novocure™

OPTUNE®

(NovoTTF™ 200A)

USER MANUAL

Document number QSD-EUUM-002-EN

Version 02

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This manual is intended for patients receiving TTFields treatment using the Optune® Treatment Kit and INE Transducer arrays (Sterile).

1 About Optune® Treatment Kit

Optune Treatment Kit a portable medical device. It delivers electric fields called "TTFields" to the tumor in the brain using INE Transducer arrays. TTFields are intended to kill cancer cells. The TTFields are transmitted at a frequency of 200 KHz and up to 707mA RMS output current.

Your doctor has prescribed Optune Treatment Kit for use at home. You may be able to use Optune Treatment Kit on your own, or you may need help from a doctor, family member, or other caregiver. Use Optune Treatment Kit as many hours per day as possible, at least 18 hours per day. Only take short breaks for personal needs.

Optune Treatment Kit is portable and has the ability to run on batteries. You can continue your normal daily life while carrying the device in a shoulder bag or backpack. The Treatment Kit includes four rechargeable batteries. Each battery will last for up to two or three hours. For sleeping, or other times when you plan to stay in the same place for a while, plug the device power supply into a standard wall outlet.

Optune does not need regular maintenance. The Optune Treatment Kit 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 source connected (a charged battery plugged into the device, or is connected to a power supply plugged into the wall) and turn it on and off. If the device is not working, an audible error indicator will beep.

A simple Troubleshooting Guide is provided in this manual (Section 21). You can also call the 24-hour technical support telephone number (Section 22).

Shave your scalp and change the INE Transducer arrays twice a week. Keep periods of time off from treatment to a minimum.

Interrupt treatment only for personal needs such as bathing, exercise, or any time where the device may be a distraction. Stop treatment to replace the INE Transducer arrays.

To take a shower, unplug the INE Transducer arrays from the device (leave the INE Transducer arrays on your head) and put a shower cap on your head so they do not get wet. You can take a full shower and wet your head when you are not wearing the INE Transducer arrays (for example, when you have taken them off but before replacing them with a new pair). You can wear a wig or hat over the INE Transducer arrays, if you wish.

2 Indications for Use

Optune Treatment Kit is intended for the treatment of patients with newly diagnosed GBM and for the treatment of patients with recurrent GBM.

Newly diagnosed GBM

NovoTTF-200A (Optune™) Treatment Kit is intended for the treatment of patients with newly diagnosed GBM, after surgery and radiotherapy with adjuvant Temozolomide, concomitant to maintenance Temozolomide. The treatment is intended for adult patients, 18 years of age or older, and should be started more than 4 weeks after surgery and radiation therapy with adjuvant Temozolomide. Treatment may be given together with maintenance Temozolomide (according to the prescribing information in the Temozolomide package insert) and after maintenance Temozolomide is stopped.

Recurrent GBM

NovoTTF-200A (Optune™) Treatment Kit is intended for the treatment of patients with recurrent GBM who have progressed after surgery, radiotherapy and Temozolomide treatment for their primary disease. The treatment is intended for adult patients, 18 years of age or older, and should be started more than 4 weeks after the latest surgery, radiation therapy or chemotherapy.

3 Contraindications, Warnings & Precautions

CONTRAINDICATIONS

Do not use Optune Treatment Kit if you are pregnant, think you might be pregnant, or are trying to get pregnant. If you are a woman who is able to get pregnant, you must use birth control when using the device. Optune Treatment Kit was not tested in pregnant women.

Do not use Optune Treatment Kit if you have significant additional neurological disease (primary seizure disorder, dementia, Progressive degenerative neurological disorder, Meningitis or encephalitis, Hydrocephalus associated with increased intracranial pressure)

Do not use Optune Treatment Kit if you are known to be sensitive to conductive hydrogels like the gel used on electrocardiogram (ECG) stickers or transcutaneous electrical nerve stimulation (TENS) electrodes. In this case, skin contact with the gel used with Optune Treatment Kit may commonly cause increased redness and itching, and rarely may even lead to severe allergic reactions such as shock and respiratory failure.

Do not use Optune if you have an active implanted medical device, a skull defect (such as, missing bone with no replacement) or bullet fragments. Examples of active electronic devices include deep brain stimulators, spinal cord stimulators, vagus nerve stimulators, pacemakers and defibrillators. Use of Optune together with implanted electronic devices has not been tested and may lead to malfunctioning of the implanted device. Use of Optune together with skull defects or bullet fragments has not been tested and may possibly lead to tissue damage or render Optune ineffective.

WARNINGS

Warning - Use Optune Treatment Kit only after receiving training from qualified personnel, such as your doctor, a nurse, other medical personnel, or Novocure Device Support Specialist who have completed a training course given by the device manufacturer (Novocure). Your training will include a detailed review of this 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 Treatment Kit without receiving this training can result in breaks in treatment and may rarely cause increased scalp rash, open sores on your head, allergic reactions or even an electric shock.

Warning - Do not use Optune Treatment Kit if you are younger than 18 years of age. It is unknown what side effects the device may cause in these cases or if it will be effective.

Warning - In case of skin irritation, which appears as redness under the transducer arrays (a mild rash), talk to your physician before starting any treatment for skin irritation. Your physician may recommend using use over-the-counter topical steroids 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. Taking a break from treatment may lower your chance to respond to treatment.

Warning - All servicing procedures must be performed by qualified and trained personnel. 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.

Warning - No modification of this equipment is allowed.

Warning – re-use of INE Transducer arrays can lead to poor contact with the scalp and may cause the device to alarm and stop working. Re-use of INE Transducer arrays can lead to worsening of the skin inflammation and rarely even to local infection. If you suffer from an infection on your scalp (puss, swelling and warmth) consult with your physician immediately.

PRECAUTIONS

Caution - Keep the Optune Treatment Kit out of the reach of children and pets.

Caution - Do not use any parts that do not come with the Optune Treatment Kit or that were not sent to you by the device manufacturer or given to you by your doctor.

Caution - Do not use the Optune Treatment Kit if any parts look damaged (torn wires, loose connectors, loose sockets, cracks or breaks in the plastic case).

Caution - Do not wet the device or INE Transducer arrays. Getting the device wet may damage it, preventing you from receiving treatment for the right amount of time. Getting the INE Transducer arrays very wet is likely to cause the INE Transducer arrays to come loose from your head. If this happens, the device will operate the notification signal and you will need to change the INE Transducer arrays.

Caution - Before connecting or disconnecting the INE Transducer arrays, make sure that the Optune power switch is in the OFF position. Disconnecting INE Transducer arrays when the device is running will cause a device notification signal to go off, and could damage the device.

Caution - Connection Cable may pose a hazard of strangulation. Avoid wearing the connection cable around your neck.

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 Treatment Kit is to be used with INE transducer arrays only.

Notice! Optune Treatment Kit and INE Transducer arrays will activate metal detectors.

Notice! You should use the Optune Treatment Kit for at least 18 hours a day to get the best response to treatment. Using Optune Treatment Kit for less than 18 hours a day lowers the chances that you will respond to treatment.

Notice! Do not stop using the Optune Treatment Kit even if you have used it less than the recommended 18 hours per day. You should stop using the device only if your doctor tells you to. Stopping treatment could lower the chances that you will respond to treatment.

Notice! If you plan to be away from home for more than 2 hours, 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. Breaks in treatment may lower your chance to respond to 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 lights up within only 1.5 hours 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. Breaks in treatment may lower your chance to respond to treatment.

Notice! Do not block the device vents located on the front and bottom of the Optune device. Blocking the vents may cause the device to overheat and operate the notification signal, leading to a break in treatment. If this happens, unblock the vents, wait 5 minutes and restart the device.

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.

4 What are the Risks of Treatment with Optune Treatment Kit?

Skin irritation is often seen under the INE Transducer arrays when using the Optune Treatment Kit. This will look like a red rash, small sores or blisters on your scalp. In general, Optune will not cause skin damage that cannot be fixed. The irritation can be treated with topical steroid cream or by moving the INE Transducer arrays. If you do not use the topical 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.

5 What are the Benefits of Treatment with Optune Treatment Kit?

Patients using Optune after their tumor reappeared lived a similar amount of time compared to patients using cancer drugs. In the clinical study, half of the patients in both groups lived for more than 6.4 months. 22 out of each 100 patients lived for one year or longer.

