NUVASIVE
Specialized Orthopedics™

External Remote Controller ERC 4P

Patient Manual

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

To Physicians: Reference the PRECICE ERC Operator's Manual and PRECICE Instructions for Use for clinical set-up and information for healthcare practitioners. Provide a copy of this PRECICE ERC Patient Manual to each patient and review it with them before treatment. Make sure to
record the patient's prescription on the next page.

To Patients: Read this entire booklet before you use the PRECICE ERC. Refer to this booklet at any time during your treatment. You can also talk to your doctor about any questions you have.

GENERAL CONTACT INFO:

NUVASIVE
Specialized Orthopedics™

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1. MY PRESCRIPTION

Date	Implant Location	Distance Per Session *(example: 0.25mm)*	Sessions Per Day *(example: 4 times/day)*	Daily Total *(example: 1.00mm)*

Where to place the ERC during each session:

(Circle the general location – there will be a specific mark on your leg or arm)

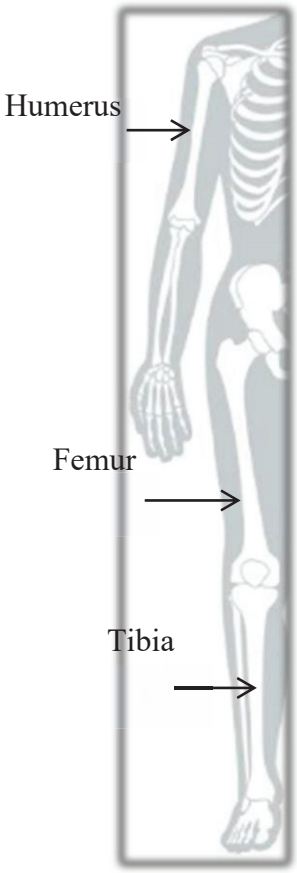
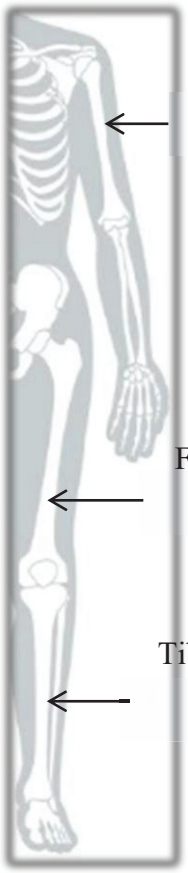
IMPLANT #1

- ☐ **Right Leg**
- ☐ **Left Leg**
- ☐ **Right Arm**
- ☐ **Left Arm**
- ☐ **Tibia**
- ☐ **Femur**
- ☐ **Humerus**

IMPLANT #2

- ☐ **Only One Implant**

- ☐ **Right Leg**
- ☐ **Left Leg**
- ☐ **Right Arm**
- ☐ **Left Arm**
- ☐ **Tibia**
- ☐ **Femur**
- ☐ **Humerus**

RIGHT SIDE	LEFT SIDE
	

Special Notes (*example*: always use crutches): _____

_____

Need help? Call:

My Provider: _____

Phone: _____

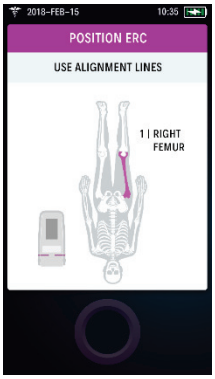
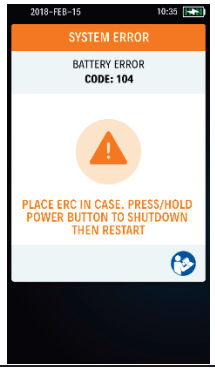
My Doctor: _____

Phone: _____

2. SYMBOLS DEFINITIONS

For Symbols Glossary, please refer to https://www.nuvasive.com/eifu/symbols-glossary
For Symbols specific to the ERC 4P reference the table below.

Symbol	Definition
IPX0	The device offers no special protection from fluid ingress.
	Go Back key(s): These are touch screen keys that provide a method to go back to a previous screen or software state when they are displayed and pressed by the user.
	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.
	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.
	Clinical Key (During Patient Mode): 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: A digital button on the touch screen display is used by users to begin therapy.
	Control Button, Solid Red: A digital button on the touch screen display is used by users to pause or stop therapy at any time.
	Alignment Line: This line symbol labeled on the ERC 4P identifies the center of the ERC 4P magnet length. It can be used as method to align the ERC magnet to the implant magnet based on the lines or sutures located on the patient's limb.

	ERC 4P Position Orientation with ARROWS: This symbol and labeling indicates the orientation of the ERC 4P relative to the patient. The patient should be able to view this symbol with arrows pointed toward their feet. LEFT indicates the left side of the unit is positioned to the left side of the patient. RIGHT indicates the right side of the unit is positioned to the right side of the patient.
	ERC 4P Position Orientation with ARROWS: This symbol and labeling indicates the orientation of the ERC 4P relative to the patient.
	Uncoupled Implant Detection: This symbol displayed indicates that the ERC 4P does not detect the implant magnet or its rotation.
	Coupled Implant Detection: This symbol displayed indicates the ERC 4P has detected the implant magnet and it is properly rotating.
	**Anatomic Instruction Screen** The patient's specific left or right side femur, tibia, or humerus will be highlighted on the screen to identify the exact limb with the PRECICE implant. There are six (6) possible locations for the implant, only one will be shown with a solid purple color.
	**System Error Screen** This screen will appear on the control panel when there has been an error with the operation of the ERC 4P. In this figure "CODE: 104" is given as an example. The screen may have a different code and information shown.

3. DEFINITIONS AND GLOSSARY

This section gives definitions to words that are used in this guide.

Active Medical Device: The term "active" means any medical device that needs a power supply. Power can be supplied by any means including electricity, battery, or gas. Examples of active devices include ventilators, pacemakers, and patient monitoring devices.

Actuator: The part of the PRECICE device that can change in length when activated.

Contraindication: Any condition that renders using the PRECICE system undesirable or inadvisable.

Coupling: Pairing of the ERC to the PRECICE device magnetically.

Distract: Distract means to extend or lengthen. The PRECICE system is used to distract or retract bones.

Retract: Retract means to shorten. The PRECICE system is used to distract or retract bones.

Electronic Device: This refers to any device that has a power cord that is plugged in for electrical power or is battery operated. Examples include computers and cell phones.

ERC: ERC refers to External Remote Controller. The ERC is used to adjust the PRECICE device that is in your leg or arm from outside of your body. The ERC system consists of the ERC and Charging Cord.

Femur: The femur is the thigh bone in the leg. It is the largest bone of the body and is situated between the hip and the knee.

Humerus: The humerus is the upper arm bone. This is the bone located between the shoulder and elbow joint.

Implant: An implant is a device that is inserted into the body for a period of time.

Intramedullary: Intramedullary refers to being inside the bone.

MRI: MRI refers to Magnetic Resonance Imaging, which is a medical technique to visualize structures inside the body.

Osteopenia: Osteopenia is a condition where the density of your bone is lower than normal.

Pacemaker: An artificial device for stimulating the heart muscle and regulating its contractions.

PRECICE Device: The PRECICE device is the adjustable implant that is implanted into your leg bone (tibia or femur) or arm bone (humerus). It is lengthened by the ERC from outside your body.

Regenerate: Regenerate refers to new growth. In this manual, it refers to new bone tissue growth.

Tibia: The tibia (or shinbone) is the large leg bone between the knee and ankle.

Troubleshooting: The process of solving problems or determining why something does not operate correctly.

4. INDICATIONS FOR USE: Why is PRECICE Used?

The NuVasive Specialized Orthopedics, Inc. (NSO) External Remote Controller, model ERC 4P, is a portable hand-held system used to non- invasively distract or retract the Precice Systems.

The Indications for Use of the ERC 4P when used with the Precice System (inclusive of Precice IMLL, Precice Unyte, Precice Stryde, and Precice Bone Transport) is indicated for limb-lengthening, open and closed fracture fixation, pseudarthrosis, mal-unions, non-unions or bone transport of long bones.

The Indications for Use of the ERC 4P when used with the Precice Plating System is indicated for limb lengthening, open and closed fracture fixation, pseudoarthrosis, mal-unions and non-unions of long bones in pediatrics and small stature adult patients.

The Indications for Use of the ERC 4P when used with the Precice Ankle Salvage System is intended for tibio-talo-calcaneal fusions. When used for TTC fusion, the Precice Ankle Salvage System may be used for open and closed fracture fixation, pseudarthrosis, mal-unions, non-unions, or bone transport of long bones adjacent to the fusion site. The device may be used for subsequent limb lengthening once tibio-talo-calcaneal fusion has been achieved.

After your doctor implants the PRECICE implant into your limb, you will use the ERC to make the device longer or shorter. The lengthening/shortening phase usually starts 5 days after your surgery. You will make the PRECICE implant a small amount longer or shorter each day (usually about 0.75 to 1 millimeter each day). This phase of your treatment could last up to 80 days. Your doctor will tell you how much and how often to adjust the PRECICE implant. Usually once a week you will visit your doctor to check on your progress. Your doctor may x- ray your leg or arm during these visits. For femur or tibia implants, your doctor will also tell you to use crutches and avoid putting weight on your leg with the PRECICE implant. For humerus implants, your doctor will tell you to avoid using and putting weight on your arm with the PRECICE implant. A good result requires your active cooperation and dedication to certain tasks. If you do not follow your doctor’s instructions, you could seriously harm yourself.

After your leg/arm has reached its goal length, you will stop using the ERC. This will let your bone heal.

During the consolidation phase, the bone heals. Your bone will change, or regenerate, from a soft material into hard bone over time. This healing process usually takes about 2 months for every inch that your bone has been lengthened or shortened. During this healing phase, it is very important that you follow all of your doctor’s instructions. You will continue to see your doctor for visits, usually once a month.

5. CONTRAINDICATIONS: Who cannot use the PRECICE system?

Important Safety Information – Read Before Use!

