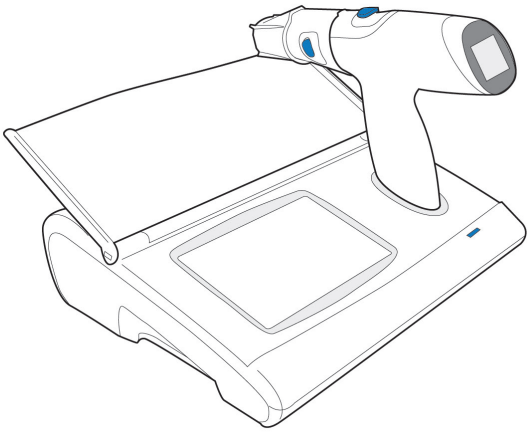
CELLECTRA® 5PSP

for VOCERYQ™
(doruxapapogene ralaplasmid and
lalikinogene sifuplasmid-gxfd) solution for intramuscular injection.

User Manual



CAUTION! READ THESE INSTRUCTIONS.

⚠ This User Manual contains important information necessary to safely and effectively operate CELLECTRA® 5PSP. This User Manual should be read before use and it should be available during use. Failure to adhere to the instructions provided in this User Manual may result in injury.

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℞ ONLY

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1. About CELLECTRA® 5PSP

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Purpose

The User Manual describes the proper use of CELLECTRA® 5PSP for VOCERYQ to treat patients with Recurrent Respiratory Papillomatosis (RRP).

Intended Use

VOCERYQ is indicated to reduce the frequency of surgical papilloma excisions in adults with recurrent respiratory papillomatosis. This indication is approved under accelerated approval based on reduction in the frequency of surgical papilloma excisions. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory study(ies).

CELLECTRA® 5PSP is intended for injection and enhanced cellular uptake of the DNA plasmids in VOCERYQ by way of intramuscular injection followed by application of intramuscular electrical pulses. The CELLECTRA® 5PSP Array is packaged sterile and is intended for single use.

CELLECTRA® 5PSP is intended to be used by trained healthcare professionals in clinical settings.

Contraindications

None known.

Warnings and Precautions

WARNINGS

Note: If any conditions below are observed on the patient, consult with the patient's physician or Inovio for the final treatment decision.

General warnings

- Do not use on areas where major blood vessels or nerves are present.
- Do not use CELLECTRA® 5PSP on patients with any significant acute or chronic medical illness if it is determined by the patient's physician that electroporation could negatively impact the patient.
- Avoid injecting directly into areas where the skin is tender, bruised, erythematous, indurated or affected by any lesions. Do not inject within 2 cm of a tattoo, keloid or hypertrophic scar.
- Do not use CELLECTRA® 5PSP on areas of the patient containing any metal implants or implantable medical device.
- Do not use CELLECTRA® 5PSP on patients with a Cardioverter-defibrillator (ICD) or pacemaker (to prevent a life-threatening arrhythmia) that is located ipsilateral to the intended deltoid injection site unless deemed acceptable by a Cardiologist or the patient's physician.
- Do not use the device in the presence of 100% oxygen gas or other volatile substances such as flammable anesthetics. This may result in explosion or fire hazard.
- Do not open or attempt to modify any part of the system. Return to INOVIO Pharmaceuticals, Inc. for repair. Opening or attempting to modify the system may result in malfunction, electrical shock, or fire hazard.
- Do not use CELLECTRA® 5PSP if it was dropped. Return the Base Station and Handset together to INOVIO Pharmaceuticals, Inc. if either the Base Station or Handset was dropped. Use of the Base Station and Handset after either was dropped may result in system malfunction or injury.
- Do not use CELLECTRA® 5PSP if any part appears to be damaged or altered. Use of a damaged or altered system may result in patient harm or ineffective treatment.
- Do not use CELLECTRA® 5PSP if any tamper-evident seal is broken. If a tamper-evident seal is broken, contact INOVIO Pharmaceuticals, Inc. for further instruction.

WARNINGS (CONT.)

- CELLECTRA® 5PSP is only for use with sterile disposable Arrays and VOCERYQ Cartridges provided for use by INOVIO Pharmaceuticals, Inc. Incompatible Arrays or VOCERYQ Cartridges may result in malfunction or injury.
- Emissions from other electronic devices may interfere with the proper operation of this device. Review the Manufacturer's Declaration – Immunity in this User Manual.
- Ensure that the CELLECTRA® 5PSP Base Station is connected to a power receptacle that provides 100 to 240 volts AC, 0.35 Amps maximum and at 50 to 60 Hz to prevent the possibility of electrical shock or fire hazard.
- Use the provided Power Supply ONLY. Using any other Power Supply may result in malfunction or fire hazard.
- If the Array is dropped, dispose of it in a Sharps container. Use of an Array after it is dropped may result in injury. The treatment may be continued with a new Array.
- Medical judgment should be used to select a needle depth that safely and effectively targets muscle. An inappropriate needle depth may result in patient harm or ineffective treatment.

General warnings

- Unplug the Base Station before cleaning CELLECTRA® 5PSP.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of CELLECTRA® 5PSP, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Do not expose CELLECTRA® 5PSP to potential sources of electromagnetic interference (EMI). Common sources of EMI may include radiofrequency identification (RFID) readers, near-field communications (NFC) systems, wireless power

WARNINGS (CONT.)

General warnings

transfer (WPT), Cellular 5G, and unique medical emitters such as electrocautery, MRI, electrosurgical units, and diathermy equipment.

Read this User Manual

- MR Unsafe - Keep away from magnetic resonance imaging (MRI) equipment.
- CELLECTRA® 5PSP is ONLY for use by trained healthcare professionals who have successfully completed CELLECTRA® 5PSP training. For training details on CELLECTRA® 5PSP, please contact INOVIO.
- Always determine proper placement of the sterile disposable Array based on the guidance of the trained healthcare professional.
- Do not use a malfunctioning device. Refer to Troubleshooting Section 5 of this User Manual.

Do not use if package damaged

- Do not use an Array or VOCERYQ Cartridge if the packaging is damaged. Using an Array or VOCERYQ Cartridge with damaged packaging may result in patient harm.

- Do not touch the needle end of the Array. Touching the needle end of the Array may result in needle sticks, infection, or injury.

PRECAUTIONS

Caution

- Keep foreign material from covering the black sensor windows near the Needle Depth Selector (see Figure 1) to avoid unintended Array errors that might require restarting the overall treatment procedure.
- Certain light sources that emit Infrared (IR) wavelengths, such as IR lamps, incandescent light, and direct sunlight located in close proximity to the Handset could influence device performance. In cases where errors are not resolved by following the specific instructions for a given error, moving the device to an area with alternate lighting conditions may resolve the error.

Environ-mental limits

- Always use CELLECTRA® 5PSP within the temperature, humidity, and atmospheric pressure ranges specified below and listed in Section 6 of this User Manual. Using the system outside these ranges may result in malfunction. Contact INOVIO Pharmaceuticals, Inc. if environmental specifications are exceeded.+18°C to +28°C (+64°F to +82°F), Less than or equal to 90% Relative Humidity, non-condensing, up to 2,000 meters (6,562 feet) above sea level.

PRECAUTIONS (CONT.)

Biological risks

- Following the electroporation procedure, carefully withdraw the Array and dispose of it in accordance with accepted medical practice and any applicable local, state, and federal laws and regulations.

Do not reuse

- Do not reuse Arrays and VOCERYQ Cartridges. Arrays and VOCERYQ Cartridges are for single-use ONLY. Reuse of Arrays or VOCERYQ Cartridges will result in system malfunction.

Use-by date

- Do not use an Array or VOCERYQ Cartridge that has passed the expiration date printed on the package label. Using an expired Array or VOCERYQ Cartridge may result in patient harm or ineffective treatment.

Sterilized using irradiation

- Do not use an Array if the packaging is damaged. Always use a clean technique when handling the Array and VOCERYQ Cartridge.

Do not resterilize

- Do not attempt to re-sterilize Arrays and VOCERYQ Cartridges. Arrays and VOCERYQ Cartridges are for single-use ONLY. Reuse of Arrays or VOCERYQ Cartridges will result in system error.

Potential Risks and Adverse Reactions

Patients treated with CELLECTRA® 5PSP may experience:

- Brief muscle contractions or tetany which may be uncomfortable.
- Temporary bleeding at the administration site.
- Anxiety related to the administration procedure.
- Vasovagal reaction/lightheadedness/dizziness related to the administration procedure.
- Muscle damage resulting in transient changes in creatine phosphokinase, and burns.

The undesirable side-effects for CELLECTRA® 5PSP are:

- Injection site pain or tenderness.
- Injection site erythema or redness.
- Injection site swelling.

To report any adverse reactions, contact INOVIO's Support Line at 1-855-INOVIO1 (466-8461).

Device Components

The CELLECTRA® 5PSP device consists of three (3) main components and two (2) additional accessory items provided in the package (Figure 1):

1. **CELLECTRA® 5PSP Base Station:** a reusable component, which serves as a charging dock for the Handset and can accept limited data inputs as well as store records (Figure 2).
2. **CELLECTRA® 5PSP Handset:** a reusable component, which is battery powered and delivers the electroporation pulse pattern. The Handset accepts the Array (Figure 3).
3. **CELLECTRA® 5PSP Array:** The sterile, single-use disposable Array consists of five (5) needle-electrodes molded into a plastic housing that also accepts the (shipped separately) VOCERYQ Cartridge. The Array accepts a standard, commercially available glass cartridge (Figure 4).

Note: The Base Station and Handset are reusable devices that do not come in contact with the patient or the VOCERYQ Cartridge. The sterile, single-use Array is the only component that comes in contact with the patient and the VOCERYQ Cartridge.

Two accessories are:

4. **USB International Power Supply:** Used for device charging and operation of Base Station.
5. **USB Flash Drive:** To be used for data download upon request.

VOCERYQ Cartridge is also required:

6. **VOCERYQ single-use cartridge:** Contains the immunotherapy to be inserted into the Array for administration **(see Figures 5 and 6).**

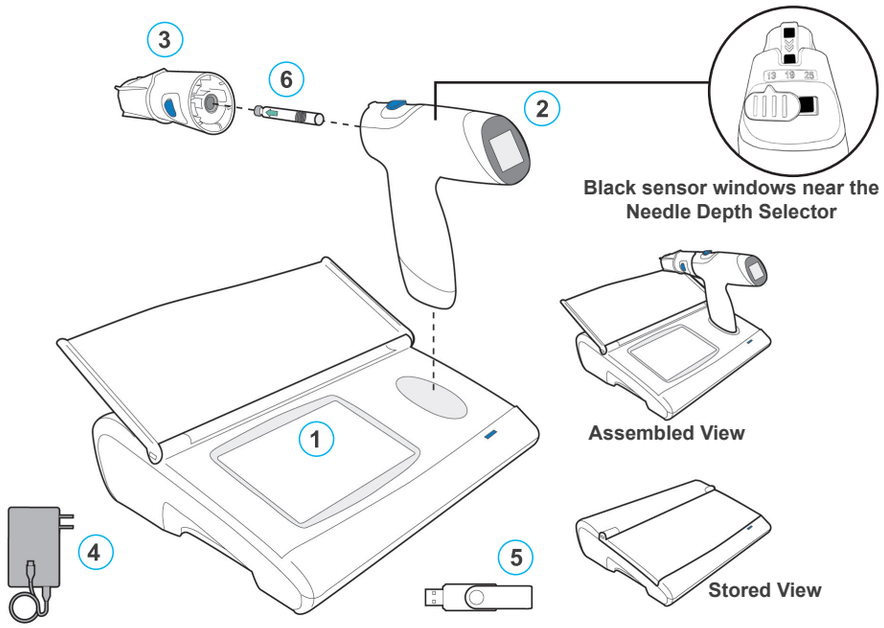

Figure 1 CELLECTRA® 5PSP components and VOCERYQ Cartridge

Base Station

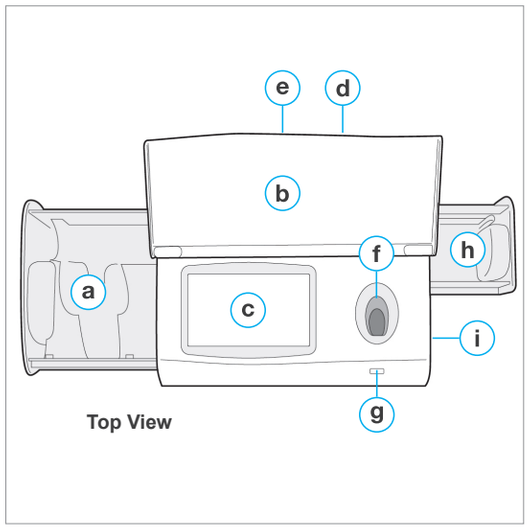

Figure 2 The parts of the Base Station

a. Handset Drawer
b. Lid (with Quick-Start Guide)
c. Base Station Touchscreen
d. Power Port (on the back)
e. Serial Number (on the back)
f. Handset Port
g. Power Light
h. Power Supply Drawer
i. USB Port

Handset

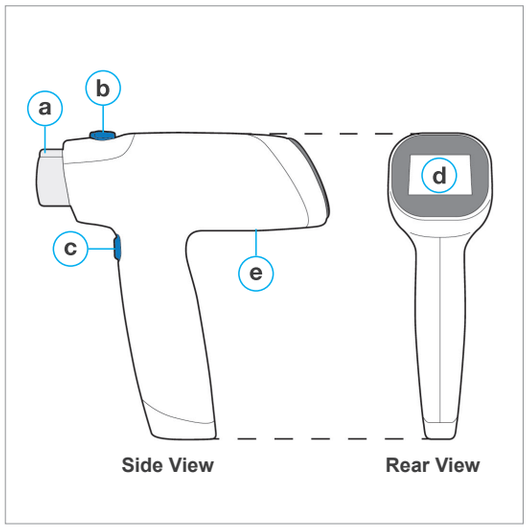

Figure 3 The parts of the Handset

a. Array Alignment Groove
b. Needle Depth Switch
c. Trigger
d. Handset Display (not a touchscreen)
e. Serial Number (underside)

Array

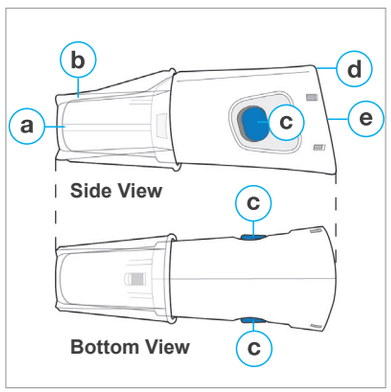

Figure 4 The parts of the Array

a. Needle End

b. Cap

c. Blue Release Buttons

d. Array Alignment Slot

e. Cartridge Port

VOCERYQ Cartridge

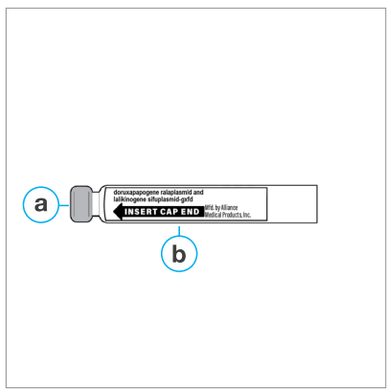

Figure 5 The VOCERYQ Cartridge supplied in Carton

a. Crimp Cap Septum

b. Cartridge

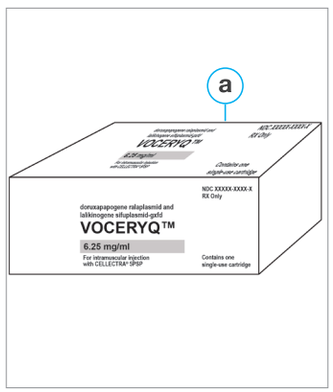

Figure 6 Carton

a. VOCERYQ Label with Expiration Date on Carton

Displays and Feedback

The system has two displays to guide the user through treatment:

- **Base Station Touchscreen** – Used to initially set up treatment and to access help information during treatment (see Figure 7).
- **Handset Display** – Guides the user through delivering treatment (see Figure 8).

