# For Locally Advanced Pancreatic Cancer

User Manual

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# 1. ABOUT THE OPTUNE PAX TREATMENT KIT AND THE ITE TRANSDUCER ARRAYS

## 1.1. DEVICE DESCRIPTION

The Optune Pax (device) is a portable, battery operated device. It produces electric fields called tumor treating fields ("TTFields") that exert physical forces to kill cancer cells. The ITE Transducer Arrays connected to the device deliver TTFields therapy to the abdomen.

Your doctor has prescribed Optune Pax for your daily use because they have determined you are a good candidate for treatment with the device. You may be able to use Optune Pax on your own, or you may need help from a doctor, family member, or other caregiver. Optune Pax should be used for at least 12 hours per day on average. Use Optune Pax for as many hours per day as possible, as longer duration of use is associated with improved treatment effectiveness. You can take short breaks for personal needs.

The Optune Pax treatment kit includes the electric field generator (the device), connection cable, power supply, batteries, battery charger and ITE transducer arrays.

When starting treatment, a trained medical professional or a representative from Novocure will teach you how to use the device, including how to place transducer arrays on your back and your abdomen according to the layout provided by your doctor, recharge and replace batteries, and plug in the device. Your Novocure representative will also teach you what to do if an alarm beeps. After this short training, with the help of a family member or caregiver if needed, you will be able to properly use the device. You will also be able to change the batteries, charge the batteries and replace the transducer arrays as needed. Refer to Section 15 to contact technical support.

The device can be carried when you are using a battery. You can continue your normal daily life while carrying the generator in a Novocure provided bag. Optune Pax is provided with four rechargeable batteries. Each battery will last for about one hour. For sleeping, or other times when you plan to stay in the same place for a while, the generator can be plugged into a standard wall outlet.

Optune Pax does not need regular maintenance. The device also does not have any settings for you to change. The only things you need to do are check that the generator has a power supply (either a charged battery or it is plugged into the wall) and turn it ON and OFF. If the generator is not working, an alarm will beep. A Troubleshooting Guide is provided in this manual (Section 14). You can also refer to technical support(Section 15).

You will need to change the transducer arrays every 3-4 days. To do so, you will need to stop treatment (i.e., turn the device OFF) to remove the arrays from your abdomen and replace them with new ones.

Keep treatment breaks to a minimum. You can interrupt treatment for personal needs such as bathing, exercise, or any time you need a planned treatment break.

There are 2 ways to clean your abdomen:

- A sponge bath if you are keeping your arrays on:

Unplug the arrays from the device. Cover the unplugged arrays and wires that are still attached to you by placing a towel around your abdomen to prevent them from getting wet while you wash the rest of your body with a soft, clean washcloth or sponge. Leave the device outside the bathroom while taking a sponge bath.

- A full shower if the arrays are intended to be removed:

Unplug the arrays from the device. Take a shower once your arrays have been unplugged. For array removal see details in Section 9.3 below. Leave the device outside the bathroom while taking a shower.

## 1.2. INTENDED PURPOSE

The Optune Pax treatment kit is intended for the treatment of adult patients with locally advanced pancreatic cancer of exocrine origin, concomitant with gemcitabine and nab-paclitaxel in accordance with guideline recommendations.

## 1.3. INTENDED USER

The treatment is intended for adult patients 18 years of age or older.

## 1.4. CONTRAINDICATIONS, WARNINGS, PRECAUTIONS AND NOTICES

### Contraindications

Do not use Optune Pax if you have an electrical implant. Use of Optune Pax together with electrical implants has not been tested and may lead to malfunctioning of the implanted device.

Do not use Optune Pax if you are known to be sensitive to gels like the gel used on electrocardiogram (ECG) stickers or transcutaneous electrical nerve stimulation (TENS) electrodes. In this case, skin contact with the gel used with Optune Pax may commonly cause increased redness and itching and rarely may even lead to severe allergies such as a fall in blood pressure and breathing difficulty.

### Warnings

**Warning** – Use Optune Pax only after receiving training from Novocure or other qualified personnel, such as your doctor, a nurse, or other medical personnel who have completed a training course given by Novocure (the device manufacturer).

Your training will include a detailed review of the patient user manual and practice in the use of the device. In addition, you will be trained in what to do if there are problems with treatment. Use of Optune Pax without receiving this training can result in breaks in treatment and may rarely cause increased skin irritation, open sores on your abdomen or back, or allergic reactions or even an electric shock.

**Warning** - In case of skin irritation, which appears as redness under the transducer arrays (a mild rash), contact your doctor who will prescribe you high potency topical steroids (hydrocortisone cream) to use when replacing the transducer arrays. Using this cream will help relieve your skin irritation. If you do not use this cream, the skin irritation can become more serious and may even lead to skin breakdown, infections, pain and blisters. If this happens, stop using the topical steroid cream and contact your doctor. Your doctor will supply you with an antibiotic cream to use when replacing transducer arrays. If you do not use this cream, your symptoms may continue and your doctor may ask you to take a break from treatment until your skin heals.

**Warning** - All device servicing must be performed by qualified and trained personnel. No modification of this equipment is allowed. If you attempt to open and service the device yourself, you may cause damage to the device. You could also get an electric shock by touching the inner parts of the device.

**Warning** - The transducer arrays are for single use and should not be taken off your body and then put back on again. If you put a used transducer array back on again, it may not stick well to your skin and the device could turn off. The transducer arrays should not be re-used. Re-use of transducer arrays can lead to poor contact with the skin and may cause the device to alarm and stop working. Re-use of transducer arrays can lead to worsening of the skin inflammation and rarely even to local infection. If you suffer from an infection on your skin (pus, swelling and warmth) consult with your doctor immediately

## Precautions

**Caution** - Do not use Optune Pax with any parts that did not come with the device, that were not sent to you by the device manufacturer, or that were not given to you by your doctor. Use of other parts, manufactured by other companies or for use with other devices, can damage the device. This may lead to a break in treatment.

**Caution** - Do not use Optune Pax if any parts look damaged (such as torn wires, loose connectors, loose sockets, cracks or breaks in the plastic case, opening in power supply). Use of damaged components can damage the device and cause a break in treatment.

**Caution** - Do not get the device, transducer arrays or other parts wet. Getting the device wet may damage it, preventing you from receiving treatment. Getting the transducer arrays very wet is likely to cause them to come loose from your skin. If this happens, the device will turn off and you will need to change the transducer arrays.

**Caution** - Before connecting or disconnecting the transducer arrays, make sure that Optune Pax power switch is in the OFF position. Disconnecting transducer arrays with the power switch in the ON position may cause a device alarm to go off and could damage the device.

**Caution** - If you have an underlying serious skin condition on the abdomen, discuss with your doctor whether this may prevent or temporarily interfere with Optune Pax treatment.

**Caution** - Do not use Optune Pax if you are pregnant, you think you might be pregnant or are trying to get pregnant. If you are a woman who is able to get pregnant, you must use birth control when using the device. Optune Pax was not tested in pregnant women. It is unknown what side effects the device may cause if you are pregnant, or if it will be effective.

**Caution** – There is a hazard of falling due to entanglement in the connection cable. You may consider clipping the cable to your belt.

**Caution** – The device dropping on the user may result in injury.

## Notices

**Notice** - Optune Pax and transducer arrays will activate metal detectors.

**Notice** - If you plan to be away from home for more than 1 hour, carry an extra battery and/or the power supply with you in case the battery you are using runs out. If you do not take a spare battery and/or the power supply, you may have a break in your treatment.

**Notice** - Make sure you have at least 12 extra transducer arrays at all times. This will last until the next transducer array shipment arrives. Remember to order more transducer arrays when there are at least 12 extra transducer arrays left. If you do not order transducer arrays on time, you may have a break in your treatment.

**Notice** - Batteries may weaken over time and need to be replaced. You will know this has happened when the amount of time the device can run on a fully charged battery begins to shorten. For example, if the low battery indicator light flashes within only 1 hour from the start of treatment, replace the battery. If you do not have replacement batteries when your batteries run out, you may have a break in your treatment.

**Notice** - You should carry the Troubleshooting Guide (see Section 14 of this patient information and operation manual) at all times. This guide is necessary to ensure Optune Pax works properly. If you do not work the device correctly, you may have a break in your treatment.

**Notice** - Do not block the device vents located on the front and back of the device. Blocking the vents may cause the device to overheat and turn off, leading to a break in treatment. If this happens, unblock the vents, wait 5 minutes and restart the device. In case the vents are blocked with pet hair/dust, return the device to the manufacturer for service.

**Notice** - Do not block the battery charger vents located on the sides of the battery chargers. Blocking the vents may cause the charger to overheat. This could prevent your batteries from charging. In case the vents are blocked with pet hair/dust, return the battery charger to the manufacturer for service.

**Notice -** Before using a transducer array, make sure its package is sealed by gently rubbing the package between thumb and pointer finger on all four sides. The package should be closed on all sides. There should be no openings in the package seal. If the package is not sealed, the transducer array may be damaged. A damaged transducer array will not work properly and may cause the device to turn off.

**Notice** - Keep the device out of the reach of children and pets.

**Notice** – The device has a cord that may cause tripping when connected to an electric socket.

**Notice** – Do not cover the device or power supply. This can lead to overheating of the device and cause superficial thermal injury.

# 2. CLINICAL BENEFIT AND CLINICAL EVIDENCE

A large clinical study, called PANOVA-3, was conducted to evaluate the use of Optune Pax to treat locally advanced pancreatic cancer. The PANOVA-3 study assessed the use of Optune Pax when used with cancer drugs (gemcitabine and nab-paclitaxel) that are approved for the treatment of pancreatic cancer, compared to the use of cancer drugs alone. The study included 571 patients; half of the patients were treated with Optune Pax together with the cancer drugs, while the other half were treated with only the cancer drugs.

The PANOVA-3 study found that using Optune Pax together with cancer drugs was more effective in treating locally advanced pancreatic cancer than using these cancer drugs alone. The group of patients assigned to receive Optune Pax with the cancer drugs lived more than 2 months longer, on average, than the group of patients who were assigned treatment with the cancer drugs alone.

