Optune Lua™ for Unresectable Malignant Pleural Mesothelioma - Patient Information and Operation Manual

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

Humanitarian Device. Authorized by Federal Law for use in adult patients with unresectable, locally advanced or metastatic, malignant pleural mesothelioma (MPM) concurrently with pemetrexed and platinum-based chemotherapy.

The effectiveness of this device for this use has not been demonstrated.

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1 GLOSSARY

Cancer – abnormal cell division that spreads without control

Carboplatin – a type of cancer drug used to treat MPM

Chemotherapy – medication used to destroy cancer cells

Cisplatin – a type of cancer drug used to treat MPM

Clinical study – a research study that involves people

Contraindications – situations when a treatment should not be used

CT scan – a procedure that uses radiation to create pictures of areas inside the body

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

Local – in one part of the body

Malignant Pleural Mesothelioma (MPM) – a type of cancer which affects the linings of the lungs

Optune Lua™ Treatment Kit – the Electric Field Generator and other parts including batteries, charger, connection cable, transducer arrays and power supply.

Pemetrexed – a type of cancer drug used to treat MPM

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 that hold insulated ceramic discs that deliver TTFields to the chest (full name: ITE transducer arrays)

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

Tumor – an abnormal growth of tissue

2 WHAT IS OPTUNE LUA AND HOW DOES IT WORK

Optune Lua is indicated for the treatment of adult patients with unresectable, locally advanced or metastatic, malignant mesothelioma (MPM) to be used concurrently with pemetrexed and platinum-based chemotherapy.

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

A doctor may prescribe Optune Lua to treat a patient with malignant pleural mesothelioma (called "MPM") which cannot be cured with surgery or radiation.

Optune Lua is used together with pemetrexed and cisplatin or carboplatin (types of cancer drugs).

Optune Lua is a portable device. It produces electric fields, called tumor treatment fields ("TTFields"). Transducer arrays connected to the device deliver TTFields to your chest. The TTFields are intended to destroy lung cancer cells.

The device and battery are carried in a shoulder bag. You should use them as much as you can.

In this manual, "Optune Lua Treatment Kit" refers to the Electric Field Generator (also called "the device"), connection cable, transducer arrays, power supply, battery, and battery charger.

3 CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS

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 qualified personnel, such as your doctor, a nurse, or other medical personnel who have completed a training course given by Novocure (the device manufacturer). Ask to see a certificate signed by Novocure that says they have completed the training course.

Your training will include a detailed review of the patient manual and practice in the use of the system. 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, allergic reactions or even an electric shock.

Warning - In case of skin irritation, which appears as redness under the transducer arrays (a mild rash), use high potency topical steroids (hydrocortisone cream) when replacing transducer arrays. This 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 break down, 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 servicing procedures must be performed by qualified and trained personnel. If you attempt to open and service the system alone you may cause damage to the system. 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 wet the device or transducer arrays. Getting the device wet may damage it, preventing you from receiving treatment for the right amount of time. 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 device 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.

Notices

Notice - The Optune Lua device 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 (Section 25) of the patient information and operation manual) at all times. This guide is necessary to ensure Optune Lua works properly. If you do not work the system 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 charger 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 device 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 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 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 damage that cannot be fixed.

The irritation can be treated with steroid cream or by moving the transducer arrays. 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 cancer drugs used to treat your kind of lung cancer, the device led to skin irritation in about two thirds of 80 patients (66%). Most of these cases were not severe and were treated with topical creams. Only a handful of patients (5%) had severe skin irritation.

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

Medical Problem	Optune Lua together with Cancer Drugs
Lower white and red blood cell counts	18 out of 80 subjects (23%)
General disorders	6 out of 80 subjects (8%)
Rash under device transducer arrays and other skin problems	4 out of 80 subjects (5%)
Breathing disorders	4 out of 80 subjects (5%)
Vomiting and Ulcer	3 out of 80 subjects (4%)
Heart disorders	3 out of 80 subjects (4%)
Infections	2 out of 80 subjects (3%)
Muscle disorders	1 out of 80 subjects (1%)
Kidney disorders	1 out of 80 subjects (1%)
Liver disorders	1 out of 80 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 plaster or to the gel
- Electrode overheating leading to pain and/or local skin burns
- Infection at the sites of electrode contact with the skin
- Local warmth and tingling sensation beneath the electrodes
- Medical device site reaction
- Muscle twitching
- Skin breakdown / skin ulcer

5 WHAT ARE THE BENEFITS OF USING OPTUNE LUA?

All patients in the clinical study used Optune Lua together with cancer drugs. Half of the patients using Optune Lua together with cancer drugs lived for more than 18.2 months after their treatment started. Also, 4 out of each 10 patients using Optune Lua together with cancer drugs were alive after two years (42%).

6 WHAT STUDIES HAVE BEEN CONDUCTED WITH OPTUNE LUA?

A clinical study, referred to as the STELLAR Study, was conducted to evaluate the use of Optune Lua in conjunction with cancer drugs to treat unresectable (unable to be removed via surgery) malignant pleural mesothelioma. The study included 80 subjects.