Patients using Optune after their tumor reappeared had a better quality of life

On the following page is a table showing the effects on the benefit of the device, when it is used correctly or incorrectly after the tumor reappeared.

Benefit from Correct and Incorrect Use of Optune

Event	Likelihood of Event	Outcome	Likelihood of Outcome
Correct use			
Use of the device for at least 18 hours a day	85 out of 98 subjects (87%)	Survival 3 months longer compared to subjects treated less than 18 hours a day	81 out of 85 (95%)
Incorrect use			
Use of the device for less than 18 hours a day	13 out of 98 subjects (13%)	Survival 3 months shorter compared to subjects treated at least 18 hours a day	12 out of 13 (92%)
Wetting the device or soaking the transducer arrays	Unknown	Treatment break	Unknown
Handling of the device by children	Unknown	Treatment break	Unknown

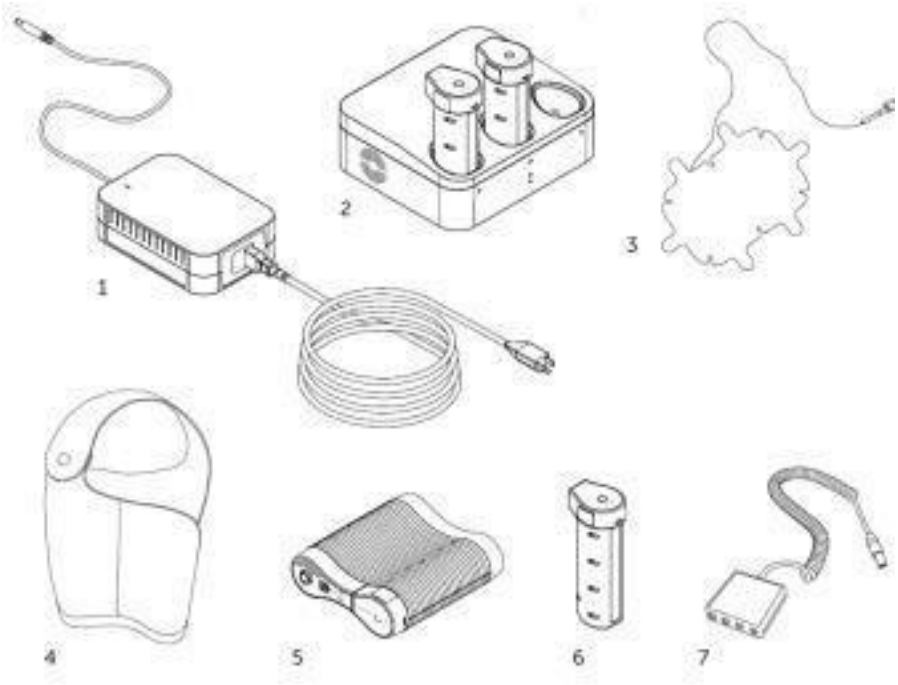
In the clinical study using Optune with temozolomide before patients' tumors reappeared, the time from the start of treatment to death was measured when half of the patients had joined the study as well as at the time when all of the total 700 patients had joined the study. The table below shows the amount of time that patients who used Optune with temozolomide were observed to be alive longer than patients who used temozolomide alone.

	Benefit of Optune + Temozolomide	
	Half of Patients in Study	All Patients in Study
Correct use	Almost 5 months longer	Almost 7 months longer
All subjects	3 months longer	Almost 5 months longer

In addition, more patients who used Optune with temozolomide were alive after 2 years than patients using temozolomide alone

	Patients Alive 2 Years after the Start of Treatment (Optune + Temozolomide vs. Temozolomide Alone)	
	Half of Patients in Study	All Patients in Study
Correct use	48% vs. 32%	43% vs. 25%
All subjects	48% vs. 34%	43% vs. 31%

6 Overview of Optune Treatment Kit



1 Plug in power supply (Model SPS9100)

2 Charger for batteries (Model ICH9100)

3 Insulated Transducer array (INE) – (Model INE9020 and INE9020W)

4 Device & battery carrying bag (Model BAG9100)

5 Optune electric field generator (the Device) (Model TFH9100)

6 Battery (Model IBH9100)

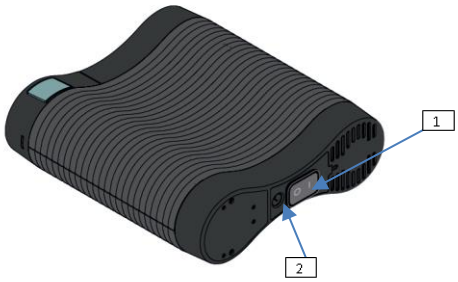
7 Connection cable & box (Model CAD9100)

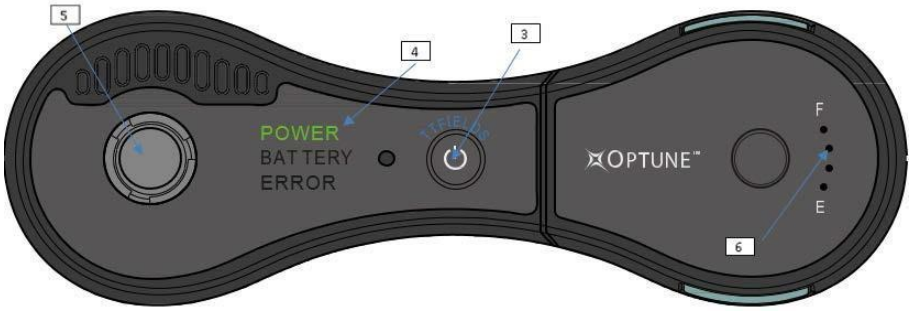
7 The Device

The Optune Treatment Kit treatment parameters are preset and cannot be changed by the patient. TTField treatment should be kept on as continuously as possible (24 hours a day, 7 days a week). Although 100% treatment time is impossible, breaks from treatment should be kept as short as possible.

You will need to learn how to place it in a carrying bag, connect a battery and operate the system.

The following controls will allow you to operate the Optune device:





1 Optune power button 2 Power Supply Connection cable socket 3 TTField therapy ON/OFF button

4 Power ON/ Error / Low Battery indicator 5 Connection Cable (CAD) socket 6 Battery Gauge

Note: Instruction on how to use INE Transducer arrays can be found in the INE Transducer array User Manual supplied with the INE Transducer arrays.

8 Before You Begin

You will need to use four (4) INE Transducer arrays at one time. Change these 4 INE Transducer arrays twice a week to continue treatment with Optune® Treatment Kit. You may change the INE Transducer arrays with the help of a doctor, a nurse or caregiver if needed.

Make sure you have an adequate supply of INE Transducer arrays to keep you going until your next visit to your physician.

