Optune Lua® for Non-Small Cell Lung Cancer (NSCLC) – Patient Information and Operation Manual

Caution: Federal law restricts this device to sale by or on the order of a physician

TABLE OF CONTENTS

1 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

Docetaxel - a type of chemotherapy used to treated lung cancer

Immunotherapy /Immune Checkpoint Inhibitors - a type of cancer treatment that helps your immune system fight cancer, such as atezolizumab, nivolumab and pembrolizumab for lung cancer

Local – in one part of the body

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

Non-small Cell Lung Cancer (NSCLC) – a type of lung cancer

Optune Lua, an electric field generator (the device) - a portable device for delivering TTFields to the lungs of patients with NSCLC

Optune Lua Treatment Kit – the electric field generator and other parts including batteries, charger, connection cable, power supply, and transducer arrays

PD-1/PD-L1 Inhibitor – a type of Immune Checkpoint Inhibitor used to treat cancer

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

Progression – when cancer continues growing 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

Topical – on the surface of the skin

Transducer Arrays – adhesive patches placed on the skin that deliver TTFields to the chest (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.

Tumor – an abnormal growth of tissue

2 INTENDED USE

Optune Lua concurrent with PD-1/PD-L1 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.

3 CONTRAINDICATIONS, WARNINGS, PRECAUTIONS & NOTICES

Contraindications

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

Do not use Optune Lua 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 Lua 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 Lua 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 Lua without receiving this training can result in breaks in treatment and may rarely cause increased skin irritation, open sores on your chest 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.

Precautions

Caution - Do not use Optune Lua 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 Lua 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 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 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, and could damage the device.

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

Caution - Do not use Optune Lua 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 Lua 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 - Optune Lua 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 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 (see Section 26 of this patient information and operation manual) at all times. This guide is necessary to ensure Optune Lua 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 - 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 your chest again, it may not stick well to your skin and the device could 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.

4 SUMMARY OF EFFECTIVENESS OF OPTUNE LUA FOR NSCLC FROM THE LUNAR STUDY

The LUNAR study found that using Optune Lua together with cancer drugs (either a PD-1/PD-L1 Inhibitor or docetaxel) was more effective in treating metastatic NSCLC than using these cancer drugs alone. In the group who used Optune Lua with cancer drugs (regardless of which cancer drug they received), these patients lived more than 3 months longer, on average, than patients who were treated with cancer drugs alone.

When looking at the study results by type of cancer drug used with Optune Lua, the LUNAR study showed:

- Using Optune Lua with PD-1/PD-L1 Inhibitors was more effective in treating metastatic NSCLC than using PD-1/PD-L1 Inhibitors alone. The difference in this subgroup was statistically significant.
- Using Optune Lua with docetaxel was somewhat more effective compared to using docetaxel alone. However, the difference in this subgroup did not provide a statistically demonstrated benefit.

Sections 5, 6 and 7 of this manual provide more information about the risks and benefits of using Optune Lua for NSCLC.

Ask your doctor for more details about the LUNAR study.

5 WHAT ARE THE RISKS OF USING OPTUNE LUA?

Skin irritation is often seen under the transducer arrays when using Optune Lua. This will look like a red rash, small sores or blisters on your chest. In general, this will not cause skin irritation that cannot be healed.

The irritation can be treated with steroid cream or by moving the transducer arrays as described in this manual. If you do not use steroid cream, the skin irritation could become more serious. This may lead to open sores, infections, pain and blisters. If this happens, stop using the steroid cream and contact your doctor.

In a clinical study of Optune Lua together with certain chemotherapy and immunotherapy cancer drugs used to treat your kind of lung cancer, the device led to skin irritation in about 89 of 141 patients (63%). Most of these cases were not severe and were treated with topical creams. Only 6 patients (4%) had severe skin irritation.

The table below shows how often serious medical problems occurred in patients using Optune Lua together with cancer drugs compared to patients using cancer drugs alone in this clinical study. The only medical problem caused by Optune Lua was skin irritation. The rest of the medical problems were due to the cancer itself or the cancer drugs used with the device.

Medical Problem	Optune Lua with Cancer Drugs	Cancer Drugs
Infections	32 out of 141 subjects (23%)	23 out of 141 subjects (16%)
Breathing disorders	26 out of 141 subjects (18%)	23 out of 141 subjects (16%)
Blood and lymphatic system disorders	10 out of 141 subjects (7%)	9 out of 141 subjects (6%)
Gastrointestinal disorders	9 out of 141 subjects (6%)	6 out of 141 subjects (4%)
Nervous system disorders	8 out of 141 subjects (6%)	5 out of 141 subjects (4%)
Neoplasms benign, malignant, unspecified	7 out of 141 subjects (5%)	3 out of 141 subjects (2%)
Heart disorders	6 out of 141 subjects (4%)	4 out of 141 subjects (3%)
General disorders	6 out of 141 subjects (4%)	7 out of 141 subjects (5%)
Metabolism and nutrition disorders	5 out of 141 subjects (4%)	2 out of 141 subjects (1%)
Injury, poisoning and procedural complications	3 out of 141 subjects (2%)	0 out of 141 subjects (0%)
Rash under arrays and other skin problems	2 out of 141 subjects (1%)	0 out of 141 subjects (0%)
Kidney disorders	1 out of 141 subjects (1%)	1 out of 141 subjects (1%)
Endocrine disorders	1 out of 141 subjects (1%)	0 out of 141 subjects (0%)
Vascular disorders	1 out of 141 subjects (1%)	0 out of 141 subjects (0%)
Hepatobiliary disorders	0 out of 141 subjects (0%)	2 out of 141 subjects (1%)
Muscle disorders	0 out of 141 subjects (0%)	2 out of 141 subjects (1%)

