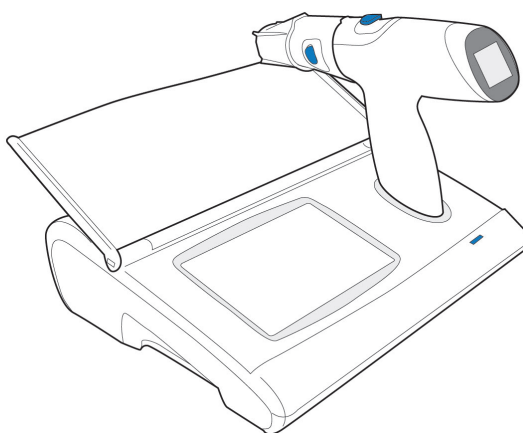




## CELLECTRA™ 5PSP Electroporation Device

### User Manual



### **CAUTION!** INVESTIGATIONAL DEVICE.



Limited by Federal (or United States) law for investigational use.  
Investigational Device. To be Used by Qualified Investigators Only.

### **CAUTION!** INVESTIGATIONAL DEVICE.



Limited by Canadian Regulation for investigational use.  
Instrument de recherche. Réservé uniquement à l'usage de chercheurs compétents'.

### **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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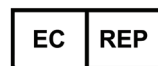
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Document: M12-006084-01\_E

Date of issue: YYYY-MM-DD

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# 1. About CELLECTRA™ 5PSP

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## Purpose

The User Manual describes the proper use of the CELLECTRA™ 5PSP Electroporation Device.

## Intended Use

The CELLECTRA™ 5PSP Electroporation Device is intended for injection and enhanced cellular uptake of Inovio DNA plasmids by way of intramuscular plasmid injection followed by the application of intramuscular electrical pulses.

The needle Array component of CELLECTRA™ 5PSP is packaged sterile and is intended for single use.

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

## Contraindications

None.

## WARNINGS

- Do NOT use on areas where major blood vessels or nerves are present.
- If it is determined by the practitioner that electroporation could negatively impact the patient, do NOT use CELLECTRA™ 5PSP on patients with any significant acute or chronic medical illness (e.g. unstable angina, class 3 or higher congestive heart failure, etc.).
- Do NOT inject into skin that is irritated, damaged, or has bruises, scars, or tattoos. Injecting into skin with these conditions may result in patient harm or ineffective treatment.
- 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 use CELLECTRA™ 5PSP on areas of the patient containing any metal implants or implantable medical device.
- Unless deemed acceptable by a Cardiologist, 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.
- CELLECTRA™ 5PSP is only for use with sterile disposable Arrays and Drug Cartridges provided for use by Inovio Pharmaceuticals, Inc. Incompatible Arrays or Drug 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.
- 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.
- 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.



General warnings

## WARNINGS (CONT.)

- 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 the CELLECTRA™ 5PSP if any tamper-evident seal is broken. If a tamper-evident seal is broken, contact Inovio Pharmaceuticals, Inc. for further instruction.
- 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.
- 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.
- Unplug the Base Station before cleaning the CELLECTRA™ 5PSP.
- Do NOT expose CELLECTRA™ 5PSP to water or any other liquid.
- MR Unsafe - Keep away from magnetic resonance imaging (MRI) equipment.



Read this User Manual

- CELLECTRA™ 5PSP is ONLY for use by qualified personnel who have successfully completed CELLECTRA™ 5PSP training. For training details on the CELLECTRA™ 5PSP, please contact Inovio according to the information at the back of the cover page.
- Always determine proper placement of the sterile disposable Array based on the guidance of the medical practitioner.
- Do NOT use a malfunctioning device. Refer to the Troubleshooting section of this User Manual.



Do NOT use if package damaged

- Do NOT use an Array or Drug Cartridge if the packaging is damaged. Using an Array or Drug 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



General Precautions

- Keep foreign material from covering the black sensor windows near the Needle Depth Selector to avoid unintended Array errors that might require restarting the overall treatment procedure.
- Certain light sources such as IR lamps located in close proximity to the Handset or direct sunlight 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.

## PRECAUTIONS (CONT.)



- Always use CELLECTRA™ 5PSP within the temperature, humidity, and atmospheric pressure ranges specified in this User Manual. Using the system outside these ranges may result in malfunction. Contact Inovio Pharmaceuticals, Inc. if environmental specifications are exceeded.



- 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.



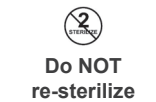
- Do NOT reuse Arrays and Drug Cartridges. Arrays and Drug Cartridges are for single-use ONLY. Reuse of Arrays or Drug Cartridges will result in system malfunction.



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



- Always use aseptic technique when handling the Array and Drug Cartridge.



- Do NOT attempt to re-sterilize Arrays and Drug Cartridges. Arrays and Drug Cartridges are for single-use ONLY. Reuse of Arrays or Drug Cartridges will result in system malfunction.



- 5PSP™ Array contains low concentration of Cobalt, a CMR substance.

*Note:* Ensure there is always access to the power cord and electric supply. If required, the power cord can be removed from the outlet to shut off power to the base station.

## 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 the CELLECTRA™ 5PSP are:

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

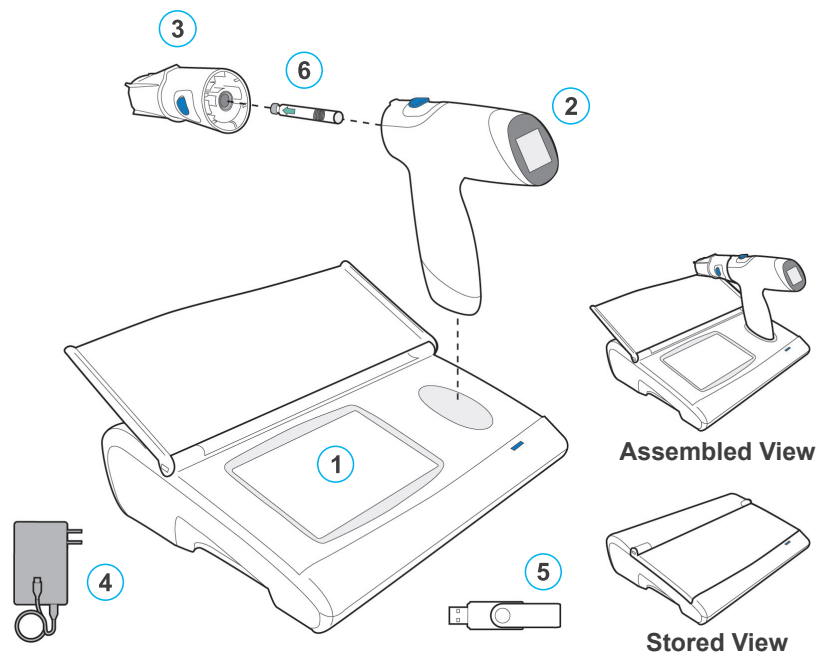
To report any adverse reactions, contact Inovio's Safety Line at +1 (267) 440-4257.

Any serious incident that has occurred in relation to the device should be reported to the competent authority of the Member State in which the user and/or patient is established and Inovio's Safety Line at +1 (267) 440-4257.

## Components

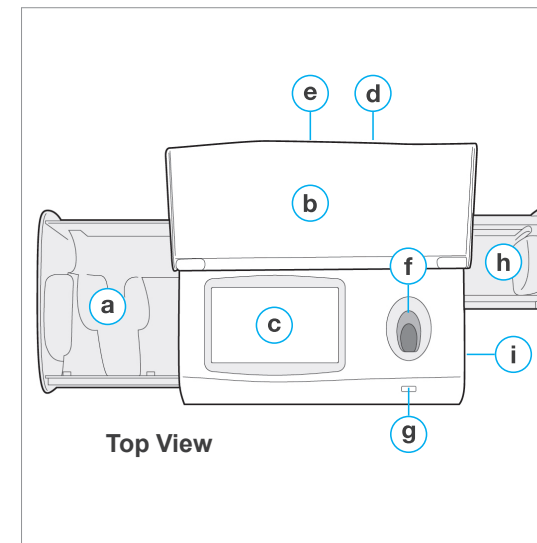
CELLECTRA™ 5PSP has 5 components plus 1 Drug Cartridge (see Figure 1):

- 1. Base Station** – Acts as a docking station for the Handset and as the primary display for entering patient information; must be used with the provided Power Supply (see Figure 2)
- 2. Handset** – Controls delivery of the drug and electrical pulses (see Figure 3)
- 3. Array (single-use, packaged sterile)** – Attaches to the Handset and contains the needles and other sensors used for drug delivery and electroporation (see Figure 4)
- 4. USB International Power supply**
- 5. Flash Drive** – Used to download data after treatment
- 6. Drug Cartridge (single-use)** – Contains the drug to be administered and is inserted into the Array (see Figure 5)



**Figure 1** CELLECTRA™ 5PSP components and Drug Cartridge

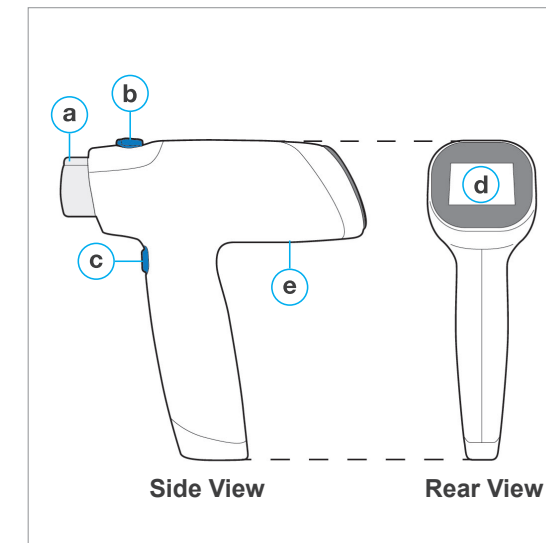
## Base Station



**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

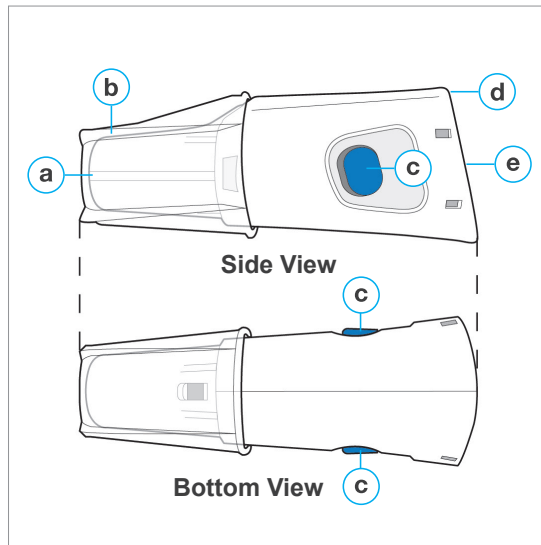
## Handset



**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

## Displays and Feedback

The system has 2 Displays to guide the user through treatment:

