For Non Small Cell Lung Cancer

User Manual

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1. ABOUT THE OPTUNE LUA TREATMENT KIT AND THE ITE TRANSDUCER ARRAYS

1.1. DEVICE DESCRIPTION

Optune Lua is a portable, battery operated device. It produces electric fields, called tumor treating fields ("TTFields"). ITE Transducer Arrays connected to the device deliver TTFields therapy to the chest. The TTFields therapy has been shown to kill tumor cells.

The device is intended for home use of at least 12 hours a day on average. The Optune Lua treatment kit refers to the Electric Field Generator (Optune Lua, the device), connection cable, power supply, battery, battery charger and ITE Transducer Arrays.

1.2. INTENDED PURPOSE

Optune Lua (NovoTTF-200T) Treatment Kit is intended for the treatment of patients with stage IV, non-squamous, non-small cell lung cancer (NSCLC), in combination with Pemetrexed (Alimta), after failure of first line treatments.

Optune Lua concurrent with immune check point inhibitors or docetaxel, is indicated for adult patients with metastatic non-small cell lung cancer who have progressed on or after a platinum-based regimen.

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 the Optune Lua treatment kit if you have an active implanted medical device. Examples of active electronic devices include deep brain stimulators, spinal cord stimulators, vagus nerve stimulators, pacemakers and defibrillators. Use of the Optune Lua treatment kit together with implanted electronic devices have has not been tested and may lead to malfunctioning of the implanted devices.

Do not use the Optune Lua treatment kit if you are known to be sensitive to conductive hydrogels 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 the Optune Lua treatment kit may commonly cause increased redness and itching, and rarely may even lead to severe allergic reactions such as shock and respiratory failure.

Warnings

Warning - Use the Optune Lua treatment kit only after receiving training from qualified personnel, such as your doctor, a nurse, or other personnel who have completed a training course given by the device manufacturer (Novocure GmbH Switzerland). Your training will include a detailed review of this manual and practice in the use of the treatment kit. In addition, you will be trained in what to do if there are problems with treatment. Use of the Optune Lua treatment kit without receiving this training can result in breaks in treatment and may rarely cause increased skin rash, open sores on your body, 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 with relevant treatment to use when replacing the transducer arrays. This will help relieve your skin irritation. If you do not use this treatment, the skin irritation can become more serious and may even lead to skin break down, infections, pain and blisters. If this happens, stop using the treatment and contact your doctor. Your doctor will provide you with alternative treatment option to use when replacing the transducer arrays. Neglecting to employ this alternative treatment, may result in the persistence of symptoms, prompting your doctor to recommend a temporary cessation of treatment until the skin has fully healed. Taking a break from treatment may lower your chance to respond to treatment.

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

Precautions

Caution – Do not use any parts that do not come with the Optune Lua treatment kit, or that were not sent to you by the device manufacturer or 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 the Optune Lua treatment kit if any parts look damaged (torn wires, loose connectors, loose sockets, cracks or breaks in the plastic case). Use of damaged components can damage the device and cause a break in treatment.

Caution - Do not get the electric field generator, transducer arrays or other parts wet or use in the shower or in heavy rain. Getting the device wet may damage it, preventing you from receiving treatment. Getting the transducer arrays very wet is likely to cause the transducer arrays 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 the Optune Lua 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.

Caution - Do not use the Optune Lua treatment kit if you are pregnant, 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. The Optune Lua treatment kit 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.

Notices

Notice! The Optune Lua treatment kit and the 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 an extra 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 you 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 in 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 (Section 14 of the patient user manual) at all times. This guide is necessary to ensure the Optune Lua treatment kit works properly. If you do not operate the treatment kit correctly, you may have a break in your treatment.

Notice! Do not block the device vents located on the front and back of the Optune Lua 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 or dust, return the device for service. Do not block the power supply vents. Blocking the vents may cause the power supply to overheat.

Notice! Do not block the battery charger vents located on the left and right sides of the battery charger. Blocking the vents may cause the charger to overheat. This could prevent your batteries from charging. If the vents become blocked with pet hair or dust, return the charger for service.

Notice - The transducer arrays are for single use and should not be taken off your body and put back on again. If you put a used transducer array back on your chest again, it may not stick well to your skin and the device could turn off.

Notice - Keep the Optune Lua treatment kit out of the reach of children and pets.

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

2. CLINICAL BENEFIT AND CLINICAL EVIDENCE

Expected clinical benefit for the patient

Patients using Optune Lua together with cancer drugs lived longer compared to patients who used cancer drugs alone.

The EF-24 (LUNAR) study was conducted to evaluate the use of Optune Lua to treat NSCLC in patients whose cancer continued to grow following treatment with platinum chemotherapies. The study assessed the use of Optune Lua when used together with cancer drugs approved for metastatic NSCLC (either docetaxel, a chemotherapy drug or immune checkpoint inhibitors) compared to the use of standard cancer drugs alone. Half of the patients were treated with Optune Lua and cancer drugs, while the other half were treated with only cancer drugs.

The study found that using Optune Lua together with cancer drugs prolonged the life of lung cancer patients more than using the cancer drugs alone.

In addition to the effects of Optune Lua on patients regardless of the standard of care drugs they received, the study evaluated the effect for each type of drug administered with Optune Lua, separately. Results by type of cancer drug used with Optune Lua showed that:

- Using Optune Lua with immune checkpoint Inhibitors prolonged the lives of patients with metastatic NSCLC more than using immune checkpoint inhibitors alone. This difference was significant.
- Patients using Optune Lua with docetaxel, a chemotherapy drug, had a more modest prolongation of life, which was not considered to be significant.