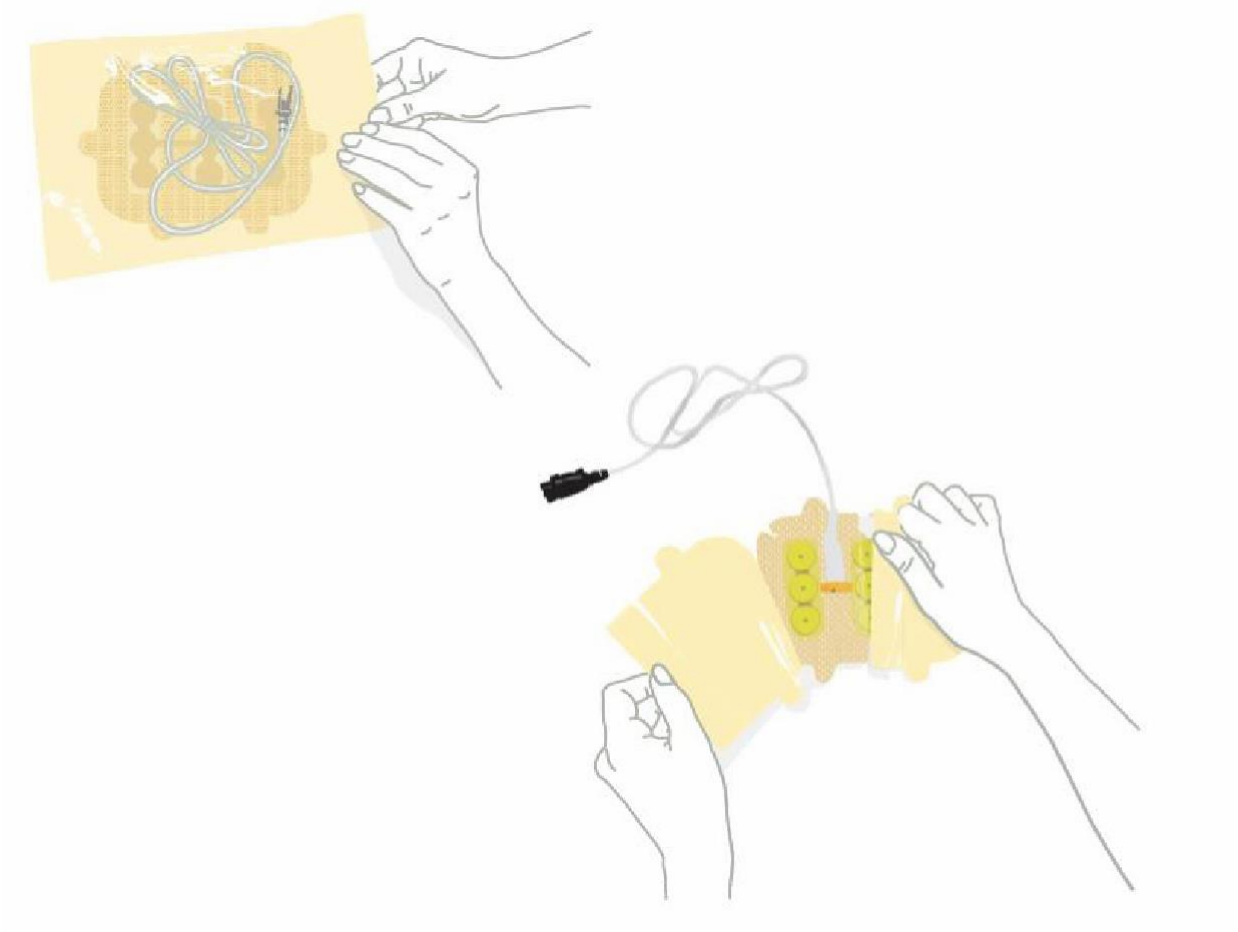
Before using an INE Transducer array make sure its package is sealed. Do not use an INE Transducer array which has been opened previously.

Although the transducer arrays are provided in individual sterile packages to minimize infection risk, you and/or your caregiver can take additional steps to further reduce the risk of infection: Always wash your hands prior to application and removal of transducer arrays; Wash your scalp between transducer array exchanges; Clean the electric razor per manufacturer’s guidelines after every shave.

9 Removing the INE Transducer Array from Its Package

Wash your hands before opening the envelope with the INE Transducer Arrays.

Open the see through envelope of four (4) INE Transducer arrays by gently pulling apart the opposing edges of the envelope as shown in the illustration.



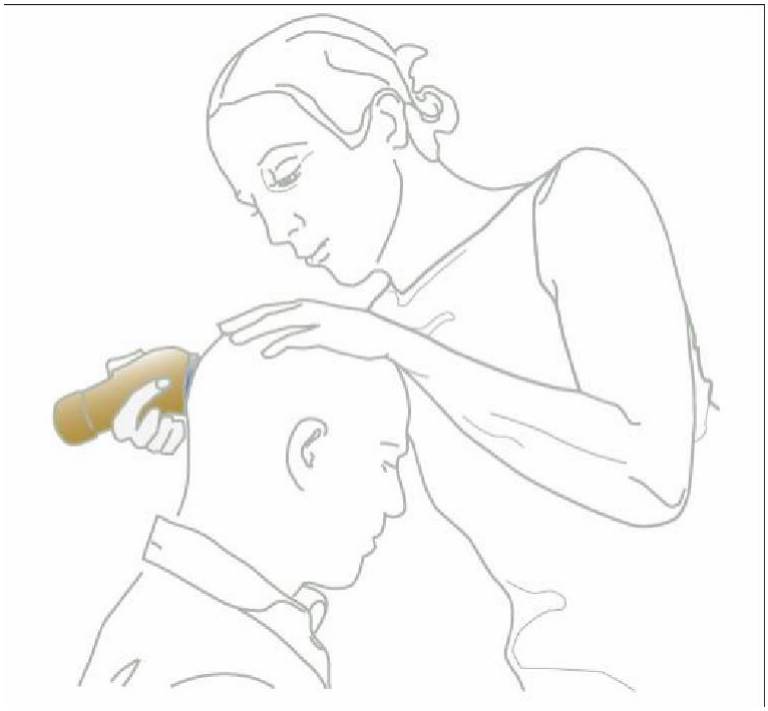
10 Preparing Your Head for INE Transducer Array Placement

Wash your head with a gentle shampoo.

If this is the first time you have used the INE Transducer arrays, ignore this step and skip ahead to the next step (shaving). If you are replacing INE Transducer arrays, you, or your doctor or caregiver if needed, should wipe the skin with baby oil to remove any remaining adhesive from previous INE Transducer arrays. Baby oil is used to remove remaining adhesive. It will not stop the device from working.

Shave your entire scalp using an electric shaver. Do not leave any stubble. Wipe your scalp with 70% Alcohol (available at your local pharmacy without a prescription).

Use an over-the-counter hydrocortisone (steroid) cream if your scalp is red. Treat open sores on your scalp like your doctor told you. If you use this cream, wait at least 15 minutes and wipe your scalp again with 70% Alcohol. Apply the INE Transducer arrays after your scalp is dry.



11 Placing The INE Transducer Arrays On Your Head

After you prepare your scalp (Section 9), put the INE Transducer arrays on your head with the help of a doctor or caregiver if needed. Twice a week, remove the INE Transducer arrays, prepare the scalp (as outlined in Section 13) and put on a new set of INE Transducer arrays. You will know it is time to change INE Transducer arrays when the device alarm beeps more often. This means that the device is not able to work properly because of hair growth. Hair growth keeps the INE Transducer arrays from making good contact with your scalp.

To place the INE Transducer arrays on your head, with the help of a caregiver or doctor if needed, follow the steps below. Note, if this is the first time you have used the INE Transducer arrays, ignore the first step (removal).

Remove the INE Transducer arrays from your head by peeling the medical tape away from your scalp.

In the Treatment Kit, there are INE Transducer arrays having two colors of connectors – black and white.

Note which color INE Transducer array goes where on your head. The INE Transducer array locations and colors are: front & back (black), right & left (white).

Prepare your skin for the INE Transducer arrays, as described in Section 4.

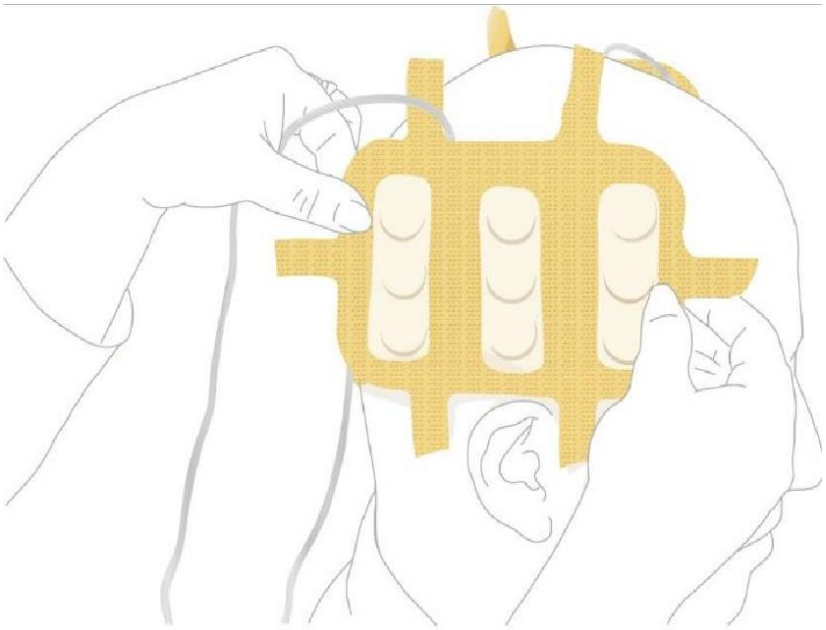
Peel off the white layer (liner) covering the gel from the first INE Transducer array.

NOTICE: make sure there is no transparent cover with blue lines over the gel! In case there is, carefully remove before proceeding.