Please read and consider the information in this guide before deciding on your treatment.

This section describes the Contraindications for the PRECICE Systems. If you have any of these contraindications, you cannot use a PRECICE device.

CONTRAINDICATIONS:
Your doctor will check the following to see if you would be a good fit for PRECICE (inclusive of Precice IMLL Precice Unyte, Precice Stryde and Precice Bone Transport):

- Patients with an irregular bone diameter that would prevent insertion of the Precice nail
- Patients in which the Precice nail would cross joint spaces or open epiphyseal growth plates
- Patients in which there is an obliterated medullary canal or other conditions that tend to retard healing such as blood supply limitations, peripheral vascular disease or evidence of inadequate vascularity
- Patients unwilling or incapable of following postoperative care instructions
- Infection or Pathological conditions of bone such as osteopenia which would impair the ability to securely fix the device.
- Patients with Gusilo open fracture Classification Grade IIIB or IIIC fractures
- Patients with pre-existing nerve palsies
- Metal allergies and sensitivities

Precice Bone Transport has the following additional contraindications:

- Patients with maximum bone defect of more than 100 mm.
- Patients with excessive skin damage and not enough soft tissue covering where the fracture sites.

Please refer to the tables below for contraindications with regard to weight and maximum distance of the treated limb to the surface of the intramedullary canal.

For Precice & Precice Unyte Nail				
Limb	**PRECICE Model**	**Nail Diameter**	**Maximum Distance of Treated Limb to Surface of IM Canal**	**Maximum Patient Weight**
Tibia	C	8.5 mm, 9.0 mm, 9.5 mm, 10.0 mm, 10.5 mm	13 mm	57 Kg
		10.7 mm, 11.5 mm, 12.5 mm	16 mm	114 kg
	J	8.5 mm	13 mm	57 Kg
		10.7 mm, 12.5 mm	16 mm	114 kg
	Q	8.5 mm	13 mm	57 Kg
		10.7 mm	16 mm	57 Kg
Femur	A-G (except C), V, X	8.5 mm, 9.0 mm, 9.5 mm, 10.0 mm, 10.5 mm	45 mm	57 kg
		10.7 mm, 11.5 mm	75 mm	114 kg
		12.5 mm	90 mm	114 kg
	H, K, U	8.5 mm	45 mm	57 kg
		10.7 mm	75 mm	114 kg
		12.5 mm	90 mm	114 kg
	N, M, P	8.5 mm	45 mm	57 kg
		10.7 mm	75 mm	57 kg
Humerus	L, M	8.5mm, 165 - 210 mm pre-distracted length	25 mm	Non-weight bearing
		8.5mm, 225 - 300 mm pre-distracted length	45 mm	Non-weight bearing

For Precice Stryde Nail				
Limb	**PRECICE STRYDE Model(s)**	**Nail Diameter**	**Maximum Distance of Treated Limb Surface to IM Canal**	**Maximum Patient Weight**
Tibia	C, SJ	10.0	13mm	150 lbs / 69 kg
		11.5	16mm	200 lbs / 91 kg
		13.0	16mm	250 lbs / 114 kg
Femur	A, B, C, E, V, X	10.0	70mm	150 lbs / 69 kg
		11.5	85mm	200 lbs / 91 kg
		13.0	100mm	250 lbs / 114 kg

For Precice Bone Transport Nail					
Limb	**PRECICE Bone Transport Model**	**Nail Diameter (mm)**	**Maximum Distance of Treated Limb Surface to IM Canal**	**Max. Patient Weight Bearing** *Use with partially threaded screws*	**Max. Patient Weight Bearing** *Use with fully threaded screws*
Tibia	C, SJ	10.0	19mm	25lbs/11kg	25lbs/11kg
		11.5	19mm	190lbs/86kg	125lbs/57kg
		13.0	19mm	250lbs/114kg	125lbs/57kg
Femur	A, B, BT, D, DT, E, V, X, SE, SB, SD, SA	10.0	64mm	25lbs/11kgs	25lbs/11kg
		11.5	69mm	190lbs/86kg	125lbs/57kg
		13.0	85mm	250lbs/114kg	125lbs/57kg

Your doctor will check the following to see if you would be a good fit for Precice Plating System:

- Infection or bone disease that would prevent successful use and operation of the device.
- Patients with Gustilo-Anderson open fracture Classification Grade IIIB or IIIC fractures
- Metal allergies and sensitivities.
- For the femur, patients whose distance from the skin surface to the Precice Plate is greater than 38mm. For the tibia, patients whose distance from the skin surface to the Precice Plate is greater than 20mm.
- Patients with a non-regular bone shape/size that would prevent placement of the Precice Plate.
- Patients whose condition tend to prevent healing such as blood supply limitations, peripheral vascular disease or evidence of inadequate vascularity.
- Patients unwilling or incapable of following care instructions after a surgical operation.

Your doctor will check the following to see if you would be a good fit for Precice Ankle Salvage System:

- Infection or bone disease that would prevent successful use and operation of the device.
- Patients with poor quantity or quality of bone that prevents stabilization or fusion of the joints.
- Patients with an insufficient plantar pad.
- Patients having an intact asymptomatic subtalar joint.
- Patients with Gustilo open fracture Classification Grade IIIB or IIIC fractures.
- Metal allergies and sensitivities.
- Patients with a non-regular bone diameter that would prevent insertion of the Precice Ankle Salvage nail.
- Patients in which there is an overly damaged medullary canal or other conditions that tend to prevent healing such as blood supply limitations, severe peripheral vascular disease or evidence of inadequate vascularity.
- Patients with severe deformity in the length of the bone
- Patients with poor tibial alignment (>10 degrees in either sagittal or coronal plane)
- Patients unwilling or incapable of following care instructions after a surgical operation.
- Patients whose maximum distance of treated limb surface to inner marrow space exceeds 25mm.

6. WHAT YOU MUST DO TO AVOID HARM (WARNINGS)

This section describes the **Warnings** associated with the ERC 4P. This will help you to avoid serious harm when using the ERC 4P. Please read all of these warnings before you use the ERC 4P.

	**1. WARNING *** **Weekly X-ray imaging to assess actual distraction length is recommended for patients undergoing lengthening.**
	**2. WARNING *** **During and after compression, X-ray imaging is recommended to assess compression and bone healing.**
	**3. WARNING *** **Proper training of the External Remote Controller is required prior to operating this device. Only use the External Remote Controller in a manner consistent with this Operator's Manual. Any alternative use may result in injury or damage to property.**
	**4. WARNING *** **This equipment 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 External Remote Controller or shielding the location.**
	**5. *WARNING*** **This device has not been tested for compatibility in Magnetic Resonance Imaging (MRI) environments and should not enter an MRI unit.**
	**6. WARNING *** **Persons with a pacemaker or a similar medical aid should not handle or be exposed to the External Remote Controller. The strong magnetic fields may affect the operation of such devices.**
	**7. CAUTION *** **The Rare-Earth Magnetics Association is not aware of any positive or negative health effects from handling rare-earth magnets. However, it is recommended that pregnant women not handle very strong rare-earth magnets (ERC).**
	**8. WARNING *** **The External Remote Controller uses a strong permanent magnet. Misuse of this system can cause serious personal injury. Always maintain a firm grip on the External Remote Controller and be aware of other objects in your work area. The External Remote Controller may be pulled away from your hands, or items may be pulled toward it if brought too close to other magnetic objects.** **Make sure there is at least 2 Feet (60 centimeters) around the work area that is free of metal objects such as instruments and tools before use. This includes personal items such as jewelry, watches, keys, and cellular phones. Do not use the ERC with metal/magnetic objects within the designated vicinity.**

	**9. WARNING *** **If this equipment is damaged, beware that magnet shards from broken magnets are very sharp. Always handle broken magnets with thick protective gloves. Contact NuVasive Specialized Orthopedics if the ERC is damaged.**
	**10. WARNING *** **Never place the External Remote Controller near electronic media or appliances. The strong magnetic field may damage magnetic media such as floppy disks, credit cards, magnetic I.D. cards, cassette tapes, video tapes or other such devices. It can also damage televisions, VCRs, computer monitors and other CRT displays.**
	**11. WARNING *** **Never operate ERC in an oxygen enriched or flammable environment.**
	**12. WARNING *** **There are no user serviceable components inside this device. Do not open the unit. Severe personal injury or damage to the equipment may result. Service should only be performed by qualified personnel.**
	**13. WARNING *** **Only use the supplied charging cord for the ERC. Contact NuVasive Specialized Orthopedics for a replacement charging cord.**
	**14. WARNING *** **Do NOT use this equipment in the presence of flammable anesthetics.**
	**15. *WARNING*** **The ERC should only be placed immediately over the area of the patient's body at the magnetic portion of the implant. 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.**
	**16. *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.**
	**17. *CAUTION*** **Although there is no evidence of neurological/soft tissue damage, the physician should consider it when prescribing for a longer session of distraction or retraction length.**
	**18. *WARNING*** **Do not operate the ERC if it is dropped from a height of 3 feet or greater. If there is physical damage to the unit (e.g. unexpected noise, cracks) do not operate. If this does occur, please call the manufacturer NuVasive Specialized Orthopedics, Inc. and a replacement unit will be provided.**

	19. *WARNING* **Do not lift the ERC unit using the adapter cord. Please return with ERC.**
	20. *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 or shorter 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 or shorten 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.**
	21. *WARNING* **Always put the ERC on the skin right over the implant and in the correct direction. Placing the ERC in the wrong location on your leg or arm could result in the bone not lengthening or shortening correctly. Your bone could harden too early if it is not lengthening or shortening correctly. You may need another surgery to make your bone the right length.**
	22. *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 implant will not lengthen or shorten properly and may result in the need for another surgery. This figure shows the correct direction to point the ERC.** 
	23. *WARNING* **To avoid infection, do not place the ERC on any open sore on your skin. You may need medical intervention or surgery to treat an infection. An open sore is any cut on your skin.**
	24. *WARNING* **Always 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.**

	**25. *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.**
	**26. *WARNING*** **Follow the instructions your doctor gives to you about how much weight to put on your leg or arm during your treatment. If you put more weight on your leg or arm than your doctor recommends, the implant could be damaged or break. This could result in the need for another surgery.**
	**27. *PRECAUTION*** **Do not store the ERC near any areas that may have extreme temperatures. Some areas may include a heater or fireplace. Extreme temperatures would be anything above 140ºF/60ºC or below 14ºF/-10ºC. The ERC has not been tested in those temperatures and may not work correctly. Refer to the Troubleshooting section if you have any problems with the ERC.**
	**28. *PRECAUTION*** **Act on all error messages. Refer to the Troubleshooting section to learn how to respond to an error message. Failure to take action after an error message could result in the ERC not working properly.**

7. WHAT ARE THE RISKS

There are risks of the surgery to implant the PRECICE implant into your limb. The anesthesia and surgical risks are the same as for any patient who undergoes a surgical procedure. The risks listed could result in the need for additional medical or surgical procedures to correct.