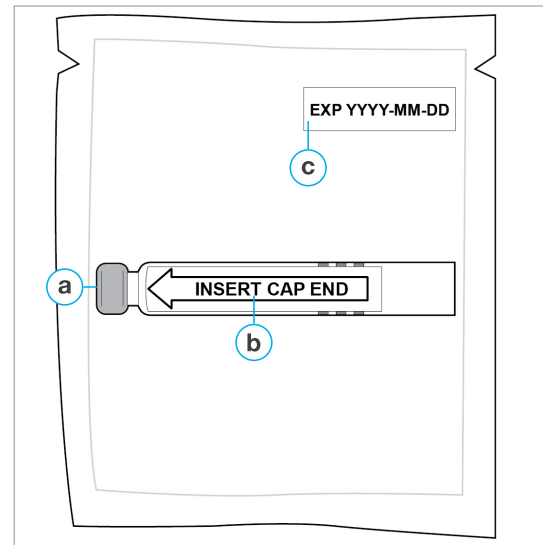
- **Base Station Touchscreen** – Used to initially set up treatment and to access help information during treatment (see Figure 6).
- **Handset Display** – Guides the user through delivering treatment (see Figure 7).

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

Additional help is available by touching icons on the Base Station.

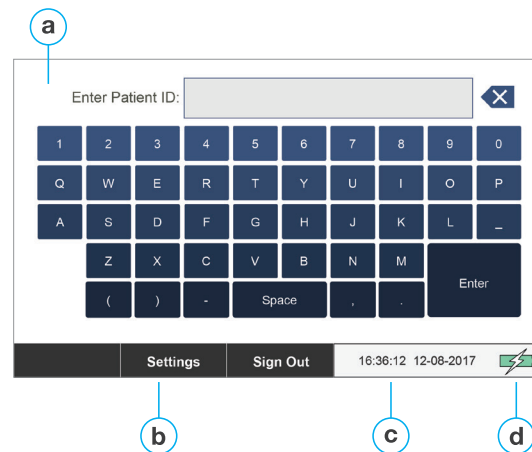
*Note:* Use of objects such as pens to touch the screen may scratch the screen.

## Drug Cartridge



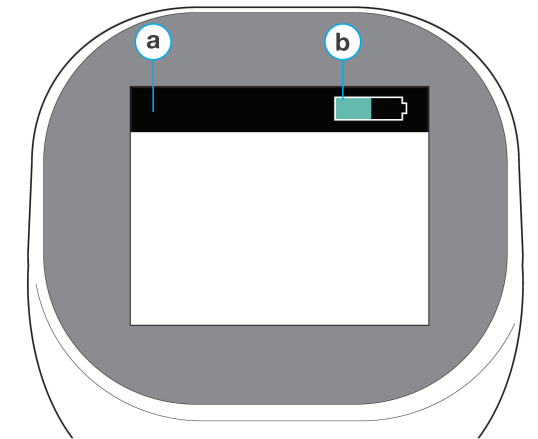
**Figure 5** The Drug Cartridge supplied in Pouch

- a. Crimp Cap Septum
- b. Cartridge
- c. Drug Label with Expiration Date on Pouch



**Figure 6** The parts of the Base Station Touchscreen

- a. Title Bar
- b. Menu Bar
- c. Date/Time
- d. Handset Connection Icon



**Figure 7** 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 the drug and delivering electrical pulses takes time (approximately 10 seconds). The Handset will alert the user when treatment is complete.

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# 2. Setup

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## Setup

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 8).

*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.

#### CAUTION!

⚠ Avoid exposing the Handset to certain light sources such as direct sunlight. Setting up the Handset in close proximity to certain light sources could influence device performance.

### 2. Dock the Handset on the Base Station (see Figure 9).

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

#### 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.

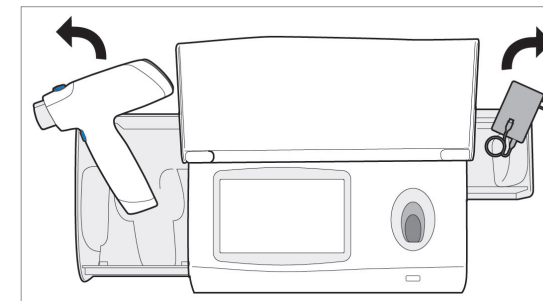


Figure 8 Handset and Power Supply

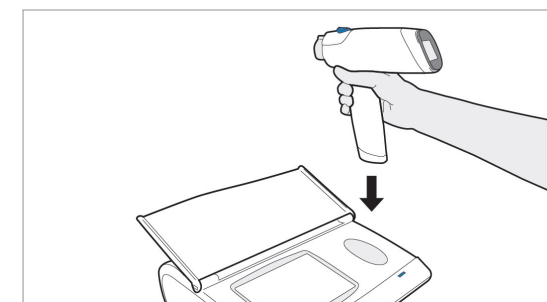


Figure 9 Dock Handset

3. Connect the Base Station to a power outlet for charging (see Figure 10).

*Note:* If the Low Battery Warning is displayed, wait for 20 minutes or until the Low Battery Warning is no longer displayed.

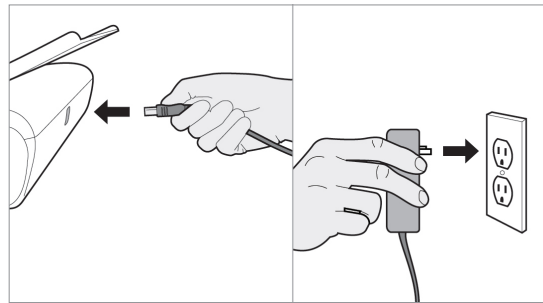


Figure 10 Connect Power Supply

4. On power up, device will initiate a Self Test and the *Start Up* screen will display on the Base Station and Handset (see Figure 11 and Figure 12).

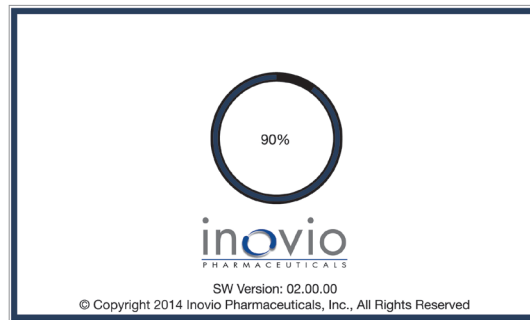


Figure 11 Self Test Screen

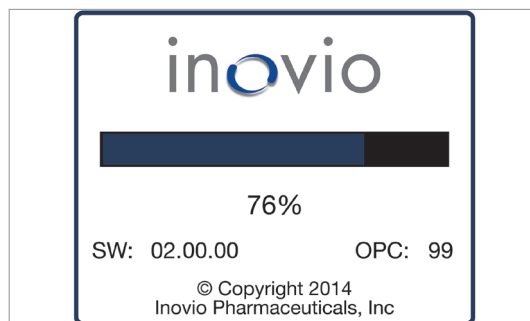


Figure 12 Start Up Screen

5. After a successful Self Test, an audible sound will play from the Base Station and Handset. The *Enter Access Code* screen is shown on the Base Station (see Figure 13) and the Handset screen will be blank.

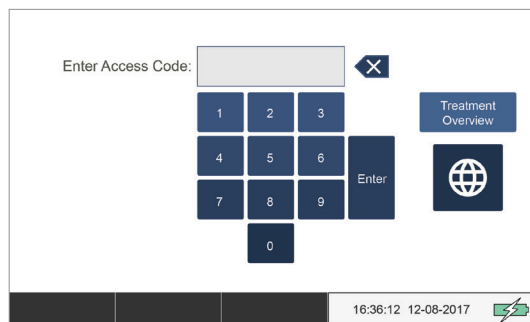


Figure 13 Enter Access Code Screen

## Settings Screens

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

6. Press *Treatment Overview* on the *Access Code* screen to see a summary of the steps to perform a treatment (see Figure 14).



Figure 14 Treatment Overview Screen

7. To change the language, press the globe icon on the *Enter Access Code* screen. Select your language using the *Up* and *Down* arrows. Then press *Confirm* (see Figure 15).

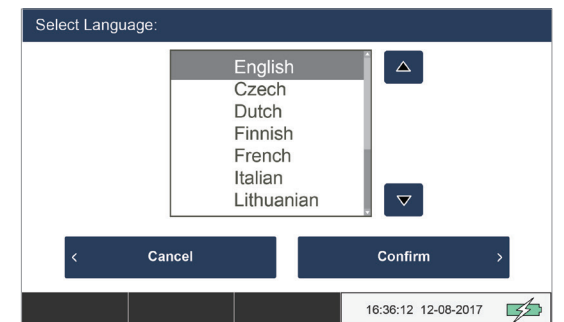


Figure 15 Select Language Screen

8. To change a setting, start by pressing **Settings** on the **Enter Patient ID** screen. You will need to enter the code 123654 on the **Enter Access Code** screen to access the **Enter Patient ID** screen (see Figure 16).