All patients in the clinical study used Optune Lua together with a cancer drug (either an immune checkpoint inhibitor or chemotherapy). About half (53%) of the patients using Optune Lua together with cancer drugs lived for more than 12 months after their treatment started. In contrast, less than half (43%) of the patients treated with cancer drugs alone lived more than 12 months after their treatment started.

When looking at patients whose lifespan on the study was more than around half the patients and less than the other half of patients, using Optune Lua together with a cancer drug (regardless of which cancer drug they received) added about 3 months to their lifespan, compared to patients who used cancer drugs alone.

Optune Lua + Immunotherapy

In the group of patients who used Optune Lua with immunotherapy, 61% lived for more than 12 months after their treatment started. In contrast, 47% of patients treated with immunotherapy alone lived for more than 12 months after their treatment started. When looking at patients whose lifespan on the study was more than around half the patients and less than the other half of patients, using Optune Lua with immunotherapy added about 8 months to their lifespan, compared to patients who used immunotherapy alone.

Optune Lua + Docetaxel

In the group of patients who used Optune Lua with docetaxel, 46% lived for more than 12 months after their treatment started. In contrast, 38% of the patients treated with docetaxel alone lived for more than 12 months after their treatment started. When looking at patients whose lifespan on the study was more than around half the patients and less than the other half of patients, using Optune Lua together with docetaxel added about 2 months to their lifespan, compared to patients who used Docetaxel alone. This addition was not considered to be significant.

In the EF-15 study median progression free survival of advanced (stage IV) NSCLC patients treated with the Optune Lua device together with Pemetrexed, following at least one line of prior chemotherapy, was more than double that of the expected median with Pemetrexed alone based on comparison with historical control data.

This multi-center clinical study has shown that Optune Lua (Formerly NovoTTF-100L) treatment together with standard chemotherapy (Pemetrexed) was well tolerated with no device related serious adverse events seen in any of the 42 patients treated with an average follow up of 6 months. No cardiac or other electric field based serious adverse events were seen in any of the patients. No increase in chemotherapy related toxicity was seen.

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

Skin irritation is often seen under the ITE Transducer Arrays when using the Optune Lua treatment kit. This will most likely look like a red rash on your body. In most cases, this will be an easily healed condition. The irritation can be treated with topical therapies or by moving the ITE Transducer Arrays. If you do not use the treatment indicated by your treating physician, the skin irritation could become more serious. This may lead to open sores, infections, pain and blisters. If this happens, stop using any topical therapy and contact your doctor to prevent Optune Lua treatment discontinuation.

In a clinical study of Optune Lua together with chemotherapy and immunotherapy cancer drugs used to treat your kind of lung cancer, the device led to skin irritation in about 87 of 133 patients (65.4%). Most of these cases were not severe and were treated with topical creams. Only 6 patients (4.5%) had severe skin irritation.

Below is a list of the possible side effects associated with the use of Optune Lua:

- Treatment related skin toxicity
- Allergic reaction to the adhesive or to the gel
- Overheating of the array, leading to pain and/or local superficial thermal injury
- Infection at the site where the array makes contact with the skin
- Local warmth and tingling sensation beneath the arrays
- Medical device site reaction
- Muscle twitching
- Skin breakdown / skin ulcer
- Bronchopleural fistula

4. MECHANISM OF ACTION AND PERFORMANCE

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

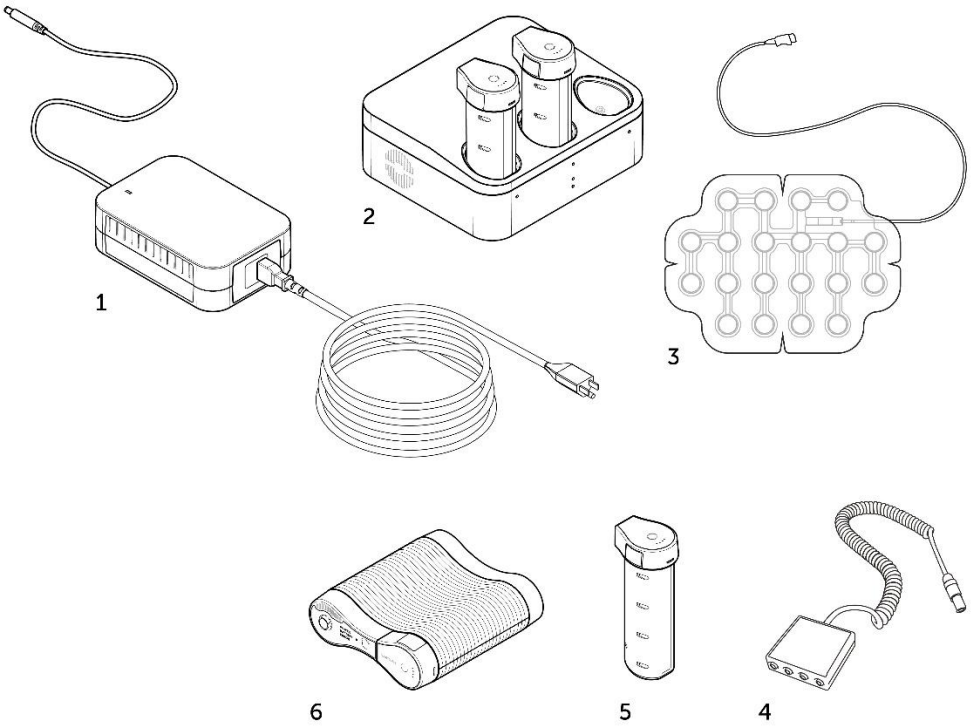
The Optune Lua treatment kit is designed to be portable. It delivers electric fields, called tumor treating fields or “TTFields” to kill cancer cells.