In the PANOVA-3 study, the use of Optune Pax together with cancer drugs did not lead to adverse interactions with the drugs. In addition, the frequency of severe medical problems was similar between the group treated with Optune Pax with the cancer drugs and the group treated with the cancer drugs only.

Use of Optune Pax led to mild or moderate skin irritation under the transducer arrays (red rash, small sores or blisters) in 209 out of the 274 patients (76%). Mild to moderate skin irritation under the arrays is an expected side effect of TTFields therapy. None of these cases of skin irritation caused damage to the skin that could not be fixed with the use of topical prescription medications (e.g. steroid creams) and shifting the placement of the transducer arrays. A small number of Optune Pax patients in the study (7) did experience a more severe skin issue that required them to take a temporary break from using Optune Pax. In all cases, the skin issue resolved.

Ask your doctor for more details about the PANOVA-3 study.

**Expected clinical benefit for the patient**

All patients in the PANOVA-3 clinical study who used Optune Pax used it together with cancer drugs (gemcitabine and nab-paclitaxel). Patients who used Optune Pax for one month or more, and who received one or more cycles of the cancer drugs lived more than 3 months longer, on average, than patients who received one or more cycles of the cancer drugs alone. Specifically, about 75% of patients who used Optune Pax with cancer drugs lived for more than 12 months after their treatment started compared to 66% of patients who used cancer drugs alone.

The following additional benefits were observed in the PANOVA-3 study:

- In the group of patients who used Optune Pax with cancer drugs, about half (49%) did not experience a worsening of their cancer within the first year, compared to 39% for patients who were treated with cancer drugs alone.
- Patients who used Optune Pax with cancer drugs lived without worsening pain about 6 months longer on average, than patients who used cancer drugs alone. Patients who used Optune Pax with cancer drugs experience better quality of life, on average, than patients who used cancer drugs alone, in terms of the time to worsening of quality of life, pain, and pancreatic pain.
- Patients who used Optune Pax with cancer drugs saw a delay in their need for pain medication by 2 months longer on average, than patients treated with cancer drugs alone.

- When looking at the use of opioid pain medication specifically, patients who used Optune Pax with cancer drugs delayed their need for opioid pain medication by 2 and a half months longer, on average, compared to patients treated with cancer drugs alone.

In particular, 42% of patients who used Optune Pax with cancer drugs were opioid-free at 1 year, compared to 32% of patients treated with cancer drugs alone.

# 3. WHAT ARE THE RISKS OF USING OPTUNE PAX TREATMENT KIT AND ITE TRANSDUCER ARRAYS?

The most common risk of using Optune Pax is skin irritation under the transducer arrays, which can look like a red rash, small sores or blisters on the abdomen. In most cases, the skin irritation is mild or moderate and treated with a steroid cream. Occasionally, the skin irritation is more severe, leading to open sores, infection and/or pain that requires stopping device use until the skin has healed.

In a large clinical study, called PANOVA-3, that evaluated the use of Optune Pax together with gemcitabine and nab-paclitaxel to treat your kind of pancreatic cancer, about 76% of Optune Pax patients experienced a skin disorder that was related to the use of the device. Most of these cases were not severe and were successfully treated with topical creams. Only 8% of Optune Pax patients had severe skin irritation.

When looking at all serious medical problems reported in the PANOVA-3 study, the **table** below shows how often serious medical problems occurred in the group of patients using Optune Pax with cancer drugs and the group of patients using only cancer drugs. The medical problems and how often those medical problems occurred in the group treated with Optune Pax and cancer drugs was similar to the group treated with only cancer drugs.

| Medical Problem | Optune Pax + Cancer Drugs | Cancer Drugs |
|---|---|---|
| Infections | 55 out of 274 subjects (20%) | 52 out of 273 subjects (19%) |
| Gastrointestinal disorders | 48 out of 274 subjects (18%) | 40 out of 273 subjects (15%) |
| Hepatobiliary disorders | 39 out of 274 subjects (14%) | 27 out of 273 subjects (10%) |
| Blood and lymphatic system disorders | 24 out of 274 subjects (9%) | 28 out of 273 subjects (10%) |
| Breathing disorders | 21 out of 274 subjects (8%) | 11 out of 273 subjects (4%) |
| General disorders | 17 out of 274 subjects (6%) | 12 out of 273 subjects (4%) |
| Heart disorders | 13 out of 274 subjects (5%) | 10 out of 273 subjects (4%) |
| Metabolism and nutrition disorders | 9 out of 274 subjects (3%) | 11 out of 273 subjects (4%) |
| Vascular disorders | 9 out of 274 subjects (3%) | 7 out of 273 subjects (3%) |
| Nervous system disorders | 6 out of 274 subjects (2%) | 2 out of 273 subjects (1%) |
| Kidney disorders | 5 out of 274 subjects (2%) | 11 out of 273 subjects (4%) |
| Injury, poisoning and procedural complications | 5 out of 274 subjects (2%) | 3 out of 273 subjects (1%) |
| Muscle and joint disorders | 2 out of 274 subjects (1%) | 3 out of 273 subjects (1%) |
| Psychiatric disorders | 2 out of 274 subjects (1%) | 3 out of 273 subjects (1%) |
| Neoplasms benign, malignant, unspecified | 0 out of 274 subjects (0%) | 1 out of 273 subjects (0.5%) |
| Immune system disorders | 0 out of 274 subjects (0%) | 1 out of 273 subjects (0.5%) |

Below is a list of other potential adverse effects (i.e., complications) associated with the use of Optune Pax together with cancer drugs, which occurred in ≥1% of patients:

- Treatment related skin disorders, including Hyperhidrosis and Skin breakdown / skin ulcer (76%)
- Fatigue (4%)
- Abdominal Pain (3%)
- Diarrhea (3%)
- Skin Injury (3%)
- Anemia (low red blood cell count) (2%)
- Infection at the site where the array makes contact with the skin (2%)
- Liver enzymes increased (2%)
- Muscle pain and Muscle twitching (2%)
- Nausea (2%)
- Overheating of the array, leading to pain and/or local skin burns (2%)
- Weight loss (2%)
- Allergic reaction to the adhesive or gel from the transducer arrays (1%)
- Local Pain under the arrays (1%)
- Swelling (1%)
- Local warmth and tingling sensation beneath the arrays (<1%)

# 4. MECHANISM OF ACTION AND PERFORMANCE

Your doctor has prescribed the Optune Pax treatment kit because you are a good candidate for treatment with the device.

The Optune Pax treatment kit is designed to be portable. It delivers electric fields, called tumor treating fields or “TTFields” to kill cancer cells.

Optune Pax delivers TTFields to your abdomen through pads that stick to your skin. These pads are connected to the device and are called “transducer arrays.” In addition to the device and the transducer arrays, the Optune Pax treatment kit also includes a connection cable, power supply, battery, and a battery charger. The device and battery are carried in a shoulder bag.

**The science behind Optune Pax**: TTFields exert physical forces on electrically charged components in dividing cancer cells, disrupting cell function. TTFields work to slow down or stop cancer cell division, leading to different forms of cell stress and cell death, that can result in downstream activation of the immune system against cancer cells.*

*These findings were published in the following studies: Kirson et al., Cancer Research 2004, Kirson et al., PNAS 2007, Salzberg et al., Onkologie 2008 and Kirson et al., BMC Medical Physics 2009.

# 5. OVERVIEW OF THE OPTUNE PAX TREATMENT KIT AND ITE TRANSDUCER ARRAYS




1. Optune Pax® - Electric Field Generator (the device) (TFP9200)
2. Charger for Optune Pax Battery (ICH9100)
3. Optune Pax Power Supply (SPS9200)
4. Optune Pax Connection Cable (CAD9100)
5. Optune Pax Battery (IBH9200)
6. ITE Transducer Arrays – Small (ITE1013B, ITE1013W)
7. ITE Transducer Arrays - Large (ITE1020B, ITE1020W)

# 6. THE DEVICE

- Optune Pax is a preset device.
- You will need to learn how to connect the battery, operate the device and place it in a carrying bag.
- The following controls will allow you to do this:

**Back** **Front**




1. Power Supply Port
2. Power Switch
3. Connection Cable (CAD) Socket
4. POWER / BATTERY / ERROR Indicators
5. TTFields ON / OFF Button
6. Battery Test Button
7. Battery Gauge

# 7. THE ITE TRANSDUCER ARRAYS

- Transducer arrays are adhesive patches placed on the abdomen to deliver TTFields to the abdomen.
- Transducer arrays are supplied sterile and are to be used with Optune Pax only.
- The transducer arrays are available in two sizes – small and large – to accommodate different body sizes. A medical professional will decide which size is right for you.
- Transducer arrays are provided with either a white connector end or a black connector end.
- For treatment start, and every time you change your arrays, you will need four (4) transducer arrays - two (2) transducer arrays with the white connector ends and two (2) transducer arrays with the black connector ends.
- Transducer arrays are disposable. Change them every 3-4 days.
- A medical professional will determine the best array layout for you and will show you where to place each of the arrays on your abdomen (front and back and sides).
- Contact Novocure to arrange for proper disposal of your used transducer arrays. Do not dispose of your used transducer arrays in household trash.