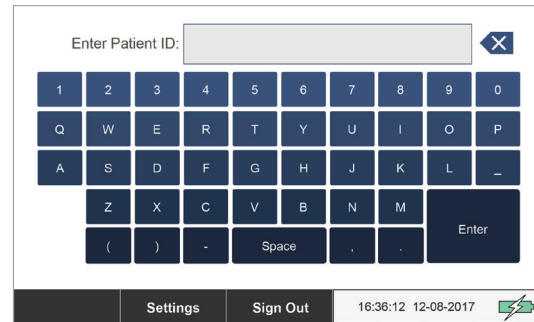


Figure 16 Patient ID Screen

9. The **Settings** screen allows you to access **Device Settings**, view information and help, or download log contents (see Figure 17).

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

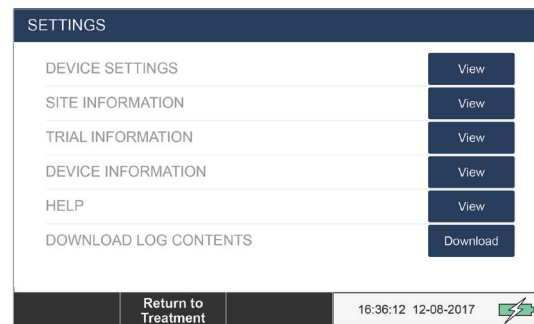


Figure 17 Settings Screen

10. 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 18).

*Note:* **Locale Settings** can also be accessed by pressing the globe icon on the **Enter Access Code** screen and then confirming the language.

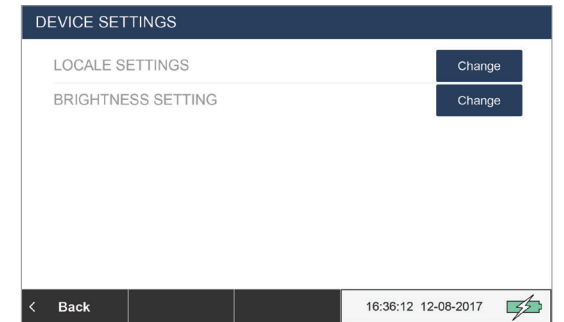


Figure 18 Device Settings Screen

11. The **Locale Settings** screen shows the current settings. Press **Change** next to a settings option to change that setting (see Figure 19).

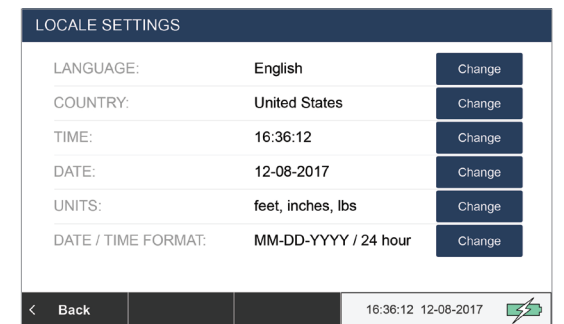


Figure 19 Locale Settings Screen

- To change the time, from the *Locale Settings* screen (see Figure 19) press *Change* to the right of *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 20).

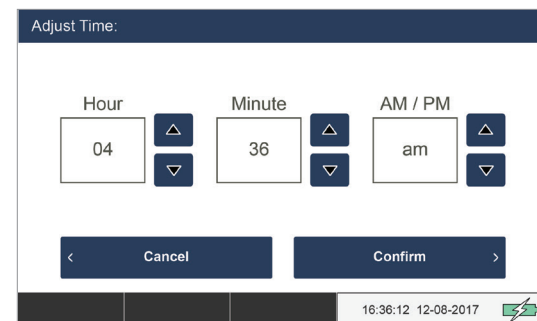
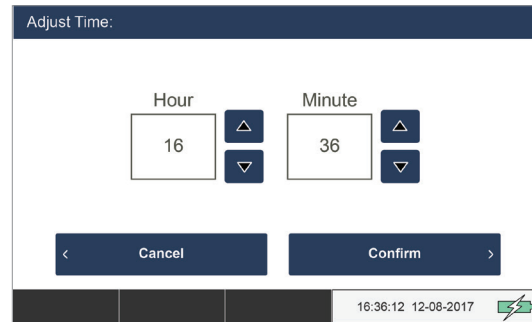


Figure 20 Adjust Time Screen

- To change the time format or date format, from the *Locale Settings* screen (see Figure 19) press *Change* to the right of *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 21).

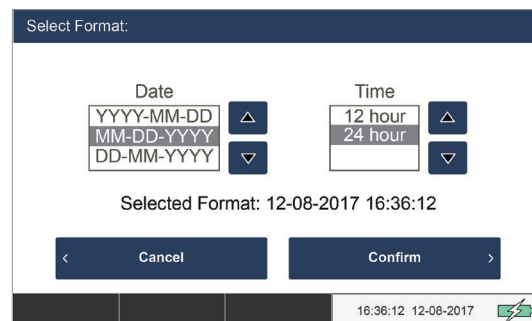


Figure 21 Select Format Screen

- To change the units used for patient height and weight, from the *Locale Settings* screen (see Figure 19) press *Change* to the right of *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 22).



Figure 22 Select Weight and Height Units

- To change the screen brightness, from the *Device Settings* screen (see Figure 18) press *Change* to the right of *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 23).



Figure 23 Locale Settings Screen

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# 3. Treatment

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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 24).**
  - 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.
2. **Inspect the Handset and Base Station for damage and visible soil before each use. Refer to Section 4 - Care Information for cleaning instructions.**
3. **Inspect the temper-evident seals on the Handset and Base Station. Do NOT use the device if any of the seals are broken (see figure 25). Contact Inovio for further instruction if any of the tamper-evident seals are broken.**
4. **Confirm the patient's current height and weight.**

### 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.

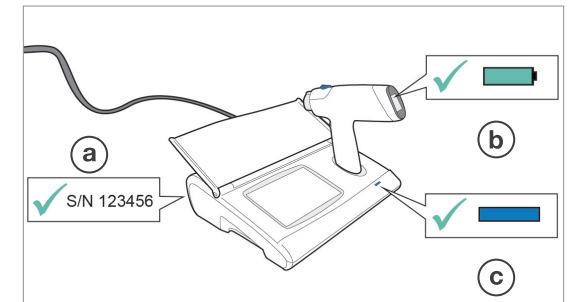


Figure 24 Base Station and Handset Checks

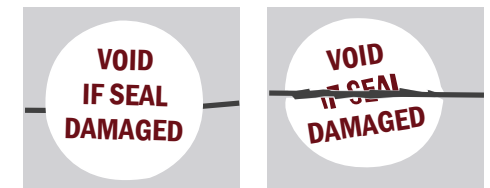


Figure 25 Example of a tamper-evident seal that is intact (left) and broken (right)

## Preparing the Drug

### 3. Gather the disposable supplies (see Figure 26):

- Array (sterile)
- Pouch containing the Drug Cartridge
- Alcohol wipes (for the Drug Cartridge and injection site)
- Gauze (for after the injection)

#### CAUTION!

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



### 4. Prior to use, perform VISUAL inspection of packaging for integrity, including tray, pouch and seal and verify the expiration date (see Figure 27).

- Verify that the correct drug has been collected.
- Verify that the Array and Drug Cartridge are not expired.

#### WARNING!

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

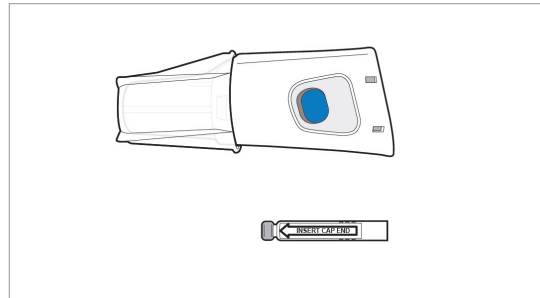


Figure 26 Array (top) and Drug Cartridge (bottom)



Figure 27 Array Packaging and Drug Cartridge Pouch

### 5. Remove the Drug Cartridge from its packaging and inspect for damage.

*Note:* Keep the Pouch for the Drug Cartridge until treatment is completed.

#### WARNING!

Do NOT use an Array or Drug Cartridge if the packaging is damaged. Using an Array or Drug Cartridge with damaged packaging may result in patient harm.



## Preparing the Base Station and the Handset

### 6. On the *Enter Access Code* screen on the Base Station, enter code 123654 (see Figure 28).

#### 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.

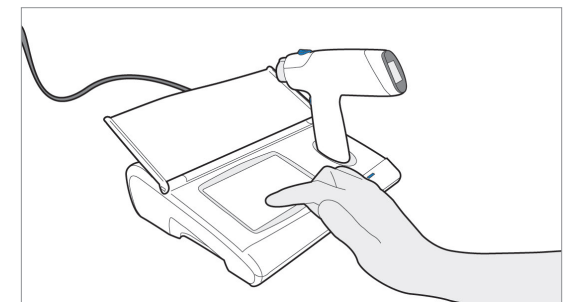


Figure 28 Base Station Entry

- 3
7. Enter the Patient ID, then press **Enter** (see Figure 29). You will need to enter the Patient ID again to confirm.

Follow the steps on each screen to prepare for treatment.

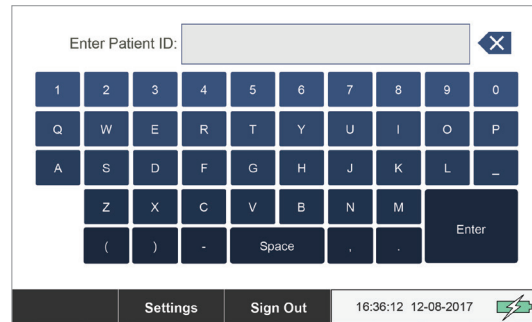


Figure 29 Patient ID Screen

8. 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 quadriceps (see Figure 30).