Optune Lua delivers TTFields to your chest 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 Lua 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 Lua: 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 LUA TREATMENT KIT AND ITE TRANSDUCER ARRAYS



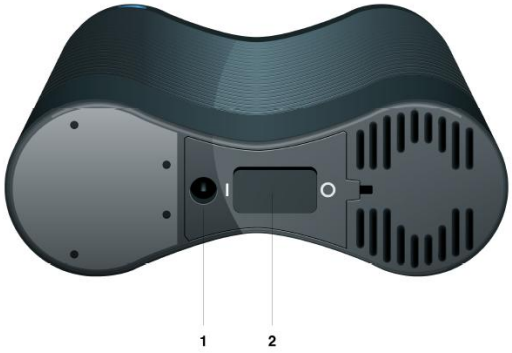
1. Optune Lua Power Supply (SPS9200)
2. Charger for Optune Lua (ICH9100)
3. ITE Transducer Array (Small: ITE1013B, ITE1013W)
   (Large: ITE1020B, ITE1020W)
4. Optune Lua Connection Cable (CAD9100)
5. Optune Lua Battery (IBH9200)
6. Optune Lua electric field generator – the device (TFT9200)

6. THE DEVICE

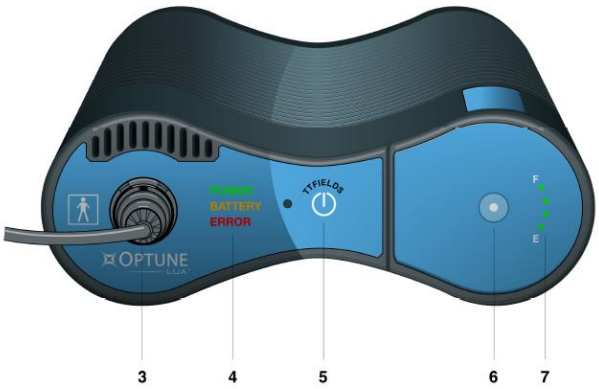
The Optune Lua device is an automatic system. The TTFields treatment should be kept on as continuously as possible (at a minimum 12 hours a day, 7 days a week). Breaks from treatment should be kept as short as possible.

You will need to learn how to place it in a carrying bag, connect a battery and operate the treatment kit. The following controls will allow you to do this:

Back



Front



1 Power Supply Port
2 Optune Lua 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 upper part of the torso to deliver TTFields to the lungs and adjacent organs.
- Transducer arrays are supplied sterile and are to be used with Optune Lua 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.