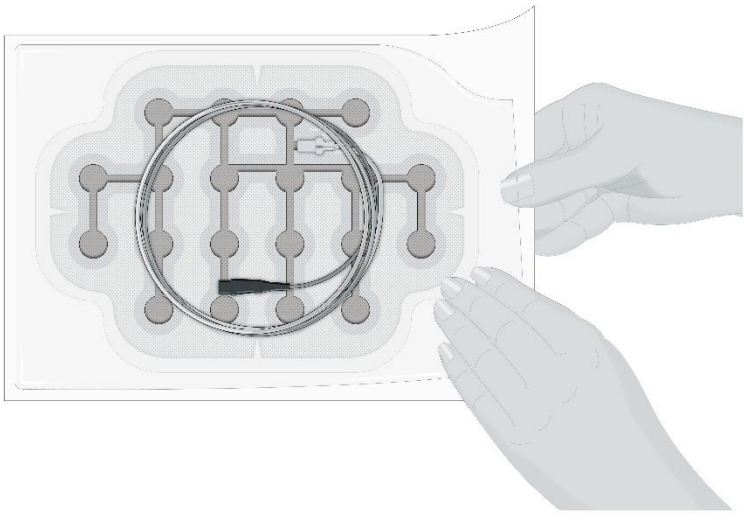
# 8. BEFORE YOU BEGIN

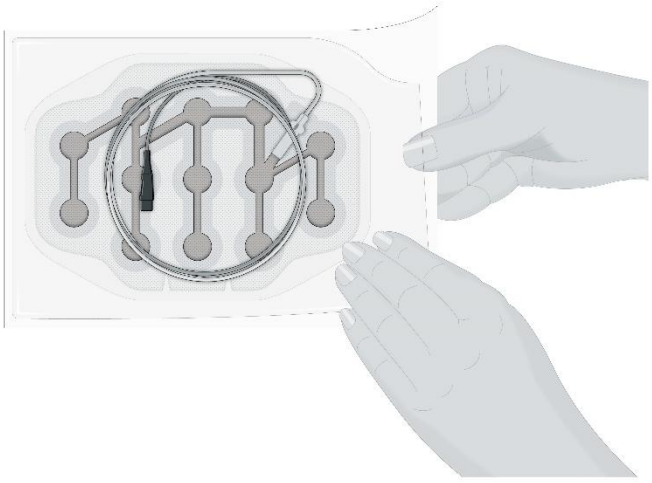
- You will need to use four (4) transducer arrays to start treatment each time you change the arrays.
- You will need to make sure you have the right sized transducer arrays as determined by your doctor and use the transducer arrays layout you received from your doctor.
- Make sure you have an ample supply of ITE Transducer Arrays to keep you going until the arrival of your next supply.

# 9. DIRECTIONS FOR USE

## 9.1. REMOVING THE TRANSDUCER ARRAY FROM ITS PACKAGE

- Open the see-through envelope of each of the four (4) transducer arrays by gently pulling apart the opposing edges of the envelope, as shown below.





## 9.2. PREPARING YOUR SKIN FOR TRANSDUCER ARRAY PLACEMENT

**General recommendations for taking care of your skin**

To prevent skin irritation under the arrays, follow these general skin care recommendations:

Washing / Bathing

- Use lukewarm water when washing your skin.
- Avoid washing with very hot water, which tends to dry out the skin.
- Use mild, fragrance-free, soaps/body washes.
- Avoid soaps/body washes that are alcohol-based, as alcohol tends to dry the skin.
- After bathing, use a soft, clean towel to lightly pat the skin dry. Avoid rubbing motion, which causes friction that can irritate the skin.

Moisturizing

- Moisturize your skin regularly, to prevent your skin from drying out.
- Use mild, fragrance-free water-based lotions.
- Avoid lotions that are alcohol-based, as alcohol tends to dry the skin.
- Remove excess residues of moisturizer or any topical skin product before applying the arrays.

Clothing

- Choose loose-fitting clothing when possible, to allow air circulation around the abdomen/arrays.
- Avoid clothing made of materials that can irritate the skin (e.g., coarse wool), as these materials may cause itching.
- Avoid clothing made of materials that are not breathable (e.g., some synthetic fabrics), as these materials may cause excessive sweating around the abdomen and arrays.
- Use mild, fragrance-free detergents to wash your clothes.

**Preparation of the skin before placing the arrays:**

- Wash hands thoroughly before preparing the skin.
- Shave the abdomen using a clean, electric shaver. Do not use razor blades, as the blades may damage the skin and lead to skin irritation. Repeat shaving the abdomen as needed when you replace the arrays.
- Wash your abdomen with a mild, fragrance-free soap and pat the skin dry.
- Apply any topical skin product prescribed or recommended by your doctor (e.g. moisturizing lotion, skin barrier film, corticosteroid, antibiotic cream) and leave it on the skin for at least 20 minutes (or per the manufacturer's instructions) to ensure absorption of the product before placing the arrays. Remove excess residues before applying the arrays.

## 9.3. PLACING THE TRANSDUCER ARRAYS

Every 3-4 days perform the following steps to remove the existing arrays and place new arrays according to the array layout provided by your doctor. If this is the first time you are applying the transducer arrays, you can skip the first step (Removal).

Recommendations on how to care for your skin under the arrays are provided. Following these recommendations will help you prevent skin irritation under the arrays and stay on therapy longer.

**Removing the arrays from the skin:**

- In general, when removing the arrays from your abdomen, avoid pulling the skin along with the array or rubbing the skin to remove any remaining adhesive left on the skin, both of which can damage skin.
- Thoroughly wet the arrays until they are fully saturated (when the adhesive softens and the hydrogel starts turning to a liquid) using lukewarm water whilst showering. Apply even tension, and slowly and gently peel back the arrays from the skin.
- Alternatively, mineral (baby) oil, or medical grade silicone-based and alcohol-free adhesive or ostomy remover may be applied to slowly and gently peel back the arrays from the skin.
- If you are using a skin barrier film, it must be removed and reapplied when replacing transducer arrays.

**Placing the arrays on the skin:**

- Wash hands thoroughly before handling the arrays.
- Follow the skin preparation recommendations above and ensure that the skin is completely dry before array placement.
- Note the black and white color of the transducer array connectors. Each pair of the same color will be positioned opposite to each other on your body: the two arrays with black connectors will be positioned opposite to each other on the body. Similarly, the two (2) arrays with white connectors will be positioned opposite to each other on your body.
- Remove the transducer array liner from one transducer array.
- Place the transducer array on your body in the same location as before but shifting the transducer array 2 cm (3/4 inch) to avoid areas of skin irritation. Ensure that pairs of arrays are moved together. Move arrays back to the original position at subsequent changes.
- Press the entire edge of the transducer array to your skin.
- Place the other three transducer arrays in the same fashion.
- You may need to ask for assistance from a friend or family member to place the transducer array(s) on your back.
- As much as possible, avoid placing the arrays over surgical hardware (e.g., screws or shunts), scars, or open wounds.
- If needed, wear cooling garments, such as cooling vests, which can help to avoid sweating.
- Shift array placement by ~2 cm (3/4 inch) at each array change, ensuring that pairs of arrays are

moved together.

- Move arrays back to the original position at subsequent changes.

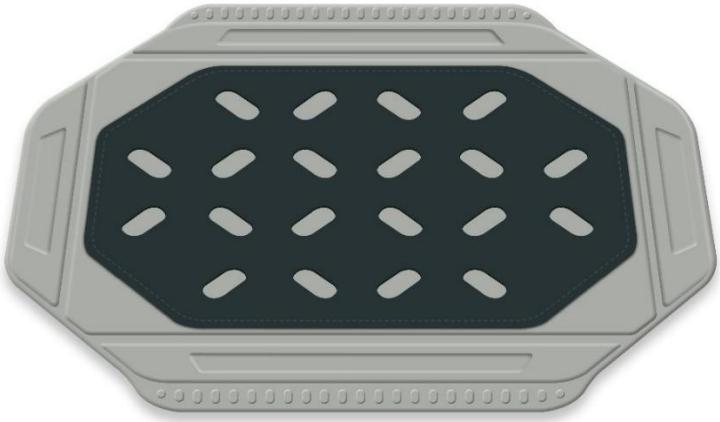
**Monitoring of the skin condition under the arrays**

- Check the skin under the arrays at every array change for signs of skin inflammation, redness, itchiness, blistering, and open wounds. Notify your doctor or nurse at the earliest signs of a skin issue.

## 9.4. TRANSDUCER ARRAY LINER REMOVAL AND APPLICATOR USE

Applicators are provided to assist in the handling of the ITE Transducer Arrays. Use this, if needed, according to the following instructions:

1. Select the applicator size according to the size of the transducer array you are using. Place the applicator on a hard surface with the black patch facing upwards.



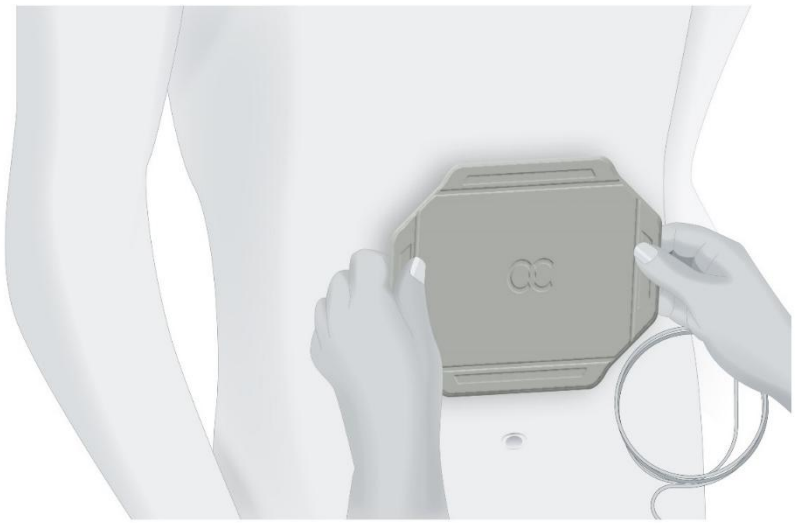
2. After removing the transducer array from its bag, place it on the applicator with the removable liner facing up. Apply medium pressure on the transducer array so it attaches to the black patch.