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

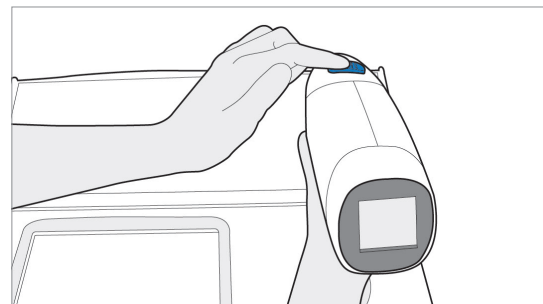


Figure 30 Needle Depth Setting

## Preparing the Injection Site

9. Wash hands and put on gloves (see Figure 31).



Figure 31 Hand Washing

10. Select an injection site in the thickest part of the deltoid muscle in the upper arm (see Figure 32).

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

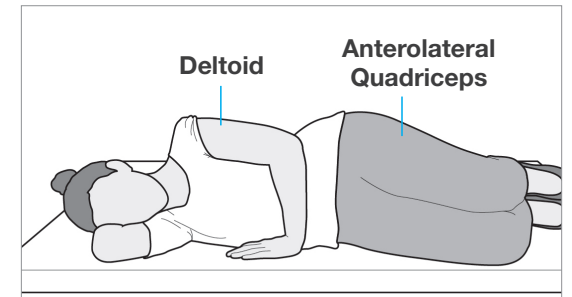


Figure 32 Patient Position

11. Position the patient so that he or she can be stabilized during treatment (Recommended position: on his/her side as shown) (see Figure 32).

12. Swab the injection site with alcohol and allow to dry (see Figure 33).

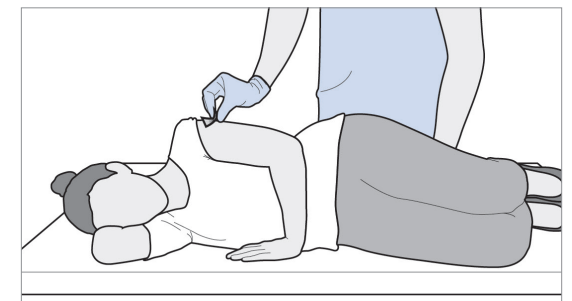


Figure 33 Alcohol Swab Injection Site

## Preparing and Assembling the Array

13. Clean the septum of the Drug Cartridge with alcohol swab and allow to dry (see Figure 34).

### CAUTION!

Ensure that the drug cartridge has reached room temperature. If the drug cartridge is too cold injection may result in patient discomfort.

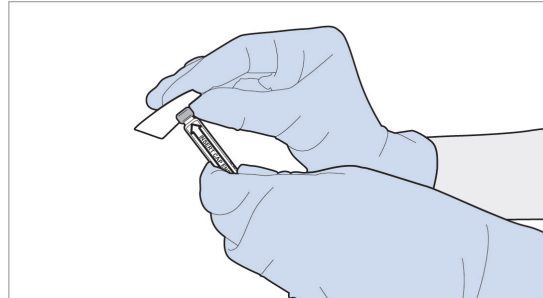


Figure 34 Alcohol Swab Drug Cartridge Septum

14. Remove the sterile Array from its packaging and inspect the Array for damage (see Figure 35).

### WARNING!

Avoid contact with the open end of the Array. Contact may result in accidental needle sticks or patient harm.

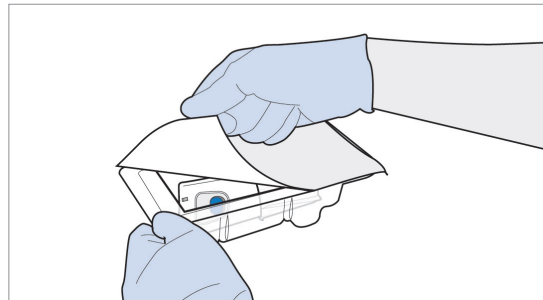


Figure 35 Remove Sterile Array from Packaging

15. Insert the Drug Cartridge into the center of the Array and firmly push until you hear an audible »click« to indicate that the Drug Cartridge is fully inserted (see Figure 36 and 37).

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

### CAUTION!

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

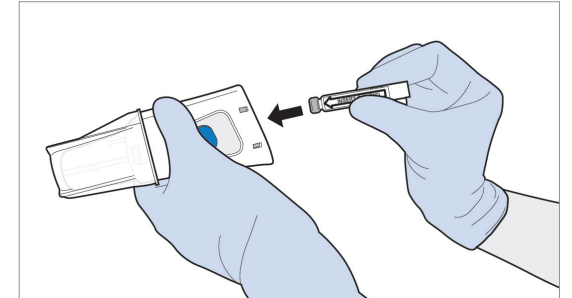


Figure 36 Insert Drug Cartridge into Sterile Array

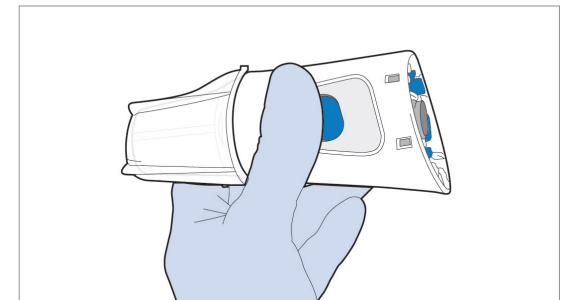


Figure 37 Assembled Sterile Array with Cartridge Inserted

16. Confirm treatment is ready to begin on Base Station. Then lift the Handset off of the Base Station (see Figure 38).

### CAUTION!

Avoid exposing the Handset to certain light sources such as direct sunlight. Using the Handset in close proximity to certain light sources could influence device performance.

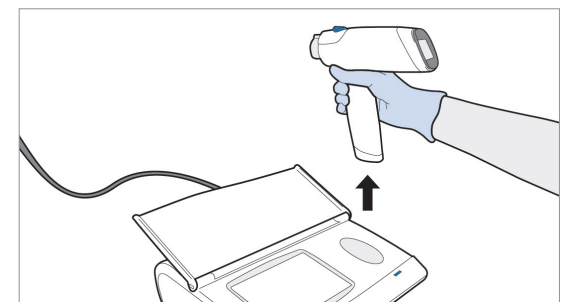


Figure 38 Remove Handset from Base Station

17. "Lift handset and attach array" is displayed on the handset (see Figure 39). The *Treatment Overview* screen is displayed on the Base Station (see Figure 40).

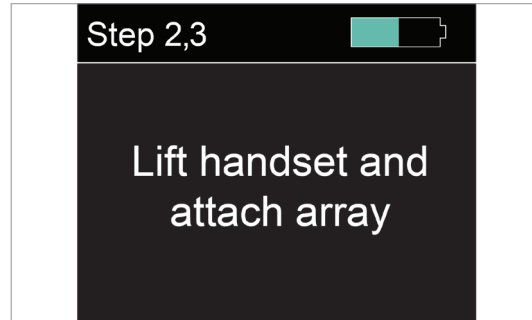


Figure 39 Attach Array Handset Display

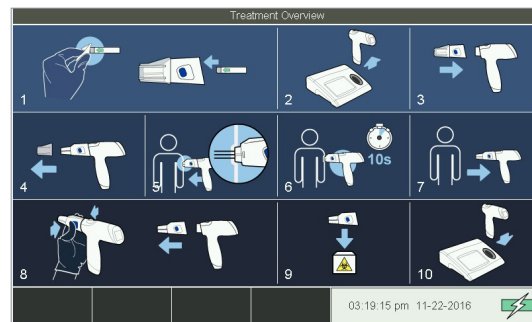


Figure 40 Treatment Overview Screen

18. Attach the assembled Array with Drug Cartridge to the Handset (see Figure 41).

- 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 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. When the Handset is ready for use, it will emit a sound and then display a confirmation message "Treatment Ready".

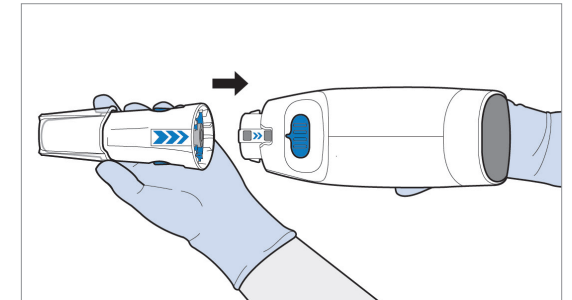


Figure 41 Attach Array to Handset

## Delivering Treatment

19. Remove the cap from the Array (see Figure 42).

**CAUTION!**  
 DO NOT press the trigger until ready to deliver treatment.

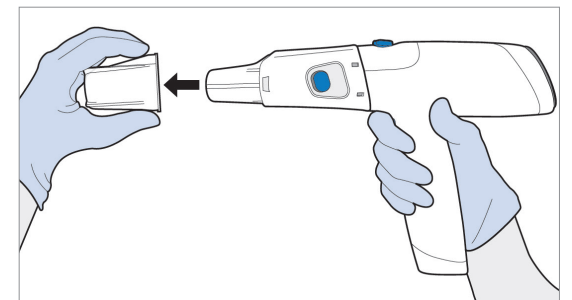


Figure 42 Remove Array Cap

20. Stabilize the patient by placing a hand firmly on the patient's limb (arm or leg) to limit movement during treatment (see Figure 43).

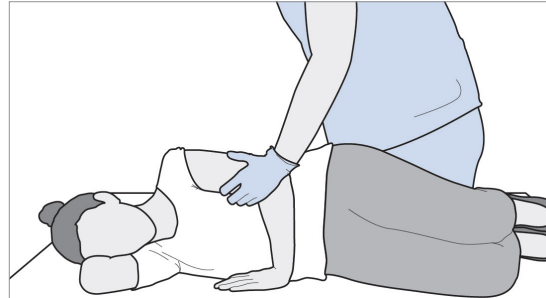


Figure 43 Stabilize Patient

21. Firmly push the Array into the thickest part of the intended muscle (deltoid or anterolateral quadriceps) to insert the needles fully (see Figure 44).

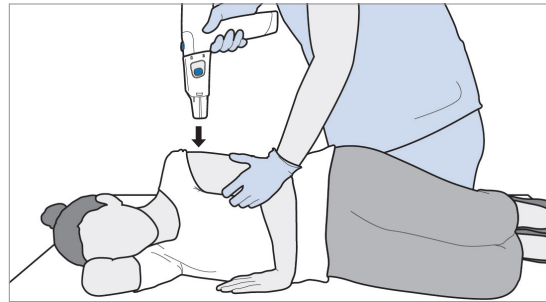


Figure 44 Deltoid shown. Patient shown in lateral position.

**CAUTION!**

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



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

22. 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 45).