If this is the first time you have used the INE Transducer arrays, put the INE Transducer arrays on your head as shown in the INE Transducer array placement diagram that your doctor gave you.

Placement is based on the location of your tumor. When changing the INE Transducer arrays, place the INE Transducer arrays on your head in the same general location as before, but shift the INE Transducer arrays about 2cm in the direction of the arrow on your INE Transducer array placement diagram.

To reduce skin irritation under the INE Transducer arrays, move the INE Transducer arrays a small amount. Place the other three INE Transducer arrays in the same way. Pull the tabs on each side of the INE Transducer arrays and press them firmly to your scalp. Press the entire edge of the INE Transducer array tape to your scalp.



12 Connecting the INE Transducer Arrays to the Device

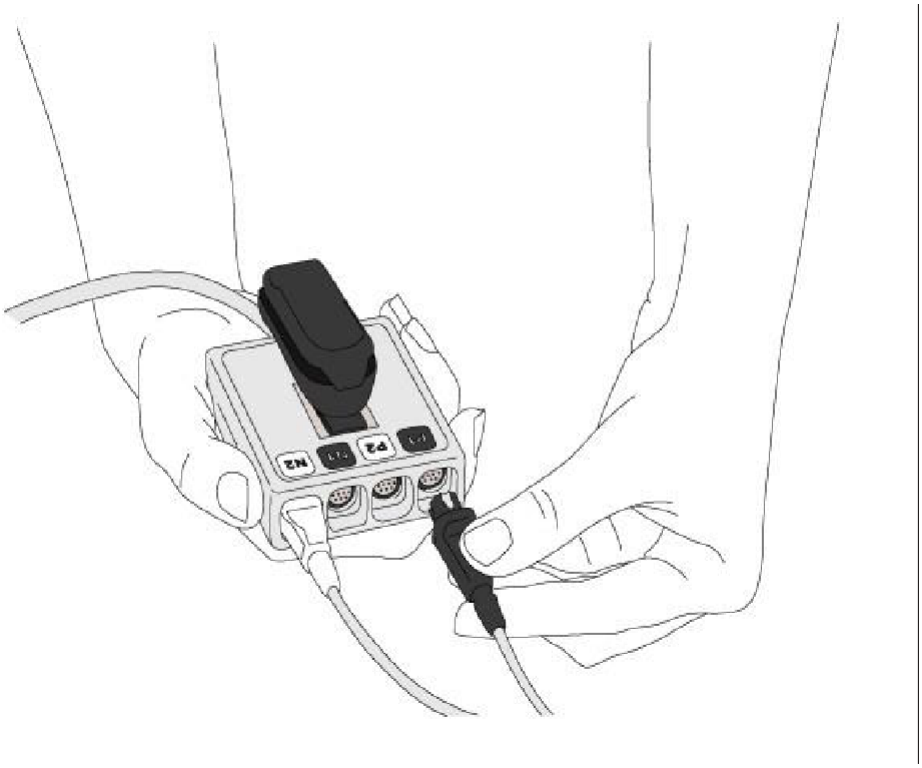
Connect each of the four INE Transducer array connectors with the black or white connector to the matching color socket on the connection cable. For example, plug the INE Transducer array with the black connector into the black socket (labeled “N1”; see diagram).

Connect the other three INE Transducer array connectors in the same way.

Press firmly to be sure the connectors are pushed in all the way. Hold the INE Transducer array wires together. Wrap them with a small piece of tape, if you wish.

You may clip the connection cable to your belt.

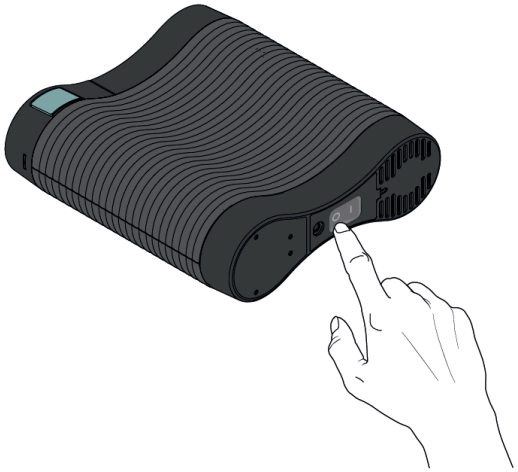
Refer to the Optune® Treatment Kit User Manual for instructions on how to start treatment.



13 Starting & Stopping the Device

To start treatment, connect a power source - either a charged battery or a power supply (see Section 8 or 10) to the device.

1. Turn the power button on the bottom of the device to the on position



2. Wait approximately 10 seconds for the self-check to be completed. The "Power" indicator on the front of the device will light up green.

If a charged battery is installed and there is no power supply plugged in, the "Battery" indicator will also light up green.

If a power supply, connected to the mains, is plugged into the device, the device will run off of the power supply and the "Battery" indicator will not illuminate.

Press the TTField therapy ON/OFF button once – this will start treatment.

The blue indicators surrounding the TTFields therapy ON/OFF button will light up and remain on for as long as treatment continues.

Note: The green, blue and yellow indicators will dim in a dark room and will brighten in a light environment. The red error indicator light will not be dimmed in any case.

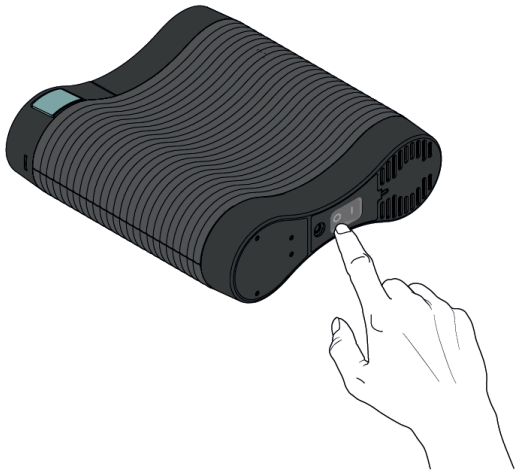
If the therapy button is not pressed within several minutes after the device is turned ON, a notification signal will sound, indicating that the device is ON but the therapy is OFF. This is a reminder to start the therapy. The therapy button should be pressed once to silence the notification signal and again to start the therapy.

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

a) When the device is running properly:

Press the TTFields button – The blue indicator surrounding the TTField therapy ON/OFF button will turn off.

Then, turn off the device by turning the power button on the bottom of the device to the off position.



b) If an Error Occurs:

If an error occurs, the device will turn off the TTFields and make a loud beeping noise. The red Error light will light up (as shown below).

To turn off the device:

1. Press the TTFields button on the front of the device to stop the notification signal. The red Error light will turn off.
2. Turn off the device by turning the power button to the off position.
3. See the Troubleshooting Guide (Section 15) for instructions on fixing problems. Restart the device and restart treatment if no problem is found. If the notification signal does not stop, contact technical support (Section 16).

c) When the Low Battery indicator lights up:

When the battery has about 20 % power left the "Battery" indicator will turn yellow, alerting you that you will need to change battery soon.

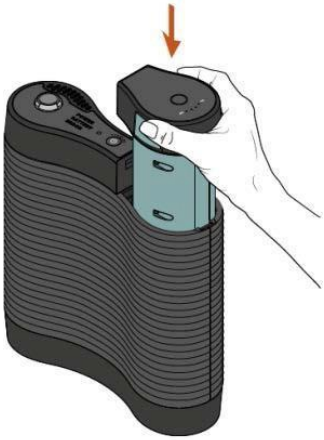
When your battery runs out (after about 2–3 hours), the notification signal will beep, and the TTFields therapy will stop. When this happens the "Battery" indicator will turn yellow and red Error light will light up. This notification signal sound is the same sound the device makes for an error. However, in this case both the yellow "Battery" and red "Error" indicators will light up instead of just the red light.

To turn off the device:

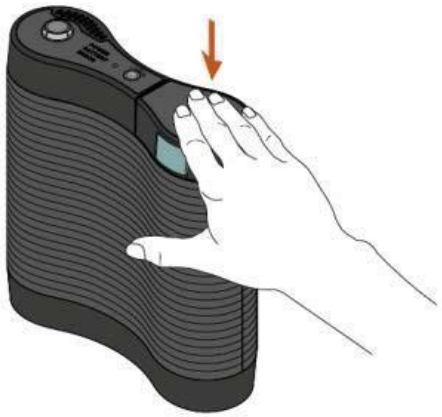
1. Press the TTFields button on the front of the device to stop the notification signal. The red Error and the yellow Battery lights will turn off.
2. Turn off the device using the on/off switch.
3. Replace the battery using the steps in Section 8.