In addition to these displays, the Base Station and Handset plays distinct sounds to confirm steps and indicate errors.

Note: Use of objects such as pens to touch the screen may scratch the screen.

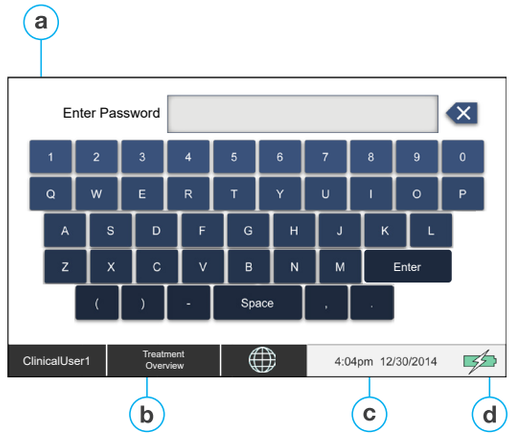

Figure 7 The parts of the Base Station Touchscreen

a. Title Bar

b. Menu Bar

c. Time/Date

d. Handset Battery Icon

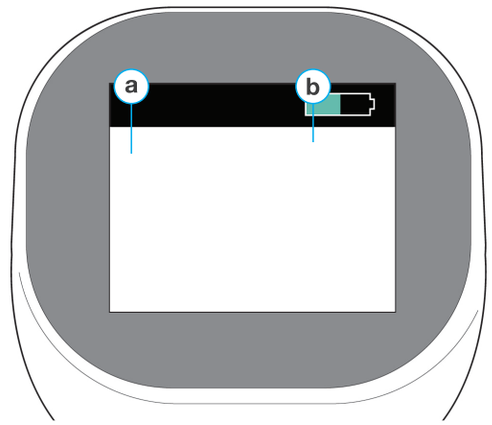

Figure 8 The parts of the Handset Display

a. Title Bar

b. Handset Battery Status

Unique Features

CELLECTRA® 5PSP has unique features:

- Each Handset is uniquely paired to a Base Station. The serial numbers on the back of the Base Station and on the bottom of the Handset must match.
- There is no communication between the Base Station and Handset when separated; the Handset must be placed onto the Base Station to share power or data.
- The Handset has an internal battery that must be charged on the Base Station before use. If the Low Battery Warning is displayed, wait for 20 minutes or until the Low Battery Warning is no longer displayed.
- The needle depth can be selected on the Handset -13 mm, 19 mm, or 25 mm. The system provides a needle depth recommendation based on a patient's height and weight.
- Injecting VOCERYQ and delivering electrical pulses takes time (approximately 10 seconds). The Handset will alert the user when treatment is complete.

2. Setup

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Device Start-up

Follow these instructions to set up CELLECTRA® 5PSP for the first time or after storage.

1. **Unpack the Handset and power supply from the drawers of the Base Station (see Figure 9).**

   Note: Each Handset is uniquely paired to a Base Station. The serial numbers on the back of the Base Station and the bottom of the Handset must match.

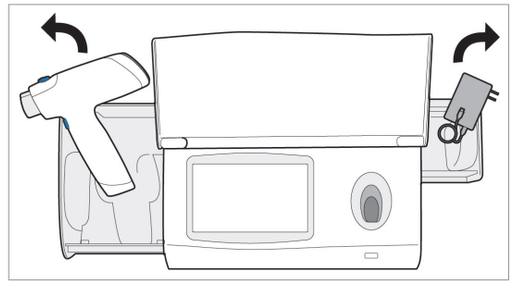

Figure 9 Handset and Power Supply

CAUTION!

⚠ Avoid exposing the Handset to light sources that emit Infrared (IR) wavelengths, such as IR lamps, incandescent light, and direct sunlight (sunlight, incandescent light, and/or other infrared wavelengths).

2. **Inspect the Base Station and Handset for damage and visible soil before each use. Refer to Section 4 - Care Information for cleaning instructions.**

3. **Dock the Handset on the Base Station (see Figure 10).**

   Note: Ensure that the Array is not attached to the Handset prior to power up.

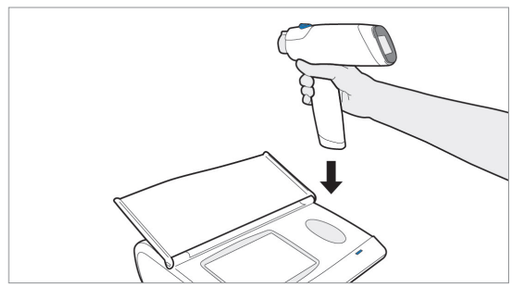

Figure 10 Dock Handset

CAUTION!

⚠ Position the Base Station and Handset so that they will not be exposed to liquids and so that the power cord will not create a tripping hazard.

CAUTION!

⚠ Do not use the Handset when it is docked in the Base Station.

Do not touch the front opening of the Handset when it is docked in the Base Station.

4. **Connect the Base Station to a power outlet for charging (see Figure 11).**

Note: If the Low Battery Warning is displayed on the Base Station and Handset, wait for approximately 20 minutes or until the Low Battery Warning is no longer displayed.

Note: Ensure there is always access to the power cord and electric supply so the power cord can be removed from the outlet to shut off power to the Base Station, if required.

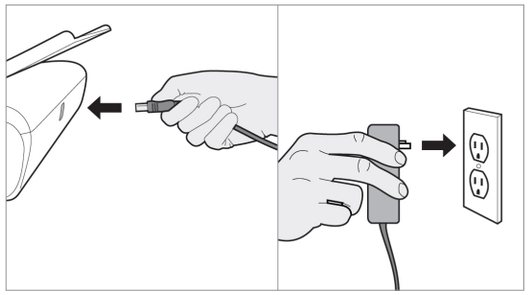

Figure 11 Connect Power Supply

5. **On power up, device will initiate a Self-Test and the *Start Up* screen will be displayed on the Base Station and Handset (see Figure 12 and Figure 13).**

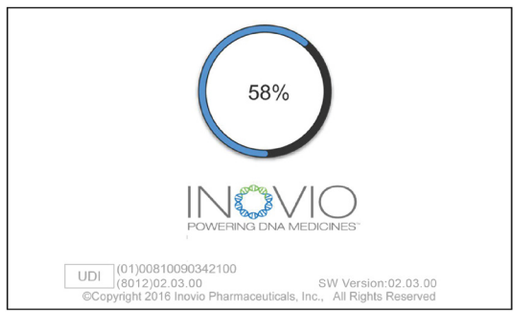

Figure 12 Self-Test Screen

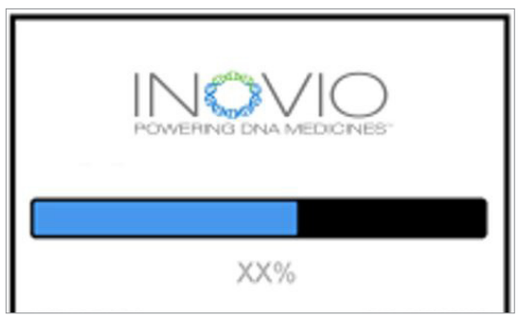

Figure 13 Start Up Screen

6. **After a successful Self-Test, an audible sound will play from the Base Station and Handset. The *Enter Password* screen is shown on the Base Station (see Figure 14) and the Handset screen will be blank.**

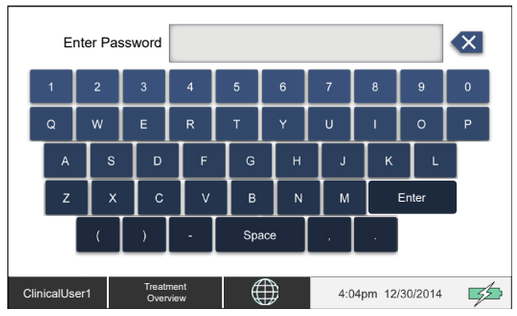

Figure 14 Enter Password Screen

7. **Press *Treatment Overview* on the *Password* screen to see a summary of the steps to perform a treatment (see Figure 15).**

Figure 15 Treatment Overview Screen

Change Settings

You can change the language, set the time and date, select units for patient height and weight, and change the screen brightness if needed.

1. **To change the language, press the on the *Enter Password* screen. Select your language using the Up and Down arrows. Then press Confirm (see Figure 16).**

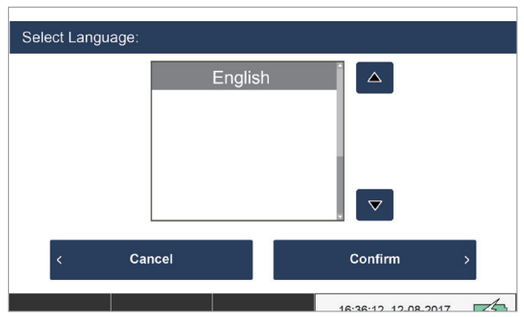

Figure 16 Select Language Screen

2. **To select a user, press the button in the lower left corner with the user name on the *Password* Screen. *Select User* using the Up and Down arrows. Then press Confirm (see Figure 17).**

   Note: Only admin users can access the user management screens.

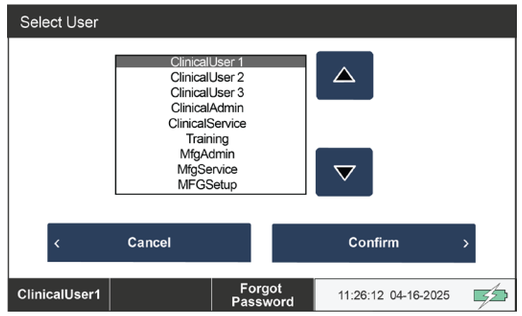

Figure 17 Select User

3. **To change a setting, start by pressing Settings on the *Enter Patient Height* screen. You will need to enter the code on the *Enter Password* screen to access the *Enter Patient Height* screen (see Figure 18).**

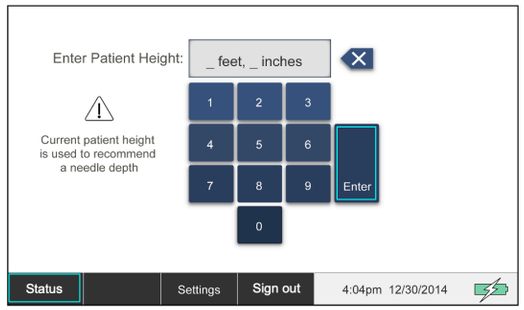

Figure 18 Enter Patient Height Screen

4. **The Settings screen allows you to access *DEVICE SETTINGS*, *CLINIC INFORMATION, USER MANAGEMENT, DOWNLOAD LOG CONTENTS, or HELP* (see Figure 19).**

   Press ***View*** next to ***Device Settings*** to change a setting.

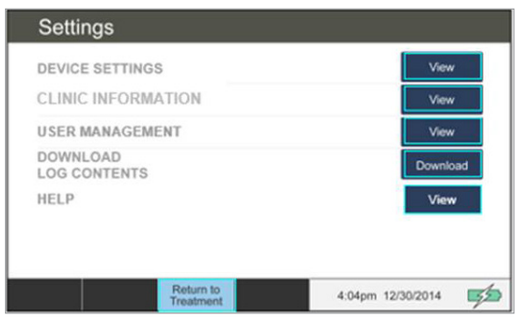

Figure 19 Settings Screen

5. **To set the time and date or select units for height and weight, press *Change* next to *LOCALE SETTINGS* on the *Device Settings* screen (see Figure 20).**

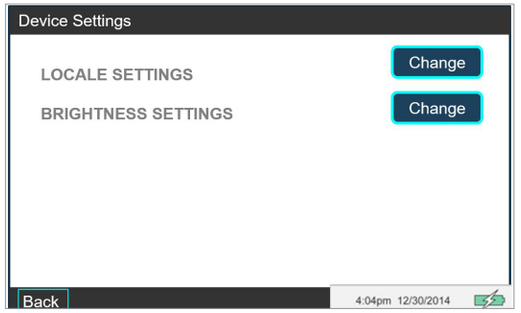

Figure 20 Device Settings Screen

6. **The *LOCALE SETTINGS* screen shows the current settings. Press *Change* next to a settings option to change that setting (see Figure 21).**

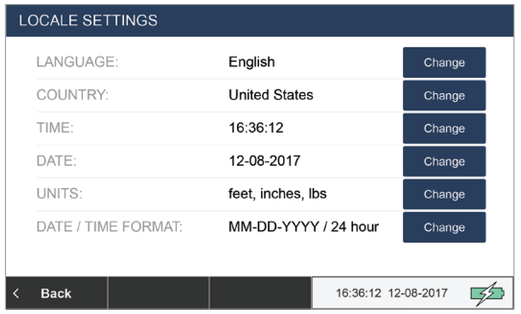

Figure 21 Locale Settings Screen

7. **To change the time, from the *LOCALE SETTINGS* screen (see Figure 21) press *Change* next to *Time* to go to the *Adjust Time* screen.**

   Press the ***Up*** and ***Down*** arrows to adjust the time. Then press ***Confirm*** when done (see Figure 22).

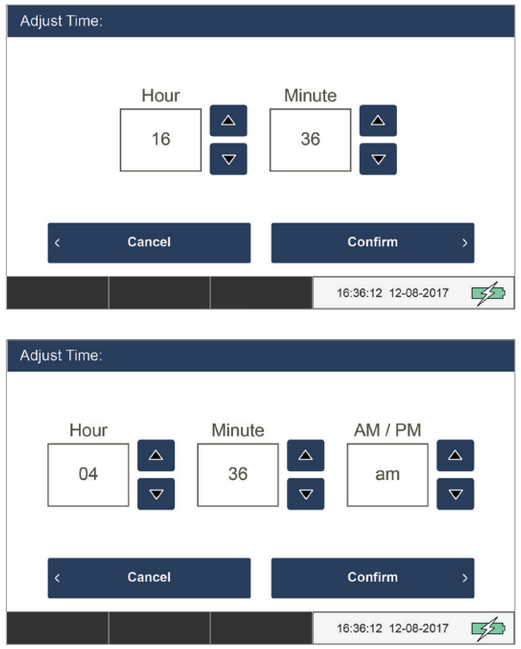

Figure 22 Adjust Time - 24 hour (top) & 12 hour (bottom) screens

8. **To change the time format or date format, from the *LOCALE SETTINGS* screen (see Figure 21) press *CHANGE* next to *Date/Time Format* to go to the *Select Format* screen.**

   Press the ***Up*** and ***Down*** arrows to adjust the time format or date format. Then press ***Confirm*** when done (see Figure 23).

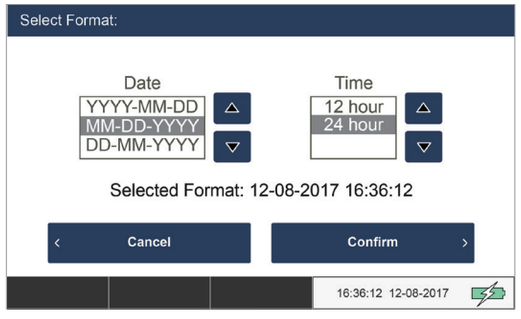

Figure 23 Select Format Screen

9. **To change the units used for patient height and weight, from the *LOCALE SETTINGS* screen (see Figure 21) press *Change* next to Units to go to the *Select Units* screen.**

   Press the ***Up*** and ***Down*** arrows to select the units for height and weight. Then press ***Confirm*** when done (see Figure 24).