The treatment takes approximately 10 seconds to complete.

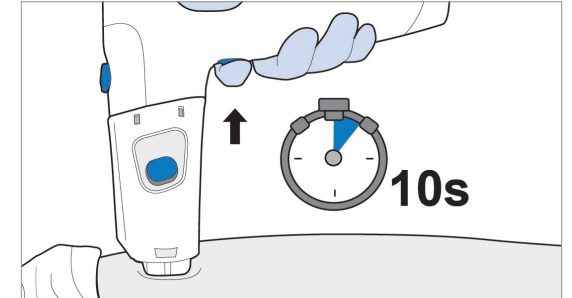


Figure 45 Treatment Time

**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.

- a. Continue to stabilize the patient's limb and wait for the Handset to emit a confirmation sound indicating that the treatment is complete.
- b. Before removing the Handset, verify that "Treatment Complete Remove array from patient" is displayed on the Handset screen (see Figure 46).

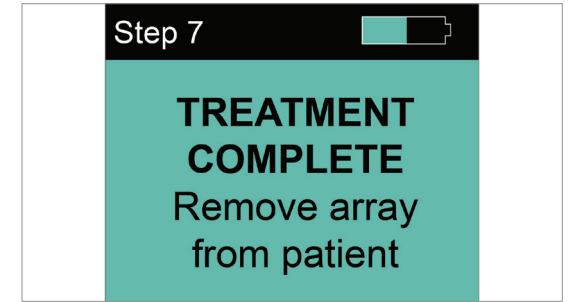
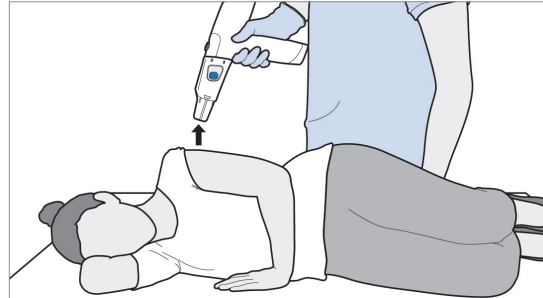


Figure 46 Treatment Complete Handset Display

**23. Withdraw the Handset from the injection site after the treatment is complete (see Figure 47).**

After the Array is removed from the injection site the shroud will lock out to permanently conceal the needles.

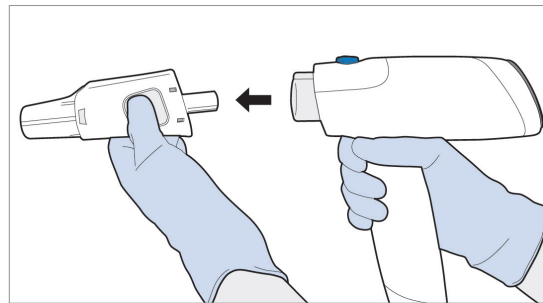


**Figure 47** Remove Handset

## Discarding Disposables and Shutting Down the System

**24. Remove the Array from the Handset (see Figure 48).**

- a. Press and HOLD the blue release buttons on both sides of the Array.
- b. Pull the Array away from the Handset.



**Figure 48** Remove Array from Handset

**25. Safely discard the assembled Array and Drug Cartridge into a suitable sharps container (see Figure 49).**

**CAUTION!**  
Do NOT attempt to remove the Drug Cartridge from the Array. Drug Cartridges are for single-use ONLY. Reuse of Drug Cartridges will result in system malfunction.

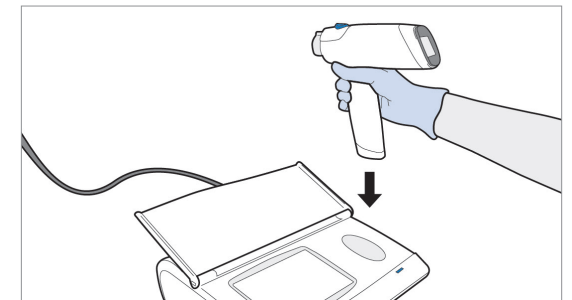
**CAUTION!**  
Do NOT reuse Arrays and Drug Cartridges. Arrays and Drug Cartridges are for single-use ONLY. Reuse of Arrays or Drug Cartridges will result in system malfunction.



**Figure 49** Dispose Array as Bio-Hazard Sharps

**26. 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.**

**27. Return the Handset to the Base Station (see Figure 50) and follow prompts on the Base Station's touchscreen to download treatment data, if required.**



**Figure 50** Place Handset in Base Station

Note: The following table provides guidance on how to appropriately complete administration of the treatment procedure when the subject did not receive drug injection and EP.

Was the Array (with Drug Cartridge inserted) attached to the Handset?	Was the Array fully inserted into tissue?	Was the trigger button pressed?	Action
Yes	Yes/No	No	Follow the device prompts to complete the procedure. A new Array and Drug Cartridge may be needed to complete the procedure.
Yes	Yes, but the Array was dislodged from tissue.	No	Follow the device prompts. Then, obtain a new Array and Drug Cartridge 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 the drug is not permitted.

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

## Storing the Handset and Power Supply

### 28. At the end of the procedure:

- Place Handset on the Base Station
- Wait 5 seconds
- Unplug power cord with the Handset docked.
- Wait until the Handset Display is turned off.
- Place both Power Supply and Handset inside Base Station drawers (see Figure 501).

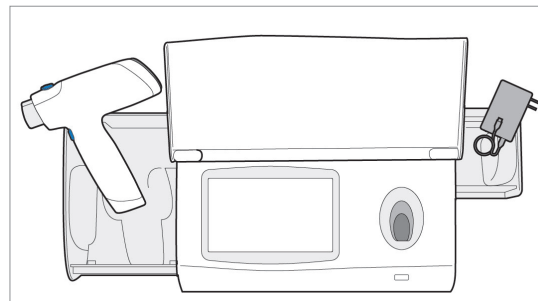


Figure 51 Store Handset and Power Supply

## Pausing or Cancelling Treatment

### • Pause Treatment:

- Prior to Step 22 (insertion into the muscle) 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 access code is required if treatment is paused for more than 60 minutes.

### • Abort Treatment:

- Tap "Sign Out" on the Base Station Touchscreen before the Drug Cartridge is inserted into the Array (Step 15).
- Once the Array has been inserted into the muscle, the assembled Array with Drug 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.

Note: The following table provides guidance on how to appropriately complete administration of the treatment procedure when the subject did not receive drug injection and EP.


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# 4. Care Information

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## Cleaning

 **CAUTION!** Do NOT expose CELLECTRA™ 5PSP to water or any other liquid.

 **CAUTION!** Do NOT use dripping wet wipes or solutions on CELLECTRA™ 5PSP.

After each use, inspect the Base Station and Handset. If visible soil is present, unplug the Base Station, then follow the cleaning steps below:

1. Remove any visible soil by thoroughly cleaning the Handset or Base Station with wipes such as Caviwipe<sup>1</sup>, or Super Sani-Cloth<sup>2</sup>, or 70% Isopropyl alcohol until soil is no longer visible.
2. Ensure all visible soil is removed. Repeat the previous steps, if needed, until soil is no longer visible.
3. If excess residue remains, remove excess residue with a water-moistened wipe. Allow to air dry.

After cleaning, inspect the Base Station and Handset:

1. If visible soil remains, repeat the cleaning steps until soil is no longer visible.
2. If visible deterioration such as corrosion, discoloration, pitting or cracked seals are observed, notify INOVIO. Discontinue use of the device.

1. EPA Registration Number 46781-13

2. EPA Registration Number 9480-4


## Maintenance


Charge the Handset at least once a month. It may take up to 4 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, return CELLECTRA™ 5PSP to Inovio Pharmaceuticals, Inc. for a factory authorized repair.

## Disposal

 **CAUTION!** Do NOT reuse Arrays and Drug Cartridges. Arrays and Drug Cartridges are for single-use ONLY. Reuse of Arrays or Drug Cartridges will result in system malfunction.

 **CAUTION!** Do NOT attempt to remove the Drug Cartridge from the Array. Drug Cartridges are for single-use ONLY. Reuse of Drug Cartridges will result in system malfunction.

Dispose of CELLECTRA™ 5PSP Base Station, Handset, assembled Array and Drug Cartridge according to any applicable local, state, and federal laws and regulations.

For clinical trial use, return CELLECTRA™ 5PSP Base Station and Handset to Inovio Pharmaceuticals, Inc. Dispose of assembled Array and Drug Cartridge according to any applicable local, state, and federal laws and regulations.

Do NOT recycle or re-sterilize.

## 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 download data from the USB port on the right side of the CELLECTRA™ 5PSP Base Station. Do not insert any personal or consumer devices into the USB ports on CELLECTRA™ 5PSP.

**System Access** - CELLECTRA™ 5PSP requires an access code as a basic level of authorization. Do not share the access code with unauthorized personnel.

**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 qualified/authorized personnel. Store the product in a physically secured location to prevent unintentional or intentional misuse. The CELLECTRA™ 5PSP product is not intended to be opened or disassembled.

**Tamper Evident Seals** - Please inspect the tamper evident seals adhered to the CELLECTRA™ 5PSP Base Station and Handset- for breaks prior to each use. If a tamper evident seal indicates the CELLECTRA™ 5PSP may have been tampered with, discontinue use of the CELLECTRA™ 5PSP and contact Inovio at the Product Complaint Line: +1 (267) 434-4099.

### Security Incidents and Vulnerabilities

If you suspect a cybersecurity incident has occurred involving the CELLECTRA™ 5PSP or if you require assistance to investigate or any further information, please contact Inovio at the Product Complaint Line: 1 (267) 434-4099.

If you suspect or identify a potential cybersecurity vulnerability in the CELLECTRA™ 5PSP, vulnerabilities may be reported through Inovio's Vulnerability Disclosure program hosted by MedISAO at [https://members.medisao.com/vulnerability\\_disclosure/](https://members.medisao.com/vulnerability_disclosure/).

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# 5. Troubleshooting

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## General Troubleshooting Tips

- When an error occurs, follow the instructions on the Handset and Base Station Display.
- If touchscreen does not respond or power on self test does not pass, remove power cord from Base Station, wait for about 5 seconds and reconnect power cord.
- If a problem cannot be resolved, call Inovio's Product Complaint Line at +1 (267) 434-4099.