Below is a list of the potential adverse effects (i.e., complications) 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 skin burns
- 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

6 WHAT ARE THE BENEFITS OF USING OPTUNE LUA?

All patients in the clinical study who used Optune Lua used it together with cancer drugs (either a PD-1/PD-L1 Inhibitor, which is a specific type of immunotherapy or docetaxel). In the group of patients who used Optune Lua, about half (53%) lived for more than 12 months after their treatment started. In contrast, less than half (42%) of the patients treated with cancer drugs alone lived more than 12 months after their treatment started.

Patients in the clinical study who used Optune Lua together with cancer drugs (regardless of which cancer drug they received) lived about 3 months longer, on average, than patients who used cancer drugs alone.

Optune Lua + PD-1/PD-L1 Inhibitors

In the subgroup of patients who used Optune Lua with PD-1/PD-L1 Inhibitors, 61% lived for more than 12 months after their treatment started. In contrast, 46% of patients in the subgroup treated with PD-1/PD-L1 Inhibitors alone lived for more than 12 months after their treatment started. Patients in the clinical study who used Optune Lua with PD-1/PD-L1 Inhibitors lived about 8 months longer, on average, than patients who used PD-1/PD-L1 Inhibitors alone.

Optune Lua + Docetaxel

In the subgroup of patients who used Optune Lua with docetaxel, 46% lived for 12 months after their treatment started. In contrast, 39% of the patients in the subgroup treated with docetaxel alone lived for 12 months after their treatment started. Patients in the clinical study who used Optune Lua with docetaxel lived about 2 months longer, on average, than patients who used docetaxel alone.

7 WHAT STUDIES HAVE BEEN CONDUCTED WITH OPTUNE LUA?

A clinical study, referred to as the LUNAR study, was conducted to evaluate the use of Optune Lua to treat non-small cell lung cancer (NSCLC) in patients whose cancer continued to grow following treatment with platinum chemotherapies. The LUNAR study assessed the use of Optune Lua when used together with cancer drugs approved for metastatic NSCLC (either a type of immunotherapy called a PD-1/PD-L1 Inhibitor or docetaxel, a chemotherapy drug) compared to the use of standard cancer drugs alone. The study included 291 patients; half of the patients were treated with Optune Lua and cancer drugs, while the other half were treated with only cancer drugs.

The LUNAR study found that using Optune Lua together with cancer drugs (either a PD-1/PD-L1 Inhibitor or docetaxel) was more effective in treating metastatic NSCLC than using these cancer drugs alone. In the group who used Optune Lua with cancer drugs (regardless of which cancer drug they received), these patients lived more than 3 months longer, on average, than patients who were treated with cancer drugs alone.

When looking at the study results by type of cancer drug used with Optune Lua, the LUNAR study showed:

- Using Optune Lua with PD-1/PD-L1 Inhibitors was more effective in treating metastatic NSCLC than using PD-1/PD-L1 Inhibitors alone. The difference in this subgroup was statistically significant.
- Using Optune Lua with docetaxel was somewhat more effective compared to using docetaxel alone. However, the difference in this subgroup was not statistically significant.

In the LUNAR study, the use of Optune Lua together with cancer drugs did not lead to adverse interactions with the cancer drugs, and the frequency of severe medical problems was similar between the group treated with Optune Lua plus cancer drugs, and the group treated with cancer drugs only.

Use of Optune Lua led to mild or moderate skin reaction under the transducer arrays (red rash, small sores or blisters) in 89 of the 141 patients (63%). This was expected. None of these cases of skin irritation caused damage to the skin that could not be fixed. The reaction went away after being treated with steroid cream and shifting the placement of the transducer arrays. Six (6) out of the 141 patients had a severe skin issue that required a break from Optune Lua treatment. In all cases, the skin issue resolved after stopping treatment.

Ask your doctor for more details about the LUNAR study.

8 ABOUT Optune Lua

Optune Lua is a medical device prescribed by doctors. It is used to treat patients with non-small cell lung cancer (or "NSCLC") whose cancer continues to grow after treatment with chemotherapy, and who cannot be treated with surgery or radiation.