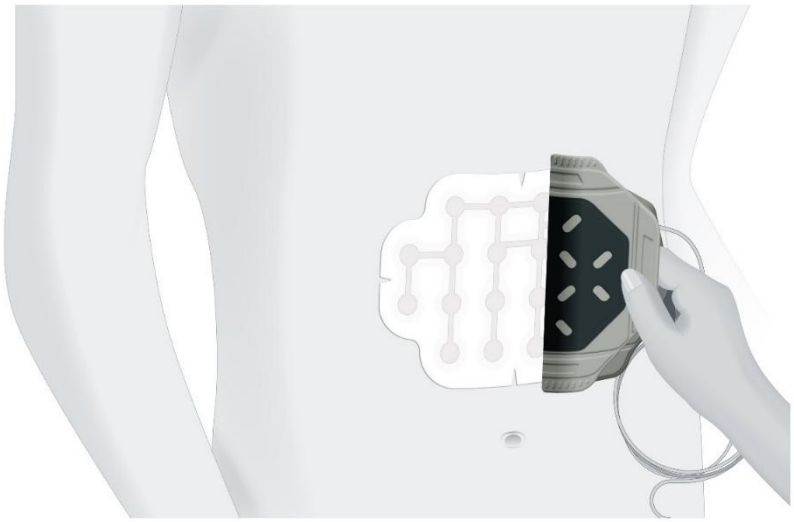
3. Start by removing the top liner. Slowly remove the liners by starting at the top corner in the middle of the array and carefully peel the liner downwards. Peel the liner parallel to the surface, from different directions if needed, to ensure the array remains flat and intact.



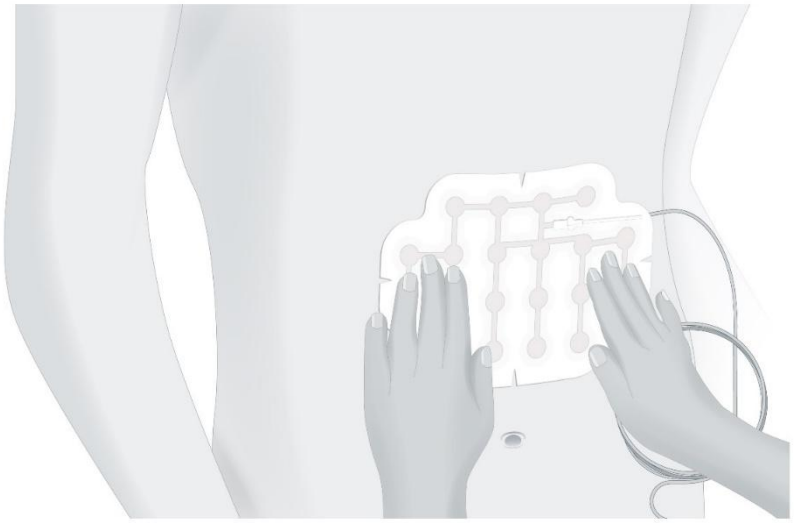
4. Using the applicator, place the transducer array on the skin according to the layout provided to you and by following the instructions in section 9.3.
   Apply pressure on the applicator. Make sure that the transducers and the edges of the transducer array tape adhere well to the skin.



5. Gently remove the applicator.



6. Apply pressure again on the transducer array to secure full contact to the skin.



In the event of poor initial placement of the transducer arrays or the inability to place arrays please repeat steps 1 to 6.

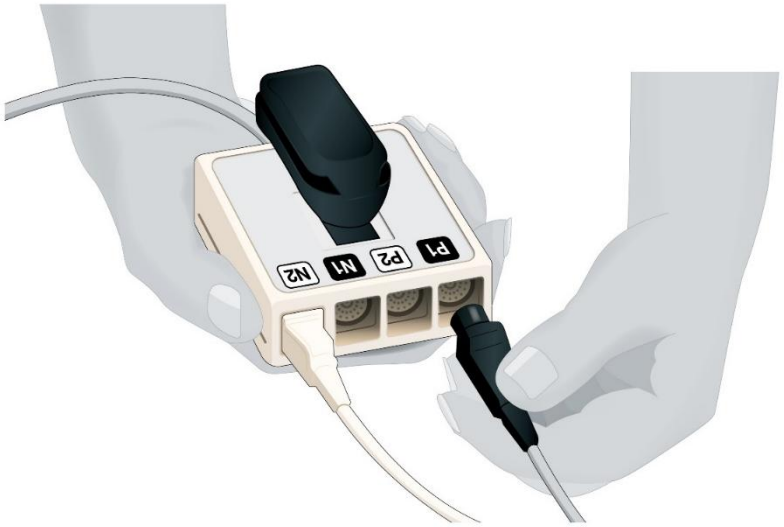
Please do not use a soiled applicator

**Cleaning the applicator**:

Rinse with cold water and detergent. Do not tumble dry. Lay in a shaded place to dry, keep away from direct heat.

## 9.5. CONNECTING THE ITE TRANSDUCER ARRAYS TO THE OPTUNE PAX DEVICE

1. Connect the four transducer array connectors (2 black and 2 white) to the corresponding black and white coded sockets on the connection cable, as shown below.
2. Press firmly to be sure the connectors are pushed in all the way.
3. Gather the transducer array wires together and loosely bind with a small piece of tape, if you wish.
4. You may clip the connection cable clip to your belt.



## 9.6. THE CONNECTION CABLE

The connection cable is the coiled, stretchy cord that runs from the connection box to the device. The four transducer array connectors (two blacks and two whites) are plugged into the connection box. The black and white coding matches with the transducer array position on the body.

To connect the connection cable to the device:

1. Verify that the arrow on the end of the connection cable is facing up and aligned with the arrow on the port of the device, as shown below.
2. Push in the connector until you hear a click. The click means that the connector is in its place.



## 9.7. STARTING & STOPPING THE DEVICE

**To start treatment:**

After you have placed the transducer arrays on your body:

1. Plug the transducer arrays into the connection cable box (Sections 9.5 and 9.6).
2. Plug the connection cable into the device, aligning the connector arrow with the socket arrow (Section 9.6).
3. Connect a power source - either a charged battery (Section 9.8) or a wall power supply (Section 9.10) to the device.
4. Turn the power switch to the ON position as shown below.



5. Wait for about 10 seconds for the device to complete a self-check. The “POWER” indicator on the front panel of the device will illuminate green as shown below.




If a charged battery is installed (and the device is not connected to a wall power supply), the "BATTERY" indicator will also illuminate green. If the device is connected to a wall power supply, it will automatically operate from the wall power supply, and the "BATTERY" indicator will turn off.



6. To start TTFields treatment, press the TTFields ON/OFF button.




The" TTFIELDS" indicator light above the ON/OFF button should illuminate blue and will stay blue while the treatment is ON.

If the blue indicator light does not illuminate, then the treatment is not running and you should check the setup and restart the procedure. If, after this, the indicator lights do not light up, consult the Troubleshooting Guide (Section 14). If you still have problems, contact Novocure technical support (Section 15).

NOTE: The green, blue and yellow indicators automatically dim in a dark room and will brighten in a light environment. The red "ERROR" indicator illumination light level is permanent.

If the "TTFIELDS" button is not pressed within 10 minutes after the device is switched ON, a notification alarm will sound along with a flashing blue "TTFIELDS" light, indicating that TTFields therapy is OFF. This is a reminder to start the therapy. To start therapy, press the "TTFIELDS" button once to silence the alarm, and again to start the therapy. The "TTFIELDS" indicator will then illuminate blue when TTFields therapy is being delivered.

**TO STOP TREATMENT:**

Stopping treatment may be performed in each of the following situations:

**A. When the device is running properly, but you need to stop treatment to take a break:**

1. Stop treatment by pressing the TTFields button. TTFields therapy stops, indicated by the blue "TTFIELDS" indicator turn OFF.

NOTE: Device power is still ON.



2. Turn OFF the device by using the power switch.



**B. If an Error occurs:**

If an error occurs, the device stops the therapy and sounds a loud beeping alarm. The red “ERROR” indicator illuminates (as shown below).




Press TTFields button to stop the alarm. The red “ERROR” indicator will turn OFF. If the alarm sound persists, proceed to the next step to silence the alarm.

1. Turn OFF the device by using the power switch.

**C. When the Low BATTERY indicator lights up:**

When your battery runs out (after about one hour), the TTFields output will shut down (device stops the therapy) and an alarm will sound.

NOTE: The alarm sound is identical to the alarm that the device sounds when an error occurs. However, in this case, both the yellow “BATTERY” and red “ERROR” indicators light up.

1. Press the TTFields button to stop the alarm. The red “ERROR” indicator turns OFF.
2. Turn OFF the device by using the power switch.
3. Replace the battery (see Section 9.8).



## 9.8. CONNECTING AND DISCONNECTING THE BATTERY

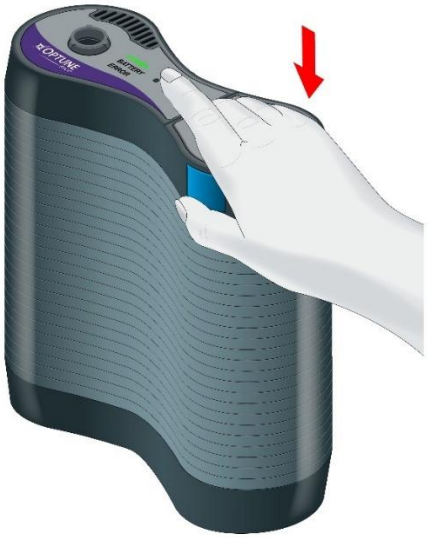
Optune Pax is provided with four rechargeable batteries. Optune Pax operation requires one battery at a time. The other three batteries should stay in the battery charger.

If you plan to be away from home for more than one hour, carry extra batteries.

1. Slide the battery into the device.
2. Gently push the battery down until a click is heard, indicating it is fully latched.

NOTE: Take care not to drop the battery in place or force it into the battery slot.

3. Replace the battery each time it runs out (when the green “BATTERY” indicator turns yellow)



Gently press down to lock the battery in place.



To remove the battery from the slot, press both blue buttons on the sides of the battery and lift up.

Recharge the batteries in the charger (Section 9.9) for 2 to 4 hours. The batteries will keep most of their charge after being removed from the charger for several days but eventually will lose their charge. It will not damage the batteries to keep them in the charger after they are fully charged so you can leave them there if they are not needed.