Half of the patients using lived for more than 18.2 months after their treatment started and half of the patients did not experience growth of their MPM for more than 7.6 months after their treatment started.

Local skin problems under the transducer arrays were seen in 57 of 80 patients in the study (red rash, small sores or blisters). This was expected. None of these cases of skin problems caused damage to the skin that could not be fixed. The irritation went away after being treated with steroid cream and moving the transducer arrays. Only 4 subjects had severe skin problems.

These problems led to stopping treatment in 3 subjects. In all cases, the rash went away after stopping treatment.

Ask your doctor for more details about the clinical studies of Optune Lua. For more information, visit our website: www.Optunelua.com

7 ABOUT OPTUNE LUA

Optune Lua is a portable medical device that delivers electric fields called “TTFields” to the chest using transducer arrays. TTFields are intended to kill cancer cells.

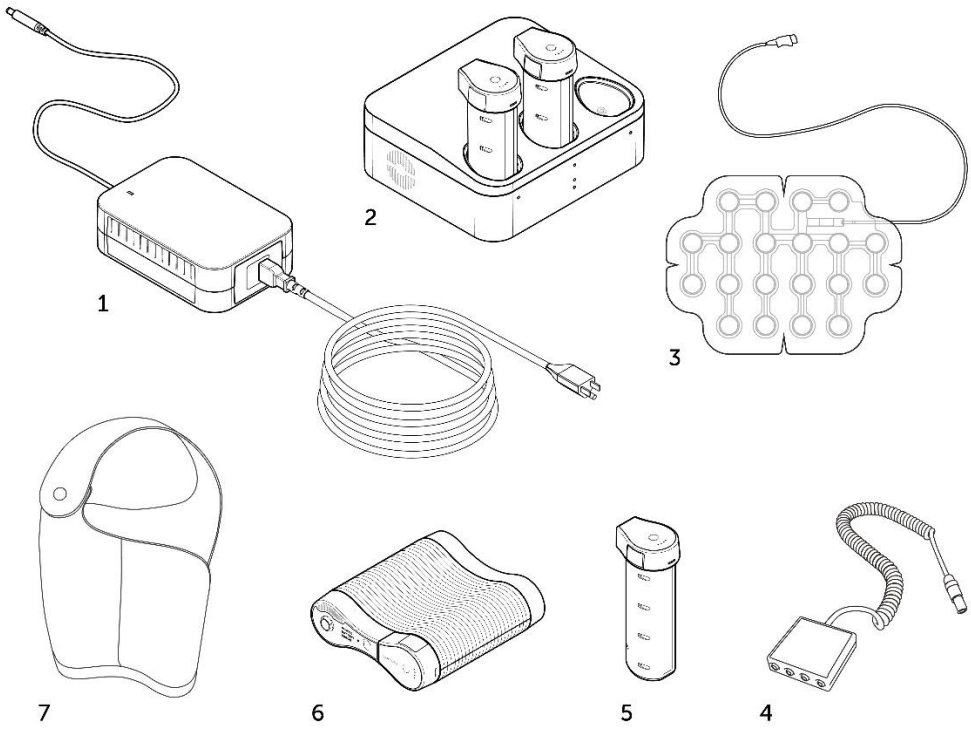
Your doctor has prescribed Optune Lua for use at home. You may be able to use Optune Lua on your own, or you may need help from a doctor, family member, or other caregiver. Use Optune Lua as many hours per day as possible. You can take short breaks for personal needs. When starting treatment, your doctor or a representative from Novocure will teach you how to use the device, replace transducer arrays, recharge and replace batteries, and plug in the device. Your Novocure representative will also teach you what to do if an alarm beeps and will give you a telephone number to call for technical support. After this short training, with the help of a family member or care provider if needed, you will be able to properly use Optune Lua. You will also be able to change the batteries, charge the batteries and replace the transducer arrays as needed.

The device can be carried when you are using a battery. You can continue your normal daily life while carrying the device in a shoulder bag. The Optune Lua Treatment Kit includes 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, plug the device 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 device has a power supply (a charged battery or is plugged into the wall) and turn it ON and OFF. If the device is not working, an alarm will beep. A Troubleshooting Guide is provided in this manual (Section 25). You can also call the 24-hour technical support telephone number (Section 26).

Change the transducer arrays at least twice a week. 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. You will need to stop treatment (turning the device OFF) to replace the transducer arrays. To take a shower, unplug the transducer arrays from the device (leave the transducer arrays on your chest) and wrap your chest with a waterproof wrapping so it does not get wet. You can take a full shower and wet your entire body when you are not wearing the transducer arrays (for example, when you have taken them off but before replacing them with a new pair).