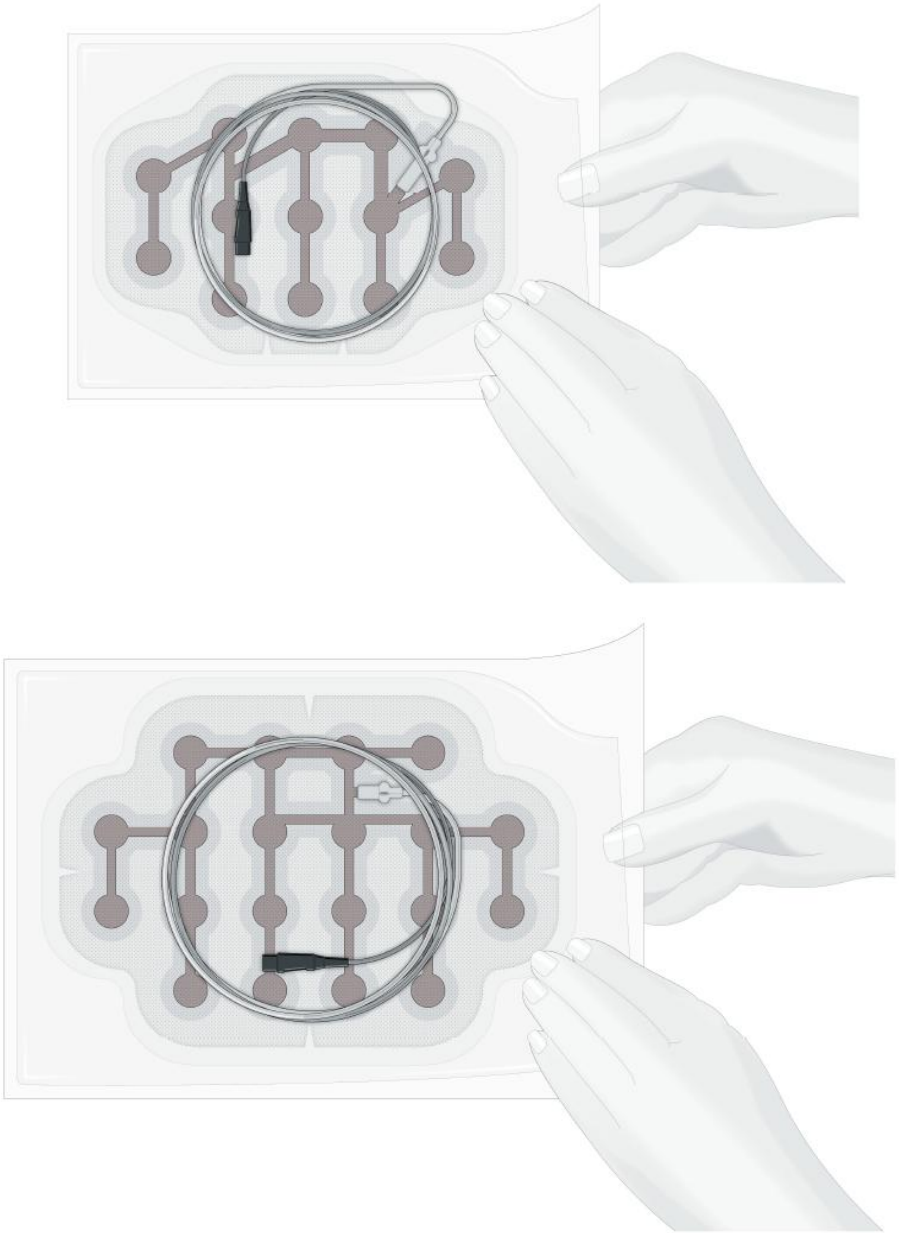
8. BEFORE YOU BEGIN

- 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 at least two times per week (every 4 days at most).
- A medical professional will determine the best array layout for you, and you will be shown where to place each of the arrays on your chest (front and back, and sides of chest).
- Contact Novocure to arrange for proper disposal of your used transducer arrays. Do not dispose of your used transducer arrays in household trash.
- Before using an ITE Transducer Array make sure the 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. Do not use an ITE Transducer Array which has been opened previously.
-
- The ITE Transducer Arrays are provided sterile and for single use. The arrays should not be re-used.
- Maintenance and cleaning – The ITE Transducer Arrays are supplied sterile for single use and thus do not require maintenance, cleaning or disinfection.

9. DIRECTIONS FOR USE

9.1. REMOVING THE TRANSDUCER ARRAY FROM ITS PACKAGE

Open the see-through envelopes of each of the four (4) ITE Transducer Arrays, by gently pulling apart the opposing edges of the envelope. Hold the transducer array as shown in the illustration



9.2. PREPARING YOUR SKIN FOR TRANSDUCER ARRAY PLACEMENT

1. Hair removal should initially be performed 2 days prior to treatment start and should be repeated every 7–10 days or as necessary. Hair removal for torso placement can be a short trim and does not need to be a close shave.
2. After shaving, wash your skin using water or gentle hypoallergenic soap only.
3. Prior to placing a new set of arrays, gently pat dry your skin with an absorbent towel to remove moisture or residue.
4. Skin should be moisturized regularly with fragrance-free moisturizers.
5. Skin barriers can be used to help prevent skin irritation before it starts. Talk to your study doctor about which skin barriers are compatible with TTFields treatment. Skin barriers must be removed and reapplied when replacing transducer arrays.
6. If any preventative topical medications are being used, they should be applied to clean skin and left uncovered (for roughly 15 to 20 minutes) to allow for proper absorption, before application of the arrays. Any residues should be removed before array placement. To remove any residues, clean the skin and gently pat dry. Avoid rubbing to minimize skin abrasion/damage.
7. Arrays should be applied to dry skin.

9.3. PLACING THE TRANSDUCER ARRAYS

At least two times per week (every 4 days at most) perform the following steps to remove the existing arrays and place new arrays according to the array layout provided by your physician. If this is the first time you are applying the transducer arrays, you can skip the first step (removal).

Removal:

1. Remove all four (4) transducer arrays already applied to your skin by peeling the medical tape away from your skin. Remove arrays gently by pulling back on the edge of the array, taking a minute to remove each array. To further minimize the risk of skin irritation you may use medical adhesive remover, water-based makeup remover, baby oil or warm water to loosen the edges of the arrays to pull them off. Unplug the cords from the connector box and step into a warm shower to loosen and remove the arrays. After array removal, skin should be thoroughly examined. Any signs of skin damage or excess irritation should be reported to the physician promptly. You may wish to keep a photo diary of any skin damage or irritation experienced. This log can then be referred back to during clinic appointments.

Placement:

1. 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.

2. Remove the transducer array liner from one transducer array. If the transducer array is flexible and difficult to manage, use the applicator for assistance as instructed in Section 8.4.

3. Place the transducer array on your chest in the same location as before, but shifting the transducer array 2 cm to avoid areas of skin irritation.

4. Press the entire edge of the transducer array tape to your skin.

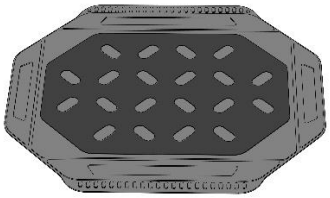
5. Place the other three transducer arrays in the same fashion.

