERC and may injure you.

a) Navigating the ERC	
	This icon allows the physician access to screens for programming the ERC.
	This icon allows the user to navigate to the next screen. This icon also allows the user to start the lengthening session.
	This icon will stop the lengthening session.
	This icon will pause the lengthening session.
	This icon allows the user to navigate back to the last screen.
	This icon allows the user to navigate forward to the next screen.
	This icon indicates that the user should reference the instruction manual for further information.

b) Step 1: Keep the ERC in its storage case. Plug the ERC into the wall outlet.	
	<ol style="list-style-type: none"> 1. Plug power cord into power supply. 2. Plug power cord into a wall outlet.

c) Step 2: Welcome Screen and Initialization.



WELCOME SCREEN

When plugged in, the ERC powers on. The display will light up and the welcome screen will display for a few seconds. You do not need to press anything on this screen.



INITIALIZATION SET UP SCREEN

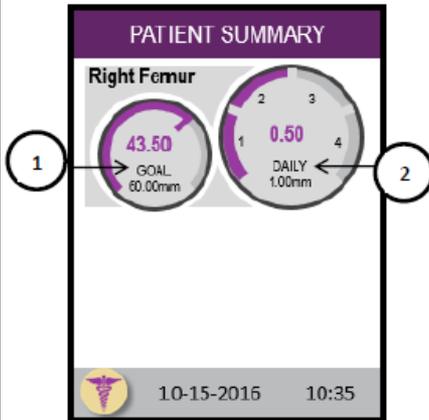
1. Keep ERC in storage case.
2. Ensure all metal items are **removed** from you and within 1 foot of you. This includes jewelry, knives, keys, credit cards, cell phones, tablets, computers, metal household items, electronic devices, etc. Non-magnetic zippers and buttons on clothing and shoes are ok.
3. Press the **blinking green GO** button to begin initialization. Initialization will take a few seconds.

(Note: This Initialization screen will only appear if your physician has turned the coupling sensor on.)



d) **Step 3: Review Patient Summary.**

This section explains the screens you will see on the control panel before starting your lengthening session. The patient summary screen below represents one prescription.

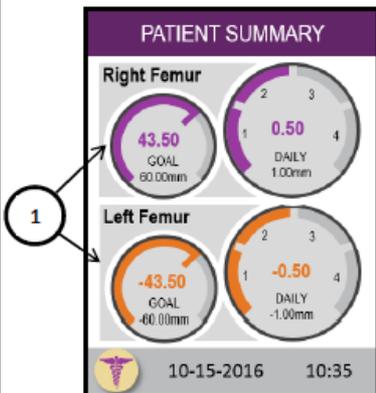


PATIENT SUMMARY SCREEN

After initialization, the patient summary screen will be shown.

- 1 "Goal" is the total amount your physician has prescribed for lengthening (i.e. 60 mm). The number in purple (i.e. 43.50 mm) is the total amount you have lengthened so far.
- 2 "Daily" is the amount your physician has prescribed for daily lengthening (i.e. 1.00 mm). The number in purple (i.e. 0.50 mm) is the amount you have lengthened that day.

After reviewing this information, press the **GREEN** button on the ERC to **GO** to the next screen. If this information is not correct, contact your doctor.

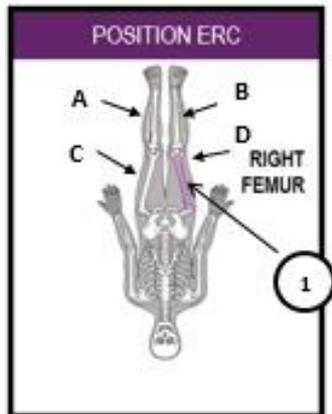


PATIENT SUMMARY SCREEN

- 1 The ERC allows two prescriptions to be entered to lengthen if you have two implants. If your physician has entered two prescriptions, a summary of each prescription will appear here before starting your lengthening session. Solid filled segments are completed sessions, and flashing segment bar identifies current session to be completed.

After reviewing this information, press the **GREEN** button on the ERC to **GO** to the next screen. If this information is not correct, contact your doctor.

e) Step 4: Aligning the ERC with the Implant Magnet.



IMPLANT LOCATION SCREEN

There are four options for the PRECICE device location:

- (A) Left Tibia, (B) Right Tibia
- (C) Left Femur, (D) Right Femur

- 1 Your implant location will be displayed. The limb to be lengthened will be highlighted in purple. In this example screen, the "Right Femur" is highlighted.

Press the **green GO** button on the ERC to align the ERC.



Right Femur Example



ERC ALIGNMENT

1. Point ERC towards feet as indicated on display.
3. Use locating window and target symbol to center ERC over implant and mark on your leg.
4. Also align with white lines on side of purple handles and base of ERC.
5. Press **green GO** button to start session.
6. Session is now started.