You can charge and use the batteries many times for about 6 to 9 months. Over time, the length of time that the batteries can run the device (before the yellow low “BATTERY” indicator illuminates and the alarm beeps) will get shorter. If the time from treatment start with a full battery to low battery alarm, audible alarm sounds and the red ”ERROR” indicator illuminates falls below 50 minutes contact technical support (Section 15) to get replacement batteries.

The battery light will turn from green to yellow when the battery charge falls below a threshold. This is an indication that the battery should be changed soon. The treatment will continue to run while the yellow low “BATTERY” indicator is illuminated until the audible alarm sounds and the red

“ERROR” indicator illuminates. Once this happens the treatment will stop and the device must be turned off and the battery replaced.

When the “BATTERY” indicator turns yellow, there are two ways to continue your treatment:

**A. Option one:**

If you are near the direct wall power supply, connect the power supply without interrupting therapy. This can be used before the battery is completely depleted, and before the device has alarmed. Follow the instructions:

1. Plug in the wall power supply to the back of the device (Section 9.10). Therapy continues while the device indicator indicates that it is no longer operated by battery power.

2. Press the two blue buttons on both battery sides and remove it by sliding outside from the device.

3. Charge the removed battery (Section 9.9).

4. Continue the therapy using the wall power supply.

**B. Option Two:**

If you are not near a wall power supply, follow the instructions to replace the battery:

NOTE: If the battery is totally depleted, start from step 2

1. Press the TTFields button to stop the therapy.

2. Turn OFF the device by using the power switch (on the back side of the device).

3. Push the two blue buttons on both battery sides and remove it by sliding outside from the device.

4. Select another fully charged battery.

5. Slide the fully charged battery into the device.

6. Gently push the battery down until a click is heard, indicating it is fully latched.

7. See the next section to check the battery gauge.

8. Turn ON the device by using the power switch and wait about 10 seconds until the device completes the self-check.

9. Start therapy by pressing the TTFields button (Section 9.7).

10. Insert the used battery into the battery charger for recharging (Section 9.9).

## 9.9. CHARGING THE BATTERY

**Checking the Battery Gauge**

While you are using Optune Pax, you may want to check how much energy is left in your battery. Checking the battery will not interfere with, or stop, your therapy.

To check the battery capacity, press once on the button on the top of the battery. The battery capacity will be indicated by the lighted gauge to the right of the button. The gauge reads from Full (F) to Empty (E) like a gas gauge in a car.






Full Charge



75% Charge



50% Charge



25% Charge



Empty

The battery charger recharges used batteries. The battery charger uses power from a standard wall outlet. Each battery sits in a slot that connects it directly to the charger.

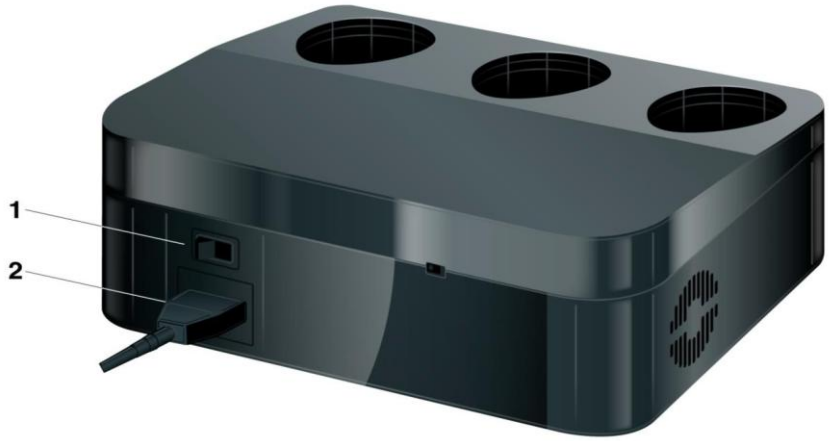
Before charging the batteries, plug the charger power cord into a standard wall outlet and turn ON the power switch at the charger rear side. The front lights of the charger will come on during a self-check then the small light in the center of the front panel will light up green indicating power is applied.

**To recharge a used battery:**

1. Place the used battery in one of the three openings in the top of the charger. Slide the battery in until it is fully in place.
2. The light directly in front of the opening where the battery is plugged in will illuminate flashing green. This indicates the battery is charging. The green light will flash faster once the battery has been charged to 95% of its capacity. You can also check the battery gauge while charging to get information regarding the amount of charge in the battery.
3. When the battery is fully charged (about 2 to 4 hours), the charge light will turn from flashing green to solid green. The solid green light will disappear upon removal of the battery or the disconnection of the charger from the standard wall outlet.

If a light on the front panel turns red, this indicates that there is a fault with the battery or charger and you should contact technical support for assistance. Do not use a battery if it creates a red light on the charger.

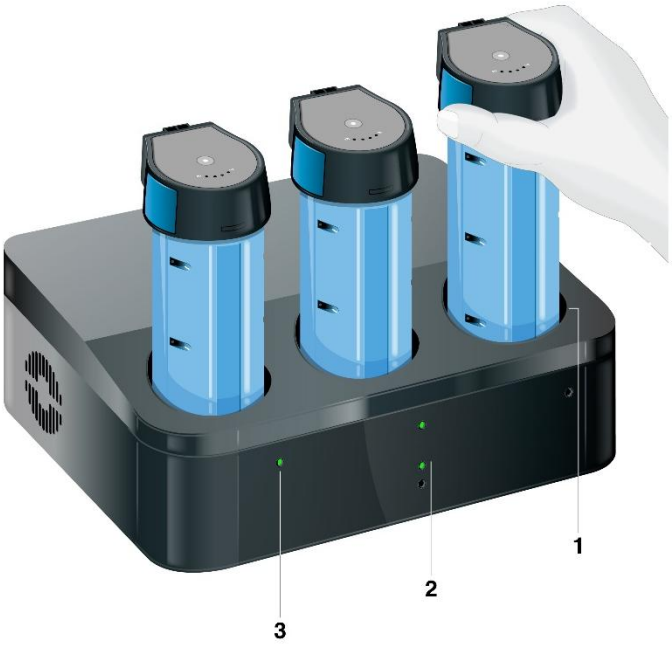
Keep the batteries in the charger even after they are fully charged. This will not harm the batteries




1. Power Switch
2. Power Cord

Battery Charger Rear View Showing the Power Switch and Where the Power Cord Connects

1. Battery Charging Slot
2. Charger Power Indicator
3. Battery Charge Indicator




Front view of the battery charger showing how the batteries are inserted into the charger

NOTE: The charger is not intended for use in the presence of flammable mixtures.

## 9.10. USING THE PLUG IN POWER SUPPLY

When you plan to stay in one place for a while, like when you are sleeping, you may use the plug-in power supply instead of the batteries. Unlike the batteries, there is no limit to how long the device can work when you use the plug-in power supply. The plug-in power supply will work with either US (120 VAC) or European (230 VAC) outlets.

NOTE: It is normal for the power supply to become warm when in use. If the power supply becomes too hot to touch, unplug it and contact technical support (Section 15).

When the device has a battery in, and is also connected to the wall power supply, it will utilize the wall power supply as the preferred power source. When the wall power cord is plugged in while the device is operated from the battery, the device will automatically switch from battery power to wall supply power.

**Connecting the Plug-In Power Supply**

1. Plug in the power supply cord into a standard wall outlet.

NOTE: You do not need to remove the battery from the device to use the wall power supply.

Note that the battery in the device will not charge while the device is plugged into the plug-in power supply.

If the TTFields are activated, you do not need to turn them OFF.

2. Plug the power supply connector into the power supply port, located on the back panel of the device (next to the power switch).
3. If the TTFields are already activated, the device will automatically switch to plug-in power supply without interruption of the therapy.
4. If the device is OFF, turn ON the power switch and wait about 10 seconds until the device completes with the self-check. Then, push the TTFields button to start the therapy (as described in Section 9.7).

**To Disconnect the Plug-In Power Supply and Go Back to Battery Power**

Ensure that a charged battery is properly inserted in the device before removing the plug-in power supply. If TTFields are activated, you need to turn them OFF before removing the plug-in power supply. The device will shut down and restart using battery power once the power supply is removed. In that case you will be required to push the TTFields button to start the therapy (as described in Section 9.7), after the self-check is completed.

1. Remove the power supply connector from the back side of the device. After about eight seconds, the “BATTERY” indicator on the front panel illuminates.
2. Store the plug-in power supply for future use.

## 9.11. DISCONNECTING FROM THE DEVICE

There are two ways to unplug the device in order to take a break from treatment:

- Unplug the connection cable from the device.
- Unplug the four transducer arrays from the connection cable.

**To Unplug the Connection Cable from the Device**

1. Stop therapy by pressing the TTFields button.
2. Turn OFF the device by using the power switch.
3. Hold the connector latch-sleeve and pull out the connection cable from the socket.

**CAUTION!** Do not pull on the cord!

You may now move around without the device, but you will still be connected to the connection cable and box.

To start treatment again after your break:

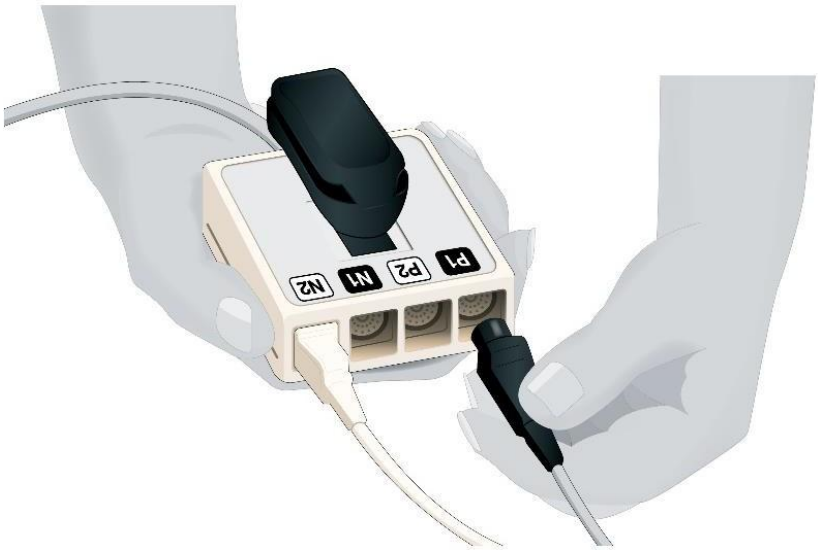
1. Plug the connection cable into the port with the arrows pointing up.
2. Turn ON the device by using the power switch. Wait about 10 seconds until the device completes with the self-check.
3. Activate TTFields by pressing the TTFields button.