Overview of the Optune Lua Treatment Kit

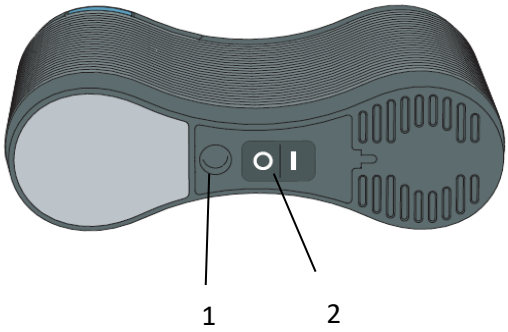


1. Power Supply (SPS9200)
2. Battery Charger (ICH9100)
3. ITE transducer array (Small: ITE1013, Large: ITE1020)
4. Connection Cable (CAD9100)
5. Battery (IBH9200)
6. Optune Lua™ electric field generator – the device (TFT9200)
7. Shoulder Bag and Strap

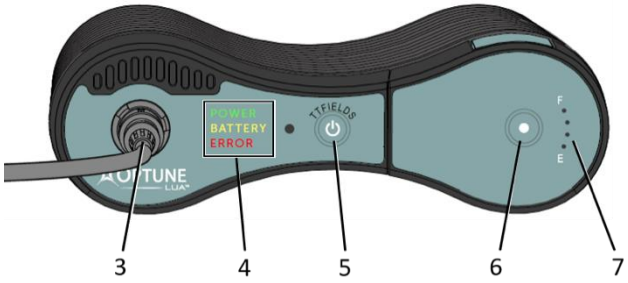
8 THE DEVICE

- Optune Lua is an automatic system.
- You will need to learn how to place it in a carrying bag, connect a battery and operate the system.
- 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

9 THE ITE TRANSDUCER ARRAYS

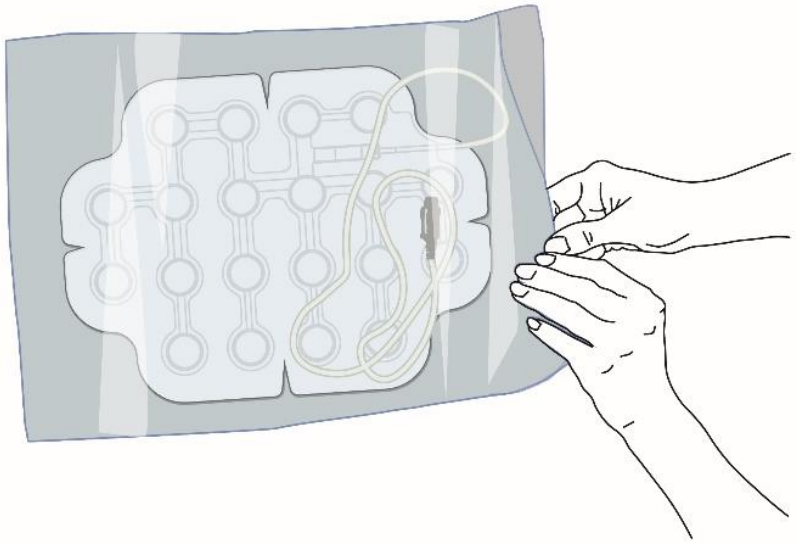
- An ITE transducer array is an adhesive patch which delivers Tumor Treating Fields to the chest.
- The ITE transducer arrays are supplied sterile and are to be used with Optune Lua only.
- ITE transducer arrays come in two sizes – small and large. You should use either large or small transducer arrays on the chest and upper abdomen, back and both sides of your thorax, depending on your body size.
- Your doctor will show you where to place each array on your chest.

10 BEFORE YOU BEGIN

- You will need four (4) ITE transducer arrays (Sterile) every 3-4 days in order to maintain treatment with Optune Lua.
- You will need to make sure you have the right sized transducer arrays for your body size.
- Make sure you have ample supply of ITE transducer arrays to keep you going until your next visit to your physician.

11 REMOVING THE ITE TRANSDUCER ARRAY FROM ITS PACKAGE

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



12 PREPARING YOUR SKIN FOR TRANSDUCER ARRAY PLACEMENT

1. Wash your skin on the chest abdomen back and flanks using a gentle soap.
2. Remove any remnant adhesive from your skin from prior transducer arrays by wiping with baby oil.
3. If you have any hair on your torso, shave your entire torso using an electric shaver. Make sure no stubble is left.
4. Wipe your skin with 70% Alcohol (medical grade – any manufacturer).
5. If the skin is red, apply the steroid cream prescribed to you by your physician.
6. If you have any sores on your skin treat them as instructed by your treating physician.
7. Wait at least 30 minutes and gently wipe your skin again with 70% Alcohol to facilitate adhesion of the transducer arrays to your skin.

13 PLACING THE TRANSDUCER ARRAYS

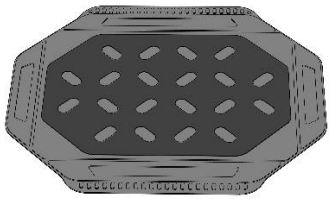
Once every 3-4 days (about twice a week) perform the following steps to replace your transducer arrays. Note, if this is the first time you use the ITE transducer arrays, ignore the first step (removal).

1. Remove the transducer arrays already applied to your skin by peeling the medical tape away from your skin.
2. 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.
3. Remove the transducer array liner from the first transducer array. If the transducer array is flexible and difficult to manage, use the applicator for assistance as instructed in section 14.
4. Place the transducer array on your chest in the same location as before but shifting the transducer array 2 cm to avoid areas of redness.
5. Place the other three transducer arrays in the same fashion.
6. You will need to ask for assistance from a friend or family member to place the back transducer array(s).
7. Press the entire edge of the transducer array tape to your skin.