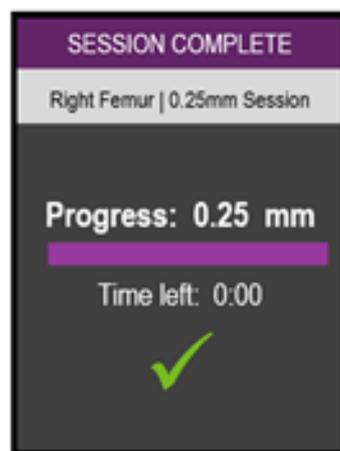
The patient's session has now started!

f) Step 5: Starting and completing your session.



The ERC is now running and your lengthening session has started.

- 1 Progress Bar: This will fill as the device lengthens to monitor your progress. When the bar is 100% full, the device has lengthened to the prescribed amount and will stop running.
- 2 Distance counter: This number will increase as the device lengthens. It will stop at the prescribed length for that session.
- 3 Time left: the amount of time left until the session is complete.
- 4 Coupling icon: this icon lets you know that the ERC is coupled with the implant.

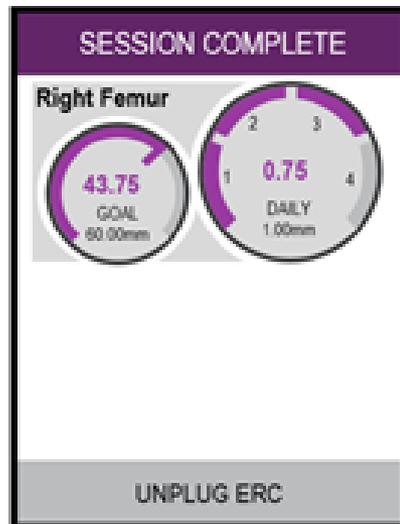


Session Complete!

After the prescribed length for the session has been achieved, the ERC will automatically stop.

You cannot adjust the length of the implant more than the daily prescription.

Press the **green GO** button to finish your session.



If you have not finished your daily lengthening, the **Session Complete** screen will appear. It will appear with a summary of your session.

Unplug your ERC.

Place the ERC and power cord in the storage case and store in a safe place not accessible by children.



The **Goal Complete** screen will appear. It appears if you have achieved the total length prescribed by your physician (i.e. 60.00mm).

Unplug your ERC.

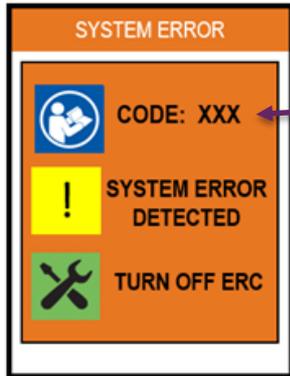
Place the ERC and power cord in the storage case. Store the case in a safe place where children cannot reach it.

Return the ERC to NuVasive Specialized Orthopedics, Inc.

The patient's session and/or goal is now complete!

TROUBLESHOOTING

ERC 3P Error Codes:



The Error Screen appears if there is a malfunction with the ERC 3P. This screen will contain instruction for the patient user to contact their physician's office to get further instructions.

A numeric value will appear beside the item labeled "CODE." The user will need to make note of the numeric error code when contacting appropriate representative for technical assistance.

Do not attempt to use a malfunctioning unit.

Contact your appropriate representative and let them know the Error Code Number. They will give you further instructions and send you a replacement ERC 3P if necessary.

- If a system error occurs, the user will see this screen.
- Error codes will have a reference number which instructs the users how to troubleshoot.
- Reference the ERC 3P Operators Manual for a complete list of all error codes.
- For questions regarding the prescription, contact the physician. For questions regarding the ERC, contact NuVasive Specialized Orthopedics™, Inc. at 949-837-3600.

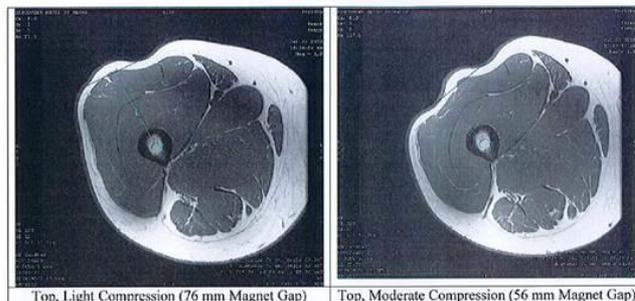
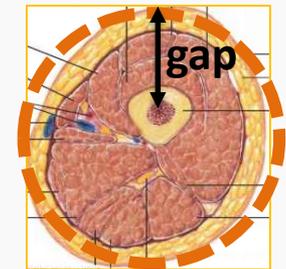
Note: additional error codes can be found in the manual.

TECHNICAL INFORMATION

ERC 3P Gap Distances

“Gap”: surface of the treated limb to the intramedullary canal

		ERC 3P*	
		Nail Size	Sensing Range
FEMUR	12.5	84mm - 30mm	
	10.7	59mm - 30mm	
	8.5	45mm - 20mm	
TIBIA	12.5	15mm - 10mm	
	10.7	15mm - 08mm	
	8.5	13mm - 06mm	



The gap distance for the ERC 3P is equal to or greater than the gap distances for ERC 1 and ERC 2P.