# 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 has a sound.

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 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	Device Fault	52
● Incorrect Needle Depth	Incorrect Needle Depth	53
● Device Fault: Treatment Failure	Device Fault	54
● Recovery After Device Fault	Device Fault	54

## Yellow Alerts

Base Station Touchscreen Message	Handset Display Message	Pg.
● Access Locked Out (not displayed on Base Station)	Access Locked Out	55
● Handset Disconnected	Handset Not Ready	55
● Handset with Array in Base Station: Drug Cartridge Used or Missing	Cartridge Used/Missing	56
● Handset with Array in Base Station: Drug Cartridge Backwards -	Cartridge Backwards	57
● Handset with Used Array in Base	Remove and discard Array	58
● Incorrect Handset for this Base	Handset blank	59
● Low Battery	Low Battery	59
● Needle Depth Does not Match	Needle Depth	60

## Yellow Alerts (cont.)

Base Station Touchscreen Message	Handset Display Message	Pg.
● Missing Depth-Setting Selector	Missing Depth Setting-Selector	61
● Needle Depth Does Not Match recommended	Needle Depth	62
● System Cannot Perform Self-Test while Handset is Disconnected	Handset Not Ready	63
● System Cannot Perform Self-Test with Array on Handset	Remove Array and Place Handset on Base Station	64
● User Initiated Treatment Abort	Treatment Aborted	65

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

Base Station Touchscreen Message	Handset Display Message	Pg.
● Faulty USB Device	blank	66
● Treatment Paused: Handset in Base	Treatment Paused	66
● Incorrect Access Code	blank	67
● Invalid Dose Number	blank	67
● Invalid Patient Height	blank	68
● Invalid Patient Weight	blank	69
● USB Device Full	blank	69

## Red Alert Messages

### 1. Device Fault: Treatment Aborted

Handset: Device Fault

#### What it means:

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

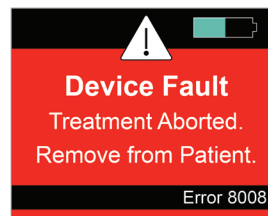
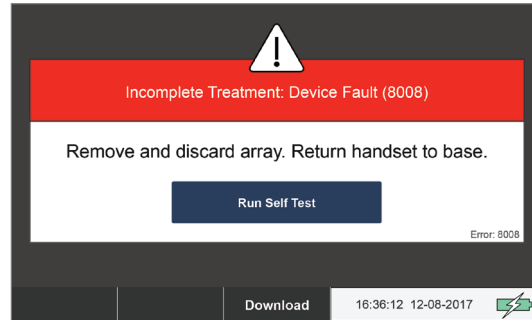
#### What to do:

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 Drug Cartridge into a suitable Sharps container.

### CAUTION!

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

5. Return the Handset to the Base Station and follow prompts on the Base Station Touchscreen. Ship the Handset and Base Station back to Inovio according to required shipping procedure.



### 2. Incorrect Needle Depth

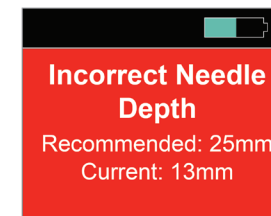
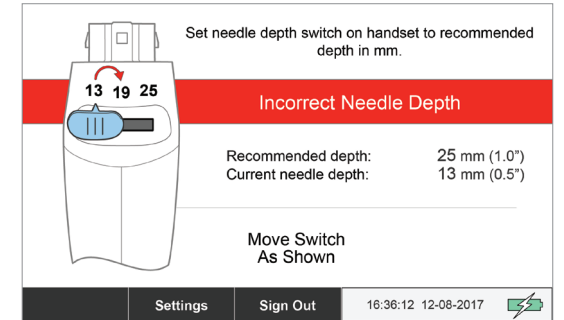
Handset: Incorrect Needle Depth

#### 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 quadriceps 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.



### 3. Device Fault: Treatment Failure

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 Drug Cartridge into a suitable Sharps container.

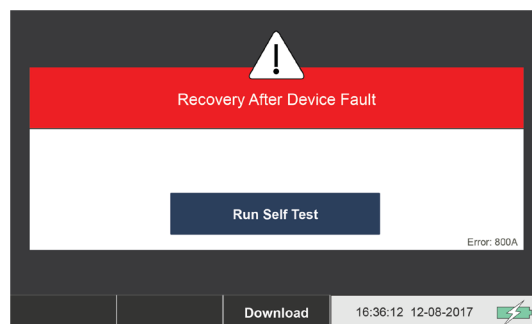
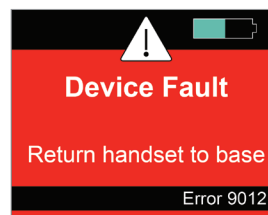
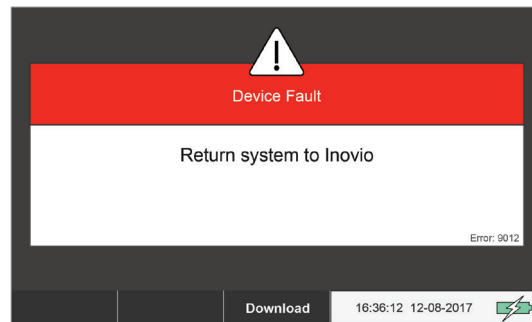
### CAUTION!



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



3. Return the Handset to the Base Station and follow prompts on the Base Station Touchscreen.



### 4. Recovery After Device Fault

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.

## Yellow Alert Messages

### 1. Access Locked Out (Displayed on Handset only)

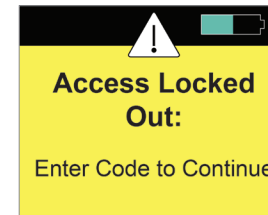
Handset: Access Locked Out

#### 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 access code to continue the treatment: 123654.



### 2. Handset Disconnected

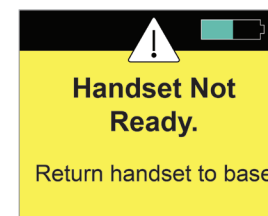
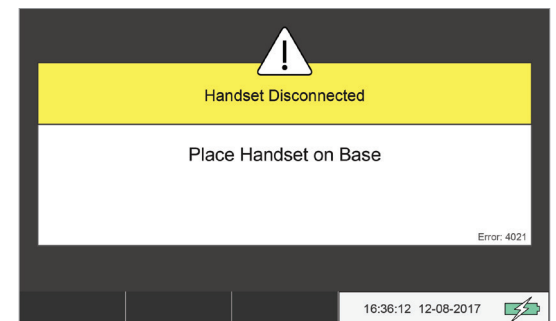
Handset: Handset Not Ready

#### What it means:

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

#### What to do:

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



### 3. Handset with Array : Drug Cartridge Used or Missing

Handset: Cartridge Used/Missing

#### What it means:

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

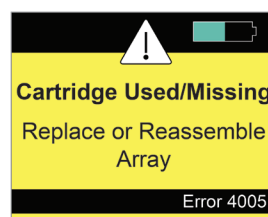
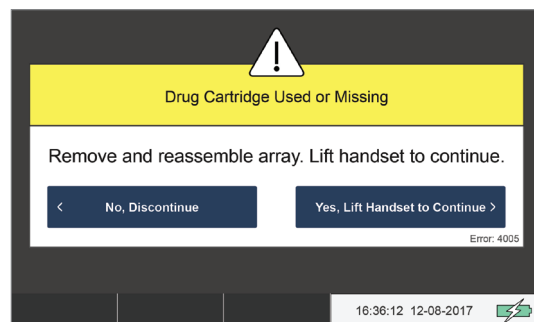
#### What to do:

1. Press and HOLD the blue release buttons on both sides of the Array. Pull the Array away from the Handset.
2. Remove the Drug Cartridge from the Array, if present.

### CAUTION!

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

3. Insert and firmly push a NEW Drug Cartridge into the Array.
4. Reattach the Array to the Handset.



### 4. Handset with Array: Drug Cartridge Backwards

Handset: Cartridge Backwards

#### What it means:

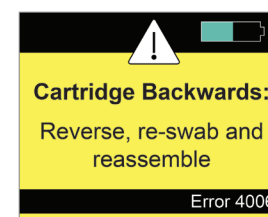
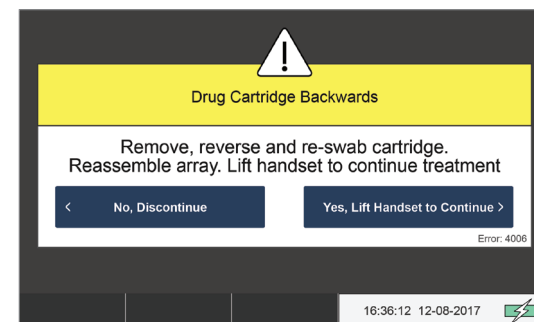
The Drug Cartridge was placed in the Array backwards.

#### 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 Drug Cartridge from the Array taking care to avoid contact with the rubber septum of the cartridge.

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

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



## 5. Handset with Used Array in Base

*Handset: Remove and discard Array*

### What it means:

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

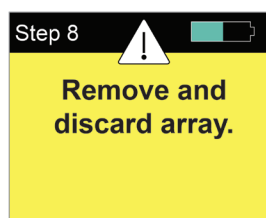
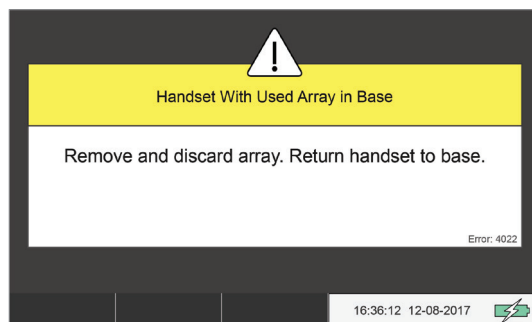
### What to do:

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 Drug Cartridge into a suitable Sharps container.
3. Return the Handset to the Base

### CAUTION!

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

Station and follow prompts on the Base Station Touchscreen.