Figure 24 Select Weight and Height Units

10. **To change the screen brightness, from the Device Settings screen (see Figure 20) press Change next to *BRIGHTNESS SETTINGS* to go to the *Adjust Brightness* screen.**

    Press the ***Up*** and ***Down*** arrows to adjust the brightness. Then press ***Confirm*** when done (see Figure 25).

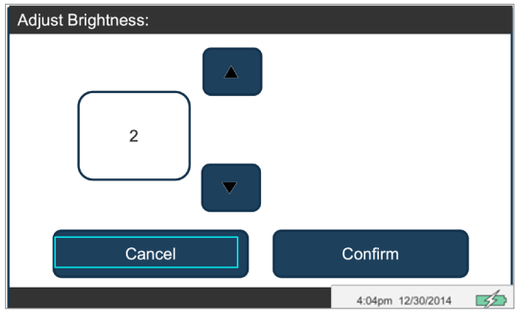

Figure 25 Adjust Brightness Screen

User Management

Steps for Adding a New User

1. Login as an admin user by selecting Clinical Admin. Then press Confirm. The Select User screen can be accessed by clicking the User button on the Enter Password screen
2. Go to Settings
3. Select User Management Settings
4. Press the Add User button (maximum three users can only be added, after that warning will pop up) (see Figure 26)
5. Enter the Username (see Figure 27)
6. Enter new password (see Figure 28)

   Note: The password requires 8 to 16 characters including at least one number.
7. Enter the confirmed password

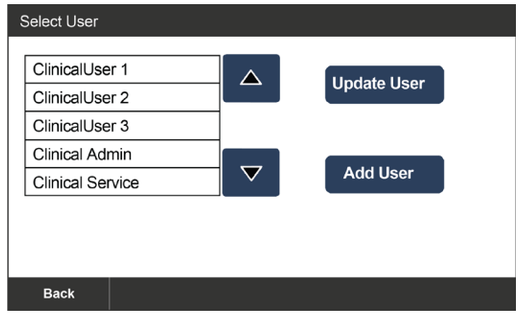

Figure 26 Select User Screen

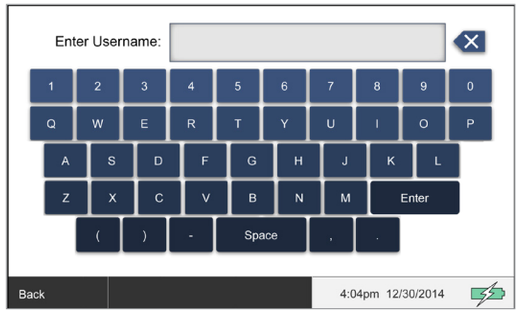

Figure 27 Enter User Name

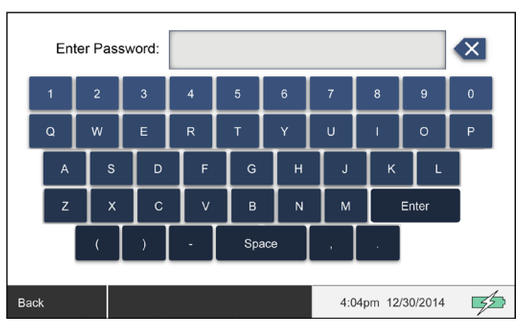

Figure 28 Enter Password

Steps to Remove, Reset Password, Activate, Deactivate

1. Login as an admin user by selecting Clinical Admin. Then press Confirm. The Select User screen can be accessed by clicking the User button on the Enter Password screen
2. Go to Settings, Select User Management settings
3. Select the specific user from the list and press the Update User button (see Figure 29)
4. Select the Activate, Deactivate, Remove, and Reset Password buttons to activate, deactivate, reset password, and remove users respectively (see Figure 30)

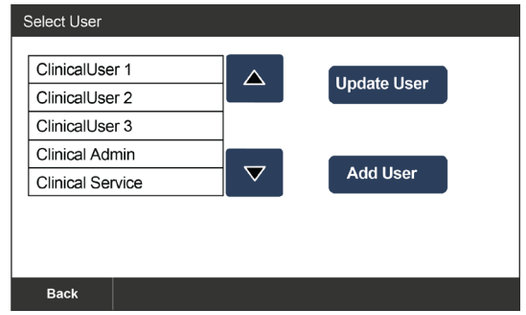

Figure 29 Select User Screen

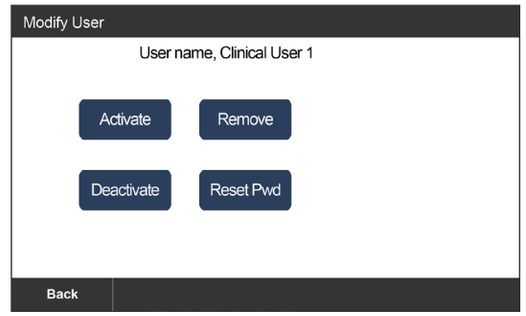

Figure 30 User Modify Screen

Steps to Recover Password (Clinic Admin and Clinic Service)

1. Press the button in the lower left corner with the user name (see Figure 31)

2. Select the admin user from the list (see Figure 31)

3. Press the Forgot Password button (see Figure 31)

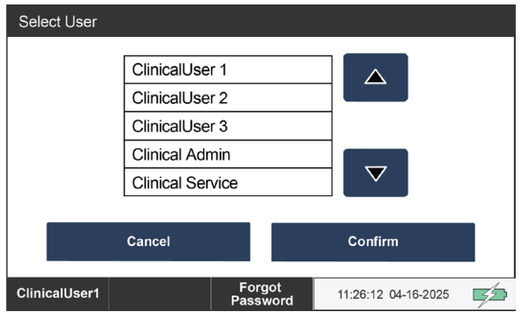

Figure 31 Select User Screen

4. Enter the security key provided by INOVIO (see Figure 32)

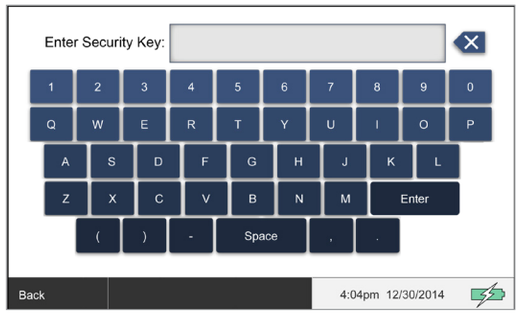

Figure 32 Enter Security Key Screen

5. Enter the new password and press the Enter key. (see Figure 33)

6. Now press the Confirm button and enter the new password and login

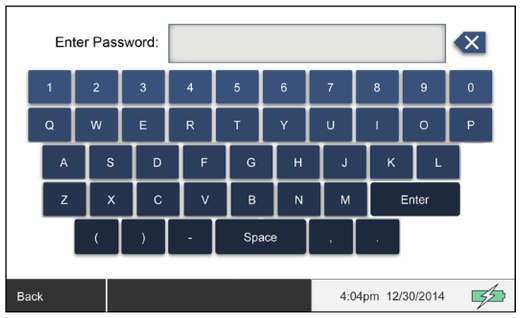

Figure 33 Enter New Password Screen

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3. Treatment

3. Treatment **27**

Before You Begin 29
Preparing VOCERYQ 30
Preparing the Base Station and the Handset 31
Preparing the Injection Site 33
Preparing and Assembling the Array 34
Delivering Treatment 37
Pausing or Aborting Treatment 40
Discarding Disposables and Shutting Down the System 41
Incomplete Treatment Guide 42
Storing the Handset and Power Supply 43

3

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Before You Begin

1. **Verify that the Base Station and Handset have been set up and powered according to Section 2 (see Figure 34).**

   a. Check that the serial numbers on the back of the Base Station and bottom of the Handset match.

   b. Check that the Handset is on the Base Station and has a green battery icon.

   c. Look for the blue power indicator on the Base Station.

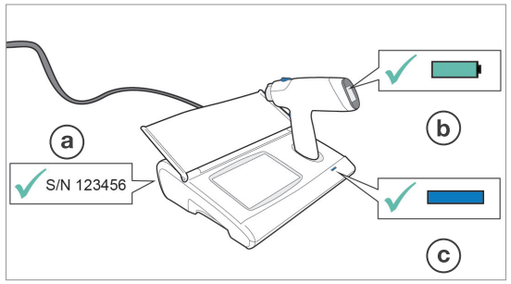


Figure 34 Base Station and Handset Checks

2. **Inspect the labels and tamper-evident seals (see Figure 35).**

   a. Inspect the product labels on the Base Station and Handset. Do not use the device if any of the product labels are no longer legible.

   b. Inspect the tamper-evident seals on the Base Station and Handset. Do not use the device if any of the seals are broken.

   c. Contact INOVIO for further instruction if any of the tamper-evident seals are broken or any product labels are not legible.

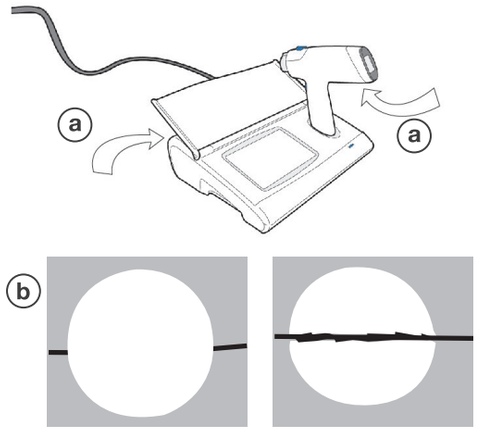


Figure 35 Example of a tamper-evident seal that is intact (left) and broken (right)

3. **Ensure the patient's Height and Weight are available and current.**

4. **Ensure another person is available to help stabilize the patient's limb during treatment.**

Note: If the patient has any conditions listed under the Warning section, consult with the patient's physician before proceeding.

CAUTION!

The system uses patient height and weight to recommend a needle depth in millimeters (mm). Incorrect values may cause an inappropriate needle depth recommendation, which may result in patient injury or ineffective treatment.

Preparing VOCERYQ

1. **Gather supplies (see Figure 36):**
   - Array (sterile).
   - Remove the carton with the VOCERYQ Cartridge from the refrigerator without removing the cartridge from the carton.
   - Alcohol wipes (for the VOCERYQ Cartridge and injection site).
   - Gauze and bandage (for after the injection).
   - Sharps container.

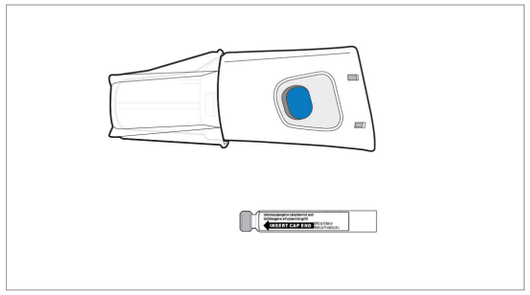


Figure 36 Array (top) and VOCERYQ Cartridge (bottom)

2. **Inspect the packaging and verify the expiration date (both Array and VOCERYQ Cartridge) (see Figure 37).**
   - **a.** Verify that VOCERYQ has been gathered.
   - **b.** Verify that the Array and VOCERYQ Cartridge are not expired.

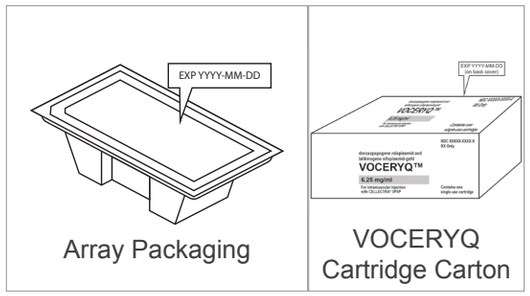


Figure 37 Array Packaging and VOCERYQ Cartridge Carton

3. **Allow the VOCERYQ Cartridge to come to room temperature.**
   - **a.** Allow VOCERYQ to reach room temperature (approximately 30 minutes).

Note: VOCERYQ in original carton should be used within 24 hours of removal from the refrigerator and may be re-refrigerated if not used; do not freeze. Upon re-refrigeration, refer to the expiry listed on the carton for shelf-life. Once removed from carton, VOCERYQ should be used within 8 hours or discarded.

WARNING!

Do not use an Array or VOCERYQ Cartridge that has passed the expiration date printed on the package label. Using an expired Array or VOCERYQ Cartridge may result in patient injury or ineffective treatment.

CAUTION!

Do not reuse Arrays and VOCERYQ Cartridges. Arrays and VOCERYQ Cartridges are for single-use ONLY. Reuse of Arrays or VOCERYQ Cartridges will result in system error.

4. **Remove the VOCERYQ Cartridge from its carton and inspect for damage (see Figure 38).**

   a. VOCERYQ Cartridge should be a clear to slightly opalescent colorless solution.

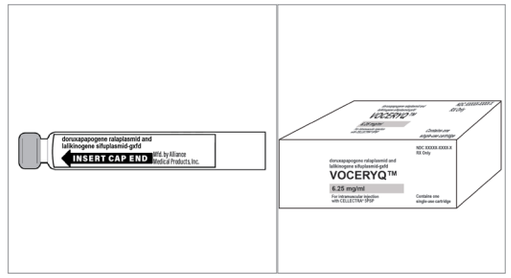


Figure 38 VOCERYQ Cartridge and Carton

WARNING!

Do not use an Array or VOCERYQ Cartridge if the packaging is damaged. Using an Array or VOCERYQ Cartridge with damaged packaging may result in patient injury.

Preparing the Base Station and the Handset

1. **On the *Enter Password* screen on the Base Station, enter the password (see Figure 39).**

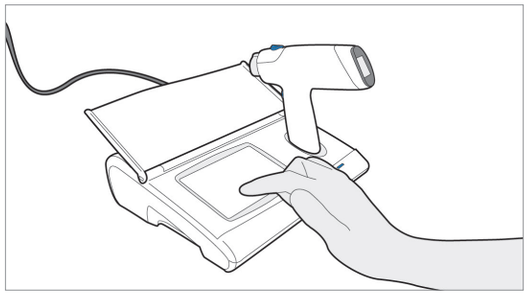


Figure 39 Base Station Entry

CAUTION!

The system uses patient height and weight to recommend a needle depth in millimeters (mm). Incorrect values may cause an inappropriate needle depth recommendation, which may result in patient injury or ineffective treatment.

2. **Enter the Patient Height then press *Enter* (see Figure 40).**

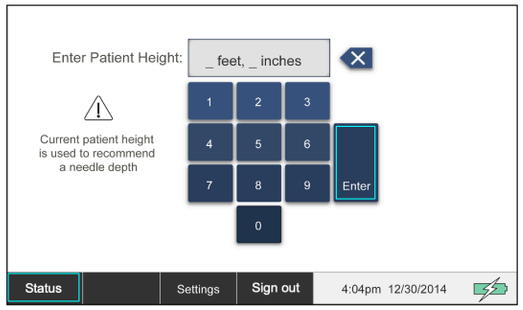


Figure 40 Patient Height

3. **Enter the Patient Weight then press *Enter* (see Figure 41).**

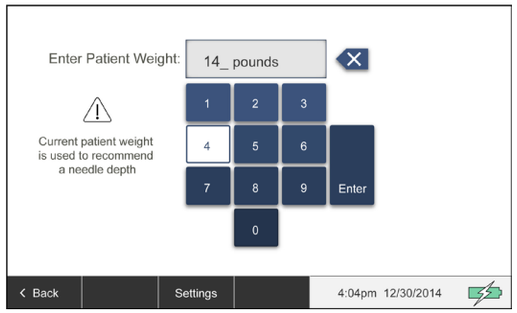


Figure 41 Patient Weight

4. **Confirm Patient Information (see Figure 42).**

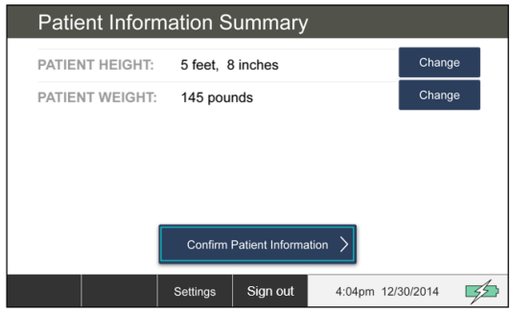


Figure 42 Patient Information Summary

5. **Confirm Needle Depth (see Figure 43).**

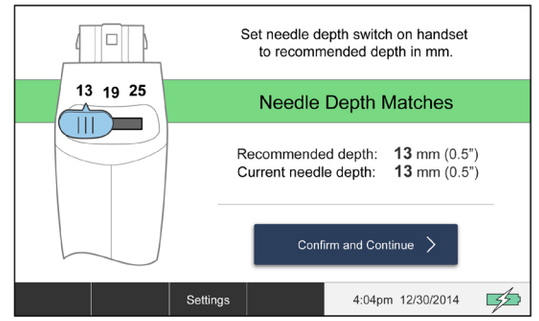


Figure 43 Recommended Needle Depth

6. **Set the needle depth on the Handset based on the recommendation of the system and clinical judgment regarding the needle length required to safely electroporate the intended deltoid or anterolateral quadricep (see Figure 44).**

Note: The Handset must remain in the Base Station while the needle depth is set.