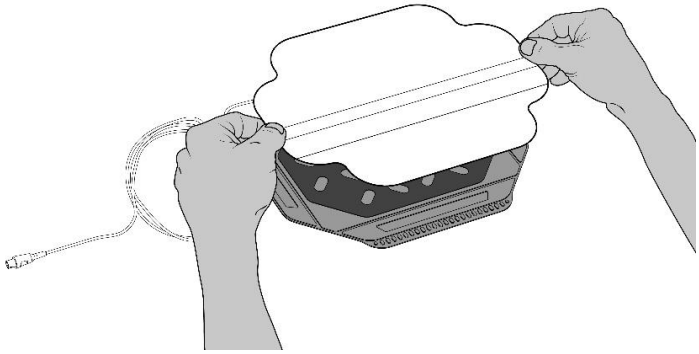
14 TRANSDUCER ARRAY LINER REMOVAL AND APPLICATOR USE

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:

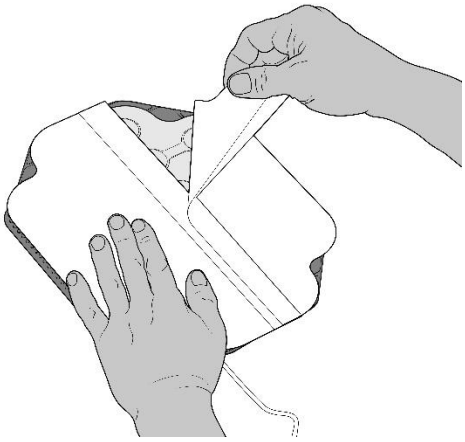
1. Select the applicator size according to the size of the transducer array you are using. Place the applicator on a hard surface with the black patch facing upwards.



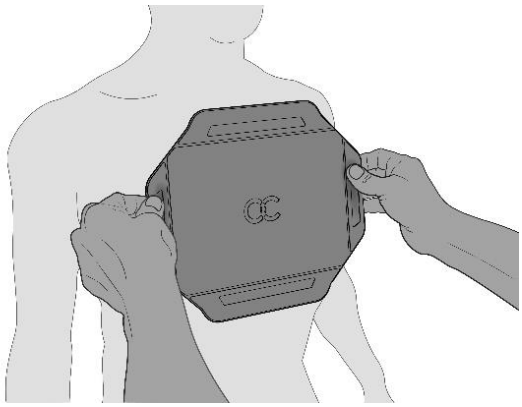
2. After removing the transducer array from its bag, place it on the applicator with the removable liner facing up. Apply medium pressure on the transducer array so it attaches to the black patch.



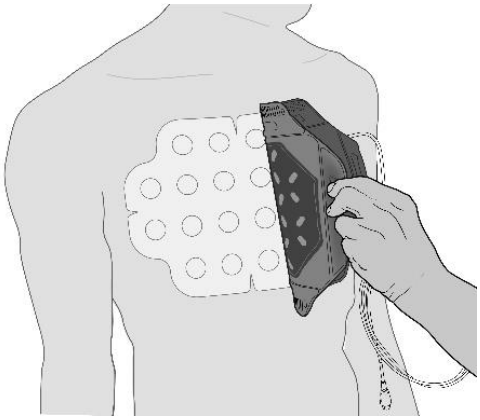
3. Start by removing the top liner. Slowly remove the liners by starting at the top corner in the middle of the array and carefully peel the liner downwards. Peel the liner parallel to the surface, from different directions if needed, to ensure the array remains flat and intact.



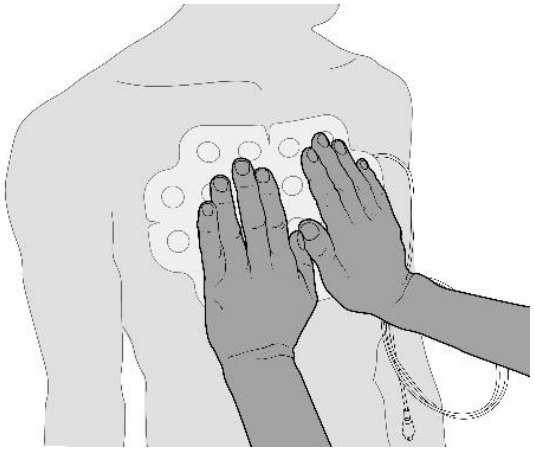
4. Using the applicator, place the transducer array on the skin according to the layout provided to you and by following the instructions in section 13. Apply pressure on the applicator. Make sure that the transducers and the edges of the transducer array tape adhere well to the skin.