6. You may need to ask for assistance from a friend or family member to place the back transducer array(s) on your back.

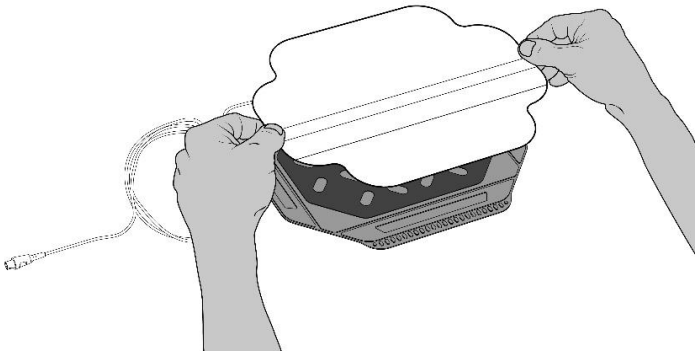
9.4. TRANSDUCER ARRAY LINER REMOVAL AND APPLICATOR USE

Support mats, called Torso Applicators (ACM00010 & ACM00012), are provided to assist in the handling of the ITE Transducer Arrays. Use this, if needed according to the following instructions:

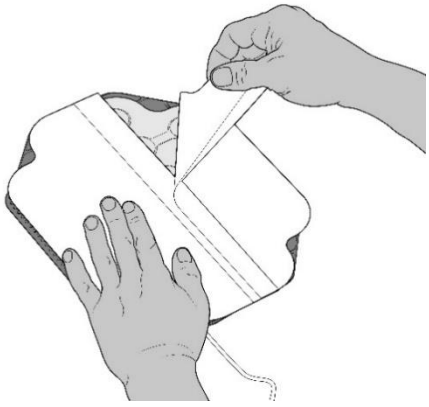
1. Select the applicator size according to the size of the transducer array you are using. Place the applicator on a hard surface with the black patch facing upwards.



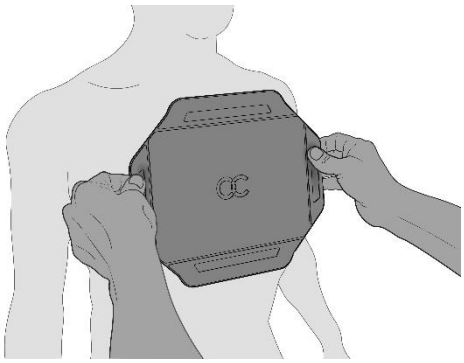
2. After removing the transducer array from its bag, place it on the applicator with the removable liner facing up. Apply medium pressure on the transducer array so it attaches to the black patch.



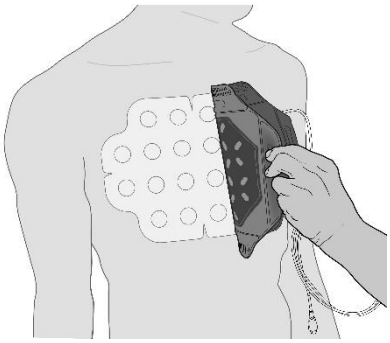
3. Start by removing the top liner. Slowly remove the liners by starting at the top corner in the middle of the array and carefully peel the liner downwards. Peel the liner parallel to the surface, from different directions if needed, to ensure the array remains flat and intact.



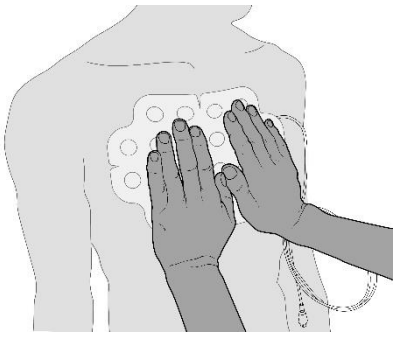
4. Using the applicator, place the transducer array on the skin according to the layout provided to you and by following the instructions in section 9.3. Apply pressure on the applicator. Make sure that the transducers and the edges of the transducer array tape adhere well to the skin.



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 LUA DEVICE

1. Connect the transducer array connectors (2 black and 2 white) to the corresponding black and white coded sockets on the Optune Lua connection cable as shown below.

2. Make sure the transducer arrays connect the following way:
   - Front transducer array (large) connects to P1 (black)
   - Back transducer array (large) connects to N1 (black)
   - Right transducer array (either large or small) connects to P2 (white)
   - Left transducer array (either large or small) connects to N2 (white)

3. Press firmly to be sure the connectors are pushed in all the way.

4. Gather the transducer array wires together and loosely bind with a small piece of tape if you wish.

5. 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 connection cable plugs into a port on the front panel of the electric field generator. The black and white coding matches with the transducer array position on the body.

To connect the connection cable to the electric field generator:

1. Verify that the arrow on the end of the connection cable is facing up and align it with the arrow on the port of the generator, 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:

The ITE Transducer Arrays should be attached to your body

1. Plug the ITE Transducer Arrays into the connection cable box (see Sections 9.5 and 9.6)
2. Plug the connection cable into the electric field generator, aligning the connector arrow with the socket arrow (see 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 generator.
4. Turn the power switch to the ON position as shown below.



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



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



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



The ”TTFIELDS” indicator, above the TTFields ON/OFF button, should illuminate blue and stay blue while the treatment is ON.

NOTE: If the blue indicator 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).

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 about 10 minutes after the device is switched ON, a notification alarm signal will sound along with a flashing blue ”TTFIELDS” light, indicating that the treatment is OFF. This is a reminder to start the therapy. To start treatment, press the “TTFields” button once to silence the alarm and again to start the treatment. The “TTFIELDS” indicator will then illuminate blue, when TTFields treatment 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 take a break :

1. Stop treatment by pressing the TTFields button. TTFields treatment stops, indicated by the blue “TTFIELDS” indicator turning 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 treatment and sounds a loud beeping alarm. The red “ERROR” indicator illuminates (as shown below).

1. Press the 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.

2. 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 treatment) 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

The Optune Lua treatment kit is provided with four rechargeable batteries. Optune Lua 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 two to four 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 six to nine 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” indicator 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 to the wall outlet to provide continuous treatment. 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 Optune Lua device (Section 9.10). Treatment 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 it out of the device.