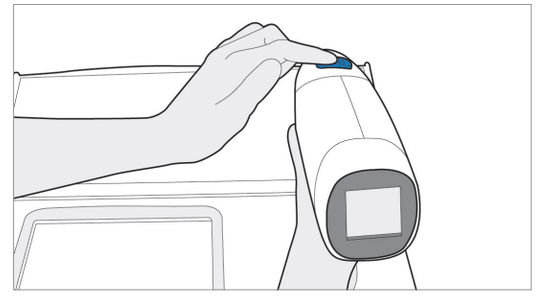


Figure 44 Needle Depth Setting

CAUTION!

Do not attempt to treat the patient while the Handset is docked in the Base Station. Do not touch the front opening of the Handset when it is docked in the Base Station.

Preparing the Injection Site

1. **Wash hands and put on gloves (see Figure 45).**

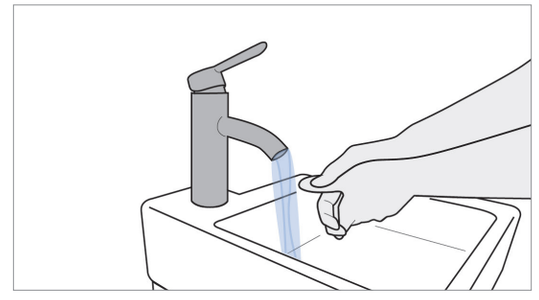


Figure 45 Hand Washing

2. **Select an injection site in the thickest part of the deltoid muscle in the upper arm (see Figure 46).**

   Note: The anterolateral quadriceps may be selected if neither deltoid is suitable.

3. **Position the patient so that they can be stabilized during treatment (Recommended position: on his/her side as shown) (see Figure 46).**

4. **Swab the injection site with alcohol and allow to dry for at least 30 seconds. (see Figure 47).**

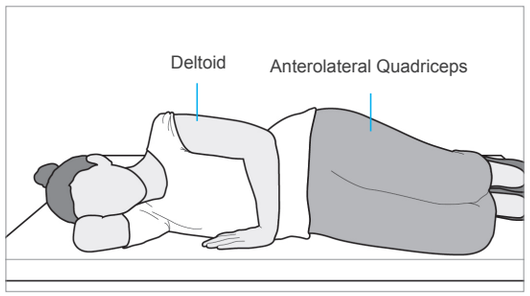


Figure 46 Patient Position

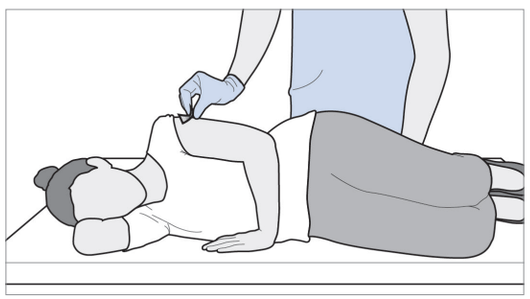


Figure 47 Cleaning the Injection Site

Preparing and Assembling the Array

1. **Clean the septum of the VOCERYQ Cartridge with an alcohol swab and allow to dry for at least 30 seconds. (see Figure 48).**

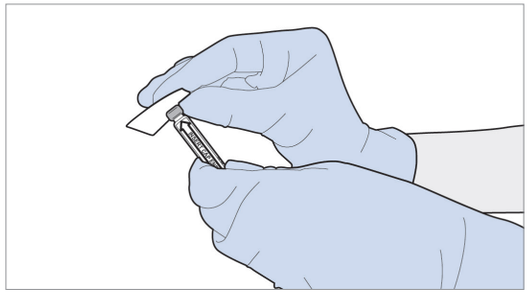


Figure 48 Alcohol Swab VOCERYQ Cartridge Septum

2. **Remove the sterile Array from its packaging and inspect for damage (see Figure 49).**

CAUTION!

Ensure that the VOCERYQ Cartridge has reached room temperature. If the VOCERYQ Cartridge is too cold, injection may result in patient discomfort.

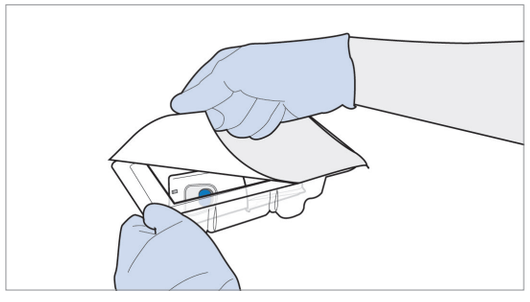


Figure 49 Remove Sterile Array from Packaging

3. **Insert the VOCERYQ Cartridge into the center of the Array and firmly push until you hear an audible »click« to indicate that the VOCERYQ Cartridge is fully inserted (see Figures 50 and 51).**

   Note: The metal cap and arrows on the VOCERYQ Cartridge should point towards the Array.

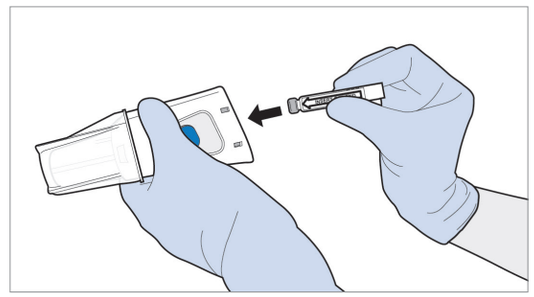


Figure 50 Insert VOCERYQ Cartridge into Sterile Array

CAUTION!

Before lifting the Handset off of the Base Station, ensure the patient's height and weight have been entered correctly, and that the needle depth has been selected.

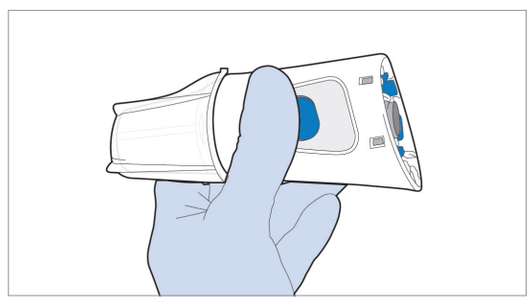
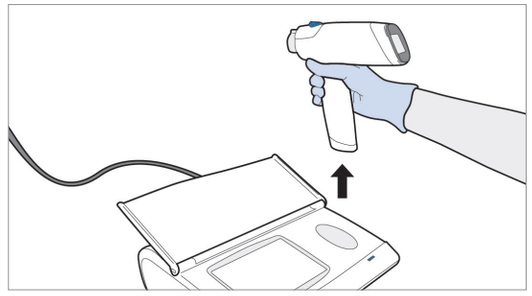


Figure 51 Assembled Sterile Array with Cartridge Inserted

CAUTION!

Avoid exposing the Handset to light sources that emit Infrared (IR) wavelengths, such as IR lamps, incandescent light, and direct sunlight (sunlight, incandescent light, and/or other infrared wavelengths).



Confirm treatment is ready to begin on the Base Station, then lift the Handset off the Base Station (see Figure 52).

Figure 52 Remove Handset from Base Station

4. **"Lift Handset and Attach Array" is displayed on the Handset (see Figure 53). The Treatment Overview screen is displayed on the Base Station (see Figure 54).**

Figure 53 Attach Array Handset Display

Figure 54 Treatment Overview Screen

5. **Attach the assembled Array with the VOCERYQ Cartridge to the Handset (see Figure 55).**

   a. Align the blue arrows on the top of the Array and Handset. The Array will only fit on one way.

   b. Ensure that the Array sits flush on the Handset on both sides.

   Note: You should hear and/or feel a »click« when the Array locks onto the Handset.

   Note: It may take several seconds for the Handset to register that the Array has been attached (see Figure 56). When the Handset is ready for use, it will emit a sound and then display a confirmation message "Remove cap. Firmly push handset, inserting needles into patient" (see Figure 57).

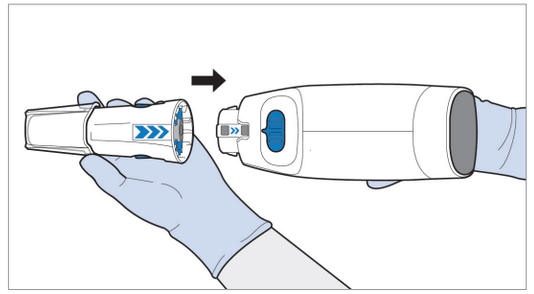


Figure 55 Attach Array to Handset

Figure 56 Array Attached

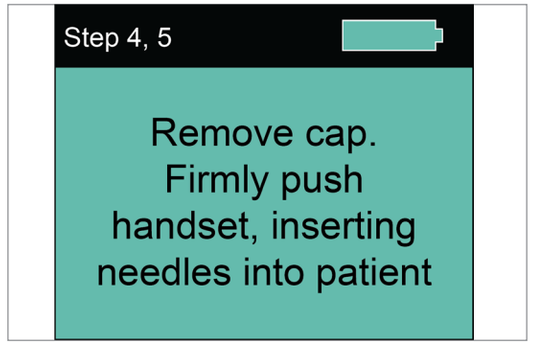


Figure 57 Treatment Ready

Delivering Treatment

1. **Remove the Array Cap (see Figure 58).**

CAUTION!
Do not press the trigger until ready to deliver treatment.

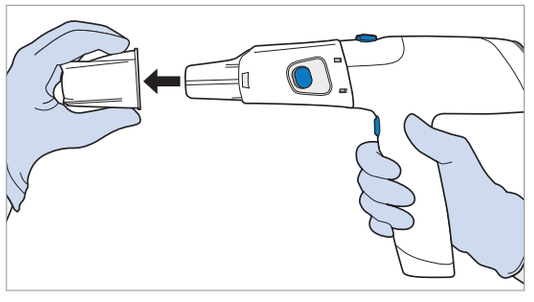


Figure 58 Remove Array Cap

2. **Stabilize the patient by placing a hand firmly near the treatment site. A second person, a dedicated Stabilizer, firmly places a hand on the patient's elbow (or knee) to limit movement during treatment. Additional support may be applied by stabilizing at the adjacent joints (i.e. shoulder or hip) (see Figure 59).**

Figure 59 Stabilize Patient

3. **Insert the needles fully by firmly pushing the Handset Array straight into the injection site (deltoid or anterolateral quadriceps) (see Figure 60).**

Note: The Array has a shroud (cover) that will retract as the needles are inserted into the muscle.

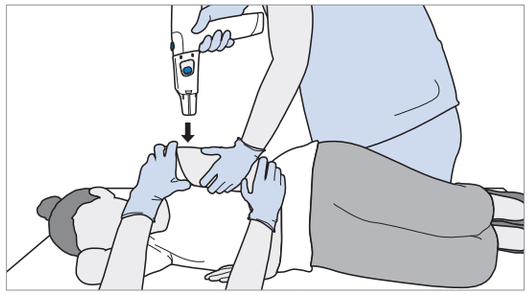


Figure 60 Deltoid shown. Patient shown in lateral position.

CAUTION!

Maintain firm contact with the patient. Stabilize the patient's limb prior to pressing the trigger. Involuntary muscle contractions may occur during delivery of the electrical pulses.

4. **Confirm the Handset displays "Press button to deliver treatment." Press and release the trigger to begin treatment. Hold the Handset firmly against the muscle until the treatment is complete (see Figure 61).**

The treatment takes approximately 10 seconds to complete.

CAUTION!

Avoid withdrawing the Handset from the injection site before the treatment is complete. Withdrawing the Handset after pressing the trigger will abort the treatment. Only withdraw the Handset in the event of an emergency to purposely abort the treatment.

Note: The Handset will produce a series of tones and show the progress of the treatment.

Continue to stabilize the patient's limb and wait for the Handset to emit a confirmation sound indicating that the treatment is complete.

Figure 61 Treatment Time

5. **Before removing the Handset, verify that "TREATMENT COMPLETE Remove array from patient" is displayed on the Handset screen (see Figure 62).**

Figure 62 Remove array from patient Display

6. **Withdraw the Handset straight out from the injection site after the treatment is complete (see Figure 63).**

   After the Array is removed from the injection site, the shroud (cover) will retract over the needles.

   Apply gauze to the injection site.

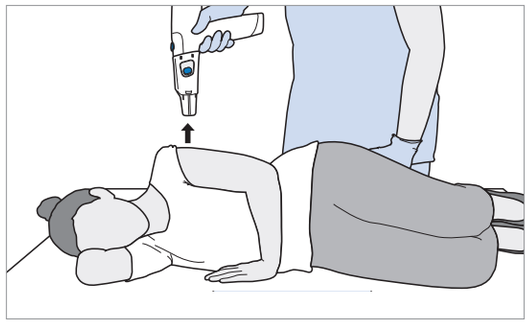


Figure 63 Remove Handset

Pausing or Aborting Treatment

1. Pause Treatment.

- Prior to insertion of the Array, treatment can be temporarily paused by placing the Handset onto the Base Station.
- Lifting the Handset will resume treatment.

Note: To prevent unauthorized access, re-entry of the password is required if treatment is paused for more than 60 minutes.

2. Abort Treatment.

- Tap “Sign Out” on the Base Station Touchscreen before the VOCERYQ Cartridge is inserted into the Array.
- Once the Array has been inserted into the muscle, the assembled Array with the VOCERYQ Cartridge must be discarded.

CAUTION!

⚠ Avoid withdrawing the Handset from the injection site before the treatment is complete. Withdrawing the Handset after pressing the trigger will abort the treatment. Only withdraw the Handset in the event of an emergency to purposely abort the treatment.

Discarding Disposables and Shutting Down the System

1. **Remove the used Array from the Handset (see Figure 64).**
   - **a.** Press and HOLD the blue release buttons on both sides of the Array.
   - **b.** Pull the Array away from the Handset.

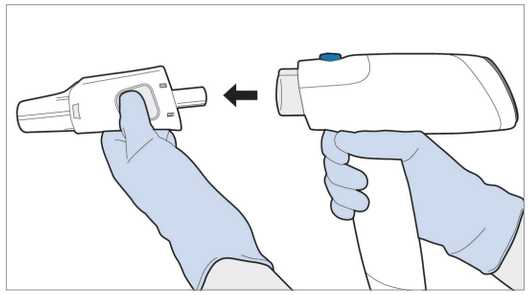


Figure 64 Remove Array from Handset

2. **Dispose of the used Array (containing the empty VOCERYQ Cartridge) into a sharps disposable container (see Figure 65).**

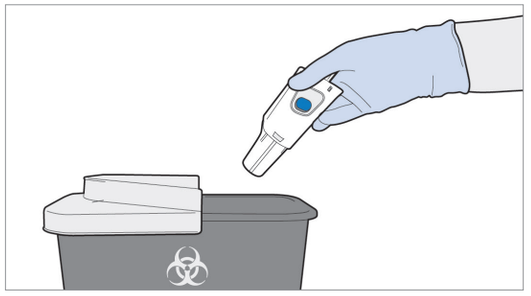


Figure 65 Dispose Array in sharps disposable container

CAUTION!