The risks associated with anesthesia and surgery include:

- You could have a reaction to the medicines given to you during the surgery.
- You could get an infection during or after the surgery.
- You could have an embolism during or after the surgery.
- You could experience some stiffness or soreness from the surgery.
- You could experience some pain from the surgery.
- You could experience some bleeding from the surgery.
- You could have an allergic reaction to the medicines.
- You could have an allergic reaction to the devices used to treat you during the surgery.
- You could have a stroke from the surgery.
- You could have a heart attack (Myocardial infarction) from the surgery.
- You could get pneumonia from the surgery.
- You could die from the surgery.

The additional potential risks of the limb lengthening/shortening procedure include:

- You may feel pain from lengthening or shortening your bone.
- There may be a delayed union or non-union of the bone (the bone does not heal).
- The screws may pull out or break.
- There may be an infection.
- The implant may malfunction or break.
- The bone can consolidate (harden) before the lengthening or shortening is complete.
- You may have stiffness of the soft tissue in your limb that may cause pain.
- You may experience muscle weakness from not using the implanted limb.
- You may experience nerve injury.

The additional risks associated with the use of the ERC include:

- Misalignment or improper location of the ERC can result in the implant not lengthening or shortening which could result in premature bone consolidation.
- Placing the ERC in the wrong direction can result in the opposite treatment (lengthening/shortening) of the implant rather than the prescribed treatment. Note that the implant cannot be shortened less than its initial programmed length.
- Over distraction or retraction could occur due to improper programming of the ERC by the physician. This could result in non-union of your bone.

8. PRODUCT DESCRIPTION

The PRECICE System (inclusive of Precice IMLL, Precice Unyte, Precice Stryde, Precice Bone Transport, Precice Plate, and Precice Ankle Salvage) includes:

- An implant that goes into your leg or arm bone and is capable of adjusting in length
  - o The actuator is the part of the device that can change in length when activated
- Screws that attach the device to your bone
- An External Remote Controller (ERC)

The implant has a part called an "actuator" that can change length. The actuator has a small magnet that allows the implant to get longer or shorter when the magnet is turned by the ERC. The ERC is a hand-held device with a large magnet. The magnet in the actuator turns when the ERC is placed on your leg or arm and turned on. When the implant gets longer, your leg or arm bone will also get longer. When the implant gets shorter, your leg or arm bone will also get shorter.

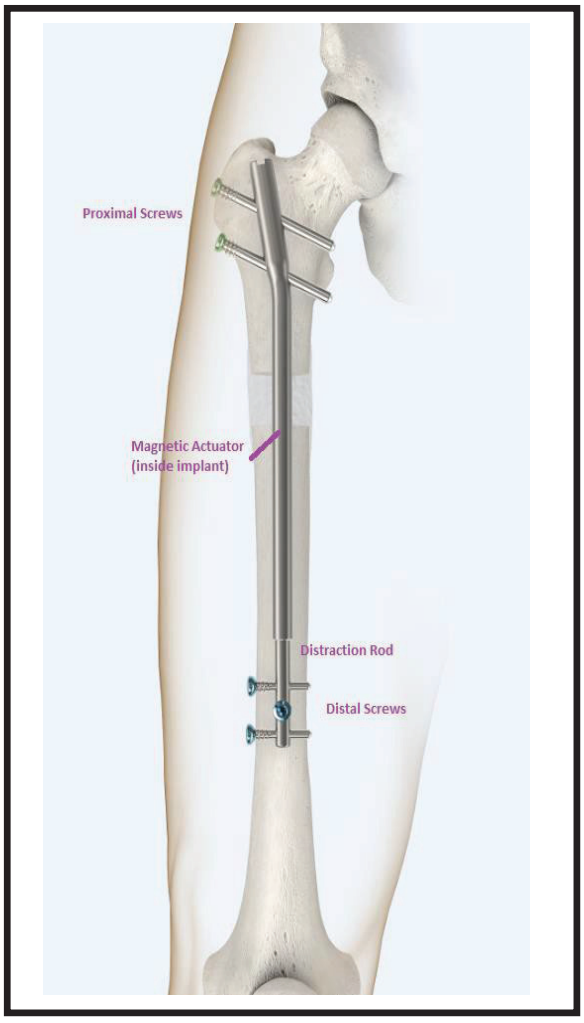


Figure 1: PRECICE device implanted in the Femur

a. What happens during and after the treatment?

There are 4 phases to your treatment.

1) **Implantation**: This phase is when you have your surgery. Your doctor implants the PRECICE implant in your limb.
2) **Lengthening/Shortening**: You will make your leg or arm longer or shorter each day in this phase. About 5 days after your surgery, you will visit your doctor to have your first lengthening or shortening. Your doctor will watch you while you use the ERC to make your leg/arm longer or shorter and answer any questions you might have. When you are at home, you will use the ERC to make your leg/arm a little longer or shorter each day (usually about 1 mm per day). Make sure you follow your doctor's instructions. You will visit your doctor about once a week to check on your progress. Your doctor may x-ray your leg/arm when you visit.
3) **Consolidation**: After your leg/arm is the right length, you will stop lengthening or shortening your leg/arm each day. Now you will let your leg/arm bone heal and get stronger. This is the consolidation phase. Your doctor will see you about once a month during this phase to check on your progress. Your doctor will tell you how much weight you can put on your leg or arm. It is important to follow all of your doctor's instructions.

PRECICE Tibia Device

4) **Removal**: The PRECICE implant will need to be removed from your leg or arm within a year of your surgery. Your doctor will schedule another surgery to remove the PRECICE implant. You will then stay in the hospital after the surgery until you heal enough to go home. Your doctor will tell you when you can continue your usual lifestyle after you have fully healed from your surgery.

b. What happens after the surgery?

- **Implantation:** You will stay in the hospital after the surgery to implant the PRECICE implant in your limb. You will get to go home once you heal. You will visit the office regularly to check if your lengthening or shortening is on track.

- **Post-Removal:** You will stay in the hospital after surgery to remove the PRECICE implant from your limb. You will get to go home once you heal.

c. Getting to know your ERC

Inside your ERC Case, you will find the ERC and Patient's Manual. The critical parts of the ERC are labeled below:

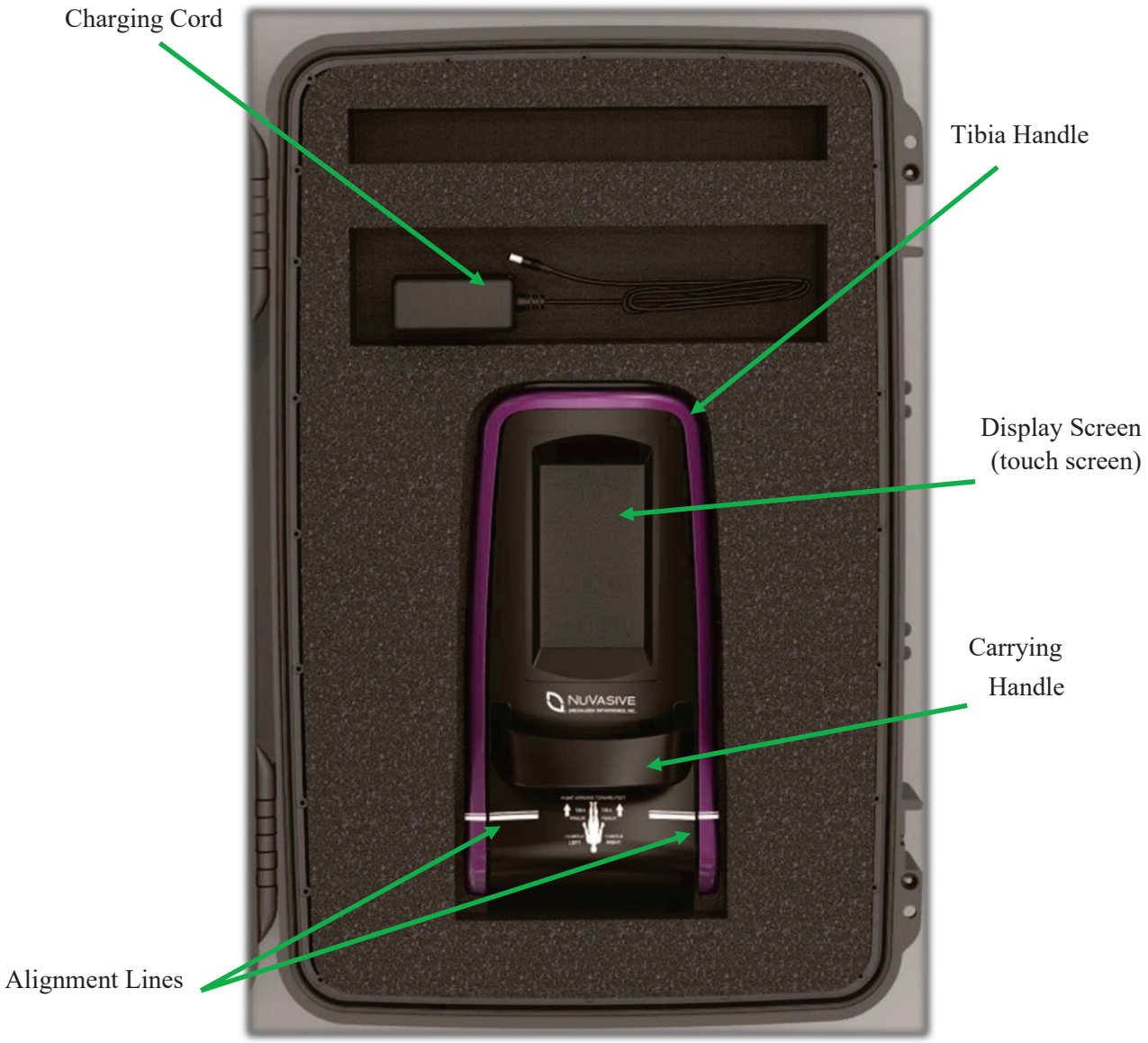


Figure 2: ERC for the PRECICE System

Figure 3: ERC Case

9. About the ERC

This section will help you to understand how to use the ERC correctly.

a. What are the functions of the ERC?