Your doctor has prescribed Optune Lua 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 Lua on your own, or you may need help from a doctor, family member, or other caregiver. Optune Lua should be used for at least 12 hours per day on average. Use Optune Lua 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 Lua treatment kit includes the electric field generator (the device), connection cable, power supply, batteries, battery charger and ITE transducer arrays.

The Optune Lua device produces TTFields that exert physical forces to kill cancer cells. The transducer arrays are placed on the chest, and connect to the device to deliver TTFields therapy to your chest. TTFields therapy has been shown to kill tumor cells.

The electric field generator can be carried in a bag provided by Novocure.

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 the front and back of your chest according to the layout provided by your physician, 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. Reference Section 28 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 Lua 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 Lua 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 26). You can also call the 24-hour technical support telephone number (Section 28).

You will need to change the transducer arrays at least two times per week (every 4 days at most). To do so, you will need to stop treatment (i.e., turn the device OFF) to remove the arrays from your chest 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.

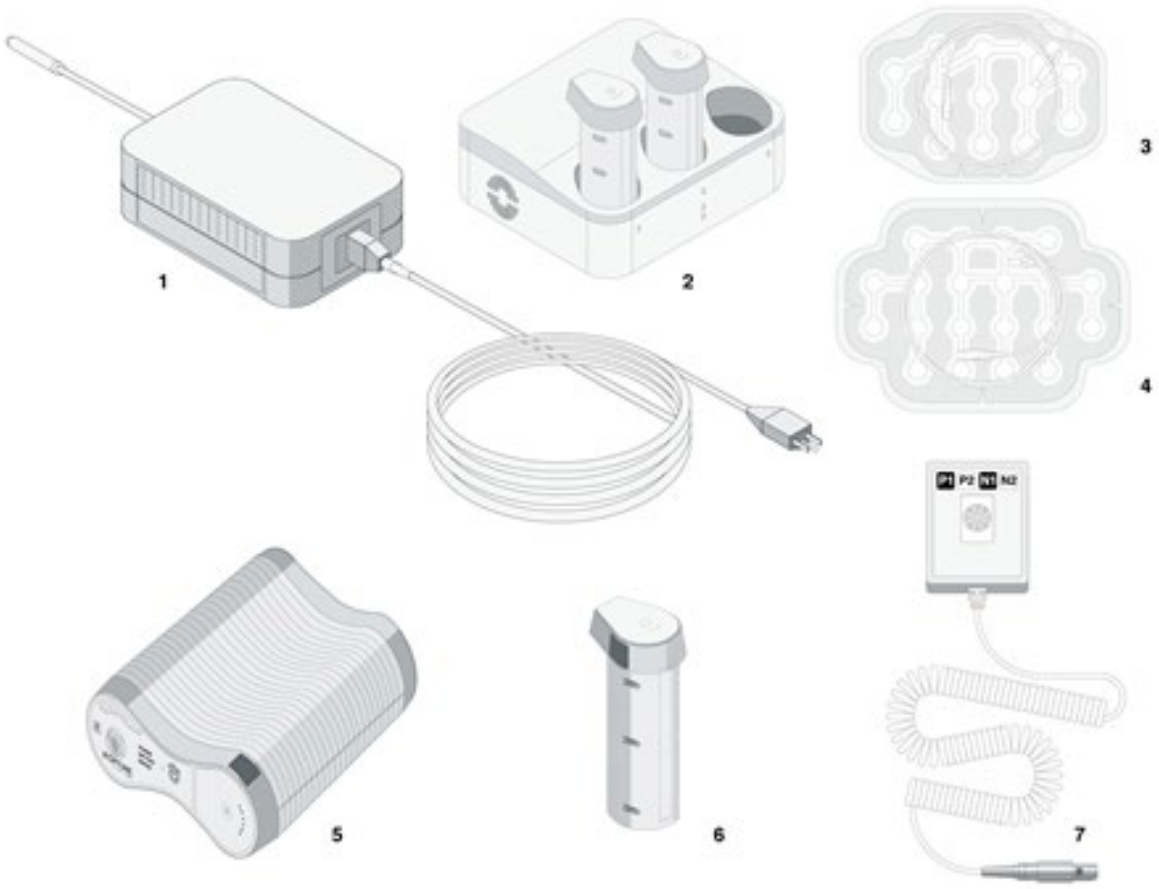
There are 2 ways to clean your upper body:

- A sponge bath with your arrays still 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 upper body to prevent them from getting wet. Leave the device outside the bathroom while taking a sponge bath.

- A full shower with your arrays completely removed:

Unplug the arrays from the device. Take a shower once your arrays have been unplugged and completely removed from your body. Leave the device outside the bathroom while taking a shower.