14 Connecting & Disconnecting the Battery

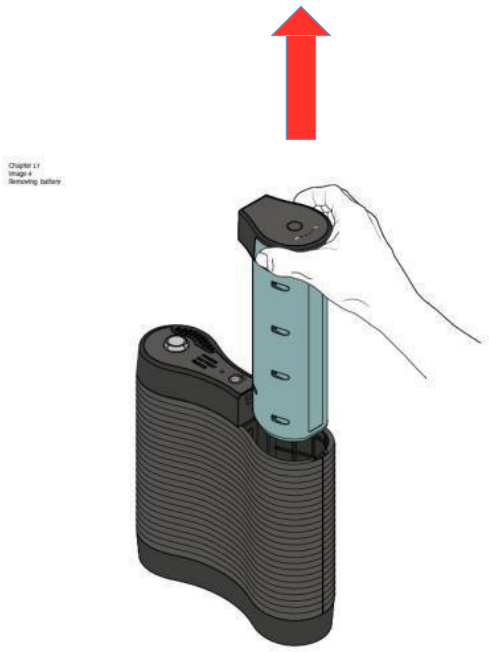
The Optune Treatment Kit comes with 4 rechargeable batteries. Batteries slide into the device, while the blue buttons on both sides of the battery are being held. The battery should be inserted until there is a "click", indicating the battery is in place. Take care not to drop the battery in place or to force it into the battery slot. Optune uses one (1) battery at a time. The other three (3) batteries should stay in the battery charger. Each battery lasts 2 to 3 hours. Replace the battery each time it runs out (when the yellow Low Battery indicator light is on, as described in Section 6). If you plan to be away from home for more than 2 hours, carry extra batteries or a power supply.



Gently press down to lock the battery in place. Make sure the battery latch is fully engaged.



To remove the battery from the slot, Press both blue buttons on the side of the battery and slide up until removed.



Recharge the batteries in the charger (see Section 9) for four to five hours. The batteries will stay charged if they are off the charger for a short time (hours, but not days). For this reason, keep the extra batteries in the charger at all times, if possible. You can charge and use the batteries many times. Over nine to twelve months, the length of time the batteries can run the device (before the low battery notification signal beeps) will get shorter. When this happens, contact technical support (see Section 16) to get replacement batteries.

When the yellow Low Battery indicator light lights up, there are two ways you can replace the depleted battery with a charged battery.

Option One: (to be used if near the direct wall power supply) allows you to change the battery without interrupting therapy. This can be used before the battery is completely depleted, and before the device has operated the notification signal. Please follow these steps:

Plug the power supply cord into bottom of the Optune device. (See Section 10)

The lights on the display panel will indicate you are no longer running on battery power.

Remove the battery from the battery slot by pressing on the blue buttons on the side of the battery.

Slide the fully charged battery in the battery slot, gently push down to lock in place.

Remove the power supply cord from the bottom of the device.

Option Two: If you are not near the power supply, or if the battery has totally depleted please replace the battery using these steps:

Turn off the notification signal by pressing the TTFields button once.

Turn off the device using the power button (on the bottom of the device).

Remove the battery from the battery slot by pressing on the blue buttons on the side of the battery.

Slide the fully charged battery in the battery slot, gently push down to lock in place.

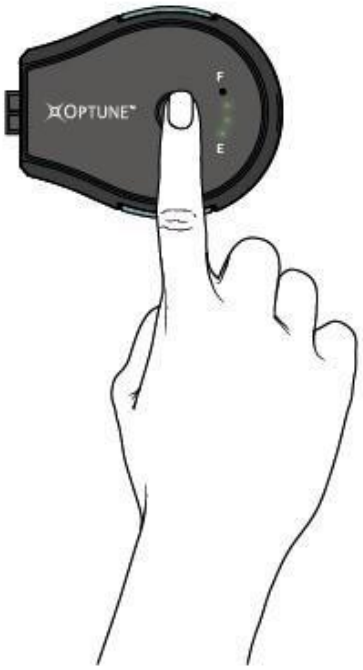
Turn on the device and start treatment by turning the power button on, wait for the system to run a self-check (this takes about 10 seconds) then press the TTFields button (see Section 6).

Place the used battery in the charger for recharging (as described in Section 9).

Checking the Battery Gauge

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

To check the battery power press the button on the top of the battery cartridge once. The remaining battery power will be indicated by the readout to the right of the button. The gauge reads from full to empty, like a gas gauge in your car.



Full Charge

75%Charge

50%Charge

25%Charge

Empty

15 Charging the Battery

The battery charger recharges used batteries. The battery charger uses power from a standard wall outlet.

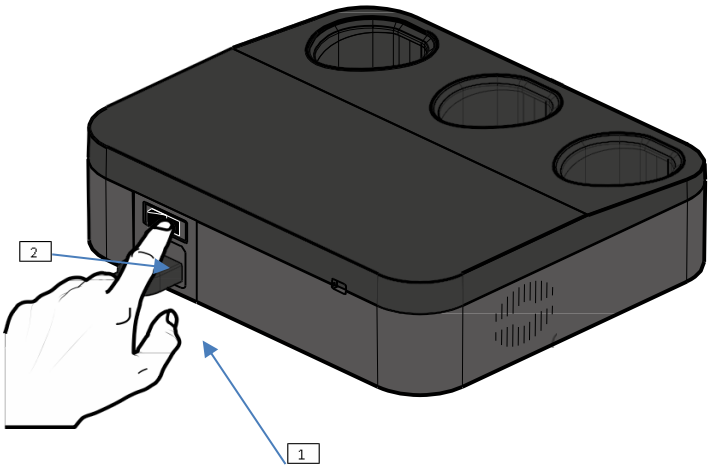
Before charging the batteries, plug the charger power cord into a standard wall outlet and turn on the power button at the back of the charger. The small light in the center of the front panel will light up green indicating power is applied.

To recharge a used battery:

3. Place the used battery in one of the three openings in the top of the charger. Push down on the battery until it is fully inserted into the slot.
4. The light directly in front of the opening where the battery is plugged in will illuminate flashing green. The flashing green indicates that the battery is charging. The light will flash faster when the battery reaches approximately 80% of a full charge.
5. When the battery is fully charged (about 4 to 5 hours), the charge light will turn from blinking green to solid green. The solid green light will disappear on removal of the battery or the disconnection of the charger from mains socket.

If the light in front of the opening turns red, this indicates that there is a fault with the battery and you should contact technical support to have it replaced. Do not use a battery if it creates a red light on the charger.

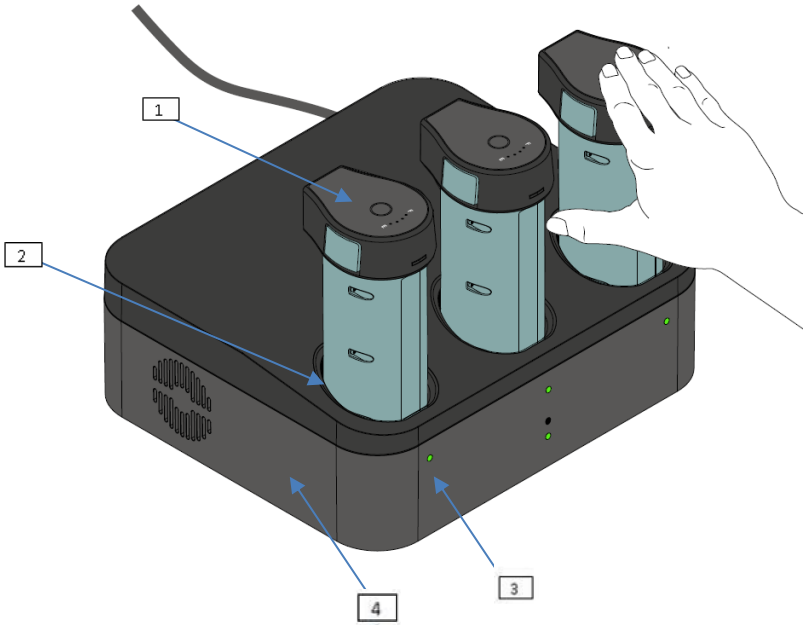
Keep the batteries in the charger even after they are fully charged. This will not harm the batteries.