You will use the ERC to lengthen or shorten the implanted PRECICE implant in your limb.

b. What are the ERC Buttons and Displays?

ERC Buttons and Displays.	
	
1	The **display screen** is used to show information about the PRECICE system. It can be controlled by touching various areas on the screen.
2	The **alignment line** is used to align the ERC over the PRECICE implant using the marked location on the limb.
3	The **power button** is used to power on and power off the ERC.

10. IMPLANT DETECTION FEATURES

The ERC 4P has features used to detect the status of the Precice implants during therapy. This section provides a summary of these detection features:

- **Coupling Detection:** The ERC 4P can detect the implant magnet rotation during therapy and provide feedback to the user of this condition. During the therapy session, the implant length displayed will change based on this condition.

- **Uncoupled Detection:** The ERC 4P can detect if the implant magnet is not rotating or is not present and provide feedback to the user of this condition. During the therapy session, the implant length displayed will not change based on this condition.

11. SET UP INSTRUCTIONS. (BEFORE YOU DO TREATMENT)

1. Choose the location where you will be doing the treatment.	
	• If using the charging cord, check that there is an electrical outlet close to the ERC. • Find a comfortable place to sit while performing the treatment. • **Make sure there are no electronic devices or items with metal within two (2) feet of the ERC treatment area**. These electronic devices could get damaged.

2. REMOVE ALL LOOSE METAL FROM YOUR TREATMENT AREA

- **Do not use the ERC within two (2) feet of metal objects.** Metal objects could be pulled very quickly to the magnet in the ERC and may injure you.
- Remove unattached metal items from the area (jewelry, knives, keys, etc.). Zippers and buttons on clothing and shoes are ok.
- Remove metal items from your clothing and body.

12. How to use the ERC

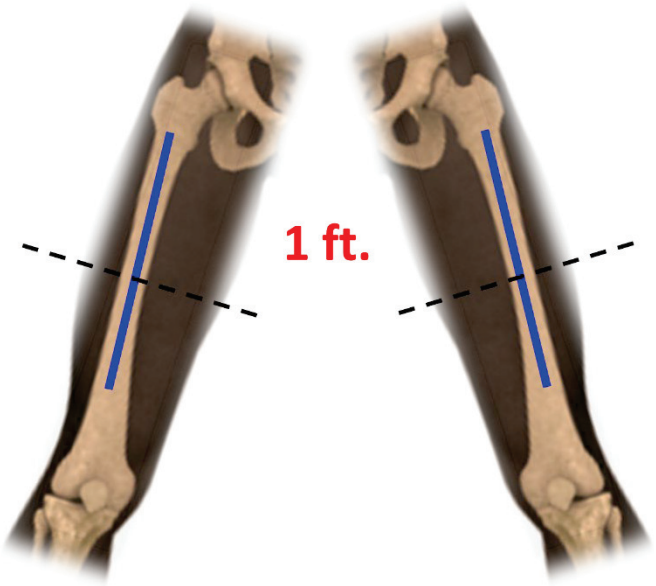
This section describes how to use the ERC to lengthen or shorten your implant.

a) Navigating the ERC	
	This icon allows the physician access to screens for programming the ERC.
	This icon also allows the user to start the lengthening session.
	This icon will stop 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) Power Button Light Indicators	
Blinking Amber	A **blinking amber** light indicates that the ERC 4P is starting up.
Blinking Amber and Red	The system requires charging. Plug-in the power supply and allow the system to charge for 15 minutes.
Solid Green	A **solid green** light indicates that the ERC 4P is in a safe state.
Blinking Green	A **blinking green** light indicates that the ERC 4P is ready to be used for treatment.
Solid Red	A **solid red** light indicates that the motor in the ERC 4P is running and the internal magnet is rotating.
Blinking Red	A **blinking red** light indicates an error with the ERC 4P. See Troubleshooting section for steps on how to fix errors.

c) If You Have MORE than One Implant.

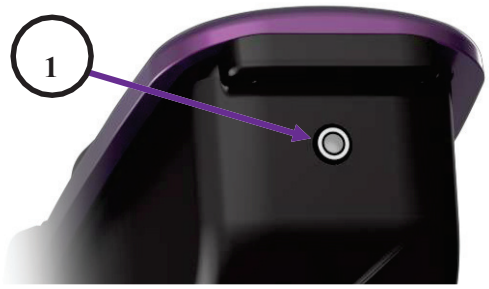
If you have more than one implant, make sure there is **at least 1 FOOT** of space between both implant locations before starting therapy.



FOR MULTIPLE IMPLANT USES

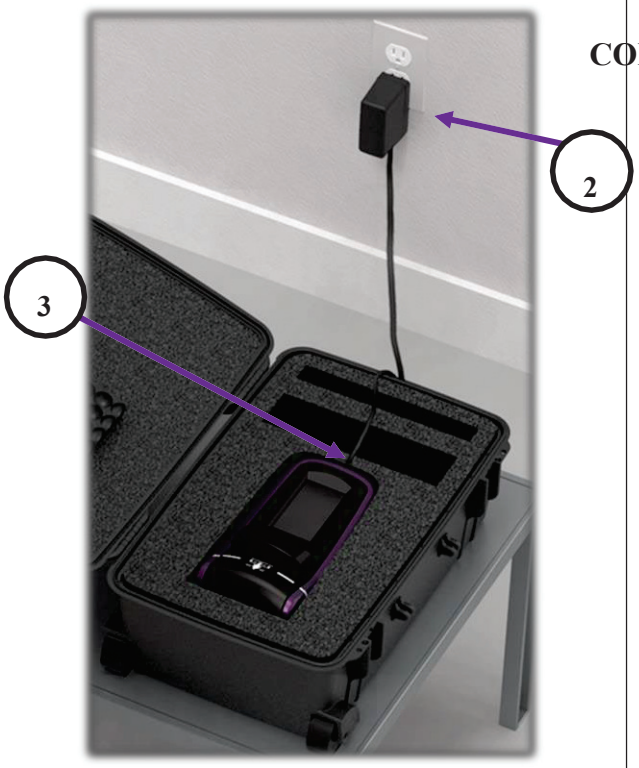
BEFORE operating the ERC, ensure that a minimum of **1 foot** is between each implant magnet location.

Step 1: Power on the ERC.



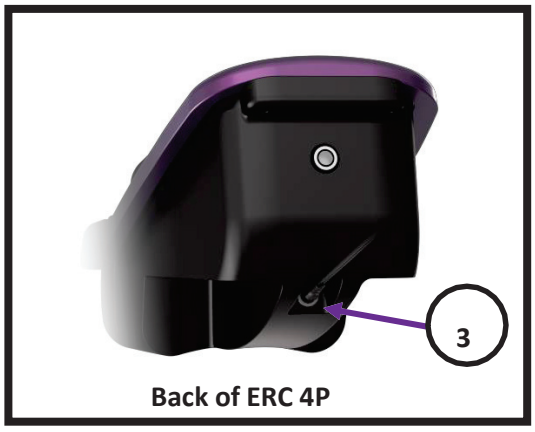
POWERING ON

1. Press power button at back of ERC.



POWERING ON WITH THE CHARGING CORD

2. Plug charging cord into a wall outlet.
3. Plug charging cord connector into ERC.

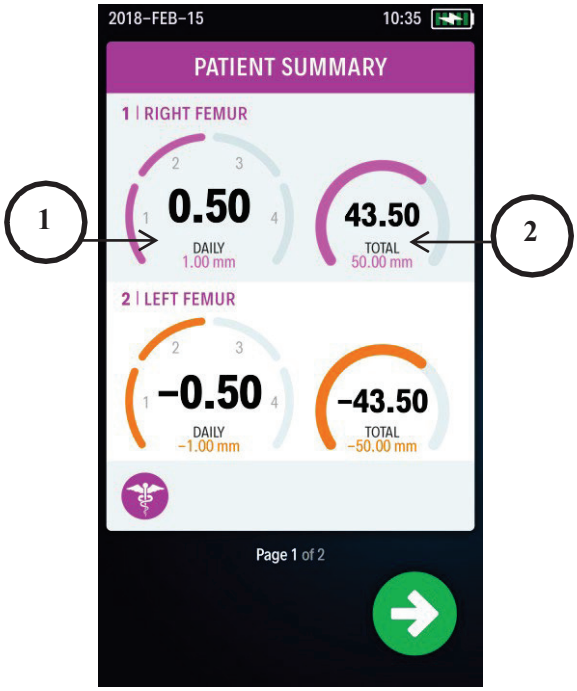


WELCOME SCREEN

When powered 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.

Step 2: Review Patient Summary.

This section explains the screens you will see on the display before starting your lengthening or shortening session.