**To Unplug the Transducer Arrays from the Connection Cable**

To take a break from treatment and completely disconnect from the device, unplug the transducer arrays from the connection cable box. The four transducer arrays are plugged into the connection cable box (as described in Section 9.6). The connection cable is plugged into the device at the P1 (patient) socket.

1. Stop treatment by pressing the TTFields button.
2. Turn OFF Optune Pax by using the power switch.
3. Unplug the four transducer arrays from the connection box by pulling their connectors.

NOTE: You may have to wiggle the transducer array connectors gently to remove them. Do not pull on the cord.



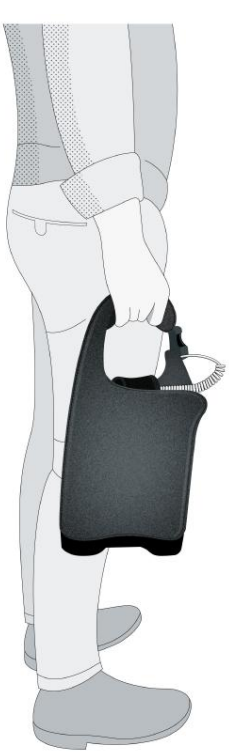

**To restart treatment:**

1. Plug the four transducer arrays into its matching color (black or white) in the connection box.
2. Turn ON the device by using the power switch and wait about 10 seconds until the device completes with the self-check.
3. Activate TTFields by pressing the TTFields button.

## 9.12. CARRYING THE DEVICE

The device with battery fit into the provided bag.

NOTE: Do not place the generator in a different bag. The generator has a fan on the inside that needs air flow. The bag that comes with the device is designed to allow for proper air flow. If you put the generator in a bag without proper air flow, it could overheat and stop the treatment. If this happens, you will hear an alarm.







# 10. GLOSSARY OF SYMBOLS

| | |
|---|---|
|  | Follow instructions for use |
| MD | Medical Device |
|  | Manufacturer information:<br>Novocure GmbH, Neuhofstrasse 21, 6340 Baar, Switzerland |
| # | Model number |
| REF | Catalogue Number |
| SN | Serial number |
| LOT | Batch code |
| UDI | Unique Device Identifier<br>Indicates a device carries Unique Device Identifying information. |
|  | Date of Manufacturing |
|  YYYY-MM-DD | Expiration date – do not use beyond this date |

| | |
|---|---|
|  | Consult the instructions for use for important cautionary information such as warnings and precautions |
|  | Contact technical support to arrange for proper disposal of equipment that is no longer in use, including used ITE transducer arrays. Separate collection of waste electric and electronic equipment is required. |
|  | Batteries are Lithium Ion.<br>Contact technical support to arrange for proper disposal of batteries that are used up or no longer in use |
|  | The ITE Transducer Arrays are for single use and should not be re-used. |
|  | The ITE transducer array pouches provide a single sterile barrier system. |
|  | The ITE Transducer Arrays are sterilized by Gamma irradiation |
|  | Do not re-sterilize |
|  | Do not use the ITE Transducer Arrays if their packaging is breached. |
|  | The Optune Pax (electric field generator, additional parts and transducer arrays) should be kept away from extreme heat and sources of radiation |

| | |
|---|---|
| **IP21** | Protects people against access to hazardous parts with fingers. Protects the equipment inside the enclosure against ingress of solid foreign objects of 12.5 mm in diameter or greater.<br>Protects the equipment inside the enclosure against ingress of vertical falling water drops. |
| **IP22** | Protects people against access to hazardous parts with fingers. Protects the equipment inside the enclosure against ingress of solid foreign objects of 12.5 mm in diameter or greater.<br>Protects the equipment inside the enclosure against ingress of vertical falling water drops when enclosure is tilted up to 15°. |
|  | Do not enter rooms with high humidity or danger of direct exposure to water while wearing the device.<br>Do not use the device if not within its carrying bag.<br>Do not expose the device to direct rain. |
|  | The charger and power supply are for indoor use only |
|  | Class II equipment per IEC 60601-1 |
|  | BF type applied part – symbolizes the part which comes in contact with the patient<br>Applied part – part of the ME equipment that in normal use necessarily comes into physical contact with the patient for ME equipment or an ME system to perform its function. |
|  | Temperature Limitations |
|  | Relative Humidity Limitations |

| | |
|---|---|
|  | Fragile, handle with care |
|  | MR UNSAFE |
| CE 0197 | CE Mark with Notified Body Number |
| EC REP | European authorized representative<br>MDSS GmbH<br>Schiffgraben 41<br>30175 Hannover, Germany |
|  | Importer details:<br>Novocure Netherlands B.V., Ekkersrijt 2066, 5692 BA Son en Breugel, The Netherlands |

# 11. ENVIRONMENTAL CONDITIONS FOR OPERATION, STORAGE AND TRANSPORTATION

**Conditions for operation**

All components of Optune Pax should be normally used under conditions specified below:

- For home use
- Charger and power supply are for indoor use only
- Not for use in shower, bath tub or sink, or in heavy rain
- Not for use in presence of flammable mixtures
- Can be dropped on floor, there shall be no safety hazard, not expected to function anymore.

Conditions of visibility: any

Cleaning: all durable treatment kit components can be periodically cleaned with damp cloth, to remove dust and regular soil.

Physical operation conditions for all components:

- Temperature range: -5°C to +40°C – device and additional parts
- Temperature range: 5°C to 27°C – transducer arrays
- Relative Humidity range: 15-93%- device and additional parts
- Relative Humidity range: 10-90% - transducer arrays
- Ambient pressure range: 700-1060hPa

Warning: The device should not be used in oxygen-rich environments or near explosive gases due to a possible fire hazard.

**Conditions for storage**

- Temperature range: -5°C to +40°C for the device and additional parts
- Temperature range: 5°C to +27°C for the transducer arrays

**Conditions for transport**

Transportation of the device, transducer arrays and additional parts shall be possible using air/ground transportation in weather protected conditions as specified below:

- Temperature range: -5°C to +40°C
- Maximal relative humidity 15-93%
- No direct exposure to water

# 12. EXPECTED LIFE

The EXPECTED SERVICE LIFE is the time period during which the ME equipment is expected to remain suitable for its intended use.

The expected service life for the Optune Pax device and all components of the treatment kit is 5 years. The expected shelf life of the ITE Transducer Arrays is 12 months. The ITE Transducer Arrays have an expiration date. Do not use the arrays after the expiration date.

# 13. DISPOSAL

Please contact Novocure to arrange for proper disposal of used transducer arrays. Do not throw them in the trash.

# 14. TROUBLESHOOTING

| Problem | Possible causes | Actions to be taken |
|---|---|---|
| Generator (the device) POWER indicator does not light up after turning ON the device | 1. Generator not connected to power source<br>2. Battery depleted<br>3. Battery malfunction<br>4. If power supply – not properly plugged into the wall<br>5. Generator malfunction<br>6. Power supply malfunction | 1. If on battery – check battery gauge to verify it is not depleted. If it is – replace with a charged battery or to power supply<br>2. Verify both the generator and the power source are properly connected and re-try<br>3. Evaluate the integrity of all connectors. Nothing should appear to be damaged or broken in any way<br>4. If the generator cannot be powered on by either the battery or the wall power supply or if anything appears to be damaged do not use the generator<br>5. Call technical support |
| Any cable detached from transducer array/ connection cable/ generator | 1. Too much physical force to cables<br>2. Generator malfunction | 1. Silence the notification signal by pressing the TTFields button<br>2. Evaluate the connectors. If intact – reconnect and re-start therapy<br>3. If anything appears damaged or cannot be properly connected do not try to use the generator<br>4. Call technical support |
| Generator dropped or wet | 1. Incorrect use | 1. Press TTFields button to stop therapy<br>2. Turn OFF power switch<br>3. Disconnect from power<br>4. Call technical support |

| Problem | Possible causes | Actions to be taken |
|---|---|---|
| Generator alarm on and low BATTERY indicator is yellow | 1. Low battery<br>Generator is turned ON, but the therapy has not been activated | 1. Replace batteryas described above in Section 9.8<br>2. Turn ON treatment<br>3. Press the TTFields button to stop the alarm<br>4. Wait a few seconds then press the TTFields button again<br>5. If the blue lights around the TTFields button light up – the therapy has now been activated<br>If the notification signal recurs within a few minutes:<br>1. Silence the notification signal and power the generator down completely<br>2. Disconnect all equipment and make sure that nothing appears to be damaged or broken. If something is – replace the damaged item before trying to power the generator back<br>3. Re-connect all equipment in proper order and power the generator back up. Verify the self-check is completed and press the TTFields button<br>4. Check vents on generator to make sure they are not blocked<br>5. If lying down, get up and move your body<br>6. Make sure transducer arrays are well stuck to the body, add tape if needed<br>7. Restart treatment<br>8. If alarm keeps going, turn OFF the generator and call technical support |

| Problem | Possible causes | Actions to be taken |
|---|---|---|
| Generator alarm is flashing, the ”TTFIELDS” indicator above the TTFields button will flash blue and audio sound 3 very short beeps, stops for 2.5 seconds and beeps 3 times again | Therapy Timeout | The notification alarm on the generator will sound if it is powered on for about 10 minutes, but therapy is not initiated.<br>This is a reminder to start therapy and does not indicate a malfunction.<br>1. Silence the notification alarm by pressing the TTFields button then wait a few seconds and press the TTFields button again to initiate treatment. The blue indicator around the TTFields button will illuminate to indicate therapy is now on.<br>2. If you encounter further alarms, please review the following troubleshooting descriptions in this section. |
| Low BATTERY indicator remains on after battery replaced | 1. Charger malfunction<br>2. Battery malfunction<br>3. Generator malfunction | 1. Replace battery with an additional charged battery<br>If problem is not fixed – call technical support |
| When powering on the generator a continuous notification alarm sounds and all lights remain on indefinitely.<br>Generator does not complete the self- check. | 1. Generator is too hot<br>2. Generator malfunction<br>3. Power Source Malfunction | 1. Power the generator off completely using the power switch<br>2. Verify the generator is not hot to the touch<br>3. Connect the generator to a different power source and try powering on again<br>4. If generator cannot be powered on by either the battery or the wall power supply or if anything appears to be damaged, please contact technical support |
| Excessive heating under arrays | 1. Arrays are too hot. | 1. Stop treatment<br>2. Verify the arrays are not hot to the touch.<br>3. Re-start treatment |
| The connection cable/arrays fail and the treatment stops. | 1. CAD board failure | 1. Call technical support<br>2. Replace the transducer arrays before restarting treatment. |