1.	Power Supply	(SPS9200)
2.	Battery Charger	(ICH9100)
3.	ITE Transducer Arrays - Small	(ITE1013B, ITE1013W)
4.	ITE Transducer Arrays - Large	(ITE1020B, ITE1020W)
5.	Optune Lua™ Electric Field Generator (the device)	(TFT9200)
6.	Battery	(IBH9200)
7.	Connection Cable	(CAD9100)

9 THE OPTUNE LUA DEVICE

- Optune Lua 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

10 THE ITE TRANSDUCER ARRAYS

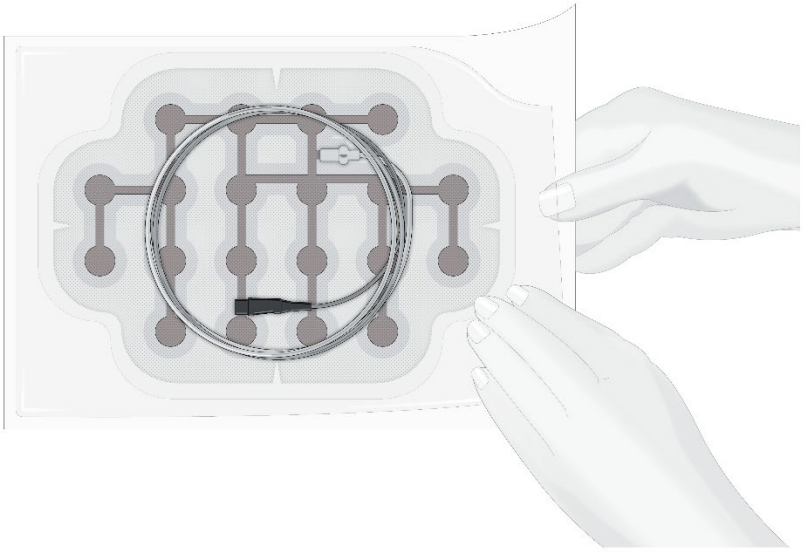
- Transducer arrays are adhesive patches placed on the chest to deliver TTFields to the lungs.
- Transducer arrays are supplied sterile and are to be used with Optune Lua only.
- The transducer arrays are available in two sizes – small and large – to accommodate different body sizes. A medical professional will decide which size is right for you.
- Transducer arrays are provided with either a white connector end or a black connector end.
- 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 will show you 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.

11 BEFORE YOU BEGIN

- You will need to use four (4) transducer arrays to start treatment and 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 your next visit to your doctor.

12 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.



13 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 your skin dry 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 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 (corticosteroid or antibiotic cream/solution) 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.

14 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.

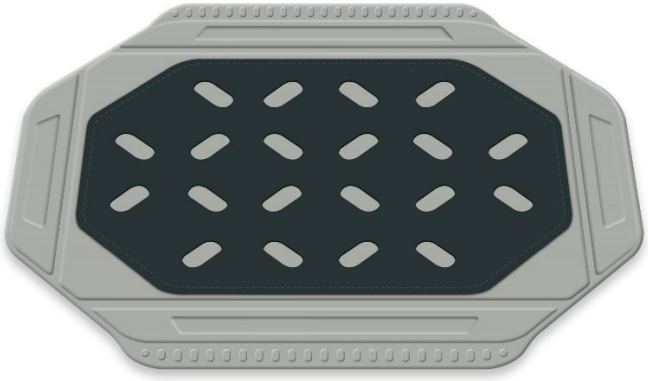
Placement:

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.
3. Place the transducer array on your chest in the same location as before but shifting the transducer array 2 cm (3/4 inch) to avoid areas of skin irritation.
4. Press the entire edge of the transducer array 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 transducer array(s) on your back.

15 ITE TRANSDUCER ARRAY LINER REMOVAL AND APPLICATOR USE

Support mats, called applicators, are provided to assist in the handling of the ITE transducer arrays. Use this, if needed according to the following instructions:

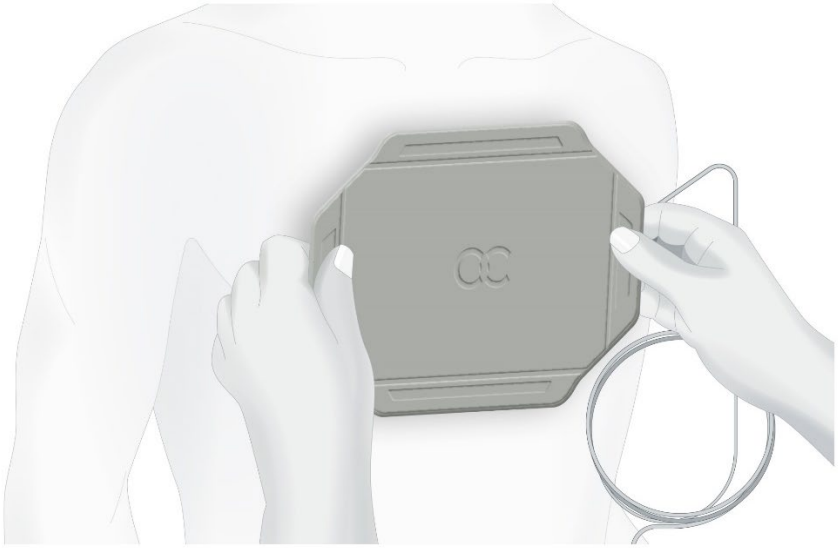
1. Select the applicator size according to the size of the transducer array you are using. Place the applicator on a hard surface with the black patch facing upwards.