3 Charge the removed battery (Section 9.9).

4 Continue the treatment 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 treatment.
2. Turn OFF the device by using the power switch (on the back of the device).
3. Press the two blue buttons on both battery sides and remove the battery by lifting it out of 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 Section 8.8 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 treatment 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 the Optune Lua treatment kit, you may want to check how much energy is left in your battery. Checking the battery will not interfere with, or stop, your treatment.

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.

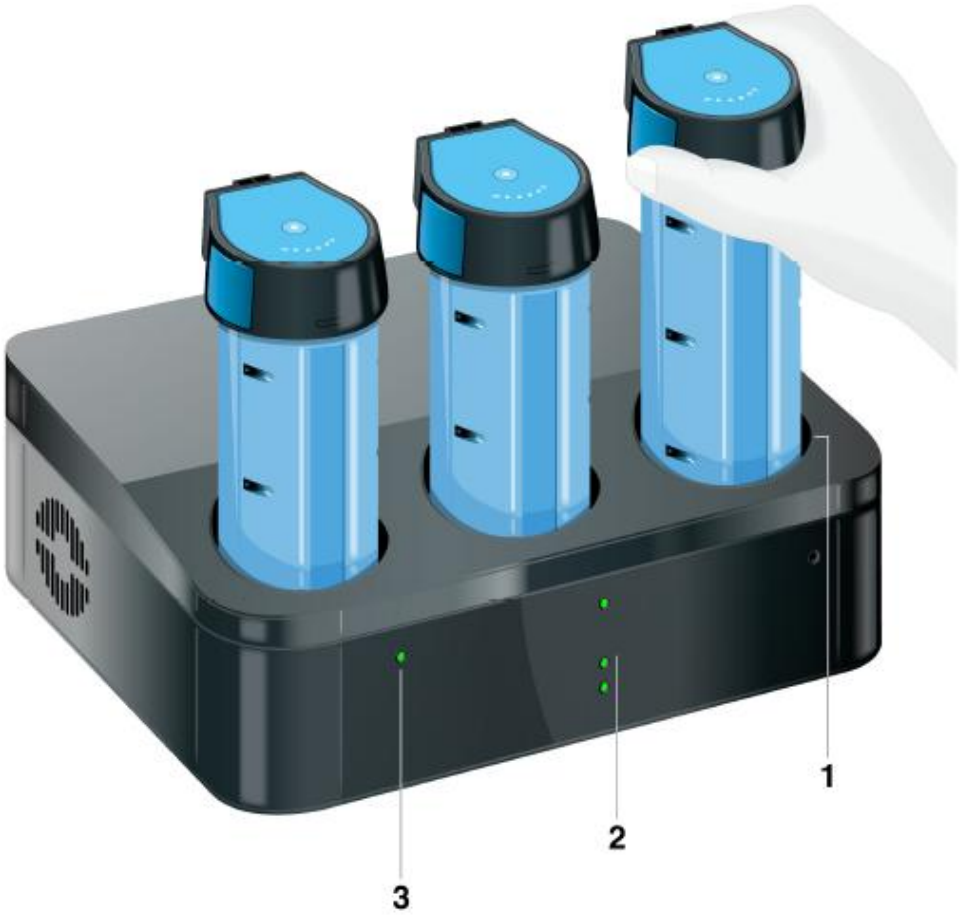
If a light on the front panel turns red, this indicates that there is a fault with the battery or charger and you should contact technical support for assistance. Do not use a battery if it creates a red light on the charger.

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.

   Please note that a battery in the device will not charge while the device is plugged into the wall 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 side of the device (next to the power switch).

3. If the TTFields are already activated, the device will automatically switch to wall power supply without interruption of the treatment.

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 treatment (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 wall power supply. If the TTFields are activated, you need to turn them OFF before removing the wall 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 treatment (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:

- To unplug the connection cable from the device.
- To unplug the four transducer arrays from the connection cable.

To Unplug the Connection Cable from the Device

1. Stop treatment 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 ITE 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 the Optune Lua device 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 ELECTRIC FIELD GENERATOR

The electric field generator with battery fit into the provided bag.

NOTE: Do not place the device in a different bag. The Optune Lua device 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 device in a bag without proper air flow, it could overheat and stop the treatment. If this happens, you will hear an alarm.

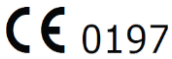
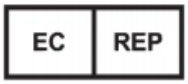
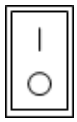


10. GLOSSARY OF SYMBOLS

	Follow instructions for use
MD	Medical Device
	Manufacturer information: Novocure GmbH, Neuhofstrasse 21, 6340 Baar, Switzerland
#	Model number
REF	Part Number
SN	Serial number
LOT	Lot Number
UDI	Unique Device Identifier Indicates a device carries Unique Device Identifying information.
	Manufacture date
 YYYY-MM	Use-by date/Expiry date

	Caution Consult the instructions for use for important cautionary information such as warnings and precautions
	Waste Electrical and Electronic Equipment recycling “WEEEE disposal” Contact technical support to arrange for proper disposal of transducer arrays that are used up or no longer in use.
	Batteries are Lithium Ion. Contact technical support to arrange for proper disposal of batteries that are used up or no longer in use
	Do not re-use: The ITE Transducer Arrays are for single use and should not be re-used.
	Indicates that the packaged products are sterile, the products have been sterilized by irradiation and the packaging is a single sterile barrier system
	Sterile/sterilization method The ITE Transducer Arrays are sterilized by Gamma irradiation
	Do not re-sterilize
	Do not use if package is damaged Do not use the ITE Transducer Arrays if their packaging is breached.
	Protect from heat and radioactive sources The Optune Lua device, additional parts and ITE Transducer Arrays should be kept away from extreme heat and sources of radiation