1 Charger Mains Cable

2 Power Button

Back view of the battery charger and rack showing where to turn the charger on and off and where to connect the charger power cord



1	Battery
2	Charger opening
3	Charger Indicator
4	Charger

Front view of the battery charger showing how the batteries are installed in the charger

Notice: The charger is considered to be disconnected from the mains only when the power cable is physically disconnected either from the mains or from the charger itself.

Notice: The charger is considered class II equipment, without signal input/ output and applied part (part which come into physical contact with the patient). Mode of operation - continuous operation. The charger is not intended for use in the presence of flammable mixtures.

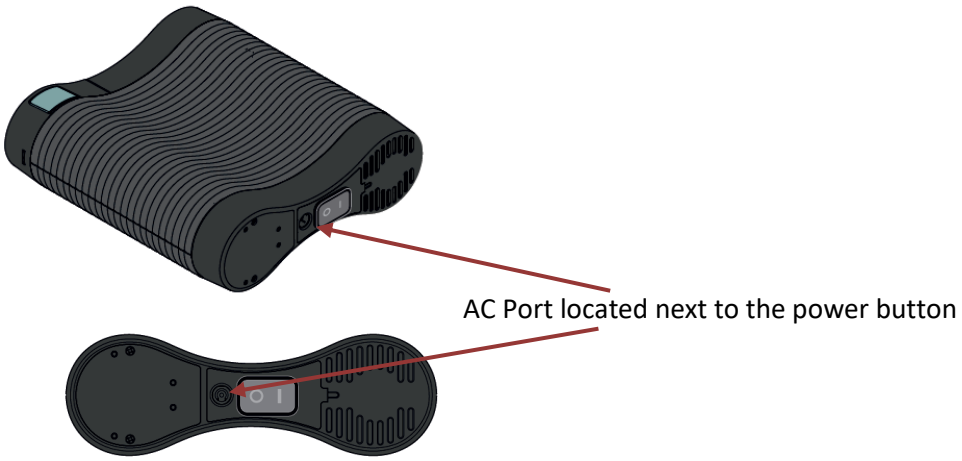
Sterilization or disinfections are not required.

16 Using the 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 U.S. (120V AC) or European (230V AC) 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 16).

When the power supply is plugged in, the device will utilize the power supply as the preferred power source. If it is running, it will automatically switch from battery power to power supply power.



Connecting the Plug-In Power Supply

1. Plug in the power supply to a standard wall outlet using the power cord that comes with the system.
2. You do not need to remove the battery from the device to use the plug in power supply. Please note that a battery in the device will not charge when plugged into the plug in power supply. Depleted batteries must be placed on the battery charger to re-charge. If the TTFields are activated you do not need to turn them off to plug in the power supply.
3. Plug the round connector of the plug-in power supply line into the round socket AC port on the back of the device (next to the power button).
4. If the TTFields are running, the device will switch to power supply power without interruption of the TTFields. If the device is not turned on, turn on the power switch and wait for the self-check to be completed (about 10 seconds). Push the TTFields button to start the device (as described in Section 6).

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

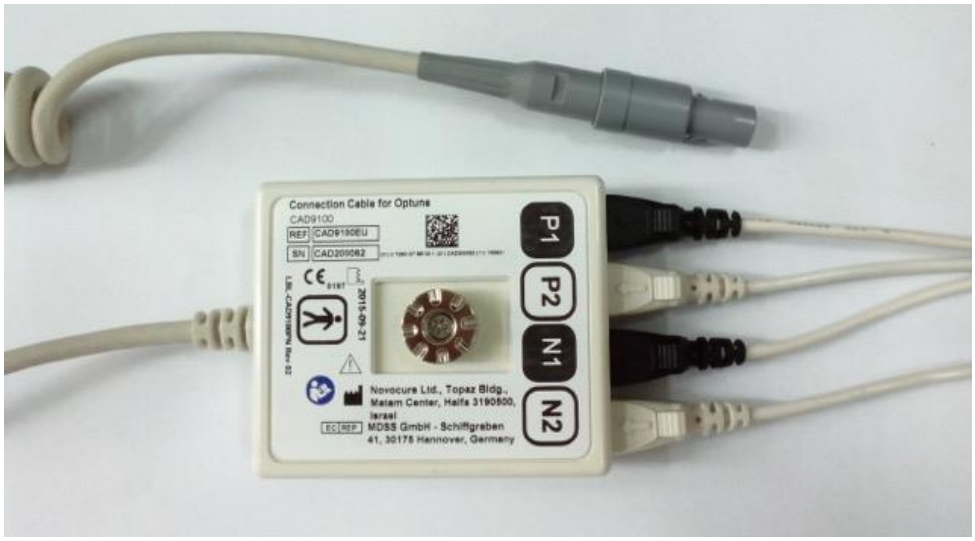
1. Ensure that a charged battery is properly installed in the device before removing the power supply. If the TTFields are running, you do not need to turn them off before removing the plug-in power supply. The device will automatically switch to battery power once the power supply is removed.
2. Remove the connector of the plug-in power supply from the socket on the back of the device.
3. If the device is not turned on, turn on the power switch and wait for the self-check to be completed (about 10 seconds). Push the TTFields button to start the device.
4. Store the plug-in power supply for future use.

17 The Connection Cable & Box

The connection cable is the coiled, stretchy cord that runs from the device to the connection box. The four transducer array connectors (2 black and 2 white) plug into the connection box. The black and white coding matches with the transducer array position on the head, Black to the back and front, white to the either side.

The connection cable plugs into the device in the socket on the left of the front panel. The connection cable socket has a picture of a person next to it and a white ring around it. The connection cable plugs into the socket with the arrow on the connector facing up. Push in the connector until you hear a snap. The snap means it is in the right place.

Note: It is important that the arrow on the connection cable face up and is aligned with the arrow on the connector socket on the device. Do not force the connection cable into the socket. It should push in easily if properly aligned.



There are two ways to unplug from the device to take a break from treatment (after turning off the device):

1. Unplug the connection cable from the device.
2. Unplug the transducer arrays from the connection cable.

To unplug the connection cable from the device:

Stop treatment by pressing the TTFields button. Turn off the device using the power button.

Unplug the connection cable from the socket by holding the sleeve and pulling. 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 connection cable socket with the arrow pointing up.
2. Turn on the device using the power button. Wait for self-check to be completed (about 10 seconds).
3. Turn on the TTFields using the TTFields button.

To unplug the transducer arrays from the connection cable:

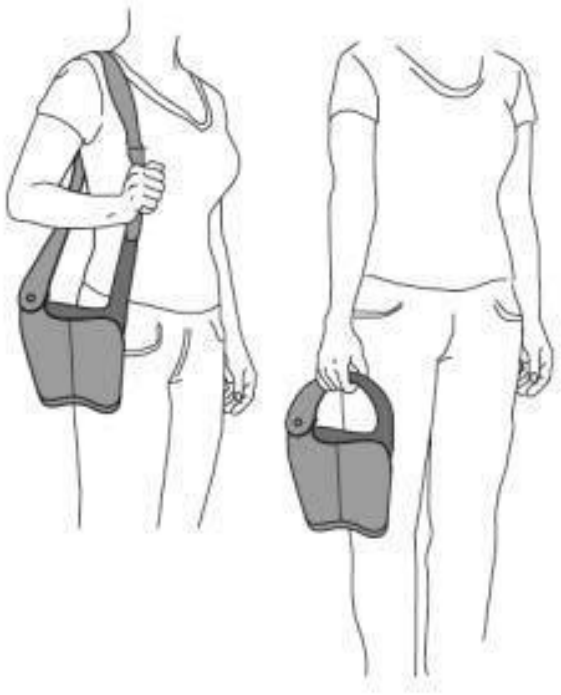
To take a break from treatment and completely disconnect from the device but leave the transducer arrays on your head, unplug the transducer array cables from the connection cable box. The four transducer arrays are plugged into the connection cable box as described in Section 11. The connection cable is plugged into the device at the connection cable socket.

1. Stop treatment by pressing the TTFields button.
2. Turn off the Optune device using the power button.
3. Unplug the transducer array connectors from the connection box by pulling as shown in the picture below. You may have to wiggle the transducer array cables to remove them.
   To restart treatment, plug the transducer arrays into the connection box. Plug each transducer array into its matching color (black or white) that goes with the transducer array's position on the head (see earlier in this section).
4. When all 4 transducer arrays are plugged in, turn on the power switch and wait for self-check to be completed (about 10 seconds). Push the TTFields button to restart treatment.