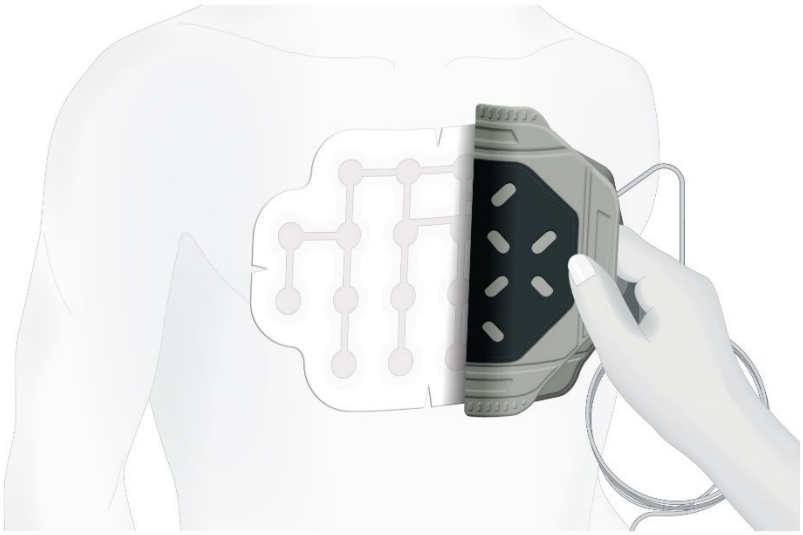
2. After removing the transducer array from its bag, place it on the applicator with the removable liner facing up. Apply medium pressure on the transducer array so it attaches to the black patch.

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.

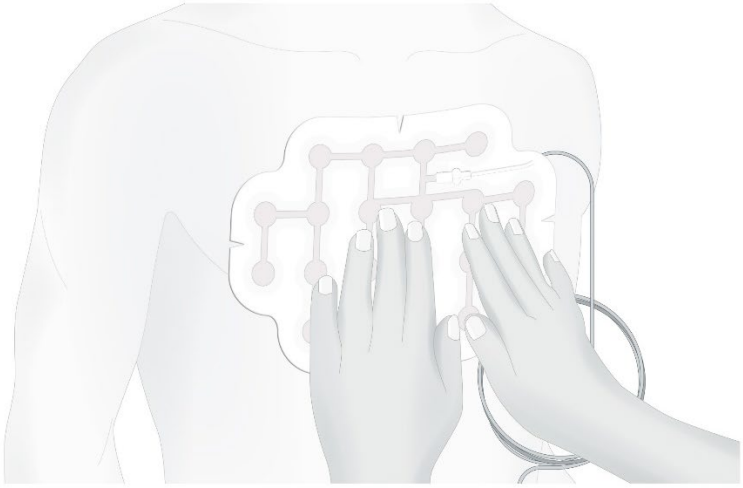
4. Using the applicator, place the transducer array on the skin according to the layout provided to you and by following the instructions in Section 14. Apply pressure on the applicator. Make sure that the transducers and the edges of the transducer array tape adhere well to the skin.