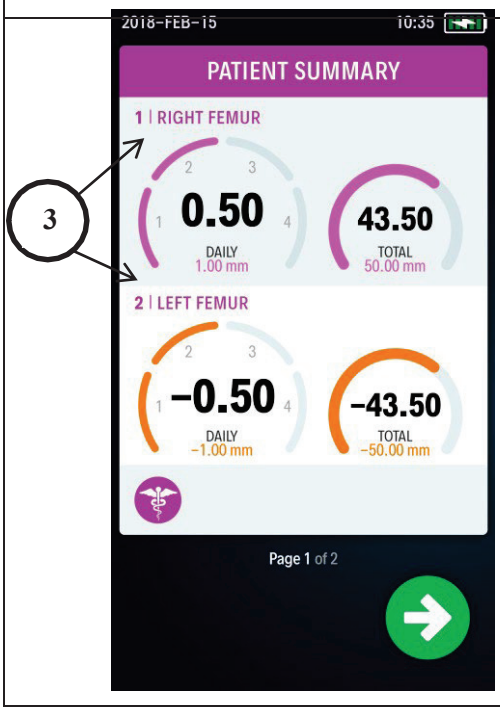
PATIENT SUMMARY SCREEN

After powering up, the patient summary screen will be shown. Review the patient summary screen to be sure the prescription information is correct.

1 "DAILY" is the amount your physician has prescribed for the entire daily treatment (i.e. 1.00 mm). The number above (i.e. 0.50) is the amount you have already lengthened or shortened that day.

2 "TOTAL" is the total amount your physician has prescribed for the entire treatment (i.e. 50 mm). The number above (i.e. 43.50) is the total amount you have lengthened or shortened so far.

After reviewing this information and ensuring it is correct, press the **GREEN ARROW** button on the screen to **GO** to the next screen. If this information is not correct, contact your doctor immediately.



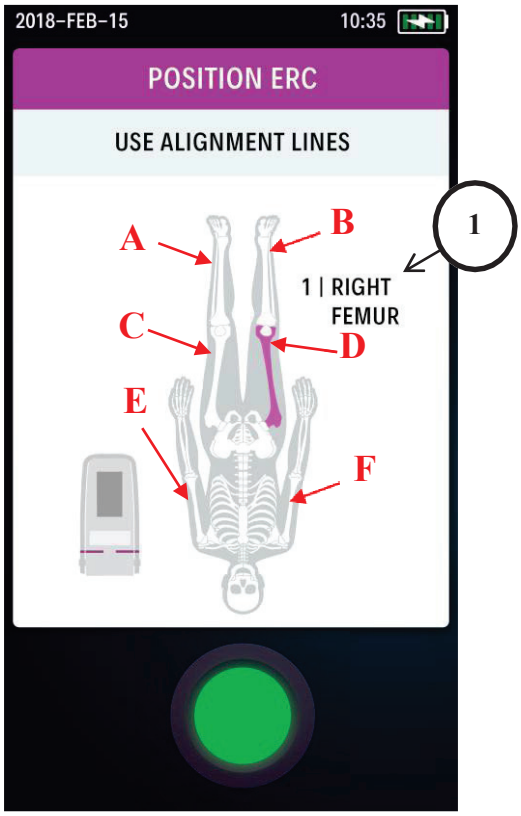
PATIENT SUMMARY SCREEN

3 The ERC allows four (4) prescriptions to be entered to lengthen or shorten if you have multiple implants. If your physician has entered multiple prescriptions, a summary of each prescription will appear before starting your session. Solid purple or orange filled segments are completed sessions and flashing segments are the current session to be completed.

The "Page 1 of 2" at the bottom of the screen will identify if additional prescriptions are on a second page.

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

Step 3: Aligning the ERC with the Implant Magnet.



IMPLANT LOCATION SCREEN

There are six options for the PRECICE implant location:

(A) Left Tibia, (B) Right Tibia
(C) Left Femur, (D) Right Femur
(E) Left Humerus, (F) Right Humerus

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 flashing **GREEN GO** button on the ERC once you have aligned the ERC.

Right Femur Example

Right Femur Example

Right Tibia Example

ERC ALIGNMENT

1. Point the ERC towards patient's feet as indicated on display.
2. Use alignment lines to center ERC over the PRECICE implant and mark on your leg.
3. Press flashing **GREEN GO** button to start session.
4. Session is now started.

Example image of right femur session.

Note: if you feel discomfort resting the ERC on your femur, it is appropriate to use a soft, thin pad as a barrier (i.e. cloth).

Example image of right tibia session.

Note: if you feel discomfort resting the ERC on your tibia, it is appropriate to use a soft, thin pad as a barrier (i.e. cloth). Or rest the ERC more to the outside of the leg.

The ERC can also be used for the tibia as shown below.

Right Tibia Example

Another example of a right tibia session.

Note: if you feel discomfort resting the ERC on your tibia like in the previous example, the ERC can also be used for the tibia as shown.

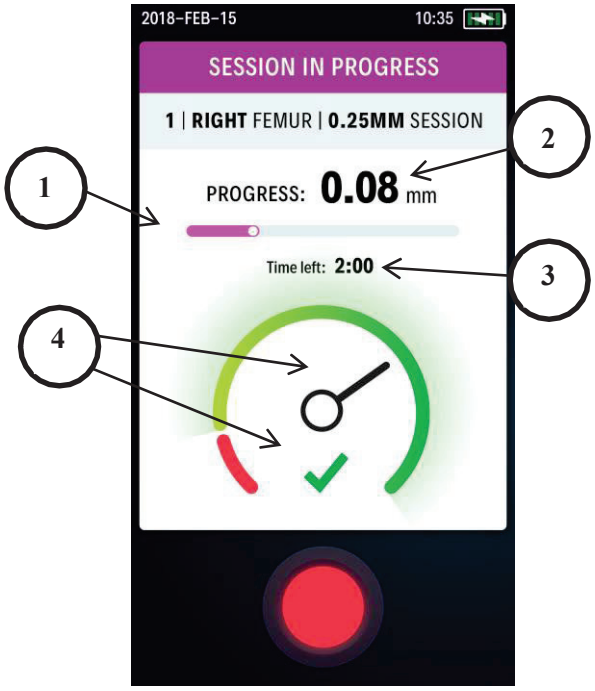
Right Humerus Example

ERC ALIGNMENT (Humerus)

1. A second person or caregiver should administer treatment.
2. Point ERC towards patient's feet as indicated on display and move to patient's arm.
3. Use alignment lines to center ERC over implant and mark on patient's arm.
4. Press flashing **GREEN GO** button to start session.
5. Session is now started.

Example of a right humerus session.

Step 4: Starting and completing your session.



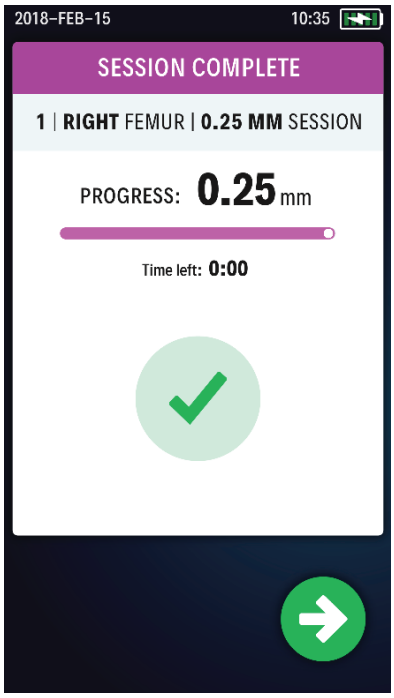
The ERC is now running and your lengthening or shortening session has started.

1. Progress Bar: This will fill as the implant lengthens or shortens to monitor your progress. When the bar is 100% full, the implant has lengthened or shortened to the prescribed amount and will stop running.

2. Distance counter: This number will increase as the implant lengthens or shortens. 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. When the gauge points to the green area and the green check mark appears, you are coupled with the implant magnet and the treatment is effective. If the ERC is not coupled with the implant magnet, the gauge will point to the red area and a red "X" appears.

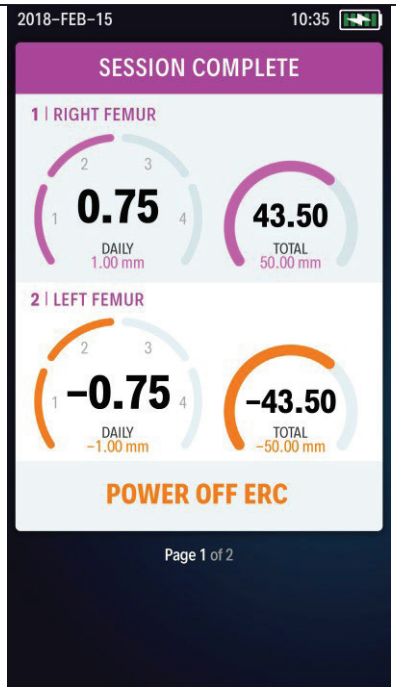


Session Complete!

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 prescribed daily prescription.

Press the **GREEN ARROW GO** button to finish your session.



If you finished a session, but have not finished your daily lengthening or shortening, the **SESSION COMPLETE** screen will appear. It will appear with a summary of your session.

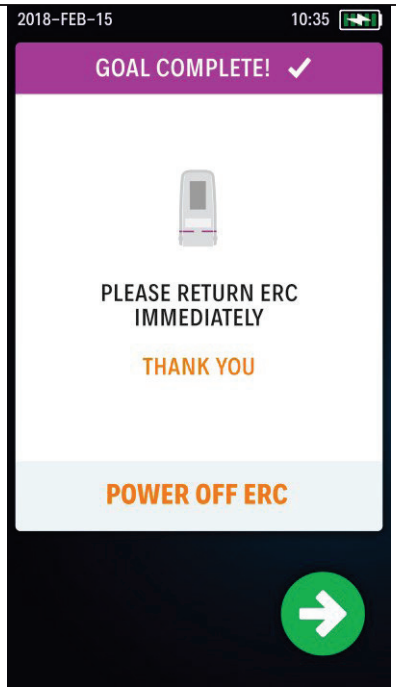
1. Turn off your ERC by pressing the Power Button.
2. Place the ERC in the storage case.
3. Close and latch storage case.
4. Store in a safe place, away from children.