IPxx	IP code: A coding system to indicate the degrees of protection provided by an enclosure against access to hazardous parts or water. **IP21:** The power supply protects persons 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 and against ingress of vertical falling water drops. **IP22:** The device protects persons 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 and against ingress of vertical falling water drops when enclosure is tilted up to 15°.
	Keep dry. Do not enter rooms with high humidity or danger of direct exposure to water while wearing the device. Do not use the device if not within its carrying bag. Do not expose the device to direct rain.
	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
	Storage Temperature range Do not expose to temperatures below -5°C or above 40°C – device and additional parts. Do not expose to temperatures below 5°C or above 27°C – transducer arrays.
	Storage humidity range. Do not expose to humidity below 15% or above 93% - device and additional parts. Do not expose to humidity below 10% or above 90% - transducer arrays.

	Fragile, handle with care
	P1 P2 N1 N2 black and white coding on the connection box
	CE Mark with Notified Body Number
	European authorized representative MDSS GmbH Schiffgraben 41 30175 Hannover, Germany
	Importer details: Novocure Netherlands B.V., Prins Hendriklaan 26, 1075 BD, Amsterdam, The Netherlands
	Power ON / OFF switch for the device and battery charger: When the switch is in the I position the device is ON and will light up green. When the switch is in the O position the device is OFF
	MR UNSAFE

11. ENVIRONMENTAL CONDITIONS FOR OPERATION, STORAGE AND TRANSPORTATION

Conditions for operation

All treatment kit components shall be normally used under conditions specified below:

- Mainly 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 the floor with no safety hazard, but is no longer expected to function.

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 treatment kit components:

- Temperature range: -5oC to +40oC – 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

Conditions for storage

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

Conditions for transport

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

- Temperature range: -5oC to +40oC
- 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 Lua device and all components of the treatment kit is 5 years.

The expected service life of the ITE Transducer Arrays is 12 months. The ITE Transducer Arrays have an expiration date. Please do not use the transducer arrays after the expiration date.

13. DISPOSAL

Please contact Novocure to arrange for proper disposal of used transducer arrays and applicators.

Do not throw them in the trash.

Novocure contacts local authorities for the determination of proper disposal method for potentially biohazardous parts.

14. TROUBLESHOOTING

Problem	Possible causes	Actions to be taken
Device POWER indicator does not light up after turning ON the device	1. Device not connected to power source 2. Battery depleted 3. Battery malfunction 4. If power supply – not properly plugged into the wall 5. Device malfunction 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 2. Verify both the device and the power source are properly connected and re-try 3. Evaluate the integrity of all connectors. Nothing should appear to be damaged or broken in any way 4. If device cannot be powered on by either the battery or the wall power supply or if anything appears to be damaged do not use the device 5. Call technical support
Any cable detached from transducer array/ connection cable/ device	1. Too much physical force to cables 2. Device malfunction	1. Silence the notification signal by pressing the TTFields button 2. Evaluate the connectors. If intact – reconnect and re-start therapy 3. If anything appears damaged or cannot be properly connected do not try to use the device 4. Call technical support
Device dropped or wet	Incorrect use	1. Press TTFields button to stop therapy 2. Turn OFF power switch 3. Disconnect from power 4. Call technical support
Device alarm on, and low BATTERY indicator is yellow	1. Low battery 2. Device is turned ON, but the therapy has not been activated	1. Replace battery as described above in Section 9.8 2. Turn ON treatment 3. Press the TTFields button to stop the alarm 4. Wait a few seconds then press the TTFields button again 5. If the blue lights around the TTFields button light up – the therapy has now been activated

Problem	Possible causes	Actions to be taken
		If the notification signal recurs within a few minutes: 1. Silence the notification signal and power the device down completely 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 device back 3. Re-connect all equipment in proper order and power the device back up. Verify the self-check is completed and press the TTFields button 4. Check vents on device to make sure they are not blocked 5. If lying down, get up and move your body 6. Make sure transducer arrays are well stuck to the body, add tape if needed 7. Restart treatment 8. If alarm keeps going, turn OFF the device and call technical support
Device 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 device will sound if it is powered on for about 10 minutes, but therapy is not initiated. This is a reminder to start therapy and does not indicate a malfunction. 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 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 2. Battery malfunction 3. Device malfunction	1. Replace battery with an additional charged battery 2. If problem is not fixed – call technical support

Problem	Possible causes	Actions to be taken
When powering on the device a continuous notification alarm sounds and all lights remain on indefinitely. Device does not complete the self-check.	1. Device is too hot 2. Device malfunction 3. Power Source Malfunction	1. Power the device off completely using the power switch 2. Verify the device is not hot to the touch 3. Connect the device to a different power source and try powering on again 4. If device cannot be powered on by either the battery or the wall power supply or if anything appears to be damaged, please contact technical support
Managing side effects		
Redness of the skin beneath the transducer arrays	Common side effect	1. Use steroid cream prescribed by your doctor when replacing transducer arrays. 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). If the redness gets worse: 1. See your treating doctor
Blisters beneath the transducer arrays	Common side effect	See your treating doctor
Itching beneath the transducer arrays	Common side effect.	1. Use steroid cream prescribed by your doctor when replacing transducer arrays. 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). If the itching gets worse: 1. See your treating doctor
Pain beneath the transducer arrays	Common side effect.	1. Stop treatment 2. See your treating doctor
Tingling “electric” sensation or uncomfortable heat under arrays	Uncommon side effect that could be caused by poor contact with skin	1. Ensure arrays are in contact with skin 2. Ensure array cables are securely connected to CAD and CAD is securely connected to the generator. 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 Lua 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 Lua

The treatment kit's 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 Lua device and transducer arrays will activate metal detectors.