5. Gently remove the applicator.

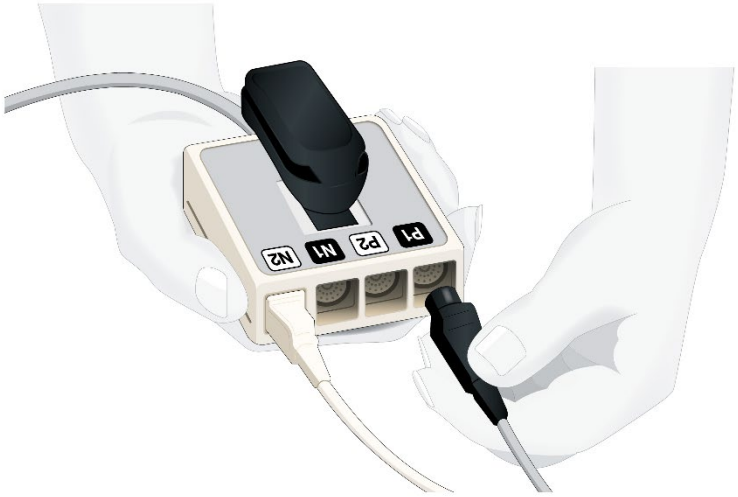


6. Apply pressure again on the transducer array to secure full contact to the skin.



16 CONNECTING THE TRANSDUCER ARRAYS TO THE 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.



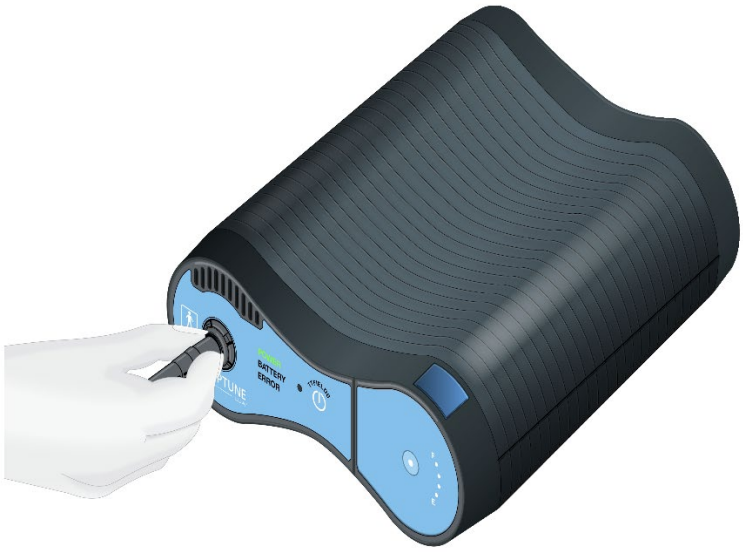
17 THE CONNECTION CABLE

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 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.



18 STARTING AND 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 16 and 17).
2. Plug the connection cable into the device, aligning the connector arrow with the socket arrow (Section 17).
3. Connect a power source - either a charged battery (Section 19) or a wall power supply (Section 21) 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.

If a charged battery is installed (and the generator is not connected to a wall power supply), the "BATTERY" indicator will also illuminate green. If the generator 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 26). If you still have problems, contact Novocure technical support (Section 28).

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 generator 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 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).

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

C. If 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 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 19).

19 CONNECTING AND DISCONNECTING THE BATTERY

Optune Lua 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 20) 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 hurt 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 28) 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 therapy 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 therapy 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 a direct wall power supply, you can 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 21). Therapy continues while the device indicator indicates that it is no longer operated by battery power.
2. Push the two blue buttons on both battery sides and remove it by sliding outside from the device.
3. Charge the removed battery (Section 20).
4. Continue the therapy using the wall power supply.

B. Option Two:

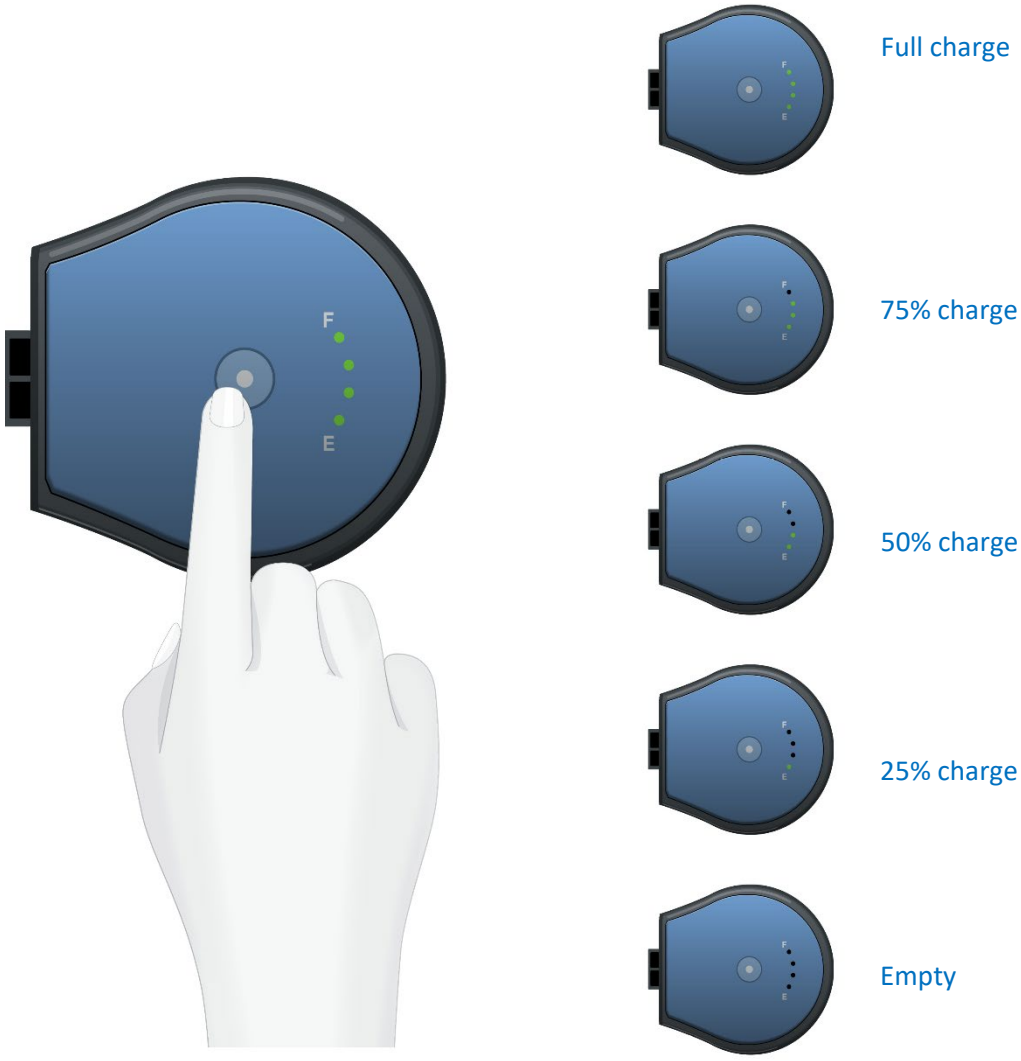
If you are not near a wall power supply, follow the instructions to replace the battery: NOTE: If the battery is totally depleted, start from step 2