5. Gently remove the applicator.

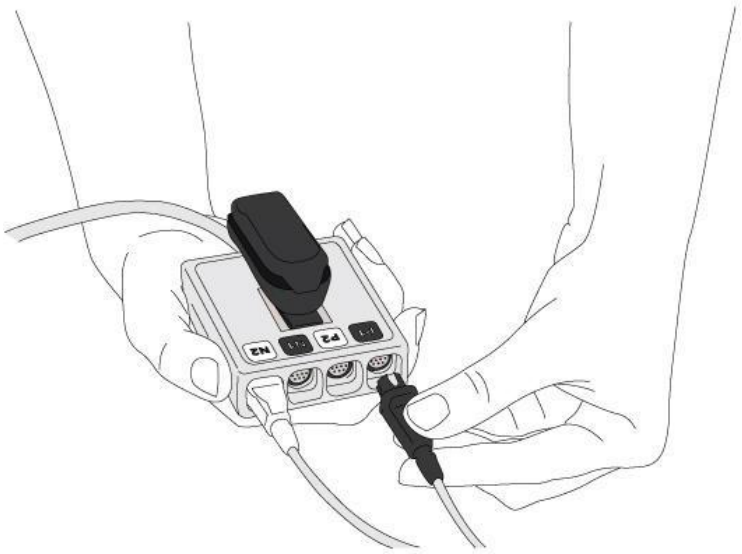


6. Apply pressure again on the transducer array to secure full contact to the skin.



15 CONNECTING THE TRANSDUCER ARRAYS TO THE DEVICE

1. Connect the four black and white transducer array connectors to the corresponding black and white coded sockets on the Optune Lua connection cable.
2. Press firmly to verify the connectors are inserted all the way.
3. Collect the transducer array wires together and bind with a small piece of tape where convenient.
4. You may clip the connection cable clip to your belt.



16 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.

Follow the instructions to connect to the device:

1. Verify that the arrow on the connection cable facing up and is aligned with the arrow on the connector socket of the device and plug in the connection cable.

2. Push in the connector until you hear a snap. It indicates that the connector is in its place.

17 STARTING AND STOPPING THE DEVICE

To start treatment:

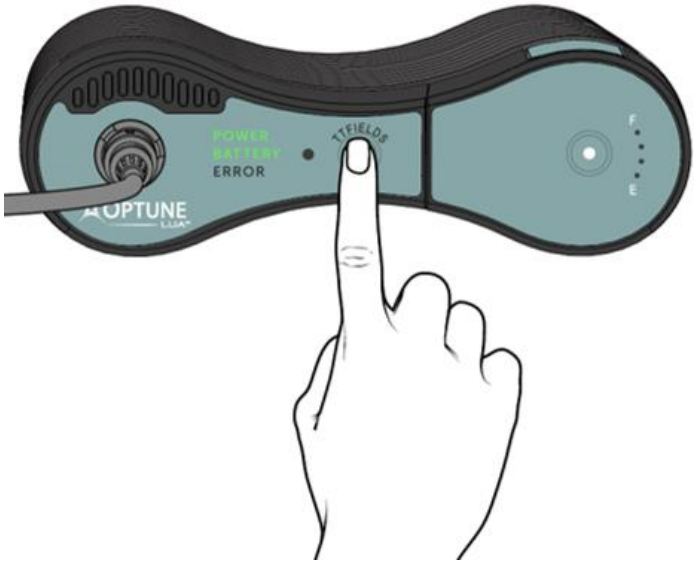
The transducer arrays should be attached to your body.

1. Plug the transducer arrays into the connection cable box (see Sections 15 and 16).
2. Plug the connection cable into the device, aligning connector arrow with socket arrow (see Section 16).
3. Connect a power source - either a charged battery (Section 18) or a power supply (Section 20) to the device.
4. Turn ON the device by using the power switch.

5. Wait about 10 seconds for the self-check to be completed, until the green “POWER” indicator illuminates.

NOTE: If a charged battery is installed (and no power supply is connected), the green "BATTERY" indicator illuminates. If the device is connected to the power supply, it will be operated from the power supply and the "BATTERY" indicator will turn off.

6. Activate TTFields by pressing the TTFields ON/OFF button.



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

NOTE:

If the blue indicator doesn’t illuminate, then the treatment is OFF and you should check the setup and restart the procedure. If, after this, the indicator lights do not light up, refer to the Troubleshooting Guide (Section 25). If you still have problems, contact Novocure technical support (Section 26).

The green, blue and yellow indicators automatically dim in a dark room. The red “ERROR” indicator illumination level is permanent.

If the TTFields button isn’t pressed within about 10 minutes after the device is turned ON, a notification signal alarm sounds along with a flashing blue ”TTFIELDS” indicator, indicating that the therapy is OFF. This is a reminder to start the therapy. The TTFields button should be pressed once to silence the alarm and again to start the therapy. The blue “TTFIELDS” indicator will then illuminate.