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

16. GLOSSARY

Cancer – abnormal cell division that spreads without control

Chemotherapy – medication used to destroy cancer cells

Clinical trial – a research study that involves people

Contraindications – situations when a treatment should not be used

EKG – Electrocardiogram

EN 60601-1 - Harmonized standards series for safety of medical devices

Electric Field Generator (the device) – a portable device for delivering TTFields to the lungs of patients with NSCLC.

ITE – Insulated Lung Transducer Arrays

Local – in one part of the body

Metastatic – when cancer has spread to a different part of your body than where it started

NSCLC – Non small cell lung cancer

Optune Lua – NovoCure's Tumor Treatment Fields Device for the treatment of NSCLC

Optune Lua treatment kit – treatment kit containing the Optune Lua device ; Connection cable ; power supply ; battery ; charger ; ITE Transducer Arrays.

Platinum-based Regimen –a treatment program using chemotherapies that contain platinum

Progression – when cancer comes back after being treated

Radiation – a treatment involving x-rays used to kill tumor cells

Steroids – When used on the skin, a medication that can reduce inflammation

Systemic – throughout the body

Topical – on the surface of the skin

Transducer array – adhesive bandages placed on the skin that hold insulated ceramic discs that deliver TTFields to the chest

TTFields – Tumor Treating Fields: Alternating electric fields, delivered using Optune Lua to the part of the body with a solid tumor. These electric fields have been shown to destroy tumor cells

Tumor – an abnormal growth of tissue

17. APPLICABLE STANDARDS

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

- EN 60601-1Medical 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 Lua treatment kit 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 Optune Lua 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 Lua (Li-Ion Rechargeable)

OUTPUT 28.8V ⎓ 86Wh

Charger for Optune Lua battery

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

Power Supply for Optune Lua

INPUT 100-240V ~ 1.1A 50/60Hz OUTPUT 28 V ⎓ 4A

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19. EMITTED RADIATION & ELECTROMAGNETIC COMPATIBILITY

The Optune Lua device and the accompanying battery charger (ICH9100) and power supply (SPS9200) need special precautions regarding EMC and need to be installed and put into service according to the EMC information provided below.

Portable and mobile RF communications equipment can affect the Optune Lua treatment kit and the accompanying battery charger.

The Optune Lua device (TFT9200) should be used with the following cables and additional parts only:

1 Connection cable (CAD9100)
2 ITE Transducer Arrays (ITE1013B; ITE1020B; ITE1013W; 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 use of accessories, parts and cables other than those specified may result in increased EMISSIONS or decreased IMMUNITY of the Optune Lua.

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 Lua treatment kit is intended for use in the electromagnetic environment specified below. The customer or the user of the Optune Lua should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The Optune Lua treatment kit 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	The Optune Lua treatment kit 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 assure 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 Lua treatment kit, 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 – ELECTROMAGNETIC IMMUNITY – for all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacturer's declaration – electromagnetic immunity			
The Optune Lua treatment kit is intended for use in the electromagnetic environment specified below. The customer or the user of the Optune Lua treatment kit 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, ± 2 kV, ± 4 kV, ±8 kV, ± 15 kV air	±8 kV contact, ± 2 kV, ± 4 kV, ±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 ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0,5 kV, ±1 kV line to line ± 0,5 kV, ± 1 kV, ±2 kV line to ground	± 0,5 kV, ±1 kV line to line ± 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 IEC 61000-4-11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 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 assure that they are 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 ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 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 ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0,5 kV, ± 1 kV line to line ± 0,5 kV, ± 1 kV, ± 2 kV line to ground	± 0,5 kV, ± 1 kV line to line ± 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 IEC 61000-4-11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles h) Single phase: at 0° 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 – ELECTROMAGNETIC IMMUNITY – for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration – electromagnetic immunity			
The Optune Lua treatment kit is intended for use in the electromagnetic environment specified below. The customer or the user of the Optune Lua treatment kit should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz (table 8.5.1) 10 V/m	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz 10 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the Optune Lua treatment kit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \frac{6}{E}\sqrt{P}$ 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. 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. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated fields in close proximity Standard IEC 61000-4-39	8A/m 30kHz CW 65A/m 134.2kHz pulse modulated 2.1kHz 7.5A/m 13.56MHz pulse modulated 50kHz	5cm distance	
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 Lua treatment kit is used exceeds the applicable RF compliance level above, the Optune Lua 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 Lua 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 assure that they are used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz (table 8.5.1) 10 V/m	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz 10 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the 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. Recommended separation distance $d = \frac{6}{E}\sqrt{P}$ 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. Field strengths from fixed RF transmitters, as deter-mined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
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 ICH9100 charger and the SPS9200 power supply are used exceeds the applicable RF compliance level above, the ICH9100 charger and the SPS9200 power supply are 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 Optune Lua treatment kit is working properly when the blue LED surrounding the TTFields button are 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 on the Optune Lua device are lit 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 Optune Lua is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Optune Lua can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Optune Lua 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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