The **DAILY COMPLETE** screen will appear if you have achieved the total length prescribed by your physician for that day (i.e. 1.00mm).

1. Turn off your ERC by pressing the Power Button.
2. If the charging cord is used, leave the ERC powered on and the charging cord plugged in until the ERC is fully charged.
3. Place the ERC in the storage case.
4. If not charging, close and latch storage case. If charging, gently place lid down.
5. Store the case in a safe place, away from children.

The **GOAL COMPLETE** screen will appear if you have achieved the total length prescribed by your physician (i.e. 50.00mm).

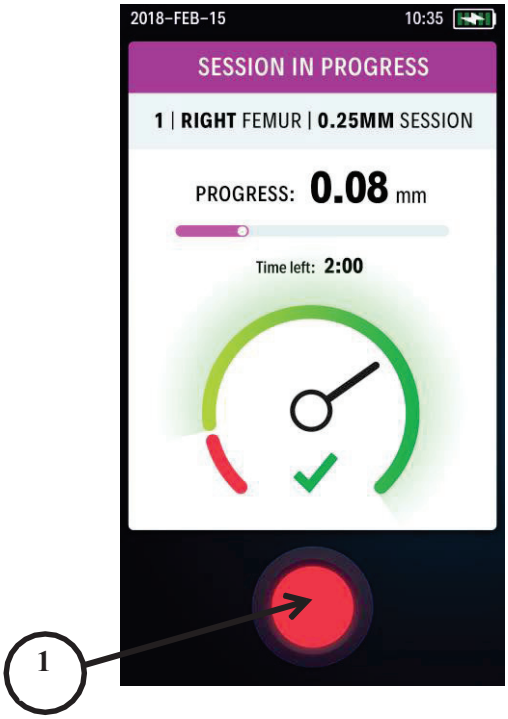
1. Turn off your ERC by pressing the Power Button.
2. If the charging cord is used, leave the ERC powered on and the charging cord plugged in until the ERC is fully charged.
3. Place the ERC in the storage case.
4. If not charging, close and latch storage case. If charging, gently place lid down.
5. Store the case in a safe place, away from children.



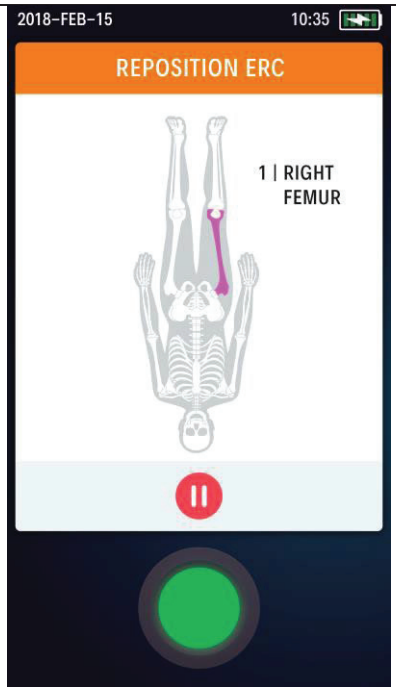
Return the ERC to NuVasive Specialized Orthopedics, Inc.

Step 5: Pausing the ERC during your session.

You may pause the ERC at any time during the session. It is not harmful to do this because the ERC remembers your progress. If you do require a pause in treatment, follow the instructions below.



1 You may press the **RED STOP** button at any time during your session. This will cause the ERC to stop immediately.



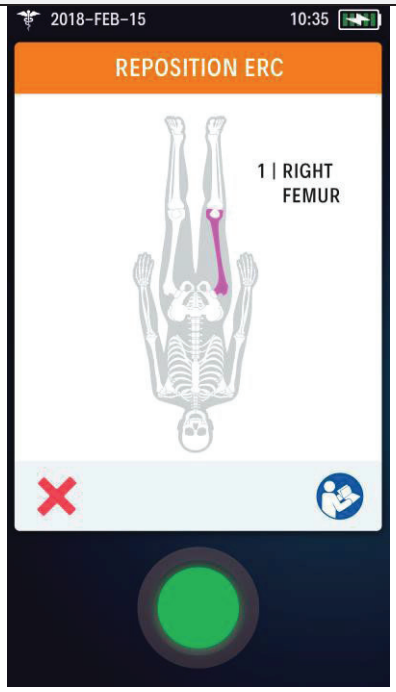
If the red stop button has been pushed, the pause screen will appear.

When ready to resume your session, align the ERC over the same limb you were just lengthening. The REPOSITION ERC screen will also highlight the correct limb. Position the ERC using the alignment lines over the mark on your leg or arm.

Once you have positioned the ERC correctly press the **GREEN GO** button to start the session.

Step 6: Screens you may see during your session.

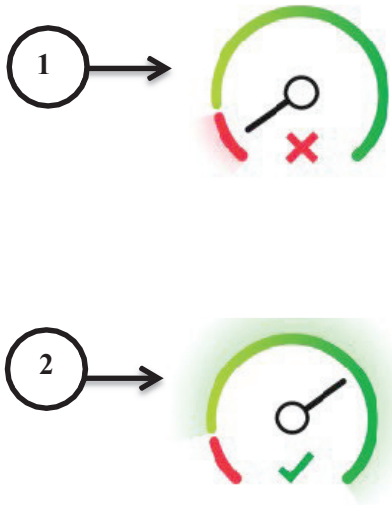
You may see any one of the following screens while using ERC.



REPOSITION ERC

This screen will display if the ERC loses coupling or connection with the magnet in the implant.

1. Reposition ERC using alignment lines on ERC. See Section ERC Alignment.
2. Press **GREEN Go** button when you are ready to resume your session.



IMPLANT STATUS ICONS

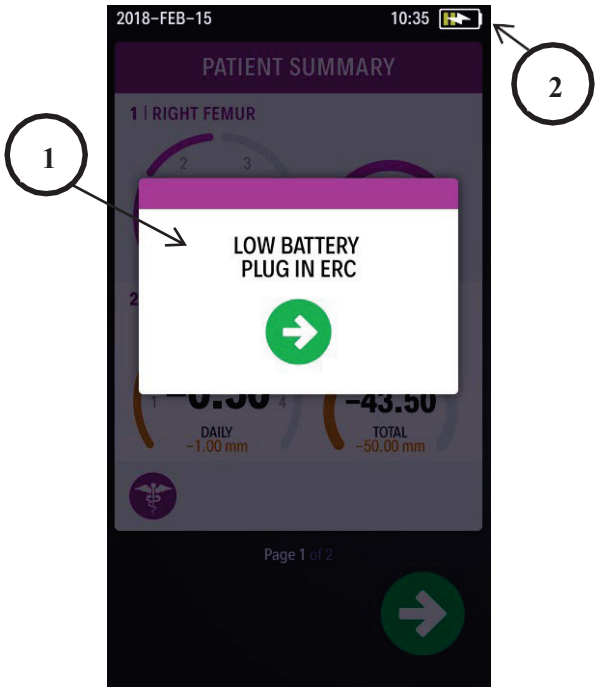
One of the IMPLANT STATUS icons will be displayed when the following happens: the SENSOR ON feature is selected and the therapy session is in progress. The IMPLANT STATUS icons will be seen in the In-Progress or Uncoupled.

1 **UNCOUPLED:** This icon means that the ERC has not connected with the implant magnet during the session.

2 **COUPLED:** This icon means that the ERC has connected with the implant magnet during the session.

13. CHARGING THE ERC

At any point during treatment the ERC may need to be charged. The ERC will indicate to you when it must be charged for two conditions **1) Low Battery** and **2) Critical Battery**. If you need to charge the ERC, follow the instructions below.



Back of ERC 4P

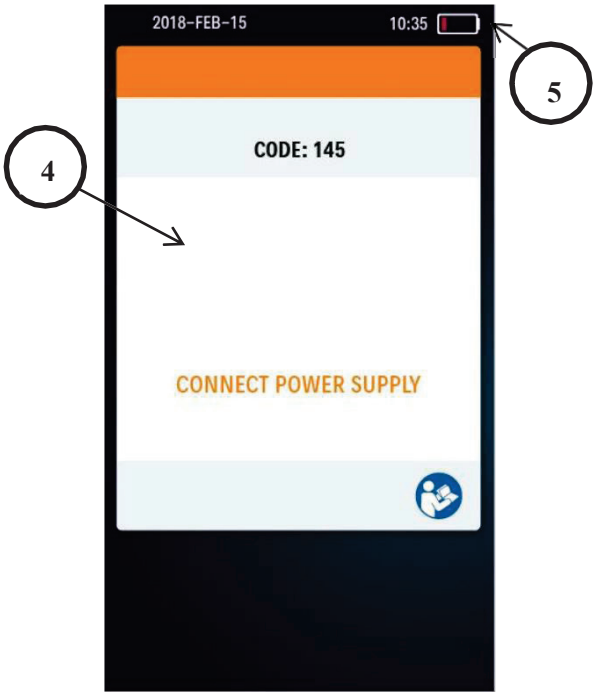
LOW BATTERY CONDITION:

1. A message will be displayed indicating the ERC battery is **LOW**.

2. A low battery condition is indicated by the **YELLOW** battery icon and two battery segments.

3. Plug the charging cord into the ERC and plug into the wall plug to charge the battery.

Once you have plugged in the ERC press the **GREEN ARROW** button.