⚠ Do not attempt to remove the VOCERYQ Cartridge from the Array. VOCERYQ Cartridges are for single-use only. Reuse of VOCERYQ Cartridges will result in system error.

CAUTION!

⚠ Do not reuse Arrays and VOCERYQ Cartridges. Arrays and VOCERYQ Cartridges are for single-use only. Reuse of Arrays or VOCERYQ Cartridges will result in system error.

3. **Examine the injection site for pain or tenderness, erythema or redness, and swelling. Apply a bandage if needed.**

4. **Immediately inspect the Handset and Base Station. If visible soil is present, follow the cleaning instructions in Section 4 to prevent any visible soil from drying.**

5. **Return the Handset to the Base Station (see Figure 66).**

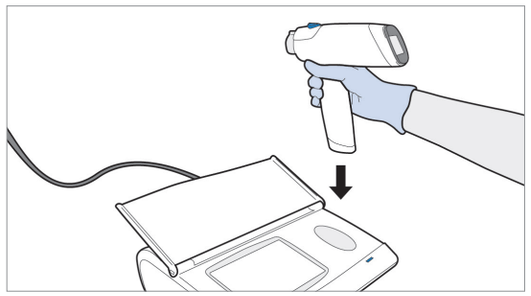


Figure 66 Place Handset in Base Station

Incomplete Treatment Guide

Note: The following table provides guidance on how to appropriately complete administration of the treatment procedure when the patient did not receive the VOCERYQ injection and Electroporation (EP).

Was the Array (with VOCERYQ Cartridge inserted) attached to the Handset?	Was the Array fully inserted into tissue?	Was the trigger button pressed?	Action
Yes	Yes	No	Follow the device prompts to complete the procedure. Reschedule the procedure if a new Array and VOCERYQ Cartridge are needed to complete the procedure.
Yes	No, but the array was locked out	No	Follow the device prompts to complete the procedure. Reschedule the procedure if a new Array and VOCERYQ Cartridge are needed to complete the procedure.
Yes	Yes, but the Array was dislodged from tissue.	No	Follow the device prompts. Reschedule the procedure if a new Array and VOCERYQ Cartridge are needed to complete the procedure.
Yes	No	Yes	Follow the device prompts to complete the procedure.
Yes	Yes	Yes	If the Handset does not display "Treatment Complete", contact INOVIO.

Re-injection of VOCERYQ is not permitted.

Note: Error messages are defined in Troubleshooting Section 5 of this User Manual.

Storing the Handset and Power Supply

1. **To store the Handset and Power Supply**

   a. Place the Handset on the Base Station.

   b. Wait 10 seconds.

   c. Unplug the power cord with the Handset docked.

   d. Wait until the Handset Display is turned off.

   e. Place both the Power Supply and Handset inside the Base Station drawers (see Figure 67).

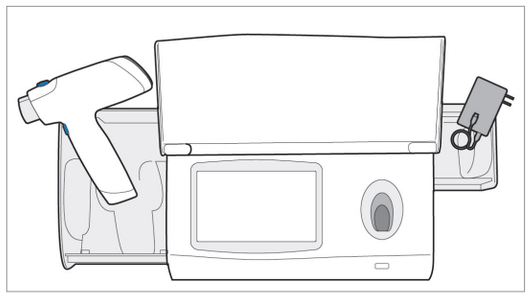


Figure 67 Store Handset and Power Supply

Note: The recommended storage temperature for the Base Station and Handset is +15°C to +30°C (+59°F to +86°F).

4. Care Information **45**

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Storage Conditions 48
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Cleaning and Disinfection

After each patient use, promptly complete the cleaning steps followed by disinfection steps below.

1. **Prior to cleaning, with the Handset docked in the Base Station, unplug the power cord from the Base Station.**

2. **Cleaning**

   a. Remove any visible soil by thoroughly cleaning the external surfaces of the Base Station and Handset with a Super Sani-Cloth[1] wipe for a minimum of one (1) minute and ensure soil is no longer visible.

   b. If necessary, use a corner of the wipe to remove any visible soil from edges.

   c. Ensure all visible soil is removed. Repeat the previous steps if needed until soil is no longer visible.

Rinsing procedure:

If excess residue remains, remove excess residue with a water-moistened wipe. Let air dry.

After cleaning, inspect the Base Station and Handset:

- If visible soil remains, repeat the cleaning steps until soil is no longer visible.
- If visible deterioration such as corrosion, discoloration, pitting, or cracked seals are observed, discontinue use of the device, and notify INOVIO.
- If any product labels are not legible, notify INOVIO. Discontinue use of the device.

⚠ **CAUTION!** Do not use an automated cleaning process or device.

⚠ **CAUTION!** Do not submerge the Base Station and Handset in water or any other liquid which may result in damage.

1. EPA registration number 9480-4

3. **Disinfection**

   a. After cleaning, thoroughly wipe down the Handset with a new Super Sani-Cloth wipe.

   b. Use a corner of the wipe to wipe down the edges. Pay particular attention to crevices and seams.

   c. To properly disinfect, ensure the treated surface remains visibly wet for at least two (2) minutes. Maintaining this wet contact time requires a minimum of four (4) wipes for the Base Station and five (5) wipes for the Handset. Use additional wipes as necessary to prevent the surface from drying before the full 2-minute period has elapsed.

Rinsing Procedure

Remove excess residue with a water-moistened wipe. Let air dry.

NOTE: For best results, perform cleaning and disinfecting procedure at room temperature (above 20°C / 68°F).

CELLECTRA® 5PSP has been validated for up to 100 cleaning and disinfection cycles. Any potential risk of damage to the device due to cleaning and disinfection for more than 100 cycles has not been validated. Always inspect the device before use.

Maintenance

Charge the Handset at least once per month. It may take up to 6 hours to fully charge the Handset. See Section 2 for charging instructions.

CELLECTRA® 5PSP does not require periodic calibration. There are no user serviceable parts inside.

In the event of any malfunction, contact your INOVIO representative to facilitate a factory authorized repair or replacement.

Storage Conditions

The storage temperature for the Base Station and Handset is: +15°C to +30°C (+59°F to +86°F) with a relative humidity of less than or equal to 75% (non-condensing).

The storage temperature for the Array is: +15°C to +25°C (+59°F to +77°F) with a relative humidity of less than or equal to 90% (non-condensing).

Disposal

Dispose of CELLECTRA® 5PSP used Array, and VOCERYQ Cartridge according to any applicable local, state, and federal laws and regulations.

Do not re-sterilize or reuse the Array.

Cybersecurity

To enable optimum protection for CELLECTRA® 5PSP, please review the following information:

Networking - CELLECTRA® 5PSP does not support networking, wireless, or remote access capabilities. Do not attempt to connect CELLECTRA® 5PSP to a network or another device.

Portable Media and USB Security - Please ensure that only authorized personnel using authorized USB storage media download data from the USB port on the right-hand side of the Base Station. Do not insert any personal USB devices or other consumer devices (such as to charge a phone) into the USB ports on the Base Station.

* Please note that treatment information exported to USB is encrypted. The confidentiality and protection of treatment data exported to USB Storage media must be maintained by end-users.

System Access - CELLECTRA® 5PSP requires a password as a basic level of authorization. The default password is provided by INOVIO. This password should be reset upon first use. End-users should also lock the device's USER INTERFACE from access when they are not present at the device by using the sign off button available in the Settings screen.

Password Management - Users, their roles, and their passwords can be customized and managed within CELLECTRA® 5PSP. Reasonably complex passwords are recommended. CELLECTRA® 5PSP supports passwords using upper case letters and numbers with a length between 8 to 16 characters. Do not share passwords with unauthorized personnel.

Malware Controls - CELLECTRA® 5PSP is designed as an embedded device and does not run a traditional operating system. CELLECTRA® 5PSP also does not support networking, wireless, or remote access capabilities. These factors reduce the risk that malware can infect CELLECTRA® 5PSP Electroporation Device. Additionally, CELLECTRA® 5PSP implements signature-based software integrity verification and encryption of data in storage and transmission. These factors prevent malware infection of

CELLECTRA® 5PSP without the use of traditional anti-malware software.

System and Security Events - CELLECTRA® 5PSP logs all errors, events, system serial numbers, software and hardware versions, configuration settings, treatment data, and user entries. Log files are encrypted and include cryptographic integrity mechanisms to ensure they cannot be modified. Logs also cannot be deleted by end-users. Clinical users may view the software version, serial number, hardware version, privacy statement, and device UDI within the user interface but do not have access to decrypt and exported device logs. Inovio will provide assistance to customers who have a need to view device logs upon request.

Backup and Restore - CELLECTRA® 5PSP allows end-users to export device logs. Treatment data and other data cannot be imported to the device. The device does not provide other backup and restore capabilities, hence end-users are recommended to export treatment data upon completion of each treatment.

Software Updates - INOVIO will directly contact customers when updates are available and will schedule service to perform updates to CELLECTRA® 5PSP.

Physical Security - CELLECTRA® 5PSP must only be accessible to authorized personnel. Store the product in a physically secured location to prevent unintentional or intentional misuse. CELLECTRA® 5PSP is not intended to be opened or disassembled.

Tamper-Evident Seals - Please inspect the tamper evident seals adhered to the Base Station and Handset for breaks prior to each use. If a tamper evident seal indicates CELLECTRA® 5PSP may have been tampered with, discontinue use of CELLECTRA® 5PSP and contact INOVIO at the Support Line: 1-855-INOVIO1 (466-8461).

System Decommissioning - Decommissioning CELLECTRA® 5PSP requires coordination with INOVIO. Contact INOVIO per terms and conditions of use to return and or replace CELLECTRA® 5PSP.

End of Life / End of Support - INOVIO support for cybersecurity for CELLECTRA® 5PSP is not expected to be interrupted or discontinued and, at this time, end of life and end of support dates are not defined. Communication will occur to customers as part of customer security routine maintenance and communications. A reasonable amount of advanced notification (e.g., at least one year) will be provided so that customers can take any necessary actions.

SBOM - Software Bill of Materials (SBOM) in a machine-readable or human-readable format is available upon request from the manufacturer. Requests may be subject to verification and confidentiality requirements.

Product Support - INOVIO is committed to supporting CELLECTRA® 5PSP and will provide advanced notice to all registered customers for end of support arrangements.

Security Incidents and Vulnerabilities

If you suspect a cybersecurity incident has occurred involving CELLECTRA® 5PSP or if you require assistance to investigate or any further information, please contact INOVIO at the Support Line: 1-855-INOVIO1 (466-8461)

If you suspect or identify a potential cybersecurity vulnerability in CELLECTRA® 5PSP, vulnerabilities may be reported through INOVIO's Vulnerability Disclosure program hosted by MedISAO at http://www.medisao.com or by contacting INOVIO at our Support Line: 1-855-INOVIO1 (466-8461).

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5. Troubleshooting

5. Troubleshooting **53**

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Other Notifications 74

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General Troubleshooting Tips

- When an error occurs, follow the instructions on the Handset and Base Station Display.
- If the touchscreen does not respond or the power on Self-Test is unsuccessful, remove the power supply for at least two (2) minutes. Plug the power supply back in and allow the device to restart.
- If a problem cannot be resolved, call the INOVIO Support Line at +1 (855) INOVIO1 (466-8461).

Overview of Error Messages and Other Priority Notifications

CELLECTRA® 5PSP has 2 types of error messages: medium to high priority and other notifications (low priority). Each error message is accompanied by a sound. If you encounter 90XX errors, contact Inovio to arrange the return of CELLECTRA® 5PSP.

Error Message Type	Priority and Meaning	Sound
Red Alert	High – May negatively affect the treatment that the patient receives	2 high beeps
Yellow Alert	Medium – May result in no treatment delivered to the patient	3 low beeps
Other Notifications	Low – Data entry errors or informational notifications	none

See display messages on the Base Station and/or Handset for appropriate instructions. The codes included below are examples of displayed alerts.

Red Alerts

Base Station Touchscreen Message	Handset Display Message	Pg.
Device Fault: Treatment Aborted: Error 8008	Device Fault	58
Self-Test Failure: Error 8061	Device Fault	58
Incorrect Needle Depth	Incorrect Depth	59
Self-Test Failure: Error 8072	Device Fault	59
Touchscreen Failure: Error 8031 or 8032	blank	60
Treatment Error: Error 8008, 8009 or 800A	Device Fault	60
Recovery After Device Fault: Error 80B4	Device Fault	60
Device Fault: Treatment Failure: Error 9012 or 900F	Device Fault	61
Device End of Life: Error 90A5, 90A6 or 90C8	Return handset to base	61

Yellow Alerts

Base Station Touchscreen Message	Handset Display Message	Pg.
Access Locked Out: Error 4001	Access Locked Out	62
Handset Disconnected: Error 4021	Handset Not Ready	62
Handset with Array in Base Station: VOCERYQ Cartridge Used or Missing: Error 4005	Cartridge Used/Missing	63
Handset with Array in Base Station: VOCERYQ Cartridge Backwards: Error 4006	Cartridge Backwards	64
Handset with Used Array in Base: Error 4022	Remove and discard Array	65

Yellow Alerts (cont.)

Base Station Touchscreen Message	Handset Display Message	Pg.
Incorrect Handset for this Base: Error 40C1	blank	66
Low Battery: Error 407B	Low Battery	66
Needle Depth Does not Match: Error 1086	Needle Depth	67
Missing Depth-Setting Selector: Error 400B	Missing Depth Setting-Selector	67
Needle Depth Does Not Match recommended: Error 1086	Needle Depth	68
System Cannot Perform Self-Test while Handset is Disconnected: Error 4023	Handset Not Ready	69
Incomplete Treatment: Error 4015	Treatment Aborted	69
System Cannot Perform Self-Test with Array on Handset: Error 4071	blank	70
User Initiated Treatment Abort: Error 4015	Treatment Aborted	71
Low Battery Error: Error 1414 or 407B	Low Battery	72
Treatment Cycle Limits: Error 40CC	blank	73
Device Life Cycle: Battery Charge: Error 40A3	blank	73
Device Life Cycle: Battery: Error 40A4	blank	73

Other Notifications: Prompt will be shown for invalid data entry.

Base Station Touchscreen Message	Handset Display Message	Pg.
Faulty USB Device: Error 4040	blank	74
Treatment Paused: Handset in Base: Error 125C	Treatment Paused	74
Incorrect Password: Error 102B	blank	75
Invalid Patient Height: Error 1086	blank	75
Invalid Patient Weight: Error 1086	blank	76
USB Device Full: Error 4041	blank	77

Red Alert Messages

1. Device Fault: Treatment Aborted

Error Code: 8008

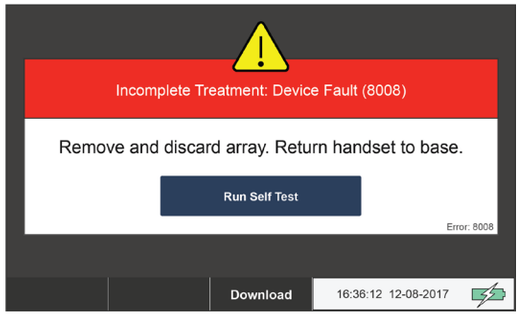
Handset: Device Fault

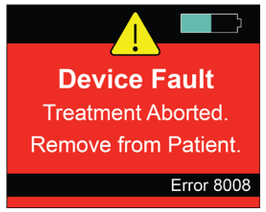
What it means:

An error prevented treatment from completing. Some of the VOCERYQ may have been delivered.