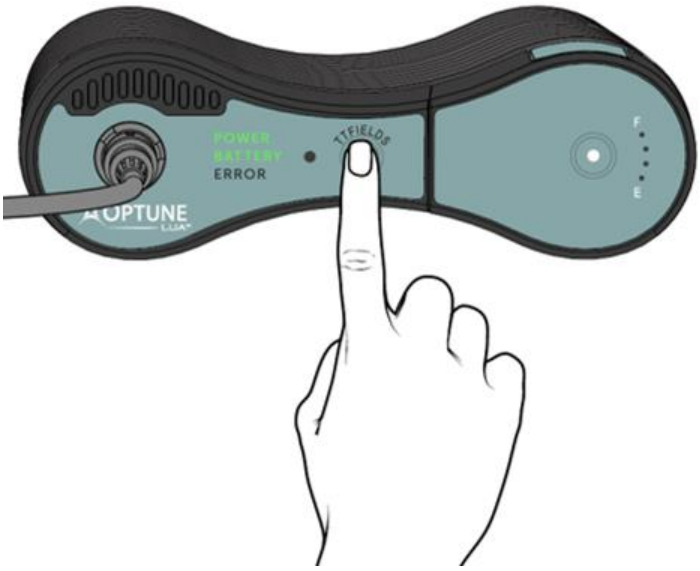
To stop treatment:

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

A. When the device is running properly, and you would need 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 treatment 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 treatment) 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 18).

18 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.

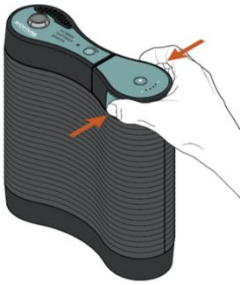
If you plan to be away from home for more than one hour, carry extra batteries.

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 19) 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 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 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 26) to get replacement batteries.

The battery light will turn from green to yellow when the battery charge falls below a threshold. This is an indication that the battery should be changed soon. The treatment will continue to run while the yellow low BATTERY indicator is illuminated until the audible alarm sounds and the red “ERROR” indicator illuminates. Once this happens the treatment will stop and the device must be turned off and the battery replaced.

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

A. Option one:

To be used if near the direct wall power supply, allows you to 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 back of the Optune Lua device (Section 20). Treatment continues while 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 device.
3. Charge the removed battery (Section 19).
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:

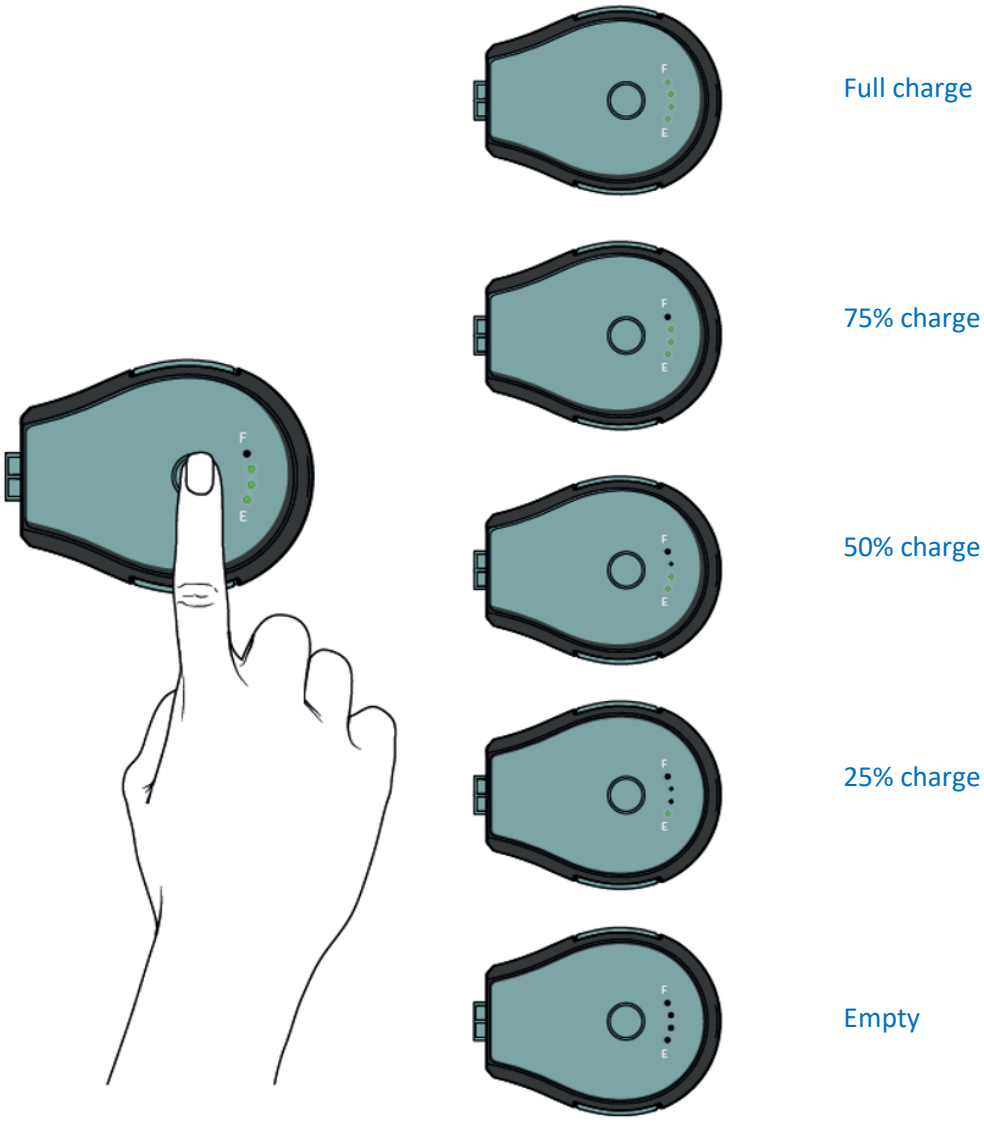
NOTE: If the battery is totally depleted, start from step 2

1. Press the TTFields button to stop the treatment.
2. Turn OFF the device by using the power switch (on the back side of the device).
3. Push the two blue buttons on both battery sides and remove it by sliding outside from 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 treatment by pressing the TTFields button (Section 17).
10. Insert the used battery into the battery charger for recharging (Section 19).