18 Carrying the Device

The electric field generator with the installed battery will fit in a carrying bag. The bag can be carried in a two ways: by the handle on top or over the shoulder or cross-body with a carrying strap attached.

Note: Do not place the device in a different bag. Optune has a fan that needs airflow. The bag that comes with the device is designed to allow for proper airflow. If you put the device in a bag without proper airflow, it could overheat and operate the notification signal.



19 Glossary of Graphic Symbols

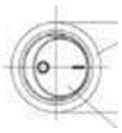
For INE transducer Arrays

	The INE Transducer arrays are sterilized by Gamma irradiation
	Do not resterilize
	**Do not** use the INE Transducer arrays if their packaging is breached
	The INE Transducer arrays are for single use and should not be re-used
	Protect from heat and radioactive sources
	**Do not** expose the INE Transducer arrays to water
	Fragile, handle with care
	Temperature range for storage is between 5°C and 27°C
	Consult instructions for use
	Caution
	Medical device
	Batch code

	INE9020/INE9020W Catalogue number
 YYYY-MM	Expiration Date
	Date of Manufacturing
	Manufacturer information
	Contact technical support to arrange for proper disposal of arrays that are used up or no longer in use.

For Device

	Caution - 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
	Do not expose to humidity below 15% or above 93%
	Manufacturer information

	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.
	For indoor use only
	Batteries are Lithium Ion. Contact technical support to arrange for proper disposal of batteries that are used up or no longer in use.
	Optune Treatment Kit parts 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
	Expiration Date
	Power ON / OFF switch for Optune : When the switch is in the I position the device is ON. When the switch is in the O position the device is OFF
	Power ON / OFF switch for the overnight 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
	Catalogue number

	Serial Number
	Class II equipment per IEC 60601-1
	Medical device

20 Disposal

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

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

21 Environmental Conditions for Normal Operation, Storage and Transportation

Conditions for operation

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

The system is intended mainly for home use.

The battery charger and the power supply are for indoor use only.

The device additional parts and transducer array are not intended for use in a shower, a bath tub or a sink, or in heavy rain. Also they are not for use in presence of flammable mixtures.

If any system parts are dropped on floor, there shall be no safety hazard, but they are not expected to function anymore.

Conditions of visibility

Any.

Cleaning

All external system components can be periodically cleaned with damp cloth, to remove dust and regular soil. Avoid using detergents or soaps.

Physical operation conditions for all system components

Temperature range: -5°C – +40°C
Relative Humidity range: 15-93%
Ambient pressure range: 700-1060hPa

Conditions for storage

Temperature range: -5°C – +40°C for the device and additional parts

Temperature range: 5°C – +27°C for the INE Transducer arrays

Relative Humidity range: 15-93% for the device and additional parts

Conditions for transport

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

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

Transportation of the INE Transducer arrays shall be possible using air/ground transportation in weather-protected conditions as specified below:

- Temperature range: 0°C – 40°C
- No direct exposure to water

Note: 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 check with Novocure if you have any questions related to travel restrictions.

22 Troubleshooting

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

INE Arrays Troubleshooting:

Problem	Possible Causes	Actions to be Taken
Redness of the skin beneath the INE Transducer arrays	Common side effect	1. Use hydrocortisone cream prescribed by your doctor when replacing INE Transducer arrays. 2. Place INE Transducer arrays in a location shifted by 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 INE Transducer arrays	Rare side effect	See your treating doctor.
Itching beneath the INE Transducer arrays	Rare side effect	1. Use hydrocortisone cream prescribed by your doctor when replacing INE Transducer arrays. 2. Place INE Transducer arrays in a location shifted by 2 cm from the last location (so the adhesive gel is between the red marks). **If the itching gets worse:** See your treating doctor.
Device power indicator does not light up after turning ON the device	1. Battery dead 2. Battery malfunction 3. Charger malfunction 4. Device malfunction	1. Replace battery. **If problem persists:** 1. Turn OFF power switch 2. Call your Device Support Specialist

Problem	Possible Causes	Actions to be Taken
Any cable detached from INE Transducer array/ connection cable/device	1. Excess physical force to cables 2. Device malfunction	1. Press TTFields button to stop therapy. 2. Turn OFF power switch 3. Call your Device Support Specialist
Device dropped or wet	Incorrect use	1. Press TTFields button to stop therapy. 2. Turn OFF power switch 3. Call your Device Support Specialist
Device alarm on	1. Low battery 2. Cable becoming loose or disconnected 3. Vents being blocked 4. Local hot spot on INE Transducer array from laying on a pillow or other insulator 5. Poor INE Transducer array contact due to hair growth or other reason 6. Device malfunction 7. Device is turned ON, but the therapy has not been activated	**If Low Battery indicator is on:** 1. Replace battery as described above 2. Turn on treatment **If the Error indicator lights up but the Low Battery indicator is not lit:** 1. Press the TTfields button to stop the alarm 2. Wait a few seconds then press the TTFields button again 3. If the three blue lights around the TTfields therapy button light up - the therapy has now been activated 4. Check all plugs to make sure nothing is loose 5. Check vents on device and charger to make sure they are not blocked 6. If lying down, move your head 7. Make sure INE transducer arrays are well stuck to the head, add tape if needed 8. Restart treatment 9. If alarm keeps going, turn off the device and contact your Device Support Specialist
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 persists – call your Device Support Specialist.

Device Troubleshooting

Problem	Possible Causes	Actions to be Taken
When powering the device on none of the lights come on	1. Device not connected to Power source 2. If battery –battery depleted 3. If power supply –not properly plugged into the wall 4. Device malfunction 5. Power source malfunction	1. If on battery – check battery fuel gauge to verify it is not depleted. If it is – replace with a charged battery or the 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 both the battery or the power supply or if anything appears to be damaged, please reach out to your device support specialist.
When powering on the device a continuous notification signal sounds and all lights remain on indefinitely. Device does not complete the self-test	1. Device is too hot 2. Device malfunction 3. Power Source Malfunction	Power the device off completely using the main switch. 1. Verify the device is not hot to the touch. 2. Connect the device to a different power source and try powering back up. 3. If device cannot be powered on by both the battery or the power supply or if anything appears to be damaged, please reach out to your device support specialist.

Any cable detached from transducer array/ connection cable/device	1. Too much physical force to cables 2. Damaged Connector	1. Silence the notification signal by pressing the TTFields button. 2. Evaluate the connectors, if intact – reconnect and re-start therapy. If anything appears damaged or cannot be properly connected do not try to use the device. please reach out to your DSS support specialist.
One of the items was dropped, opened or got wet	Incorrect use	If you are on therapy using the damaged item – stop the therapy, power the device down and reach out to your device support specialist.
Notification signal sounds several minutes after the device was powered on	Therapy Timeout	The device will operate the notification signal at a different frequency if it is powered on for several minutes but therapy is not initiated. This is a reminder for you to start therapy and does not indicate a malfunction. Silence the notification signal by pressing the TTFields button then wait a few seconds and press the TTFields button again. The blue indicator around the TTFields button will blink and then stay on to indicate therapy is now on. If you encounter further notifications please review the general "notification signal" section below.

Error indicator is on and there is an notification signal after treatment was initiated	1. Low battery 2. A connection is loose or disconnected 3. The device is too hot 4. Local hot spot on transducer array from laying on a pillow, for example 5. Poor transducer array contact due to hair growth or other reason 6. Damaged array Device malfunction Connection box malfunction	If the Battery indicator is yellow: 1. Silence the notification signal by pressing the TTFields button – Power the device down completely – replace the battery with a fully charged one. If the Error light lights up but the Battery indicator is green or off: 1. Press the TTFields button to stop the notification signal. 2. Wait a few seconds and try to re-start therapy. If the notification signal recurs within: Stop the notification signal and power the device down completely. Disconnect all plugs 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 up. 3. Re-connect all connections in proper order and power the device back up. Verify the self-test is completed and press the TTFields Button. 4. If lying down, reposition your head. Make sure transducer arrays are stuck well to the head with each disc making direct skin contact, add tape if needed. If contact seems to be no longer optimal – replace the arrays. 5. If you are in a hot environment try moving to a cooler place or turning a fan on. 6. If the notification signal keeps going off call Your device support specialist.