What to do:

1. Withdraw the Handset from the patient.
2. Apply gauze to the injection site, if necessary.
3. Press and HOLD the blue release buttons on both sides of the Array. Pull the Array away from the Handset.
4. Safely discard the assembled Array and VOCERYQ Cartridge into a suitable sharps container.
5. Return the Handset to the Base Station and follow prompts on the Base Station Touchscreen.





CAUTION!

Do not reuse Arrays and VOCERYQ Cartridges. Arrays and VOCERYQ Cartridges are for single-use ONLY. Reuse of Arrays or VOCERYQ Cartridges will result in system malfunction.

2. Self-Test Failure

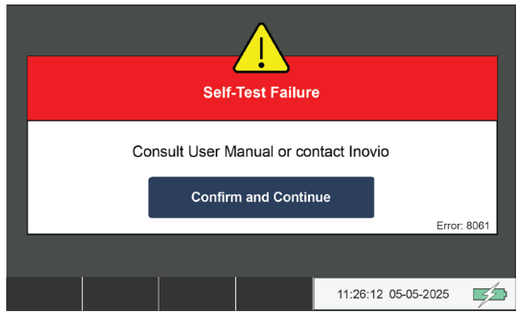
Error Code: 8061

Handset: Device Fault

What it means: Memory initialization failure.

What to do:

Press ***Confirm and Continue*** to continue.



3. Incorrect Needle Depth

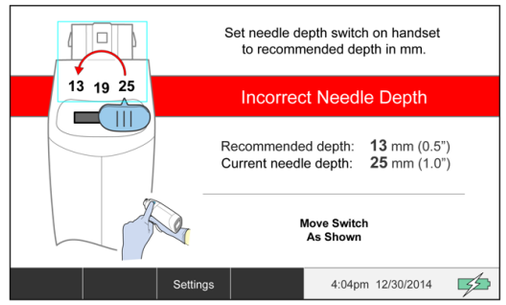
Handset: Incorrect Depth

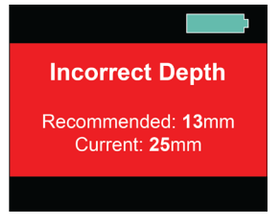
What it means:

The needle depth switch on the Handset significantly differs from the needle depth recommended by the system.

What to do:

1. Use clinical judgment to select a needle length to safely electroporate the intended deltoid or anterolateral quadricep muscle.
2. Change the needle depth switch on the top of the Handset to a needle depth that is appropriate for the patient.
3. Check the accuracy of the height and weight entered and make sure the correct units were used (e.g., kg vs. lbs). If the Red Alert remains after verifying the height and weight are correct the needle depth setting must be increased or decreased by at least one increment (e.g., from 25 to 19 mm) in order to continue.





4. Self-Test Failure

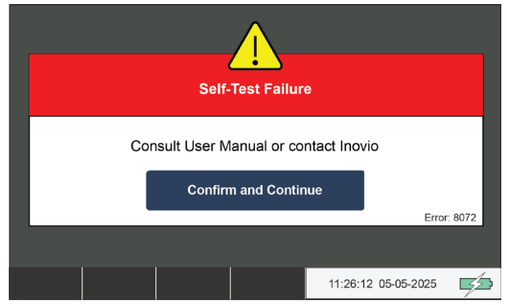
Error Code: 8072

Handset: Device Fault

What it means: During power up the MEMS sensor for motion detection failed.

What to do:

Press ***Confirm and Continue*** to continue.



5. Touchscreen Failure

Error Code: 8031 or 8032

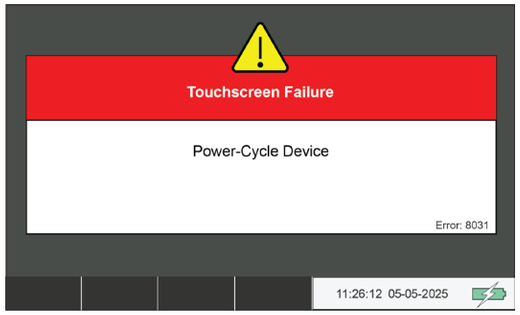
Handset: blank

What it means:

The Base Station Touchscreen does not respond to touch.

What to do:

- Remove the power supply for at least two (2) minutes. Plug the power supply back in and allow the device to restart.



6. Treatment Error

Error Code: 8008, 8009, or 800A

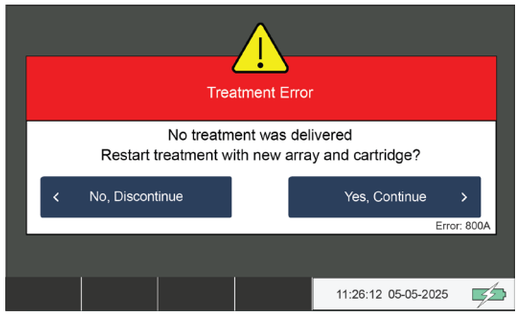
Handset: Device Fault

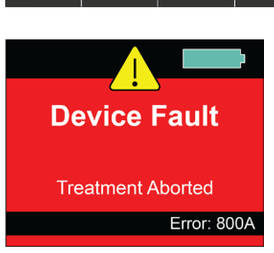
What it means:

No treatment was delivered.

What to do:

Follow prompts on device. Refer to Incomplete Treatment Guide in Section 3 for additional information.





7. Recovery After Device Fault

Error Code: 80B4

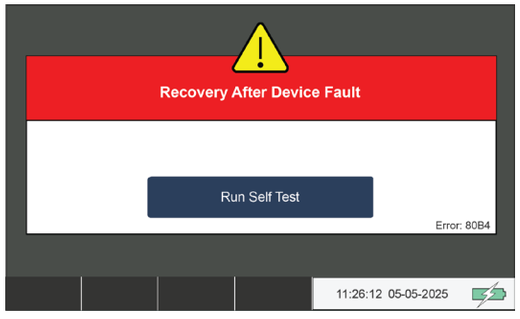
Handset: Device Fault

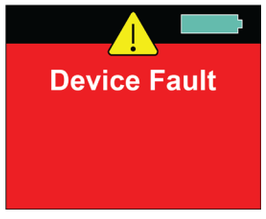
What it means:

A Self-Test needs to be run on the Handset.

What to do:

Press ***Run Self-Test*** to continue or remove the power supply for at least two (2) minutes. Plug the power supply back in and allow the device to restart.





8. Device Fault: Treatment Failure

Error Code: 9012 or 900F

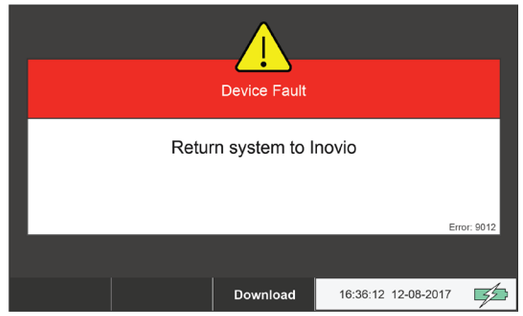
Handset: Device Fault

What it means:

The device experienced an error and was unable to complete the treatment.

What to do:

1. Press and HOLD the blue release buttons on both sides of the Array. Pull the Array away from the Handset.
2. Safely discard the assembled Array and VOCERYQ Cartridge into a suitable sharps container.
3. Return the Handset to the Base Station.
4. Call INOVIO Support Line at: +1 (855) INOVIO1 (466-8461) to arrange the return of CELLECTRA® 5PSP.



CAUTION!

Do not reuse Arrays and VOCERYQ Cartridges. Arrays and VOCERYQ Cartridges are for single-use ONLY. Reuse of Arrays or VOCERYQ Cartridges will result in system malfunction.

9. Device End of Life

Error Code: 90A5, 90A6 or 90C8

Handset: Return Handset to Base

What it means:

The device has reached end of life.

What to do:

Call INOVIO Support Line at: +1 (855) INOVIO1 (466-8461) to arrange the return of CELLECTRA® 5PSP.

Yellow Alert Messages

1. Access Locked Out

Error Code: 4001

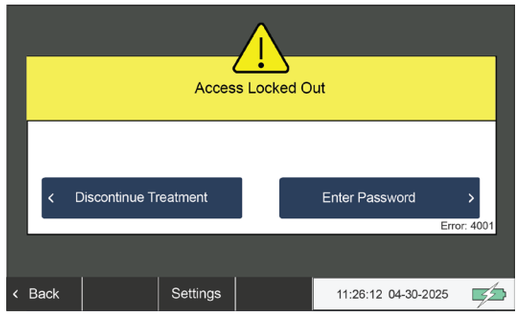
Handset: Access Locked Out

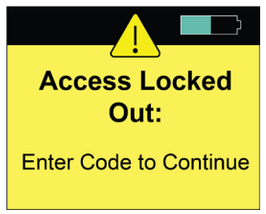
What it means:

Treatment did not start within the allotted time. The system has locked to prevent unauthorized access. Sign in again to continue.

What to do:

1. Return the Handset to the Base Station.
2. Re-enter the password to continue the treatment.





2. Handset Disconnected

Error Code: 4021

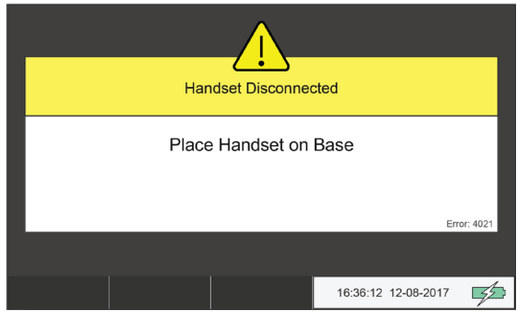
Handset: Handset Not Ready

What it means:

The Handset was removed from the Base Station before the system was ready.

What to do:

Place the Handset into the Handset Port on the Base Station.



3. Handset with Array in Base Station: VOCERYQ Cartridge Used or Missing

Error Code: 4005

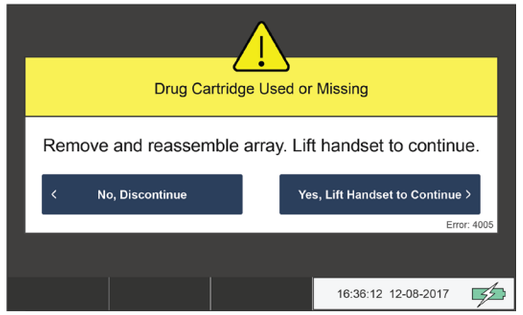
Handset: Cartridge Used/Missing

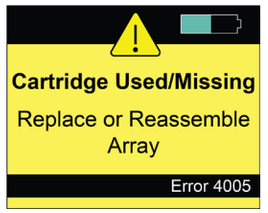
What it means:

The VOCERYQ Cartridge in the Array is either used or missing.

What to do:

1. Press and HOLD the blue release buttons on both sides of the Array. Pull the Array away from the Handset.
2. Remove the VOCERYQ Cartridge from the Array, if present.
3. If a new VOCERYQ Cartridge is available, insert and firmly push the VOCERYQ Cartridge into the Array.
4. Reattach the Array to the Handset.





CAUTION!

Do not reuse Arrays and VOCERYQ Cartridges. Arrays and VOCERYQ Cartridges are for single-use ONLY. Reuse of Arrays or VOCERYQ Cartridges will result in system malfunction.

4. Handset with Array in Base Station: VOCERYQ Cartridge Backwards

Error Code: 4006

Handset: Cartridge Backwards

What it means:

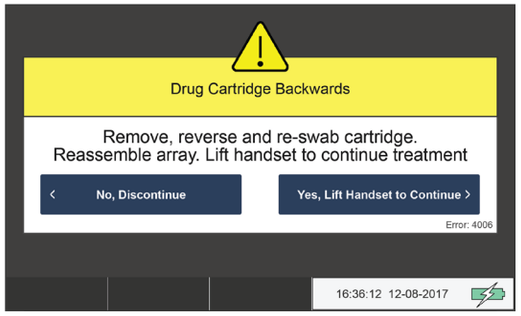
The VOCERYQ Cartridge was placed in the Array backwards.

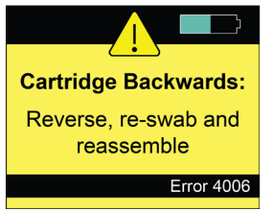
What to do:

1. Press and HOLD the blue release buttons on both sides of the Array. Pull the Array away from the Handset.
2. Remove the VOCERYQ Cartridge from the Array taking care to avoid contact with the rubber septum of the Cartridge.

Note: Clean the rubber septum of the VOCERYQ Cartridge with an alcohol wipe again if it is contacted at any time during the removal or re-insertion.

3. Ensure that the metal cap and arrows on the VOCERYQ Cartridge point towards the Array.
4. Re-insert and firmly push the VOCERYQ Cartridge into the Array.
5. Reattach the Array to the Handset.





5. Handset with Used Array in Base

Error Code: 4022

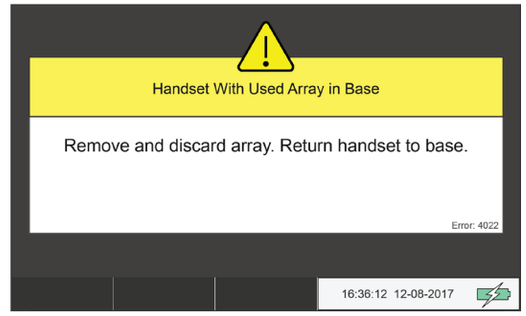
Handset: Remove and discard Array

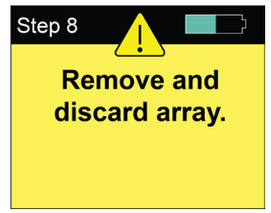
What it means:

The Handset was placed onto the Base Station before discarding the used Array.

What to do:

1. Press and HOLD the blue release buttons on both sides of the Array. Pull the Array away from the Handset.
2. Safely discard the used assembled Array and VOCERYQ Cartridge into a suitable sharps container.
3. Return the Handset to the Base Station and follow prompts on the Base Station Touchscreen.





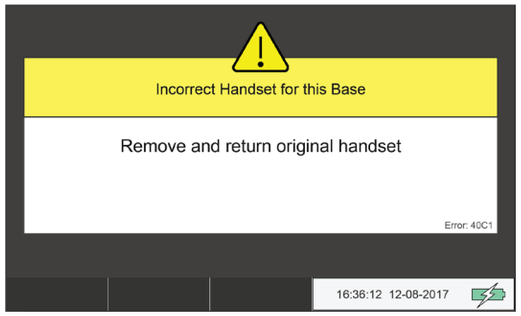
CAUTION!

Do not reuse Arrays and VOCERYQ Cartridges. Arrays and VOCERYQ Cartridges are for single-use ONLY. Reuse of Arrays or VOCERYQ Cartridges will result in system malfunction.

6. Incorrect Handset for this Base

Error Code: 40C1

Handset: blank



What it means:

The Handset and Base Station do not match. Each Base Station has its own, unique Handset. Handsets and Base Stations are not interchangeable. The serial numbers at the back of the Base Station and bottom of Handset must match.