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 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.



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.

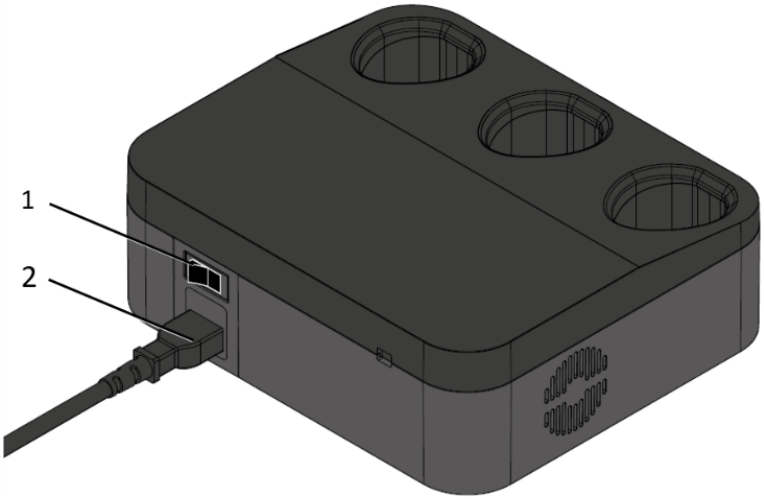
To recharge a used battery:

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.

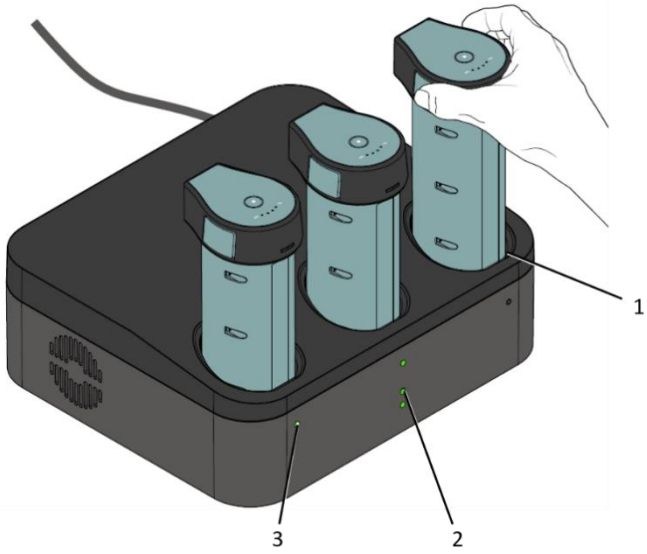
Keep the batteries in the charger even after they are fully charged. This will not harm the batteries.

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.

20 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 26).

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 17).

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 17), 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.

21 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 transducer arrays from the connection cable box. The four transducer arrays are plugged into the connection cable box (as described in Section 15). The connection cable remains plugged into the device 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:

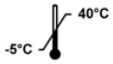
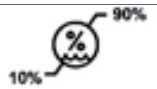
1. Plug the four transducer arrays into its matching color (black or white) in the connection box.
2. Turn ON the device by using the power switch and wait about 10 seconds until the device completes with the self-check.
3. Activate TTFields by pressing the TTFields button.

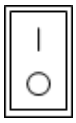
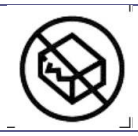
22 CARRYING THE DEVICE

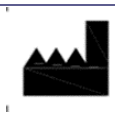
Both the electric field generator and the battery fit in a carrying bag. The bag can be carried in one of three ways: by the handle on top or over the shoulder/ cross-body with a carrying strap attached, or as a backpack as shown below.

NOTE: Do not place the device in a different bag. Optune Lua 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.

23 GLOSSARY OF GRAPHIC SYMBOLS

	Consult the instructions for use for important cautionary information such as warnings and precautions
	Date of Manufacturing
	Fragile – handle with care
	Follow instructions for use
	Do not expose to temperatures below -5°C or above 40°C - Generators
	Do not expose to temperatures below 41°F or above 81°F - Arrays
	Do not expose to humidity below 15% or above 93% - Generators
	Do not expose to humidity below 10% or above 90% - Arrays
	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
	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.