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 with the self-check.
9. Start therapy by pressing the TTFields button (Section 18).
10. Insert the used battery into the battery charger for recharging (Section 20).

Checking the Battery Gauge

While you are using Optune Lua, 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.



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 substances.

21 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 28).

When the device has a battery in, and is also connected to the plug-in power supply, it will utilize the plug-in 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 plug-in power supply.

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

If 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 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 18).

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 18), 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.

22 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 16). 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 Lua 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:

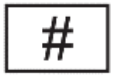
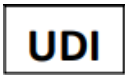
1. Plug the four transducer arrays into its matching color (black or white) in the connection box.
2. Turn ON the device by using the power switch and wait about 10 seconds until the device completes with the self-check.
3. Activate TTFields by pressing the TTFields button.

23 CARRYING THE DEVICE

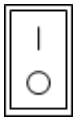
The device with battery fit into the provided bag.

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.

24 GLOSSARY OF GRAPHIC SYMBOLS

	Follow instructions for use
	Manufacturer information: Novocure GmbH, Business Village D4, Park 6/Platz 10, 6039 Root, Switzerland
	Model number
	Catalogue number
	Serial number
	Batch code
	Unique Device Identifier 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 for waste electric and electronic equipment is required.
	Batteries are Lithium Ion. Contact technical support to arrange for proper disposal of batteries that are used up or no longer in use.
	Fragile – handle with care
	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 resterilize
	Do not use the ITE transducer arrays if their packaging is breached.
	The Optune Lua (electric field generator, additional parts and transducer arrays) should be kept away from extreme heat and sources of radiation
IP21	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. Protects the equipment inside the enclosure against ingress of vertical falling water drops.
IP22	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. 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. Do not use the device if not within its carrying bag. 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 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.

	Do not expose to temperatures below 23°F or above 104°F (-5°C or above 40°C) – Generators Do not expose to temperatures below 41°F or above 81°F (5°C or above 27°C) - Arrays
	Do not expose to humidity below 15% or above 93% - Device Do not expose to humidity below 10% or above 90% - Transducer Arrays
	MR UNSAFE
	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
Rx only	Prescription device

25 ENVIRONMENTAL CONDITIONS FOR OPERATION, STORAGE AND TRANSPORTATION

Conditions for operation

All components of Optune Lua 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: 23°F to 104°F (-5°C to +40°C) - device and additional parts
- Temperature range: 41°F to 80°F (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: 23°F to 104°F (-5°C to +40°C) for the device and additional parts
- Temperature range: 41°F to 80°F (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: 23°F to 104°F (-5°C to +40°C)
- Maximal relative humidity 15-93%
- No direct exposure to water

Expected Service 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 9 months.

- Transducer arrays have an expiration date. Please do not use the arrays after the expiration date.

26 TROUBLESHOOTING

When contacting your device support specialist or My Novocure, please have the serial number of the equipment accessible

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 2. Battery depleted 3. Battery malfunction 4. If power supply – not properly plugged into the wall 5. Generator 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 generator 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 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 5. Call technical support at 855.281.9301
Any cable detached from transducer array/ connection cable/ generator	1. Too much physical force to cables 2. Generator 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 generator 4. Call technical support at 855.281.9301
Generator 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 at 855.281.9301
Generator alarm on and low BATTERY indicator is yellow	1. Low battery 2. Generator is turned ON, but the therapy has not been activated	1. Replace batteryas described above in Section 19 2. Turn ON treatment 3. Press the TTFields button to stop the alarm 4. Wait a few seconds then press the TTFields button again 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 generator 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 generator back 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 4. Check vents on generator 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 generator and call technical support at 855.281.9301
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. 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.