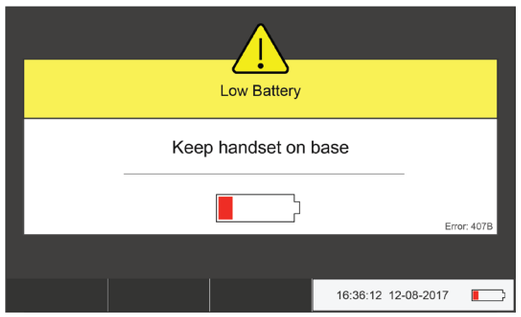
What to do:

1. Remove the current Handset.
2. Locate the Handset having the serial number listed in the notification. The serial number is printed on a label on the bottom of the Handset and back of the Base Station.
3. Place the Handset into the Handset Port on the matching Base Station.

7. Low Battery

Error Code: 407B

Handset: Low Battery

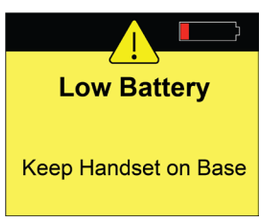


What it means:

The internal battery of the Handset is too low to complete a treatment.

What to do:

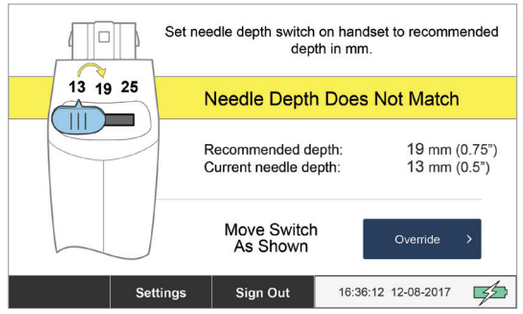
Place the Handset on the Base Station to recharge. The alert will disappear once the Handset has enough battery power to continue.



8. Needle Depth Does Not Match

Error Code: 1086

Handset: Needle Depth

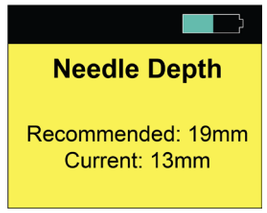


What it means:

The needle depth switch on the Handset significantly differs from the needle depth recommended by the system.

What to do:

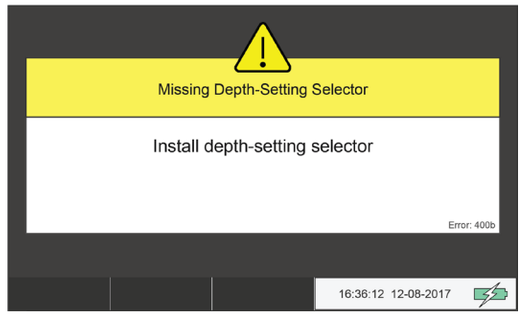
1. Use clinical judgment to select a needle length to safely electroporate the intended deltoid or anterolateral quadricep muscle.
2. Change the needle depth switch on the top of the Handset to a needle depth that is appropriate for the patient.
3. Check the accuracy of the height and weight entered and make sure the correct units were used (e.g., kg vs. lbs). If the Yellow Alert remains after verifying the height and weight are correct the needle depth setting must be increased or decreased by at least one increment (e.g., from 25 to 19 mm) in order to continue.



9. Missing Depth-Setting Selector

Error Code: 400B

Handset: Missing Depth-Setting Selector



What it means:

The Needle Depth Switch has been removed from the Handset.

What to do:

Slide the Needle Depth Switch back onto the top of the Handset.

10. Needle Depth Does Not Match recommended

Error Code: 1086

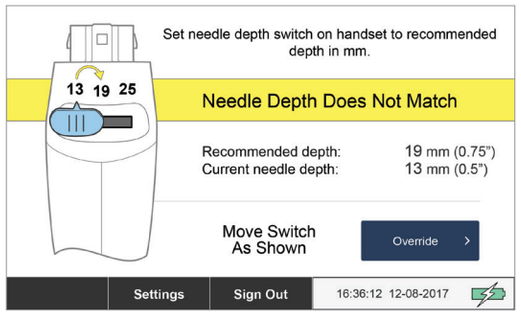
Handset: Needle Depth

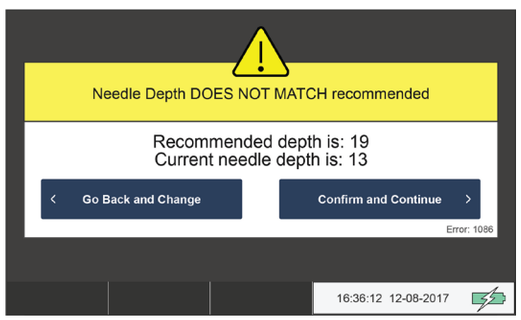
What it means:

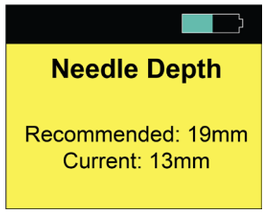
The Needle Depth Switch on the Handset does not match the needle depth recommended by the system.

What to do:

1. Double-check the Needle Depth Switch on the top of the Handset. It shows needle depth in millimeters (e.g., 13 mm, 19 mm, or 25 mm).
2. Either:
   - Move the Needle Depth Switch on the top of the Handset to the recommended depth.
   - Or press Go Back and Change or Confirm and Continue to continue with the current needle depth based on clinical judgment. The Base Station will prompt to confirm the choice.







11. System Cannot Perform Self-Test while Handset is Disconnected

Error Code: 4023

Handset: Handset Not Ready

What it means:

The Handset is not connected to the Base Station.

What to do:

Place the Handset into the Handset Port on the Base Station.

12. Incomplete Treatment

Error Code: 4015

Handset: Treatment Aborted

What it means:

The patient may have received partial treatment.

What to do:

1. Follow prompts on device.
2. Do not reattempt treatment with the patient whom error was encountered.

13. System Cannot Perform Self-Test with Array on Handset

Error Code: 4071

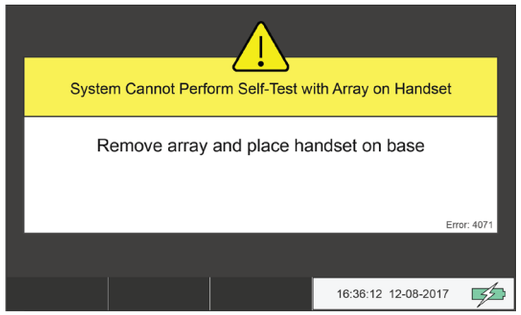
Handset: blank

What it means:

The Array is attached to the Handset when it should not be attached.

What to do:

1. Press and HOLD the blue release buttons on both sides of the Array. Pull the Array away from the Handset.
2. Safely discard the assembled Array and VOCERYQ Cartridge into a suitable sharps container.
3. Place the Handset into the Handset Port on the Base Station.



CAUTION!

Do not reuse Arrays and VOCERYQ Cartridges. Arrays and VOCERYQ Cartridges are for single-use ONLY. Reuse of Arrays or VOCERYQ Cartridges will result in system malfunction.

14. User Initiated Treatment Abort

Error Code: 4015

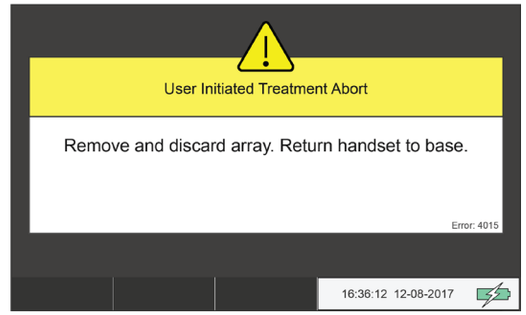
Handset: Treatment Aborted

What it means:

The Handset was pulled away from the patient, causing the treatment to abort. Some of the VOCERYQ may have been delivered.

What to do:

1. Apply gauze to the injection site, if necessary.
2. Press and HOLD the blue release buttons on both sides of the Array. Pull the Array away from the Handset.
3. Safely discard the assembled Array and VOCERYQ Cartridge into a suitable sharps container.
4. Return the Handset to the Base Station and follow prompts on the Base Station Touchscreen.



CAUTION!

Do not reuse Arrays and VOCERYQ Cartridges. Arrays and VOCERYQ Cartridges are for single-use ONLY. Reuse of Arrays or VOCERYQ Cartridges will result in system malfunction.

15. Low Battery Error:

Error Code: 1414 or 407B

Handset: Low Battery

What it means:

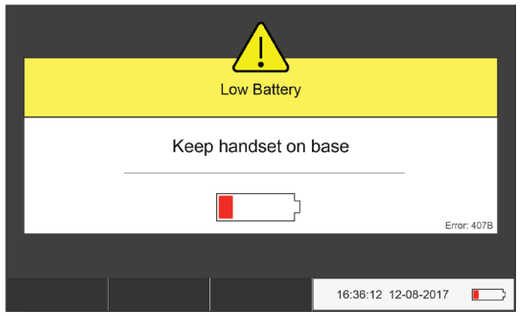
The Handset has been off the Base Station too long for the remaining battery charge (approximately 30 minutes).

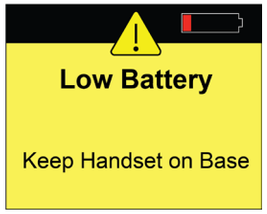
What to do:

1. Follow device prompts to dock the Handset onto the Base Station to charge.
2. Once sufficient charge is achieved, proceed with treatment by selecting “Yes. Continue”.
3. If the battery is critically low, it may take up to 6 hours to resume treatment.

Mitigating this error:

Keep the Handset docked until you are ready to administer the treatment.





16. Treatment Cycle Limit

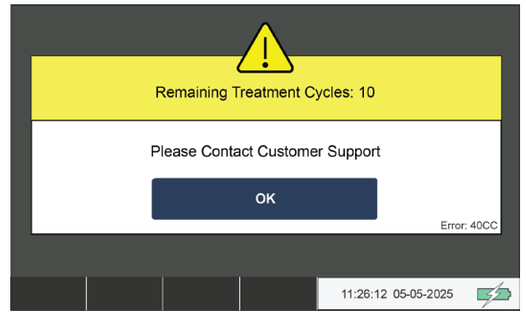
Error Code: 40CC

What it means:

Device close to end of life.

Device Treatment Cycles:

- Warning at 90 treatments
- Lockout at 100 treatments



17. Device Life Cycle: Battery Charge

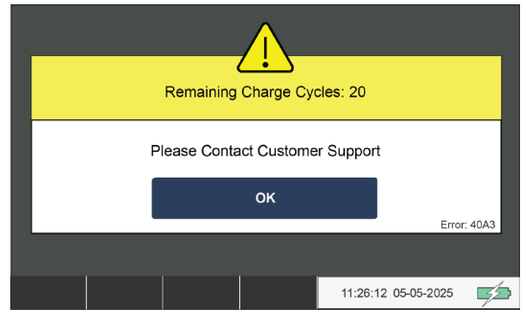
Error Code: 40A3

What it means:

Device close to end of life.

Remaining Battery Charge Cycles:

- Warning at 240 cycles
- Lockout at 260 cycles



18. Device Life Cycle: Battery

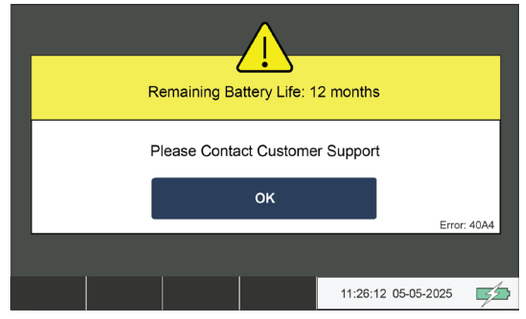
Error Code: 40A4

What it means:

Device close to end of life.

Remaining Battery Life:

- Warning at 4 years
- Lockout at 5 years



Other Notifications

1. Faulty USB Device

Error Code: 4040

Handset: blank

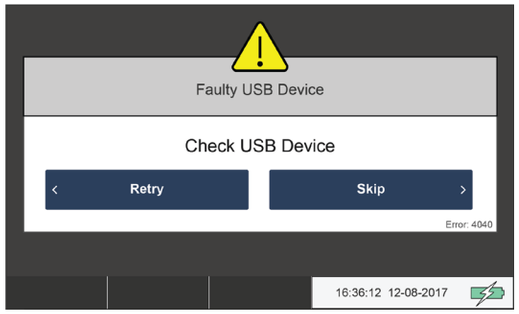
What it means:

The Base Station could not read the USB device.

What to do:

Either:

- Insert a different USB device and press **Retry** to try to download the treatment data again.
- Or press **Skip** to skip downloading treatment data to the USB device.



2. Treatment Paused: Handset in Base

Error Code: 125C

Handset: Treatment Paused

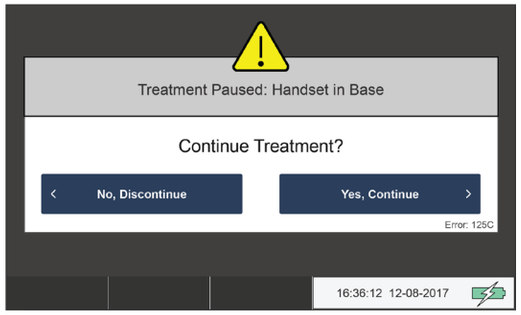
What it means:

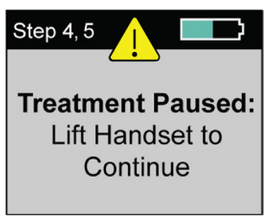
The Handset was placed onto the Base Station before completing treatment.

What to do:

Either:

- Lift the Handset from the Base Station and press **Yes, Continue** to continue with treatment.
- Or press **No, Discontinue** to quit the current treatment. You will be prompted to confirm your choice.





3. Incorrect Password

Error Code: 102B

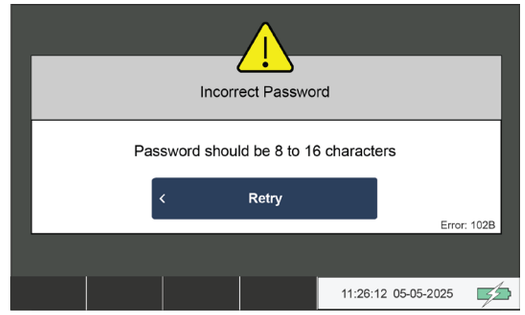
Handset: blank

What it means:

An incorrect password was entered.

What to do:

Press Retry, then enter the correct password.



4. Invalid Patient Height

Error Code: 1086

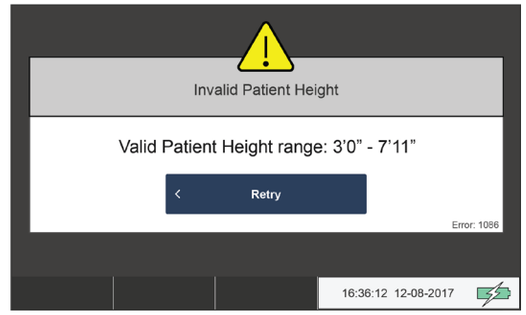
Handset: blank

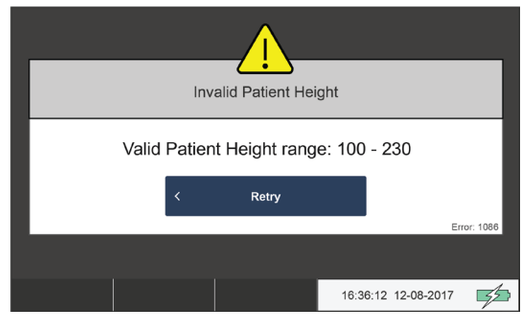
What it means:

A patient height was not entered, or a height that is out of range was entered.

What to do:

1. Ensure that the patient's current height is available.
2. Press Retry to use the keypad to enter a patient height. Ensure that the height is entered correctly with the correct units (e.g., ft in for US-Standard, cm for Metric).





CAUTION!

The system uses patient height and weight to recommend a needle depth in millimeters (mm). Incorrect values may cause an inappropriate needle depth recommendation, which may result in patient harm or ineffective treatment.