	Optune Lua (device, additional parts and transducer arrays) should be kept away from extreme heat and sources of radiation
	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.
 YYYY-MM	Expiration date – do not use beyond this date
	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
	Do not use the ITE transducer arrays if their packaging is breached.
	The ITE transducer arrays are for single use and should not be re-used.
	The ITE transducer arrays are sterilized by Gamma irradiation
	The ITE transducer array pouches provide a single sterile barrier system.
	Do not resterilize
	Batch code
	Catalogue number
	Serial number
	Class II equipment per IEC 60601-1

Rx only	Prescription device
	Manufacturer information: Novocure GmbH, Business Village D4, Park 6/Platz 10, 6039 Root, Switzerland
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°.
	MR UNSAFE

24 ENVIRONMENTAL CONDITIONS FOR OPERATION, STORAGE AND TRANSPORTATION

Conditions for operation

All system components shall be normally used under conditions specified below:

- For home use.
- For indoor use only (charger and power supply)
- 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 system components can be periodically cleaned with damp cloth, to remove dust and regular soil.

Physical operation conditions for all system components:

- Temperature range: -5°C to +40°C (23°F to 104°F)
- Relative Humidity range: 15-93%
- Ambient pressure range: 700-1060hPa

Conditions for storage

- Temperature range: -5°C to +40°C (23°F to 104°F) for the device and additional parts
- Temperature range: 5°C to +27°C (41°F to 81°F) 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: -5°C to +40°C (23°F to 104°F)
- Maximal relative humidity 15-93%
- No direct exposure to water

Expected Service Life

- Optune Lua device – 12 months
- Connection cable – 11 months
- Power supply – 5 years
- Battery – 11 months (or until the expiration date)
- Charger – 7 years
- ITE transducer arrays have an expiration date. Please do not use the arrays after the expiration date.

25 TROUBLESHOOTING

Note, when calling your device support specialist or the technical support line, please have the serial number of the equipment accessible

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 at 855.281.9301
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 at 855.281.9301
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 at 855.281.9301
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 18 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

Problem	Possible causes	Actions to be taken
		been activated 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 at 855.281.9301
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.

Problem	Possible causes	Actions to be taken
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 at 855.281.9301
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
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	Rare side effect	See your treating doctor
Itching beneath the transducer arrays	Rare 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	Rare side effect	1. Stop treatment 2. See your treating doctor

26 ASSISTANCE AND INFORMATION

Technical support:

For technical support call 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 system'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 MyNovocure Support if you have questions related to travel restrictions.

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

27 DISPOSAL

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

28 MALIGNANT PLEURAL MESOTHELIOMA (MPM)

What is Cancer of the Linings of the Lungs?

In simple terms, lung cancer is a growth of cells that form a tumor in the lungs. MPM is a type of lung cancer that develops from the linings of the lungs. Just like any other form of cancer, these tumors can spread to other parts of the lungs and even to the rest of the body. Even before the tumor grows and spreads, it could cause problems breathing, coughing, bleeding and other problems. Symptoms of lung cancer depend on where and how big the tumor is.

About 3,000 patients in the U.S. are diagnosed with MPM every year. MPM is usually caused by exposure at work to asbestos. MPM is a very serious disease. Less than 5% of patients with MPM are alive after 5 years even using the best available treatments.

Can Cancer of the Linings of the Lungs Be Treated?

There are currently four main options to treat MPM:

Surgery – Few patients can be cured by taking out all of the tumor

Radiation – Following surgery, some patients have radiation therapy

Cancer Drugs – most MPM patients take cancer drugs. There are several approved drugs to treat MPM.

Optune Lua together with cancer drugs

Radiation therapy and surgery can help people with MPM live longer than if they had no treatment. Adding Optune Lua to cancer drugs may help people with MPM to live longer than with cancer drugs alone. Surgery, radiation and cancer drugs have side effects. These side effects include pain, hair loss, skin irritation, nausea, vomiting, loss of appetite, effects related to breathing, and tiredness. Optune Lua leads to skin related problems under the transducer arrays in many people.

29 INPUT/OUTPUT SPECIFICATIONS

The Optune Lua treatment kit including the battery charger are considered Class II medical electrical equipment according to EN 60601-1.

The device mode of operation is continuous. The device is portable when battery operated, and is stationary equipment when connected to the power supply.

The applied part (transducer arrays) is classified as BF.

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

NOTE: The maximum temperature of the transducer arrays is 41°C ± 1°C (approximately 106°F ± 2°F).

Disinfection is not required for any components of the Optune Lua treatment kit.

The ITE transducer arrays are provided sterile for single use.

Battery for Optune Lua (Li-Ion Rechargeable)

OUTPUT: 28.8V ⎓ 86Wh

Charger for Battery for Optune Lua

INPUT: 100-240V ~ 1.5A 50/60Hz

OUTPUT: 3 X 33.6 V ⎓ 1.3A

Power Supply for Optune Lua

INPUT: 100-240V ~ 1.1A 50/60Hz

OUTPUT: 28 V ⎓ 4A

30 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 Optune Lua System 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 Optune Lua Treatment Kit is used to deliver intermediate-frequency electric fields to the patient's scalp 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 24, 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 the Optune Lua device.

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.

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 system 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 system 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 System, 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 (model NovoTTF-200T) system 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	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 NovoTTF-200T treatment kit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $dd = \frac{6}{EE}\sqrt{PP}$ 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 $dd = \frac{6}{EE}\sqrt{PP}$ 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.

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 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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