## 6. Incorrect Handset for This Base

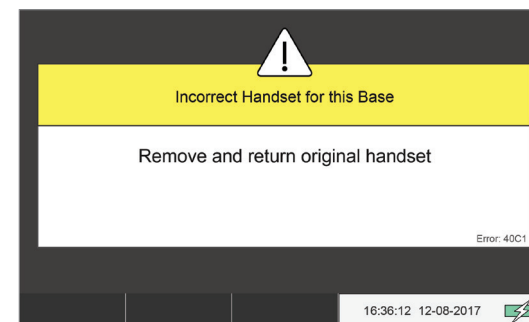
*Handset: Blank*

### 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

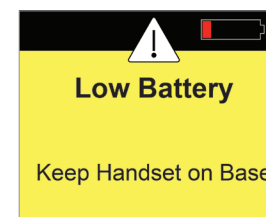
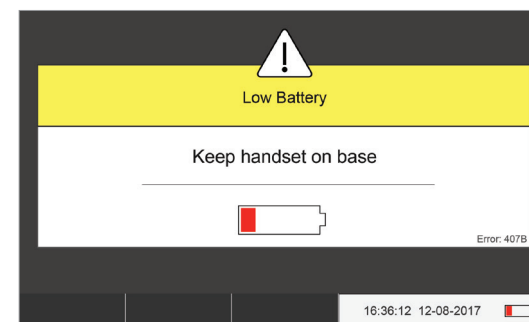
*Handset: Low Battery*

### 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

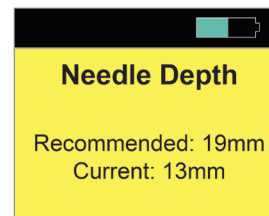
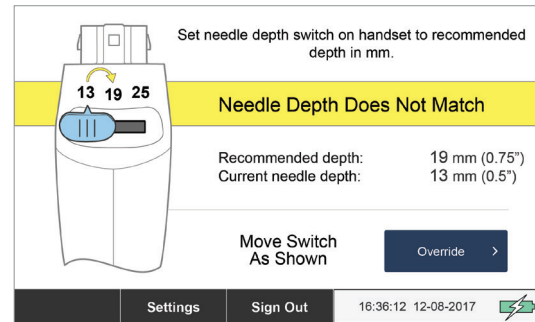
Handset: Needle Depth

### 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 electroperate 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

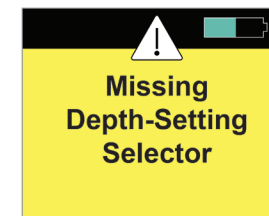
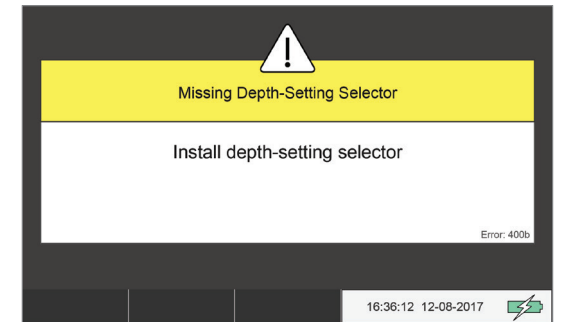
Handset: Missing Depth Setting-Selector

### 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

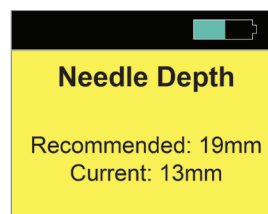
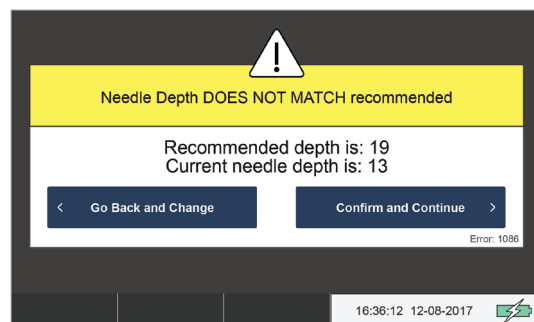
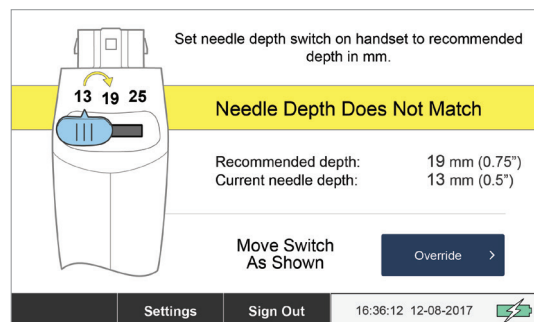
*Handset: Needle Depth*

### 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

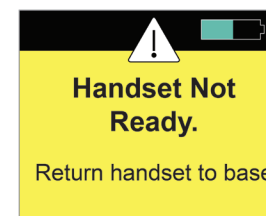
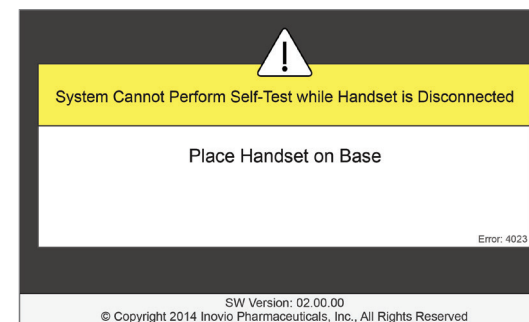
*Handset: Handset Not Ready*

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

*Handset: Remove Array and Place Handset on Base*


### What it means:

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

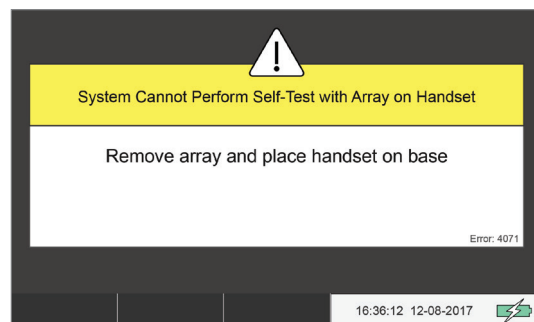
### What to do:

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 Drug Cartridge into a suitable Sharps container.

### CAUTION!

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

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



## 13. User Initiated Treatment Abort

*Handset: Treatment Aborted*


### What it means:

The Handset was pulled away from the patient, causing the treatment to abort. Some of the dose 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 Drug Cartridge into a suitable sharps container.

### CAUTION!

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

4. Return the Handset to the Base Station and follow prompts on the Base Station Touchscreen.



## Other Notifications

### 1. Faulty USB Device

Handset: blank

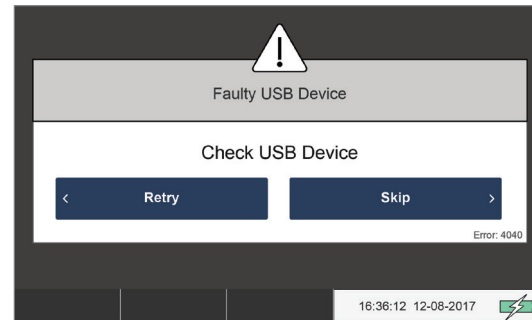
#### What it means:

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

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 to continue with treatment.
- Or press **No, Discontinue** to quit the current treatment. You will be prompted to confirm your choice.



### 3. Incorrect Access Code

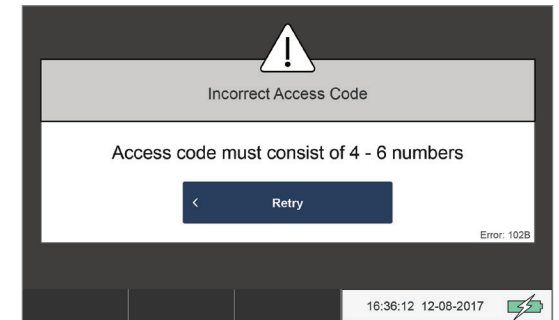
Handset: blank

#### What it means:

An incorrect access code was entered.

#### What to do:

Press **Retry**, then enter the correct access code.



### 4. Invalid Dose Number

Handset: blank

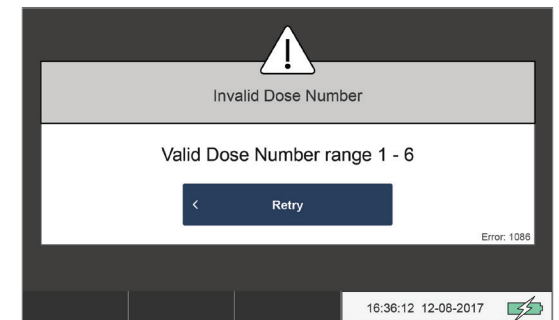
#### What it means:

A dose number was not entered, or a dose number that is out of range was entered. The dose number is used when a patient needs more than one dose (e.g., "2" for the patient's second treatment).

#### What to do:

Either:

- Press **Retry** to use the keypad to enter a dose number. The dose number must be between 1 and 6.
- Or press **Skip** to leave the dose number blank, if applicable.



## 5. Invalid Patient Height

Handset: blank

### What it means:

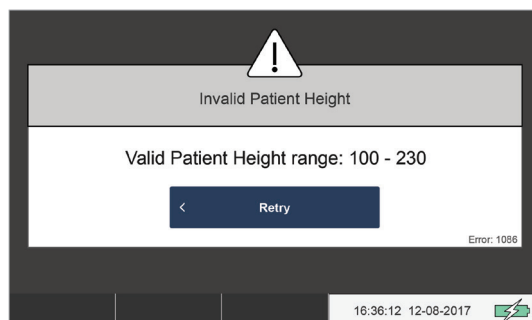
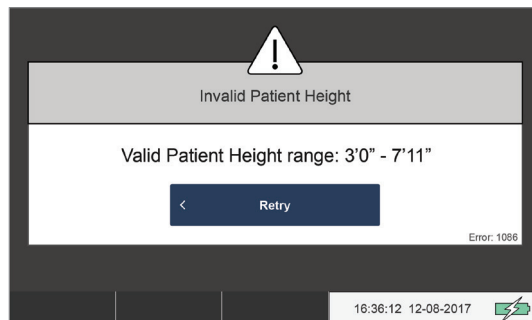
A patient height was not entered, or a height that is out of range was entered.