**Managing Side Effects**

| Side Effect | Possible causes | Actions to be taken |
|---|---|---|
| Redness of the skin beneath the transducer arrays | Very common side effect<br><br>(Occurring in 11% of patients in incidences for device related adverse events in the PANOVA-3 study) | 1. Use steroid cream prescribed by your doctor when replacing transducer arrays.<br>2. Place transducer arrays in a location shifted by 3/4 of an inch (2 cm) from the last location (so the adhesive gel is between the red marks).<br><br>If the redness gets worse:<br><br>1. See your treating doctor |
| Blisters beneath the transducer arrays | Common side effect<br><br>(Occurring in 4% of patients in incidences for device related adverse events in the PANOVA-3 study) | 1. See your treating doctor |
| Itching beneath the transducer arrays | Very common side effect<br><br>(Occurring in 15% of patients in incidences for device related adverse events in the PANOVA-3 study) | 1. Use steroid cream prescribed by your doctor when replacing transducer arrays.<br><br>2. Place transducer arrays in a location shifted by 3/4 of an inch (2 cm) from the last location (so the adhesive gel is between the red marks).<br>If the itching gets worse:<br><br>1. See your treating doctor |
| Pain beneath the transducer arrays | Common side effect<br><br>(Occurring in 1% of patients in incidences for device related adverse events in the PANOVA-3 study) | 1. See your treating doctor |
| Tingling “electric” sensation or uncomfortable heat under arrays | Uncommon side effect that could be caused by poor contact with skin (Occurring in <1% of patients in incidences for device related adverse events in the PANOVA-3 study) | 1. Ensure arrays are in contact with skin<br>2. Ensure array cables are securely connected to CAD and CAD is securely connected to the device.<br>3. If the sensation persists, call technical support. |

# 15. ASSISTANCE AND INFORMATION

**Technical support**

For technical support, contact your Device Support Specialist. His/her contact information will be supplied to you separately.

If you are unable to get a hold of your Device Support Specialist, you can contact the EMEA Novocure technical support email: SupportEMEA@novocure.com or patientinfoEMEA@novocure.com.

Please describe the problem and provide the following information when you contact:

NAME (First/Last)

EMAIL

TELEPHONE (optional)

COUNTRY:

QUESTION:

Please also have the device serial number on hand when you contact the DSS or Technical Support. The serial number can be found on the bottom of the device (TTFields Generator)

**Clinical support**

If you feel any change in your health or any side effects from the treatment call your doctor right away.

**Reporting**

If you experience a serious incident that occurs while using the Optune Pax treatment kit and ITE Transducer Arrays you should report it to the manufacturer (Novocure) and the competent authority of the Member State in which you reside.

**Traveling with Optune Pax**

The batteries contain lithium ion material and are restricted from being checked as luggage for passenger aircraft travel. They can be carried in the passenger cabin. Please contact your DSS if you have questions related to travel restrictions.

Note: The Optune Pax device and transducer arrays will activate metal detectors.

When traveling to another country with the Optune Pax device, use the suitable electric cable that was provided with the Optune Pax treatment kit. Travel adapters should not to be used with the Optune Pax treatment kit.

# 16. GLOSSARY

| | |
|---|---|
| **Cancer** – | abnormal cell division that spreads without control |
| **Chemotherapy** – | a type of medication used to destroy cancer cells |
| **Contraindications** – | situations when a treatment should not be used |
| **Local** – | in one part of the body |
| **Locally advanced pancreatic cancer –** | pancreatic cancer that cannot be removed surgically |
| **Nab-paclitaxel –** | a drug used to treat pancreatic cancer |
| **Opioid pain medication –** | used to relieve moderate to severe pain |
| **Optune Pax, Electric Field Generator (the device) –** | a portable device for delivering TTFields to the abdomen of patients with Pancreatic Adenocarcinoma. |
| **Optune Pax treatment kit** – | treatment kit containing the Optune Pax device; Connection cable; power supply; battery; charger; ITE Transducer Arrays. |
| **Progression** – | when cancer continues growing after being treated |
| **Steroids** – | when used on the skin, a medication that can reduce inflammation |
| **Topical** – | on the surface of the skin |
| **Transducer arrays** – | adhesive patches placed on the skin that deliver TTFields to the abdomen (full name: ITE transducer arrays). |
| **Tumor Treating Fields (TTFields) –** | alternating electric fields, delivered using transducer arrays to the part of the body with a solid tumor. TTFields have been shown to kill tumor cells. |

# 17. APPLICABLE STANDARDS

The Optune Pax treatment kit electronic components and the sterile transducer arrays comply with the latest editions of the following safety standards:

- EN 60601-1 Medical electrical equipment - Part 1: General requirements for safety
- EN 60601-1-2 Medical electrical equipment-Part 1-2: General requirements for safety-Collateral standard: Electromagnetic compatibility-Requirements and tests
- EN 60601-1-11- Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- EN 60601-1-6 Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
- EN 62366-1 – Application of usability engineering to medical devices
- EN 62304 - Medical device software. Software life-cycle processes

# 18. INPUT OUTPUT SPECIFICATIONS

The Optune Pax treatment kit including the battery charger is considered class II equipment according to EN 60601-1.

Mode of operation – continuous. The device is portable when battery-operated and stationary equipment when connected to the power supply.

The applied part is classified as BF.

The treatment kit is not intended for use in the presence of flammable mixtures.

NOTE: The maximum temperature of the transducer arrays shall be 41°C±1°C

Disinfection is not required.

The ITE Transducer Arrays are provided sterile for single use.

**Battery for Optune Pax (Li-Ion Rechargeable)**

OUTPUT 28.8V ⎓ 85Wh

**Charger for Optune Pax battery**

INPUT 100-240V ~ 1.5A 50/60Hz OUTPUT 3X33.6 V ⎓ 1.3A

**Power Supply for Optune Pax**

INPUT 100-240V ~ 1.2A 50/60Hz OUTPUT 28 V ⎓ 5A

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# 19. EMITTED RADIATION & ELECTROMAGNETIC COMPATIBILITY

The Optune Pax treatment kit, which includes the Optune Pax device (TFP9200) and the following additional parts, is suitable for use in home healthcare environment, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. The Optune Pax device (TFP9200) must only be used with these additional parts. The use of accessories, parts and cables other than those specified may result in increased emissions or decreased immunity of the Optune Pax treatment kit.

1. Connection Cable (CAD9100)
2. Transducer Arrays (ITE1013B, ITE1013W, ITE1020B, ITE1020W)
3. Battery (IBH9200)
4. Power Supply (SPS9200)
5. Battery Charger (ICH9100)
6. Unshielded AC mains cables for indoor use only with a maximal length of 1.5m

The Optune Pax Treatment Kit is used to deliver intermediate-frequency electric fields to the patient's abdomen via transducer arrays. The device together with the other treatment kit components is to perform its essential performance so that the treatment will be delivered to the patient as intended.

Essential Performance for Optune Pax device (model NovoTTF-200P) is defined as delivering the treatment at 150 ±5% kHz and a 4000 ±15% mA peak-to-peak.

Note that a stop in therapy by the device due to recognition of a potentially hazardous situation is allowed for a short period of time as long as the device resumes therapy once it is turned on again to deliver the treatment at 150 ±5% kHz and 4000 ±15% mA peak-to-peak.

**Normal Operation**

The Optune Pax device is working properly when the blue LED surrounding the TTFields button is lit and no notification signal sounds. The ICH9100 charger is working properly when all the LEDs are lit. The SPS9200 power supply is working properly when the blue LED surrounding the TTFields button is on and no notification signal sounds.

The Optune Pax treatment kit requires special precautions regarding electromagnetic disturbances and must be installed and used according to the environmental conditions specified in Section 11, and according to the EMC information provided below.

The use of accessories, parts and cables other than those specified may result in increased EMISSIONS or decreased IMMUNITY of Optune Pax.

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 the Optune Pax Treatment Kit, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result, which means the device may stop. In case of stop in therapy, the device should be turned on again to resume therapy.

Users should be aware that there is a risk of stop in therapy due to proximity to common emitters such as (RFID) readers, electronic security systems (e.g., metal detectors, electronic article surveillance), 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 case of stop in therapy, the device should be turned on again to resume therapy.

Users should be aware that there is a risk of stop in therapy due to electrostatic discharges (ESD) directly to the Optune Pax Treatment Kit or to metallic objects in proximity to the Optune Pax Treatment Kit. In case of stop in therapy, the device should be turned on again to resume therapy.