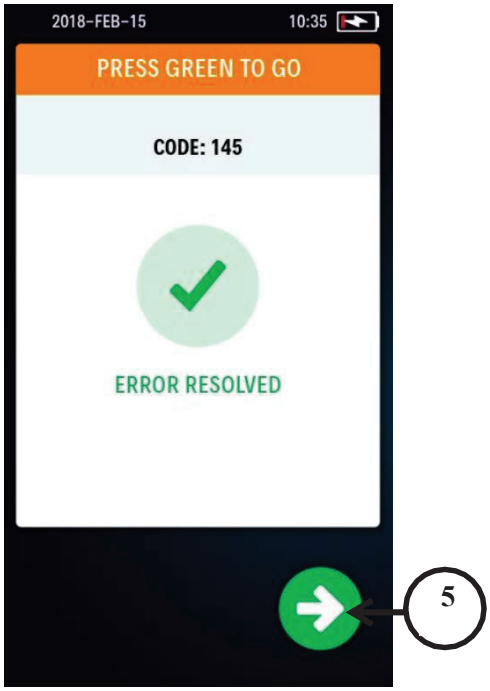


CRITICAL BATTERY CONDITION:

4 An error screen will be displayed indicating the ERC battery is **CRITICAL**.

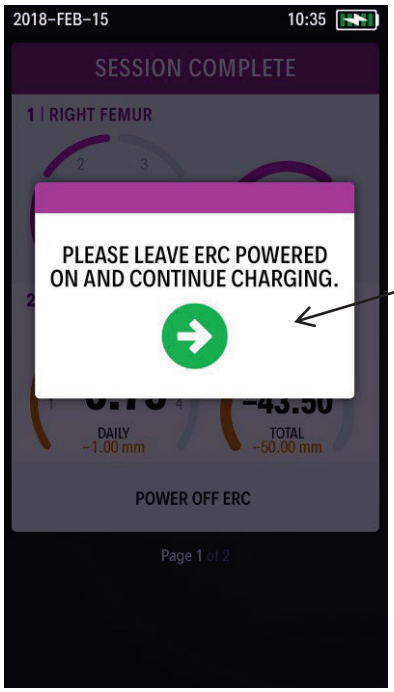
5 Additionally, the battery icon becomes **RED** and one battery segment remains.

You **must** plug in the ERC to charge the battery.



CRITICAL BATTERY CONDITION:

5 Once you have plugged in the ERC, you may continue the previous session by pressing the **GREEN ARROW** button to dismiss the error screen and continue where you left off.

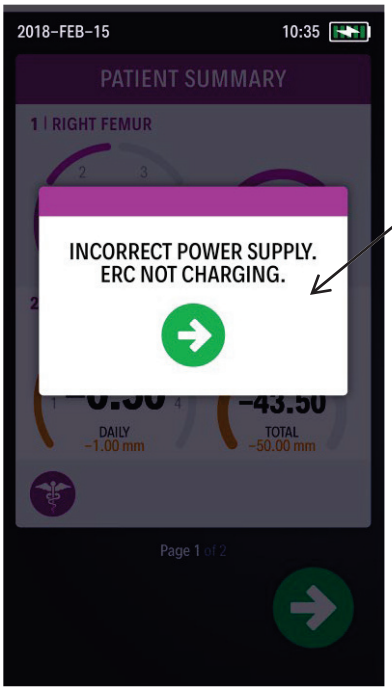


CHARGING AFTER A TREATMENT

6

This message will pop up on the screen after a session has been completed and the charging cord is connected into the ERC.

1. Leave the ERC powered on and plugged in.
2. Place the ERC in the case with the cord connected and plugged in.
3. Gently rest the top of the case over the ERC. Do not latch the case closed on the charging cord.
4. Press the GREEN ARROW button.



INCORRECT POWER SUPPLY

7

This message will appear if the wrong charging cord is plugged into the ERC.

Plug in the supplied charging cord into the ERC.

Once you have plugged the appropriate charging cord into the ERC, press the **GREEN ARROW** button.

14. INSPECTING, CLEANING, STORING AND OTHER INFORMATION

a. Inspecting the ERC

- Before each use, check the condition of all the ERC parts. If there are wires showing, visible cracks, loose components, or damage, call your doctor for replacements.
- The ERC has no user serviceable parts. Do not attempt to open it.

b. Cleaning

- To clean and disinfect, wipe with 70% Isopropyl Alcohol wipes or equivalent. Be sure that all parts are dry before putting the ERC back in the case. Please clean and disinfect ERC prior to returning the ERC and its contents.
- Do not dispose of the ERC in the trash. Please return the ERC and its contents in the storage case to NuVasive Specialized Orthopedics, Inc.

c. Travel and International Use:

- It is not recommended to travel during your treatment. If travel is necessary, check with your doctor first. If you travel outside of the country during lengthening or shortening, ask your doctor about giving you an ERC that will work for where you will be going.
- Air Travel with your ERC. The ERC is not considered "Carry On" luggage. If you travel by airplane, the ERC must be placed with the checked luggage. NuVasive Specialized Orthopedics, Inc. has a document that can be given to the airlines to allow for air travel with the ERC. Contact NuVasive Specialized Orthopedics, Inc. if needed.

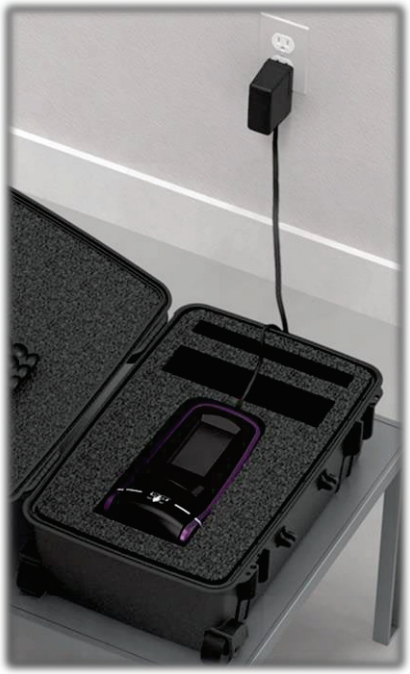
Disposal:

Do not dispose of the External Remote Controller in the trash. Please return it in its protective case to NuVasive Specialized Orthopedics or call for disposal directions. Do not incinerate this equipment. The External Remote Controller contains a rare earth magnet which burns extremely hot if ignited.

d. Storing the ERC while not charging

ERC AND POWER CORD SHOULD BE STORED IN THE CASE AND AWAY FROM CHILDREN WHEN NOT IN USE.	
	1. Place ERC and charging cord in storage case. 2. Make sure that all parts are inside and away from case edges. 3. Close, latch and lock case. 4. It is okay for metal to be near the ERC while it is inside the closed storage case. **5.** Store case indoors. Do not store close to a heater, fireplace, or in other areas that may have extreme temperatures. (**Do not store the ERC above 140ºF/60ºC or below 14ºF/-10ºC**).

e. Storing the ERC while charging

ERC AND POWER CORD SHOULD BE STORED IN THE CASE AND AWAY FROM CHILDREN WHEN NOT IN USE.	
	1. When charging in between sessions, place ERC in storage case and keep the ERC powered on. 2. Make sure that all parts are inside and away from case edges. 3. **DO NOT latch and lock case while the charging cord is connected into a wall outlet and connected to the ERC.** Latching and locking the case can break the charging cord. 4. Gently rest the top of the case over the ERC. 5. It is okay for metal to be near the ERC while it is inside the closed storage case and the lid is covering the ERC. **6.** Store case indoors. Do not store close to a heater, fireplace, or in other areas that may have extreme temperatures. (**Do not store the ERC above 140ºF/60ºC or below 14ºF/-10ºC**).

15. MORE ABOUT YOUR CONDITION

Lifestyle Changes:

Limit your activities and try to not put weight on your leg or arm during your entire treatment. Rough activity and putting weight on your leg or arm can lead to an injury. It can also cause the implant to break. Your doctor may have you use equipment such as crutches or a wheelchair to avoid putting extra weight on your limb during your treatment. If your implant is in your arm, your doctor may advise you to use a sling.

Do not participate in any high-impact sports for the entire time you have the implant. Some examples of rough sports are weightlifting, tumbling, gymnastics, or rowing. You can do those sports once your doctor tells you it is okay.

The life style changes you will experience during the various treatment stages are as follows:

Implantation: You will be admitted to the hospital and may need to stay in the hospital after your surgical procedure. This is typically 5 days. At this time, your activities will be limited and will not be at home.

Lengthening/Shortening: During this phase, your doctor will advise you to keep your weight off of your implanted limb. For lower limbs, you may require crutches or a wheelchair to get around. You will have regular (usually once a week) visits with your doctor to check on your progress.

Consolidation: During this phase you will still need to keep your weight off of your implanted limb. Your doctor will advise you on your weight-bearing ability. You may still need crutches or a wheelchair and have limited mobility for lower limb implants. You will also need to have regular (usually monthly) visits to your doctor to check on your progress.

Removal: After your bone has healed, you will require another surgery to remove the PRECICE implant. During this time, you will be hospitalized for your recovery. At this time, your activities will be limited and you will not be at home.

Need to Adhere to Care Regimen:

It is important that you follow the treatment schedule and prescription given by your doctor. Go back to this instruction guide when necessary. If you do not follow your doctor's instructions, the PRECICE implant may not lengthen or shorten properly. Additional surgery may be required.

Your doctor will tell you when you need to return for regular visits. Usually, you will return to the doctor’s office once a week during lengthening or shortening. You will return about once a month during consolidation. If your ERC malfunctions, you should call your doctor for a replacement ERC.

Discuss any pain or discomfort you are having with your doctor. Your doctor may want to adjust your prescription during your treatment if you are experiencing pain or discomfort.

Talk to your doctor if you have questions about your treatment. Your doctor can also provide more information on the PRECICE system.

16. TROUBLESHOOTING. (ERRORS)

This section lists the problems that you may have when using the ERC and how to troubleshoot them.