Battery indicator is Yellow though the battery gauge is showing the battery is full	1. Battery malfunction 2. Device malfunction	1. Replace battery with an additional charged battery. 2. Connect the original battery to the charger. If problem continues across multiple batteries OR if one of batteries would not charge or causes the charger LED to turn red call your device support specialist.
Redness of the skin under the transducer arrays	Common side effect	1. Use over-the-counter 0.1% hydrocortisone cream when switching transducer arrays. 2. Shift transducer arrays 3/4 of an inch from the last location (so the adhesive gel is between the red marks). If the redness gets worse: See your doctor.
Blisters under the transducer arrays	Rare side effect	See your doctor for a prescription antibacterial cream. Use as your doctor tells you.
Itching under the transducer arrays	Rare side effect	1. Use over-the-counter 0.1% hydrocortisone cream when switching transducer arrays. 2. Shift transducer arrays over 3/4 of an inch from the last location (so the adhesive gel is between the red marks). If the itching gets worse: See your doctor.
Pain under the transducer arrays	Rare side effect	Stop treatment. See your doctor.

23 Assistance & Information

Technical support:

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

If you are unable to get a hold of your Device Support Specialist, you can contact the EMEA Novocure technical support at 00800-88 34 35 37 (00800-TTFields); email: SupportEMEA@novocure.com.

Please state the following information when you contact:

NAME (First/Last)

EMAIL

Telephone (optional)

COUNTRY:

QUESTION:

Clinical support:

If you feel any change in your health or any side effects from the treatment call the investigator at the center, which is treating you.

24 Appendix A – Applicable Standards

The Optune Treatment Kit electronic components comply with the latest editions of the following 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
- EN ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied

Sterile transducer arrays comply with the latest editions of the following 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 General requirements for basic safety and essential performance - Collateral Standard: Usability
- EN 62366-1 – Application of usability engineering to medical devicesEN 62366-1:2015– Application of usability engineering to medical devices
- EN ISO 15223-1Medical devices — Symbols to be used with medical device
- labels, labeling and information to be supplied
- EN ISO 10993-1 - Biological evaluation of medical devices - Part 1: Evaluation and testing
- EN ISO 10993-5 Biological evaluation of medical devices - Part 5: Tests for in-vitro cytotoxicity

- EN ISO 10993-10 - Biological evaluation of medical devices - Part 10: Tests for irritation and delayed type hypersensitivity
- EN ISO 10993-12– Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
- EN 556-1 - Sterilization of medical devices - Requirements for medical devices to be designated "Sterile" - Part 1: Requirements for terminally sterilized medical devices
- EN ISO 11607-1 - Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- EN ISO 11607-2 - Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes.
- EN ISO 11137-1 Sterilization of healthcare products –radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.
- EN ISO 11137-2 Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose.
- ISO 11137-3 Sterilization of health care products -- Radiation -- Part 3: Guidance on dosimetric aspects of development, validation and routine control.
- EN ISO 11737-1 Sterilization of medical devices -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products.
- ISO 11737-2 Sterilization of medical devices -- Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
- ISO 14644-1 Cleanrooms and associated controlled environments--Part 1: Classification of air cleanliness by particle concentration.

Charger for portable batteries complies with the latest edition of the following standards:

- EN 61000-6-1 - Electromagnetic compatibility (EMC) – Part 6-1: Generic standards
  Immunity for residential, commercial and light-industrial environments
- EN 61000-6-3 - Electromagnetic compatibility (EMC) – Part 6-3:
  Generic standards – Emission standard for residential, commercial and light-industrial environments
- IEC 60950-1 - Information technology equipment – Safety, Part 1: General requirements
- BS EN 62368-1 - Audio/video, information and communication technology equipment. Safety requirements

25 Appendix B – Input Output Specifications

The Optune 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 system is not intended for use in the presence of flammable mixtures.
Disinfection is not required.

The INE Transducer arrays are provided sterile for single

use.

Battery for Optune Treatment Kit (Li-Ion Rechargeable)

OUTPUT 28.8 V ⎓ 96Wh

Charger for Optune Treatment Kit batteries

INPUT 100-240V ⎓ 3.15A 50/60Hz ⎓ OUTPUT 3X33.6 V 2.9A

Power supply for Optune Treatment Kit

INPUT 100-240V ⎓ 1.1A 50/60Hz ⎓ OUTPUT 28 V 2.8 A

26 Appendix C – Emitted Radiation & Electromagnetic Compatibility

The Optune Treatment Kit and the accompanying battery charger (ICH9100) and power supply (SPS9100) 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 Treatment Kit system and the accompanying battery charger.

The Optune device should be used with the following cables and additional parts only:

1. CAD9100 connection cable
2. INE9000 INE Transducer array (Sterile)
3. IBH9100 battery
4. SPS9100 power supply
5. ICH9100 charger
6. Unshielded AC mains cables for indoor use only with a maximal length of 1.5m

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

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

Guidance and manufacturer's declaration – electromagnetic emissions Optune Treatment Kit is intended for use in the electromagnetic environment specified below. The customer or the user of Optune Treatment Kit should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	Optune Treatment Kit uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Optune 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 SPS9100 power supply** are intended for use in the electromagnetic environment specified below. The customer or the user of the ICH9100 charger and the SPS9100 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 SPS9100 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 SPS9100 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 Treatment Kit, the ICH9100 charger and the SPS9100 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 Treatment Kit is intended for use in the electromagnetic environment specified below. The customer or the user of Optune Treatment Kit should assure that it is used in such an environment.			
Emissions test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV N/A	

Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	 N/A	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	N/A	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 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 SPS9100 power supply** are intended for use in the electromagnetic environment specified below. The customer or the user of the ICH9100 charger and the SPS9100 power supply 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	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.

Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	±1 kV line to line ±2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input Power frequency (50/60 Hz) magnetic field	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT 3 A/m	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT 3 A/m	Mains power quality should be that of a typical commercial or hospital environment. 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			

Normal operation: The Optune Treatment Kit is working properly when the blue LED surrounding the TTFields button are lit and no notification signal sounds. The ICH9100 charger is working properly when all the LEDs are lit. The SPS9100 power supply is working properly when the blue LEDs surrounding the TTFields button on Optune Treatment Kit are lit and no notification signal sounds.

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 Treatment Kit is intended for use in the electromagnetic environment specified below. The customer or the user of Optune 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 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of Optune Treatment Kit including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 1{,}2\sqrt{P}$ 800 MHz to 2,5 GHz $d = 1{,}2\sqrt{P}$

			where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (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. b) Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 A t 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 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 Optune Treatment Kit is used exceeds the applicable RF compliance level above, Optune 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 Optune Treatment Kit b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

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

Recommended separation distances between portable and mobile RF communications equipment and Optune Treatment Kit			
Optune Treatment Kit is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of Optune Treatment Kit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Optune Treatment Kit as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = [\frac{3,5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3,5}{E_1}]\sqrt{P}$	800 MHz to 2,5 GHz $d = [\frac{7}{E_1}]\sqrt{P}$
0,01	0.116	0.116	0.233
0,1	0.368	0.368	0.736
1	1.16	1.16	2.33
10	3.68	3.68	7.36
100	11.6	11.6	23.2
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated 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. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

27 Appendix D – Glossary

Cancer – abnormal cell division that spreads without control

Chemotherapy – medication used to destroy cancer cells

Clinical trial – a research study that involves people

Contraindications – situations when a treatment should not be used

Glioblastoma Multiforme (GBM) – a type of brain cancer; other medical names for GBM are "glioblastoma", "grade IV glioma" or "grade IV astrocytoma"

INE Transducer Array – array of insulated transducers applied to the scalp to deliver the TTFields.

Local – in one part of the body

MRI scan – a procedure that uses a magnet to create pictures of areas inside the body

Optune Treatment Kit (previously NovoTTF-200A) – (also called TTField generator or NovoTTF-200A device) – A portable device for delivering TTFields to the brain of patients with recurrent or newly diagnosed GBM

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

28 Appendix E – Expected Service Life

Expected service life reflects the average time during which the equipment specified below is expected to work without malfunctioning. Please continue using the equipment if it passed its expected service life and do not stop the treatment.

Optune device and additional parts expected service life is as below:

Optune device – 12 months

Connection cable – 11 months

Power supply – 5 years

Battery – 11 months (or until the expiration date)

Charger – 7 years

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

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