**Table 1 – Guidance and MANUFACTURER'S declaration – ELECTROMAGNETIC EMISSIONS – for all ME EQUIPMENT and ME SYSTEMS**

| Guidance and manufacturer's declaration – electromagnetic emissions | | |
|---|---|---|
| The Optune Pax treatment kit is intended for use in the electromagnetic environment specified below. The customer or the user of the Optune Pax should assure that it is used in such an environment. | | |
| Emissions test | Compliance | Electromagnetic environment – guidance |
| RF emissions CISPR 11 | Group 1 | Optune Pax 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. |
| RF emissions CISPR 11 | Class B | Optune Pax is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions IEC 61000-3-2 | Class A | |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | Complies | |

| Guidance and manufacturer's declaration – electromagnetic emissions | | |
|---|---|---|
| The ICH9100 charger and the SPS9200 power supply are intended for use in the electromagnetic environment specified below. The customer or the user of the ICH9100 charger and the SPS9200 power supply should ensure that it is used in such an environment. | | |
| Emissions test | Compliance | Electromagnetic environment – guidance |
| RF emissions CISPR 11 | Group 1 | The ICH9100 charger and the SPS9200 power supply use RF energy only for their internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions CISPR 11 | Class B | The ICH9100 charger and the SPS9200 power supply are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions IEC 61000-3-2 | Class A | |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | Complies | |

Warning: The Optune Pax device, the ICH9100 charger and the SPS9200 power supply should not be used adjacent to or stacked with other equipment.

**Table 2 – Guidance and MANUFACTURER'S declaration – ELECTROMAGNETICIMMUNITY – for all ME EQUIPMENT and ME SYSTEMS**

| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
|---|---|---|---|
| Optune Pax is intended for use in the electromagnetic environment specified below. The customer or the user of Optune Pax should assure that it is used in such an environment. | | | |
| Emissions test | IEC 60601 Test level | Compliance level | Electromagnetic environment – guidance |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±8 kV contact,<br>± 2 kV, ± 4 kV,<br>±8 kV, ± 15 kV air | ±8 kV contact,<br>± 2 kV, ± 4 kV,<br>±8 kV ± 15 kV air | The relative humidity should be at least 5%. |
| Electrical fast transient/burst IEC 61000-4-4 | ±2 kV for power supply lines<br>±1 kV for input/output lines | ±2 kV for power supply lines<br>±1 kV for input/output lines<br>100 kHz repetition frequency | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge<br>IEC 61000-4-5 | ± 0,5 kV, ±1 kV line to line<br>± 0,5 kV, ± 1 kV, ±2 kV line to ground | ± 0,5 kV, ±1 kV line to line<br>± 0,5 kV, ± 1 kV, ±2 kV line to ground | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines<br>IEC 61000-4-11 | 0 % UT; 0,5 cycle<br>At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br><br>0% UT; 1 cycle and 70 % UT; 25/30 cycles<br>Single phase: at 0°<br><br>0 % UT; 250/300 cycle | 0 % UT; 0,5 cycle<br>At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br><br>0 % UT; 1 cycle and 70 % UT; 25/30 cycles<br>Single phase: at 0°<br><br>0 % UT; 250/300 cycle | Mains power quality should be that of a typical commercial or hospital environment. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 30 A/m | 30 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| NOTE UT is the a.c. mains voltage prior to application of the test level. | | | |

| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
|---|---|---|---|
| The ICH9100 charger and the SPS9200 power supply are intended for use in the electromagnetic environment specified below. The customer or the user of the ICH9100 charger and the SPS9200 power supply should ensure that they are used in such an environment. | | | |
| Emissions test | IEC 60601 Test level | Compliance level | Electromagnetic environment – guidance |
| Electrostatic discharge (ESD)<br>IEC 61000-4-2 | ± 8 kV contact<br>± 2 kV, ± 4 kV,<br>± 8 kV, ± 15 kV air | ± 8 kV contact<br>± 2 kV, ± 4 kV,<br>± 8 kV, ± 15 kV air | The relative humidity should be at least 5%. |
| Electrical fast transient/burst<br>IEC 61000-4-4 | ±2 kV for power supply lines<br>±1 kV for input/output lines | ±2 kV for power supply lines<br>±1 kV for input/output lines<br>100 kHz repetition frequency | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge<br>IEC 61000-4-5 | ± 0,5 kV, ± 1 kV line to line<br>± 0,5 kV, ± 1 kV, ± 2 kV line to ground | ± 0,5 kV, ± 1 kV line to line<br>± 0,5 kV, ± 1 kV, ± 2 kV line to ground | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines<br>IEC 61000-4-11 | 0 % UT; 0,5 cycle<br>At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br><br>0% UT; 1 cycle and 70 % UT; 25/30 cycles<br>Single phase: at 0°<br><br>0 % UT; 250/300 cycle | 0 % UT; 0,5 cycle<br>At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br><br>0 % UT; 1 cycle and 70 % UT; 25/30 cycles h)<br>Single phase: at 0°<br><br>0 % UT; 250/300 cycle | Mains power quality should be that of a typical commercial or hospital environment. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 30 A/m | 30 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| NOTE UT is the a.c. mains voltage prior to application of the test level = 120V and 230V | | | |

**Table 3 – Guidance and MANUFACTURER'S declaration – ELECTROMAGNETICIMMUNITY – for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING**

| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
|---|---|---|---|
| Optune Pax is intended for use in the electromagnetic environment specified below. The customer or the user of Optune Pax should assure that it is used in such an environment. | | | |
| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment – guidance |
| Conducted RF<br>IEC 61000-4-6 | 3 V<br>0,15 MHz – 80 MHz<br>6 V in ISM bands between 0,15 MHz and 80 MHz<br>80 % AM at 1 kHz<br>(table 8.5.1) | 3 V<br>0,15 MHz – 80 MHz<br>6 V in ISM bands between 0,15 MHz and 80 MHz<br>80 % AM at 1 kHz | Portable and mobile RF communications equipment should be used no closer to any part of Optune Pax, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br>Recommended separation distance<br>$d = \frac{6}{E}\sqrt{P}$<br>Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m.<br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range.<br>Interference may occur in the vicinity of equipment marked with the following symbol:<br> |
| Radiated RF<br>IEC 61000-4-3 | 10 V/m | 10 V/m<br>80 MHz to 2.7 GHz<br>80 % AM at 1 kHz | |
| NOTE These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | | |

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Optune Pax treatment kit is used exceeds the applicable RF compliance level above, the Optune Pax treatment kit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Optune Pax treatment kit.

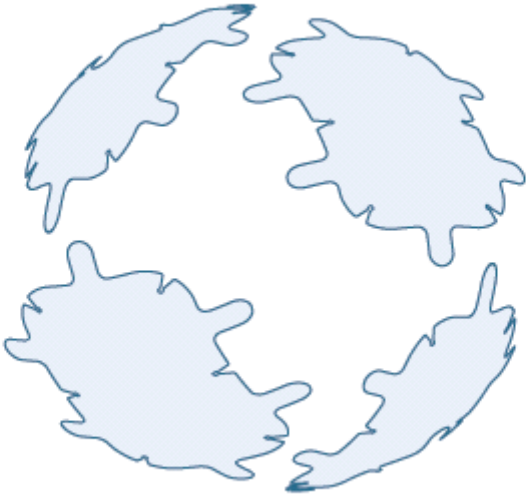
| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
|---|---|---|---|
| The ICH9100 charger and the SPS9200 power supply are intended for use in the electromagnetic environment specified below. The customer or the user of the ICH9100 charger and the SPS9200 power supply should ensure that they are used in such an environment. | | | |
| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment – guidance |
| Conducted RF<br>IEC 61000-4-6 | 3 V<br>0,15 MHz – 80 MHz<br>6 V in ISM bands between 0,15 MHz and 80 MHz<br>80 % AM at 1 kHz<br>(table 8.5.1) | 3 V<br>0,15 MHz – 80 MHz<br>6 V in ISM bands between 0,15 MHz and 80 MHz<br>80 % AM at 1 kHz | Portable and mobile RF communications equipment should be used no closer to any part of ICH9100 charger and the SPS9200 power supply, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br>Recommended separation distance<br>$d = \frac{6}{E}\sqrt{P}$<br>Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m.<br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range.<br>Interference may occur in the vicinity of equipment marked with the following symbol:<br> |
| Radiated RF<br>IEC 61000-4-3 | 10 V/m | 10 V/m<br>80 MHz to 2.7 GHz<br>80 % AM at 1 kHz | |
| NOTE These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | | |

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ICH9100 charger and the SPS9200 power supply are used exceeds the applicable RF compliance level above, the ICH9100 charger and the SPS9200 power supply should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ICH9100 charger and the SPS9200 power supply.

Normal operation: The device is working properly when the blue LED surrounding the TTFields button is lit and no notification signal sounds. The ICH9100 charger is working properly when all the LEDs are lit. The SPS9200 power supply is working properly when the blue LEDs surrounding the TTFields button are on and no notification signal sounds.

**Table 4 – Recommended separation distances between portable and mobile RF communications equipment and the ME EQUIPMENT or ME SYSTEM – for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING**

| Rated maximum output power of transmitter W | Separation distance according to frequency of transmitter m | | | | | | |
|---|---|---|---|---|---|---|---|
| | 380 – 390MHz | 430 – 470MHz | 704 – 787MHz | 800 – 960MHz | 1700 – 1990MHz | 2400 – 2570MHz | 5100 – 5800MHz |
| The customer or the user of Optune Pax can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Optune Pax as recommended below, according to the maximum output power of the communications equipment. | | | | | | | |
| 0.2 | 0.3 | 0.3 | 0.3 | 0.3 | 0.3 | 0.3 | 0.3 |
| 1.8 | 0.3 | 0.3 | 0.3 | 0.3 | 0.3 | 0.3 | 0.3 |
| 2 | 0.3 | 0.3 | 0.3 | 0.3 | 0.3 | 0.3 | 0.3 |
| NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | | | | | | |
| For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. | | | | | | | |



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