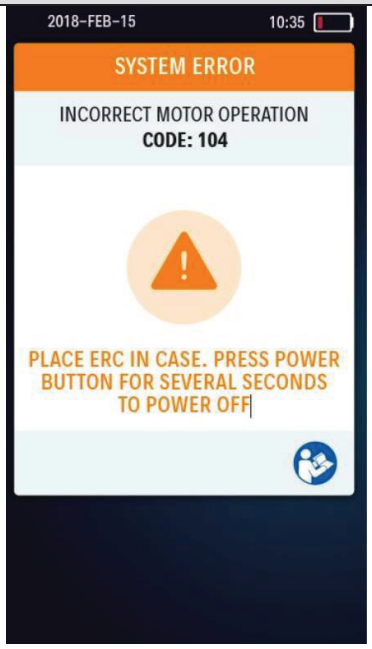
If you cannot fix a problem, call your doctor for help.

a. Problem Solving

Problem	Possible Reason	Possible Solution
You missed a treatment	You forgot your treatment session	Contact your doctor for help.
Display screen does not light up	The ERC does not have power	1. Make sure that the ERC battery is charged by plugging the charging cord into the ERC and a working outlet. 2. If the charging cord is already plugged in, try plugging the adapter into a different outlet.
	The ERC is damaged	Contact NuVasive Specialized Orthopedics, Inc.
The ERC is cracked or damaged	ERC was accidently dropped	Do not use the ERC. Call your doctor for a replacement.
Your prescription is incorrect	Your prescription was programmed incorrectly	Contact your doctor.
No session required screen comes on (Session Complete)	You have reached your daily prescription	Wait until the next day. (The daily maximum is calculated using a 24-Hour timer)

b. Error Codes

For questions regarding your prescription, contact your physician. For questions regarding your ERC, contact NuVasive Specialized Orthopedics, Inc. at 855-435-5477.

ERC ERROR CODES		
		**ERROR SCREEN** This screen will appear if there is a malfunction with the ERC. Depending on the error code, contact your physician or NuVasive Specialized Orthopedics, Inc. and let them know the Error Code Number. They will give you further instructions and possibly send you a replacement ERC.
POSSIBLE ERROR CODE	**DESCRIPTION**	**WHAT TO DO**
Code 020	Power Button Stuck	If the Power Button is stuck, then this error will occur. Ensure the Power Button is not being held down while the ERC is powered on. If this error still persists, then the ERC must be replaced. Contact NuVasive Specialized Orthopedics, Inc.
Code 021	ERC Malfunction	Disconnect the power supply and hold down the power button for several seconds until the power button LED is off. Wait several minutes for the display to be off and then power on the ERC.
Code 064	ERC Malfunction	Power down the ERC by pressing or holding the power button and restart the system. If this error still persists, then the ERC 4P must be replaced. Contact NuVasive Specialized Orthopedics, Inc.

Code 069 **Code 071** **Code 083** **Code 084**	ERC Malfunction	The ERC must be replaced. Contact NuVasive Specialized Orthopedics, Inc.
Code 85	Component Error	If the charging cord connected into the ERC is malfunctioning, then this error will occur. Power down the ERC and remove the charging cord. The ERC must be replaced. Contact NuVasive Specialized Orthopedics, Inc.
Code 86 **Code 87** **Code 88** **Code 89**	ERC Malfunction	The ERC must be replaced. Contact NuVasive Specialized Orthopedics, Inc.
Code 93	Motor Error	This error will occur if the ERC motor is running too fast. Power down the ERC. Remove the charging cord if it is connected into the ERC. The ERC must be replaced.Contact NuVasive Specialized Orthopedics, Inc.
Code 94	Motor Error	This error will occur if the ERC motor is running too slow. Power down the ERC by pressing or holding the power button and restart the system. If this error persists, then the ERC must be replaced. Contact NuVasive Specialized Orthopedics, Inc.
Code 100	System Error	This error will occur if there is a system communication malfunction with the ERC. Power down the ERC by pressing or holding the power button and restart the system. If this error persists, then the ERC must be replaced. Contact NuVasive Specialized Orthopedics, Inc.
Code 104	Incorrect Motor Operation error	If the motor has been detected to be running at a time when it should not, this error will occur. Remove ERC from body immediately, place in case, press and hold Power Button to shut down. Once it is powered off, try to restart the device. If the device does not restart, the ERC must be replaced because the motor is not working properly. The ERC must be replaced. Contact NuVasive Specialized Orthopedics, Inc.
Code 105	Incorrect motor operation error	If the motor has been detected to be running in the opposite direction during therapy, this error will occur. The ERC must be replaced. Contact NuVasive Specialized Orthopedics, Inc.

Code 106	Motor Not Rotating Error	This error will occur if the motor has been detected to not be rotating during therapy. The ERC must be replaced. Contact NuVasive Specialized Orthopedics, Inc.
Code 114 **Code 116**	Motor Rotating Error	Power down the ERC by pressing or holding the power button and restart the system. If this error persists, then the ERC must be replaced. Contact NuVasive Specialized Orthopedics, Inc.
Code 121	Motor Fault Error	This error will occur if a problem has been detected with the motor. This may occur if the motor has been running for long periods of time. Allow time for the motor to cool down. Power down the ERC by pressing or holding the power button and restart the system. If this error still persists, the ERC must be replaced. Contact NuVasive Specialized Orthopedics, Inc.
Code 130	Temperature Too Hot	This error will occur if the temperature of the ERC 4P is too hot. The ERC must be placed in a cooler environment and allowed to cool down. If this error persists, the ERC must be replaced. Contact NuVasive Specialized Orthopedics, Inc.
Code 131	Temperature Too Cold	This error will occur if the temperature of the ERC 4P is too cold. The ERC must be placed in a warmer environment and allowed to warm up. If this error persists, the ERC must be replaced. Contact NuVasive Specialized Orthopedics, Inc.
Code 140 **Code 141**	Battery Error	This will occur if the battery is malfunctioning. The ERC must be replaced. Contact NuVasive Specialized Orthopedics, Inc.
Code 142	Battery Error	This will occur if the battery is malfunctioning. Plug-in the power supply to use of the ERC.
Code 143	Battery Too Hot Error	If the ERC battery is too hot, then this error will occur. The ERC must be placed in a cooler environment and allowed to cool down. If this error persists, the ERC must be replaced. Contact NuVasive Specialized Orthopedics, Inc.

Code 144	Battery Error	The ERC must be replaced. Contact NuVasive Specialized Orthopedics, Inc.
Code 145	Low Battery Error	This error will occur if the battery is low. Connect the charging cord into the ERC. If this error persists, the ERC must be replaced. Contact NuVasive Specialized Orthopedics, Inc.
Code 146	Battery Error	This will occur if the battery is malfunctioning. The ERC must be replaced. Contact NuVasive Specialized Orthopedics, Inc.
Code 147	Battery Error	This will occur if the battery charging is malfunctioning. Plug-in the power supply to use of the ERC.
Code 200 **Code 201**	System Error	Power down the ERC by pressing or holding the power button and restart the system. If this error persists, then the ERC must be replaced. Contact NuVasive Specialized Orthopedics, Inc.

17. SPECIFICATIONS

Description	**Rating**	**Units**
Displayed Travel Accuracy	±10% + ±0.3	mm
Operating Temperature	5 – 35 (41 – 95)	ºC (ºF)
Operating Relative Humidity	30 – 95 (Non Condensing)	%
Storage Temperature	-10 – 60 (14 – 140)	ºC (ºF)
Storage Relative Humidity	5 – 95 (Non Condensing)	%
Input Power Voltage (Single Phase)	80 – 230	VAC
Input Power Frequency	47 / 63	Hz
Input Power Current (Maximum)	1	A
Weight: ERC 4P	3.4 (7.5)	kg (lbs)
ERC 4P with Carrying Case	10.4 (22.9)	kg (lbs)

Description	**Rating**
Classification for Shock Protection	Class II No reliance on protective earth, double insulated
Applied Part Type Shock & Leakage Current	Type BF (Basic Floating)
Defibrillation Rating	Not Defibrillator Proof
Anesthetic Use	Do NOT use this equipment in the presence of flammable anesthetics (Neither AP nor APG)
Method of Sterilization	Non-Sterile
Pollution Degree	Pollution Degree 2 (Office Environment)
Over Voltage Category	Category II
Ingress Protection	IPX0 Not Protected from fluid ingress

Guidance and manufacturer's declaration – electromagnetic emissions		
The ERC is intended for use in the electromagnetic environment specified below. The customer or the user of the ERC should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Class B	The model ERC 4P for Precice may emit unintentional electromagnetic energy during normal operation up to permissible limits suitable for use in domestic establishments and in establishments directly connected to a low-voltage power supply network.
RF emissions CISPR 11	Class B	The ERC is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The ERC is intended for use in the electromagnetic environment specified below. The customer or the user of the ERC should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 2, 4, 8 kV (contact) ± 2, 4, 8, 15 kV (air) ± 2, 4, 8 kV (indirect, HCP and VCP)	Complies	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Short Interrupts: 0% at ½ cycle 0% at 1 cycle 70% at 25 cycles for 50Hz 70% at 30 cycles for 60Hz	Complies	Mains power quality should be that of a typical commercial or hospital environment. If the user of the model ERC 4P for Precice requires continued operation during power mains interruptions, it is recommended that the model ERC 4P for Precice be powered from an uninterruptible power supply.
Power frequency (50 Hz) magnetic field IEC 61000-4-8	30 A/m at 230V	Complies	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">The ERC is intended for use in the electromagnetic environment specified below. The customer or the user of the model ERC should assure that it is used in such an environment.</td></tr>
<tr><th>IMMUNITY test</th><th>IEC 60601 TEST LEVEL</th><th>Compliance level</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 Vrms
150 kHz to 80 MHz</td><td>3 Vrms

3 V/m</td><td rowspan="2">Portable and mobile RF communications equipment should be used no closer to any part of the ERC, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
$d = 1.2\sqrt{P}$

$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
$d = 2.3\sqrt{P}$ 800MHz to 2.5 GHz

where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]

Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3 V/m
80 MHz to 2.5 GHz</td><td></td></tr>
<tr><td colspan="4">NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</td></tr>
<tr><td colspan="4">a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ERC is used exceeds the applicable RF compliance level above, the ERC should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ERC.
b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

Recommended separation distances between portable and mobile RF communications equipment and the External Remote Controller			
The ERC is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ERC can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ERC as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = 2.3\sqrt{P}$	**80 MHz to 800 MHz** $d = 2.3\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1.0	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

The products discussed herein may be protected by one or more of the patents found at: www.nuvasive.com/pat

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