*Minimum distance is in effect when Coupling Sensor is active.

Cleaning and Maintenance

- To clean the external surfaces of the ERC 3P, wipe with 70% isopropyl alcohol or Lysol® disinfectant wipes. Do not submerge any component of the ERC 3P in liquid.
- In between patients, wipe the ERC 3P with 70% isopropyl alcohol or Lysol® disinfectant wipes to disinfect the unit.

Description	Rating	Units
Displayed Travel Accuracy ¹	±10% + ±0.3	mm
Operating Temperature	10 – 40 (50 – 104)	°C (°F)
Operating Relative Humidity	30 - 75	%
Storage Temperature	-10 – 60 (14 – 140)	°C (°F)
Storage Relative Humidity	5 – 95 (Non Condensing)	%
Input Power Voltage (Single Phase)	100 – 240	VAC
Input Power Frequency	50 / 60	Hz
Input Power Current (Maximum)	2.3	A
Weight: ERC 3P	4 (9)	kg (lbs)
ERC 3P with Carrying Case	11 (24)	kg (lbs)
Maximum Continuous On Time	10	Minutes
On Time/Off Time	10 / 90	%



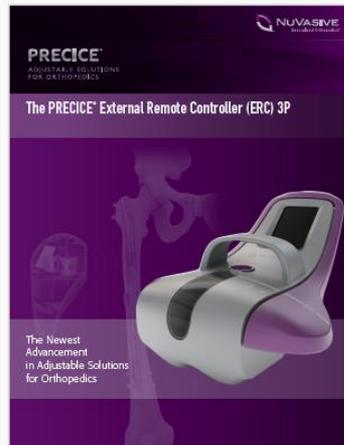
ERC 3P COLLATERAL

ERC 3P Collateral

The following collateral materials are available for use:



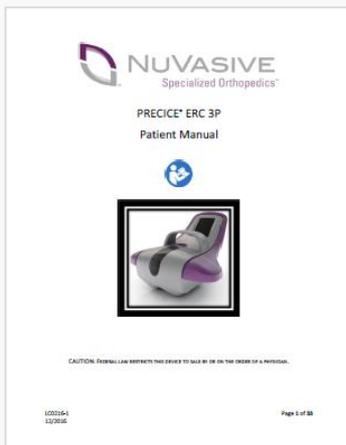
ERC 3P Quick Reference Guide



ERC 3P Informational Sell Sheet



ERC 3P Airlines Statement of Conformance



ERC 3P Patient Manual



ERC 3P Operator's Manual



THANK YOU!



For more information about this product, please contact your local sales representative.

101 Enterprise, Suite 100 | Aliso Viejo, CA 92656 Phone: 949-837-3600 | Fax: 949-837-3664



Medpace Medical Device B.V. Maastrichterlaan 127-129 - NL 6291 EN Vaals

Tel. +31.43.306.3320 | Fax: +31.43.306.3338

The implantable device is only to be used by a trained licensed physician. Weekly X-ray imaging to assess actual distraction length is recommended. Only use the ERC in a manner consistent with the Operator's Manual; any alternative use may result in injury or damage to the device. The ERC may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the ERC or shielding the location. Persons with a pacemaker or a similar medical aid should not handle or be exposed to the ERC. The strong magnetic fields may affect the operation of such devices. The ERC uses strong permanent magnets. Misuse of this device can cause serious personal injury. Make sure the work area is free of metal objects before use. This includes personal items such as jewelry, watches, keys, and cellular phones. Always return the ERC to its protective case when not in use. Only operate the device by holding onto both of the handles provided. The ERC may be pulled away from your hands if brought too close to other magnetic objects.

Always maintain a firm grip on the ERC and be very aware of other objects in your work area. If the device is damaged, beware that magnet shards from broken magnets are very sharp. Always handle broken magnets with thick protective gloves. Never place the ERC near electronic media or appliances. Do not open the unit; severe personal injury or damage to the device may result. Only use the supplied power cord or an equivalent hospital grade cord rated for 10 Amps minimum. Do not use this device in the presence of flammable anesthetics. If retraction of the implant is needed, never retract the implant more than the amount lengthened over the previous day. Failure to follow this warning may result in pulling biological material that may have adhered to the rod of the implant into the internal space of the actuator of the implant. The ERC should only be placed immediately over the area of the patient's body at the magnetic portion of the IMLL. Do not place the ERC near any other parts of the body, for example, portions of the body which may contain ferromagnetic material-containing implants. When the ERC is not being actively used on the patient, it should always be kept within its protective case. This device has not been tested for compatibility in Magnetic Resonance Imaging (MRI) environments and should not enter an MRI unit. Please refer to the PRECICE IMLL System instructions for use for complete Important Safety Information. Caution: Federal law restricts this device to sale by or on the order of a physician.

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