5. Invalid Patient Weight

Error Code: 1086

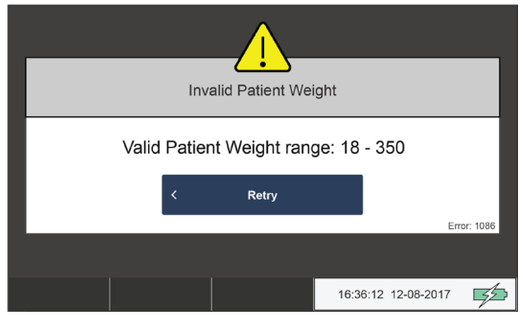
Handset: blank

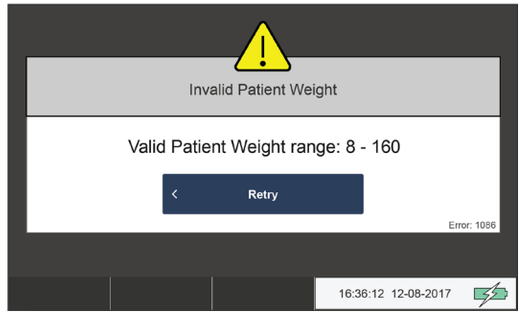
What it means:

A patient weight was not entered, or a weight that is out of range was entered.

What to do:

1. Ensure that the patient's current weight is available.
2. Press Retry to use the keypad to enter a patient weight. Ensure that the weight is entered correctly with the correct units (e.g., lb for US-Standard, kg for Metric).





CAUTION!

The system uses patient height and weight to recommend a needle depth in millimeters (mm). Incorrect values may cause an inappropriate needle depth recommendation, which may result in patient harm or ineffective treatment.

6. USB Device Full

Error Code: 4041

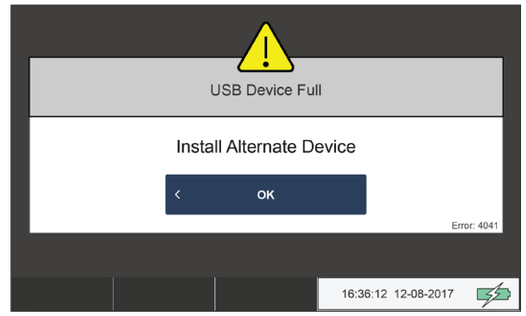
Handset: blank

What it means:

There is not enough storage space on the USB device to download the treatment data.

What to do:

Insert a different USB device provided by INOVIO and press OK to try to download the treatment data again.



6. Technical and Reference Information

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Self-Assessment Questions 86

Answers 88

Symbols 90

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Technical Information

PHYSICAL SPECIFICATIONS	
Dimensions	343 mm L x 254 mm W x 102 mm D (13.5”L x 10”W x 4”D).
Weight	2.9 kg (6.4 pounds).
Operating Conditions	+18°C to +28°C (+64°F to +82°F), Less than or equal to 90% Relative Humidity, non-condensing, up to 2,000 meters (6,562 feet) above sea level.
Storage	Base Station and Handset: +15°C to +30°C (+59°F to +86°F). Less than or equal to 75% Relative Humidity, non-condensing. Array: +15°C to +25°C (+59°F to +77°F). Less than or equal to 90% Relative Humidity, non-condensing.
Shipping Limitations	+5°C to +40°C (+41°F to +104°F), less than or equal to 90% Relative Humidity, non-condensing.
Input Voltage	100 to 240 volts VAC, 50-60 Hz, 0.5 Amps (A) maximum.
Other Electrical Character-istics	• Class II Medical Equipment: protection against electric shock relies on DOUBLE INSULATION. There are neither provisions for protective grounding nor reliance upon special installation grounding conditions. • BF Equipment: device has conductive contact with the patient. • Internally-powered equipment. • Lithium Ion Battery - Lifecycle: 5 years.

PERFORMANCE SPECIFICATIONS	
Voltage	10-208 V maximum (varies with patient tissue impedance; 5 V for device operation).
Pulse Width	52 milliseconds (ms).
Maximum Pulse Current	520 mA.
Maximum Pulse Current Density	1.68 A/cm2.
Operating modes	The device has two modes of operation, current controlled or voltage controlled with a fixed upper limit (max 208 V).
Phase Charge	Delivered Charge = 26 millicoulombs (max) = 0.5 A x 0.052 seconds.
Net Charge	Intramuscular = 78 millicoulombs (max) = 0.5 A x 0.052 seconds x 3 pulses.
Pulse Shape	Unipolar rectangular DC current pulse.
Field Strength	~ 200 V/cm (Max).

6

Session Duration	1-7 pulses delivered per session, preset by manufacturer, based on indication. Each pulse will last 52 ms at up to 0.5 A (10-200 V depending on individual tissue resistance) at 0.198 to 3 second intervals. Session duration = ~ 2 minutes (taking into consideration the cleaning of the treatment area, the positioning of electrodes, VOCERYQ injection, impedance check, firing delay, etc.). The electroporation itself takes from ~ 1-8 seconds, after the firing delay (dependent on number of pulses and amount of time programmed between pulses).

Note: If the performance described in the PERFORMANCE SPECIFICATIONS table is not maintained, the device will disable electroporation, default to a safe state, and trigger an error indication.

CELLECTRA® 5PSP is intended to be used by trained healthcare professionals in clinical settings who have successfully completed CELLECTRA® 5PSP training.

CELLECTRA® 5PSP is NOT an intentional radiator.

CELLECTRA® 5PSP is NOT Life-Supporting Equipment.

EMC Specifications

Manufacturer's Declaration – Emissions

CELLECTRA® 5PSP is intended for use in the electromagnetic environment specified below. The user of CELLECTRA® 5PSP should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions CISPR 11	Group 1	CELLECTRA® 5PSP uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
	Class A	CELLECTRA® 5PSP is intended for use in a professional healthcare facility environment, such as Doctor's Offices and Clinics.
Harmonics IEC 61000-3-2	Class A	CELLECTRA® 5PSP is intended for use in a professional healthcare facility environment, such as Doctor's Offices and Clinics.
Flicker IEC 61000-3-3	Complies	CELLECTRA® 5PSP is intended for use in a professional healthcare facility environment, such as Doctor's Offices and Clinics.

Note: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

WARNING!

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING!

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Manufacturer's Declaration – Immunity

CELLECTRA® 5PSP is intended for use in the electromagnetic environment specified below. The user of CELLECTRA® 5PSP should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
ESD IEC 61000-4-2	±8kV Contact ±2kV, ±4kV, ±8kV, ±15kV Air	±8kV Contact ±2kV, ±4kV, ±8kV, ±15kV Air	The relative humidity should be at least 5%.
EFT IEC 61000-4-4	±2kV Mains 100 kHz repetition frequency ±1kV I/Os 100 kHz repetition frequency	±2kV Mains 100 kHz repetition frequency Not applicable	Main power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5kV, ±1kV Line-to-line ±2kV Line-to-ground	±0.5kV, ±1kV Line-to-line Not applicable	Main power quality should be that of a typical commercial or hospital environment.
Voltage Dips, Short Interruptions, and Voltage Variations IEC 61000-4-11	0% U_T; 0.5 cycle at 8 phase angles At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% U_T; 1 cycle at 0° and 70% U_T; 25/30 cycles Single phase at 0° 0% U_T; 250/300 cycle	0% U_T; 0.5 cycle at 8 phase angles At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% U_T; 1 cycle at 0° and 70% U_T; 25/30 cycles Single phase at 0° 0% U_T; 250/300 cycle	Main power quality should be that of a typical commercial or hospital environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Power Frequency Magnetic Field IEC 61000-4-8	30A/m 50 Hz or 60 Hz	30A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be that of a typical commercial or hospital environment.
Conducted Disturbances Induced by RF Fields IEC 61000-4-6	3 $V_{r.m.s.}$ 0.15 MHz - 80 MHz 6 $V_{r.m.s.}$ in ISM bands between 0.15 MHz and 80 MHz 80% AM 1 kHz	3 $V_{r.m.s.}$ 0.15 MHz - 80 MHz 6 $V_{r.m.s.}$ in ISM bands between 0.15 MHz and 80 MHz 80% AM 1 kHz	Not applicable
Proximity Magnetic Fields IEC 61000-4-39	8 A/m at 30 kHz 65 $A_{r.m.s.}$/m at 134.2 kHz 7.5 $A_{r.m.s.}$ /m at13.56 MHz	Not applicable 65 $A_{r.m.s.}$/m at 134.2 kHz 7.5 $A_{r.m.s.}$ /m at13.56 MHz	Power frequency magnetic fields should be that of a typical commercial or hospital environment.
Radiated RF EM Fields. Proximity Fields from RF Wireless Communications Equipment IEC 61000-4-3	3 V/m 80 MHz -2.7 GHz 80% AM at 1kHz	= 3 V/m 80 MHz -2.7 GHz 80% AM at 1kHz	Except as indicated in the table below, portable and mobile communications equipment should be separated from CELLECTRA® 5PSP by no less than distances calculated using the equation below: D=1.2*√P 150 kHz to 80 MHz D=1.2*√P *d* = 6/E*√P D=2.3*√P Where P is the maximum power in watts (W) and *d* is the minimum separation distance in meters. (m) and *E* is the immunity test level in V/m. Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels. Interference may occur in the vicinity of equipment containing a transmitter.

WARNING!

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of CELLECTRA® 5PSP, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Do not expose CELLECTRA® 5PSP to potential sources of electromagnetic interference (EMI). Common sources of EMI may include radiofrequency identification (RFID) readers, near-field communications (NFC) systems, wireless power transfer (WPT), Cellular 5G, and unique medical emitters such as electrocautery, MRI, electrosurgical units, and diathermy equipment.

In the event of an electromagnetic (EM) disturbance during a treatment, the handset display may flicker, the treatment may be interrupted, or the device may stop and default to a safe state.

For transmitters specified in the table below, the recommended separation distance is 30 cm (12 inches).

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 - 390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
450	430 - 470	GMRS 460, FRS 460	FM [C] ± 5 kHz deviation 1kHz sine	2	0.3	28
710	704 - 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9
745						
780						
810	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28
870						
930						

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
1720	1700 - 1900	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
1845						
1970						
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28
5240	5100 - 5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9
5500						
5785						

NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and CELLECTRA® 5PSP may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a. For some services, only the uplink frequencies are included.

b. The carrier shall be modulated using a 50% duty cycle square wave signal.

c. As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Reference Information

Self-Assessment Questions

Answer these YES/NO questions to test your understanding of CELLECTRA® 5PSP. The answers are on the following page.

1. **Can CELLECTRA® 5PSP be used to deliver VOCERYQ and electrical pulses to make VOCERYQ delivery more effective?**
2. **Does CELLECTRA® 5PSP have 3 main components (Base Station, Handset, and Array) that can only be used with VOCERYQ Cartridges?**
3. **Can the Array and the VOCERYQ Cartridge be reused?**
4. **Do the Base Station and Handset each have displays that communicate wirelessly and that guide the user through the process of using CELLECTRA® 5PSP?**
5. **Does CELLECTRA® 5PSP allow selection of a needle depth and provide a needle depth recommendation based on a patient's height and weight?**
6. **Are the Handset and power supply stored in drawers on either side of the Base Station?**
7. **Can Handsets be mix-and-matched with different Base Stations?**
8. **Can CELLECTRA® 5PSP be positioned near a sink?**
9. **Can the Handset be used immediately after setting up the system?**
10. **Is the patient's anterolateral quadriceps an acceptable injection site?**
11. **Does the Array have to be handled with clean technique?**
12. **Can the VOCERYQ Cartridge be inserted into the Array in any orientation?**
13. **Can the Array be attached to the Handset in any orientation?**
14. **Will the patient experience muscle contractions during the injection that will require stabilizing of the patient?**
15. **Can the Handset be immediately removed from the patient after pressing the trigger button to start treatment?**
16. **Can the Array be reused if the patient is supposed to receive more than one treatment?**

17. Can wet wipes be used to clean the Base Station and Handset?

18. Can CELLECTRA® 5PSP be returned to INOVIO for any maintenance or repairs?

19. When not in use, can the Handset and Power Supply be stored in the Base Station's built-in drawers?

20. Does CELLECTRA® 5PSP emit a sound and or display an error message whenever there is an issue?

21. For help with a problem, can the user refer to the Troubleshooting section of the User Manual, or contact INOVIO's Support Line?

Answers

1. YES

2. YES

3. NO – The Array and VOCERYQ Cartridge are single-use components that cannot be reused.

4. NO – The Base Station and Handset do not share a wireless connection when separated.

5. YES

6. YES

7. NO – Each Handset is uniquely paired to a Base Station. The serial numbers at the back of the Base Station and at the bottom of the Handset must match.

8. NO – CELLECTRA® 5PSP must be kept away from water sources or other liquids that may damage the electronics.

9. NO – The internal battery of the Handset must be charged on the Base Station before use.

10. YES - Injection is acceptable into the deltoid or anterolateral quadricep muscle.

11. YES

12. NO – The VOCERYQ Cartridge only fits one way. The arrows on the VOCERYQ Cartridge should point into the Array.

13. NO – The Array only fits one way. Match the slot on the Array with the groove on the top of the Handset.

14. YES – In order for treatment to be successful, the electrical pulses will cause muscle contractions which may be unpleasant to the patient. Stabilizing the arm for the deltoid or the anterolateral quadricep for thigh injections should help minimize the discomfort.

15. NO – WAIT for the treatment to finish (approximately 10 seconds). The Handset display will beep and show "Treatment Complete" when the treatment has finished. Do NOT remove the Handset during the treatment, unless it is an emergency. Removing the Handset early will abort the treatment.

16. NO – Never reuse the Array or VOCERYQ Cartridge.

17. NO – Only clean the Base Station and Handset with Super Sani-Cloth. Only use water-moistened wipes to remove excess residue.

18. YES

19. YES

20. YES

21. YES

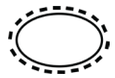
Symbols

The following symbols may be found on CELLECTRA® 5PSP, in its accompanying documentation, or on its packaging labels. These symbols provide instructions regarding the proper and safe use of CELLECTRA® 5PSP. Some of these symbols may not have meaning in every region, and are listed for informational purposes only. This table shows what each symbol means.

	Caution		Consult instructions for use
	General Warning		Refer to user manual
	Class II Equipment		Sharp element
	Manufacturer		Date of manufacture
	Catalog number		Lot number
	Sterilized using irradiation		Use-by date
	Temperature limit		Indoor use only
	Humidity limitation		Do not resterilize
	Atmospheric pressure limitation		Do not re-use
	Do not use if package is damaged and consult instructions for use		Non-ionizing electromagnetic radiation
	Separate collection for waste electrical and electronic equipment (WEEE)		UL Mark for Canada and US
	Type BF Applied Part		Non-pyrogenic
SN	Serial Number	UDI	Unique Device Identifier

Symbols (cont.)

The following symbols may be found on CELLECTRA® 5PSP, in its accompanying documentation, or on its packaging labels. These symbols provide instruction regarding the proper and safe use of CELLECTRA® 5PSP. Some of these symbols may not have meaning in every region, and are listed for informational purposes only. This table shows what each symbol means.

℞ ONLY	Medical prescription required	IP22	Protected against solid foreign objects of 12.5 mm or greater, and against vertically falling water drops when enclosure tilted up to 15°
VI	Energy Efficiency Level 6	D	Demko Mark
IPX1	Protected against vertically falling water drops when enclosure tilted up to 15°		Packaging Unit
MR	MR Unsafe - keep away from magnetic resonance imaging (MRI) equipment	CE	CE Mark
	Single sterile barrier system with protective packaging outside		Single sterile barrier system
RoHS	RoHS Mark		Biological risks