### 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.

### 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).



## 6. Invalid Patient Weight

Handset: blank

### What it means:

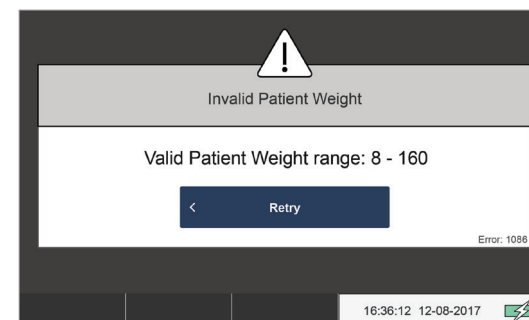
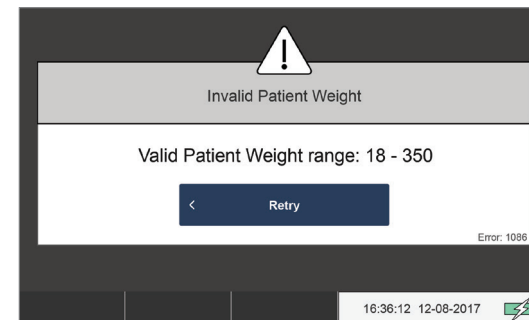
A patient weight was not entered, or a weight that is out of range was entered.

### 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.

### 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).



## 7. USB Device Full

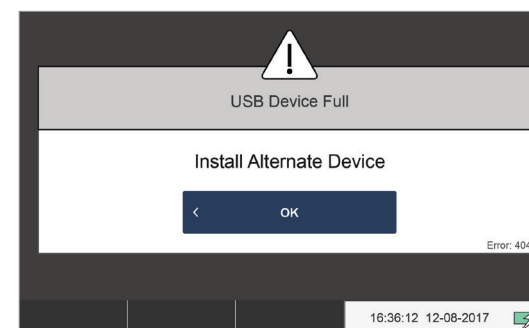
Handset: blank

### 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 and press **OK** to try to download the treatment data again.



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# 6. Reference Information

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## Self-Assessment Questions

Answer these true/false questions to test your understanding of CELLECTRA™ 5PSP. The answers are on the following page.

1. Can the CELLECTRA™ 5PSP be used to deliver drug and electrical pulses to make drug delivery more effective?
2. Does the CELLECTRA™ 5PSP have 3 main components: Base Station, Handset, and Array, that can only be used with specific Drug Cartridges?
3. Can the Array and the Drug 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 the 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 the 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 aseptic technique?
12. Can the Drug 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 the 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 the 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 Helpline?

## Answers

1. True
2. True
3. False – The Array and Drug Cartridge are single-use components that cannot be reused.
4. False – The Base Station and Handset do not share a wireless connection when separated.
5. True
6. True
7. False – 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. False – the CELLECTRA™ 5PSP must be kept away from water sources or other liquids that may damage the electronics.
9. False – The internal battery of the Handset must be charged on the Base Station before use.
10. True - Injection is acceptable into the deltoid or anterolateral quadricep muscle.
11. True
12. False – The Drug Cartridge only fits one way. The arrows on the Drug Cartridge should point into the Array.
13. False – The Array only fits one way. Match the slot on the Array with the groove on the top of the Handset.
14. True – 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. False – 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 cancel the treatment.

16. False – Never reuse the Array or Drug Cartridge.
17. False – Only clean the Base Station and Handset with wipes such as Caviwipe<sup>1</sup>, or Super Sani-Cloth<sup>2</sup>, or 70% Isopropyl alcohol. Only use water-moistened wipe to remove excess residue.
18. True
19. True
20. True
21. True

1. EPA Registration Number 46781-13  
2. EPA Registration Number 9480-4

## Technical Information

### PHYSICAL SPECIFICATIONS

<b>Dimensions</b>	343 mm L x 254 mm W x 102 mm D (13.5"L x 10"W x 4"D)
<b>Weight</b>	2.9 kg (6.4 pounds)
<b>Operating Conditions</b>	+5°C to +33°C (+41°F to +91°F), 20% to 85% Relative Humidity, non-condensing, up to 2,000 meters (6,500 feet) above sea level
<b>Storage</b>	+13°C to +33°C (+55°F to +91°F). Keep dry
<b>Shipping Limitations</b>	-20°C to +60°C (-4°F to 140°F). Keep dry
<b>Input Voltage</b>	100 to 240 volts VAC, 50-60 Hz, 0.5 Amps (A) maximum
<b>Other Electrical Characteristics</b>	<ul style="list-style-type: none"> <li>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.</li> <li>BF Equipment: device has conductive contact with the patient.</li> <li>Internally-powered equipment.</li> <li>Lithium Ion Battery - UL2054 approved - Lifecycle: 5 years</li> </ul>

### PERFORMANCE SPECIFICATIONS

<b>Voltage</b>	10-200 V maximum (varies with patient tissue impedance; 5 V for device operation)
<b>Pulse Width</b>	52 milliseconds (ms)
<b>Maximum Pulse Current</b>	500 mA
<b>Maximum Pulse Current Density</b>	1.68 A/cm <sup>2</sup>
<b>Operating modes</b>	The device has two modes of operation, current controlled or voltage controlled with a fixed upper limit (max 200 V)
<b>Phase Charge</b>	Delivered Charge = 26 millicoulombs (max) = 0.5 A x 0.052 seconds
<b>Net Charge</b>	Intramuscular = 78 millicoulombs (max) = 0.5 A x 0.052 seconds x 3 pulses
<b>Pulse Shape</b>	Unipolar rectangular DC current pulse
<b>Field Strength</b>	~ 200 V/cm (Max)
<b>Session Duration</b>	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, drug 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 for use in a professional healthcare facility environment such as Doctor's Offices and Clinics.

CELLECTRA™ 5PSP is NOT an intentional radiator.


CELLECTRA™ 5PSP is NOT Life-Supporting Equipment.


### 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	0% $U_T$ ; 0.5 cycle at 8 phase angles	Main power quality should be that of a typical commercial or hospital environment.
	At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°	At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°	
	0% $U_T$ ; 1 cycle at 0° and	0% $U_T$ ; 1 cycle at 0° and	
	70% $U_T$ ; 25/30 cycles Single phase at 0°	70% $U_T$ ; 25/30 cycles Single phase at 0°	
	0% $U_T$ ; 250/300 cycle	0% $U_T$ ; 250/300 cycle	

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
<b>Power Frequency Magnetic Field</b> 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.
	3 V <sub>r.m.s.</sub>	3 V <sub>r.m.s.</sub>	
<b>Conducted Disturbances Induced by RF Fields</b> IEC 61000-4-6	0.15 MHz - 80 MHz 6 V <sub>r.m.s.</sub> in ISM bands between 0.15 MHz and 80 MHz 80% AM 1 kHz	0.15 MHz - 80 MHz 6 V <sub>r.m.s.</sub> in ISM bands between 0.15 MHz and 80 MHz 80% AM 1 kHz	Not applicable
<b>Proximity Magnetic Fields</b> IEC 61000-4-39	8 A/m at 30 kHz 65 A <sub>r.m.s.</sub> /m at 134.2 kHz 7.5 A <sub>r.m.s.</sub> /m at 13.56 MHz	Not applicable 65 A <sub>r.m.s.</sub> /m at 134.2 kHz 7.5 A <sub>r.m.s.</sub> /m at 13.56 MHz	Power frequency magnetic fields should be that of a typical commercial or hospital environment.
<b>Radiated RF EM Fields. Proximity Fields from RF Wireless Communications Equipment</b> 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	<p>Except as indicated in the table below, portable and mobile communications equipment should be separated from the CELLECTRA™ 5PSP by no less than distances calculated using the equation below:  <math>D=1.2*\sqrt{P}</math>  150 kHz to 80 MHz  <math>D=1.2*\sqrt{P}</math>  <math>d = 6/E*\sqrt{P}</math>  <math>D=2.3*\sqrt{P}</math></p> <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.</p>



**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.



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



























Test frequency (MHz)	Band <sup>a)</sup> (MHz)	Service <sup>a)</sup>	Modulation <sup>b)</sup>	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 - 390	TETRA 400	Pulse modulation <sup>b)</sup> 18 Hz	1,8	0,3	27
450	430 - 470	GMRS 460, FRS 460	FM <sup>c)</sup> ± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704 - 787	LTE Band 13, 17	Pulse modulation <sup>b)</sup> 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 <sup>b)</sup> 18 Hz	2	0,3	28
870						
930						
1 720	1 700 - 1 900	GSM 1800; CDMA 1900; GSM 1 900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation <sup>b)</sup> 217 Hz	2	0,3	28
1 845						
1 970						
2 450	2 400 - 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation <sup>b)</sup> 217 Hz	2	0,3	28
5 240	5 100 - 5 800	WLAN 802.11 a/n	Pulse modulation <sup>b)</sup> 217 Hz	0,2	0,3	9
5 500						
5 785						

NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the 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.






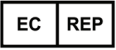




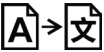


## Symbols

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
	Biological risks		Refer to user manual
	Class II Equipment		Sharp element
	Manufacturer		General warning sign
	Catalog number		Lot number
	Sterilized using irradiation		Use-by date
	Temperature Limitation		Indoor use only
	Humidity Limitation		Do not re-sterilize
	Atmospheric Pressure Limitation		Do not reuse
	Do not use if package is damaged		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
	Serial Number		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.

	CE Mark		Protected against solid foreign objects of 12.5 mm or greater, and against vertically falling water drops when enclosure tilted up to 15°
	Energy Efficiency Level 6		Demko Mark
	Protected against vertically falling water drops when enclosure tilted up to 15°		Authorized Representative in the European Community
	Keep dry		Packaging Unit
	MR Unsafe - keep away from magnetic resonance imaging (MRI) equipment		Medical Device
	Translation		Single sterile barrier system
	Single sterile barrier system with protective packaging outside		