Problem	Possible causes	Actions to be taken
Low BATTERY indicator remains on after battery replaced	1. Charger malfunction 2. Battery malfunction Generator malfunction	1. Replace battery with an additional charged battery If problem is not fixed – call technical support at 855.281.9301
When powering on the generator a continuous notification alarm sounds and all lights remain on indefinitely. Generator does not complete the self-check.	1. Generator is too hot 2. Generator malfunction Power Source Malfunction	1. Power the generator off completely using the power switch 2. Verify the generator is not hot to the touch 3. Connect the generator to a different power source and try powering on again 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

27 MANAGING SIDE EFFECTS

Side Effect	Possible causes	Actions to be taken
Redness of the skin beneath the transducer arrays	Common side effect (Occurring in 1-3% of patients in incidences for device related adverse events in the LUNAR study)	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 (Occurring in 1-3% of patients in incidences for device related adverse events in the LUNAR study)	1. See your treating doctor
Itching beneath the transducer arrays	Common side effect (Occurring in 1-3% of patients in incidences for device related adverse events in the LUNAR study)	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 (Occurring in 1-3% of patients in incidences for device related adverse events in the LUNAR study)	1. Stop treatment 2. See your treating doctor
Tingling “electric” sensation or uncomfortable heat under arrays	Rare side effect that could be caused by poor contact with skin (Occurring in 0.1-<1% of patients in incidences for device related adverse events in the LUNAR study)	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.

28 ASSISTANCE AND INFORMATION

Technical support:

For technical support call My Novocure at 1-855-281-9301 (toll free) or email support@mynovocure.com.

Call or email technical support for help with operation of the system, troubleshooting alarms, or to get replacement parts or transducer arrays.

Clinical support:

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

Traveling with Optune Lua

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 My Novocure Support if you have questions related to travel .

Note: Optune Lua generator and transducer arrays will activate metal detectors.

Contact your Device Support Specialist if you plan to travel and if you have questions related to travel restrictions. His/ her contact information will be supplied to you separately.

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 be used with the Optune Lua treatment kit.

29 DISPOSAL

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

30 ABOUT NON-SMALL CELL LUNG CANCER (NSCLC)

What is Metastatic Non-Small Cell Lung Cancer (NSCLC)?

In simple terms, lung cancer is a growth of cells that form a tumor in the lungs. Lung cancer often starts in the cells that line the airways. Metastatic lung cancer is a type of lung cancer that has spread far from the main lung cancer. Common body parts which the cancer tend to spread to are: brain, liver, bone, adrenal glands, and spread from one lung to the other lung. Symptoms of metastatic lung cancer depends on where the cancer is, and may include: problems breathing, coughing, chest pain, pain in bone and spine and other problems.

About 230,000 patients in the U.S. are diagnosed with lung cancer every year. More than half of them have metastatic NSCLC. Cigarette smoking is the major cause of lung cancer. NSCLC is a very serious disease.

Can Metastatic Non-Small Cell Lung Cancer (NSCLC) Be Treated?

There are currently four main options to treat metastatic NSCLC:

Targeted therapy – some patients positive for driver mutation supporting tumor growth can be treated with targeted therapy.
Immunotherapy – some patients positive for protein that prevent or slow down the immune response can be treated with immunotherapy.
Chemotherapy – most patients take cancer chemotherapy drugs alone or together with immunotherapy. Docetaxel is commonly used to treatment patients with recurrent disease.

Optune Lua – together with immunotherapy or docetaxel.

Targeted therapy, immunotherapy and chemotherapy (together or separately) can help people with metastatic NSCLC live longer than if they had no treatment. Patients with recurrent disease may be treated again with the same treatment type or be treated with different therapy. Adding Optune Lua to immunotherapy or docetaxel may help people with recurrent metastatic NSCLC to live longer than with immunotherapy or docetaxel alone. Targeted therapy, immunotherapy, and chemotherapy have side effects. These side effects include pain, hair loss, rash, itching, blisters, nausea, vomiting, tears in the digestive tract, immune cells attack of healthy cells, loss of appetite, effects related to breathing, and tiredness. Optune Lua leads to skin related problems under the transducer arrays in many people.

31 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 N/A

32 INPUT OUTPUT SPECIFICATIONS

The Optune Lua treatment kit including the battery charger are 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 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

33 EMITTED RADIATION AND ELECTROMAGNETIC DISTURBANCES

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 generator and the accompanying battery charger.

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

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 Lua Treatment Kit is used to deliver intermediate-frequency electric fields to the patient's torso 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 Lua device (model NovoTTF-200T) 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 Lua 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 Lua treatment kit requires special precautions regarding electromagnetic disturbances and must be installed and used according to the environmental conditions specified in Section 25, 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 Lua.

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 Lua 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 Lua Treatment Kit or to metallic objects in proximity to the Optune Lua 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 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	Optune Lua 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 Lua 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 generator, 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			
Optune Lua is intended for use in the electromagnetic environment specified below. The customer or the user of Optune Lua 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			
Optune Lua is intended for use in the electromagnetic environment specified below. The customer or the user of Optune Lua 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 NovoTTF- 200T, 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: 
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 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: 
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 generator 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 is 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 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.							

Manufacturer information:
Novocure GmbH, Business Village D4, Park 6/Platz 10, 6039 Root, Switzerland