

OPTUNE GIO™

User Manual

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1. Glossary of Medical Terms

Cancer – abnormal cell division that spreads without control

Chemotherapy – medication used to destroy cancer cells

Clinical trial – a research study that involves people

Contraindications – situation when a treatment should not be used

Electric Field Generator (the device) – a portable device for delivering Tumor Treating Fields to the brain of patient with recurrent or newly diagnosed GBM

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

Local – in one part of the body

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

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

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

Recurrence/Recurrent – when cancer comes back after removal

Steroids – when taken by mouth or IV (through the vein), a medication used to lower swelling around a brain tumor and help with symptoms related to the brain. When used on the skin, a medication that can reduce inflammation.

Systemic – throughout the body

Temozolomide (TMZ) – a type of cancer drug used to treat newly diagnosed GBM

Topical - on the surface of the skin

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

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

Tumor – an abnormal growth of tissue.

2. What is Optune Gio and How Does it Work?

Your doctor has prescribed Optune Gio because you are a good candidate for the device.

Optune Gio is a treatment for adult patients (18 years of age or older). Optune Gio is used after surgery and radiation together with and after maintenance chemotherapy if possible. A discussion of brain cancer and treatment options is found at the end of this Patient Manual in Section 28.

A doctor may use Optune Gio to treat a patient with newly diagnosed brain cancer (called glioblastoma multiforme, or “GBM”) in the higher parts of the brain, together with temozolomide (a type of cancer drug).

A doctor may also use Optune Gio to treat a patient with GBM that reappears after they have had chemotherapy (cancer drugs). When Optune Gio is used after it reappears it is used alone, instead of standard medical therapy for GBM.

Indications for Use

Optune Gio is intended as a treatment for adult patients (18 years of age or older) with histologically-confirmed glioblastoma multiforme (GBM).

Optune Gio with temozolomide is indicated for the treatment of adult patients with newly diagnosed, supratentorial glioblastoma following maximal debulking surgery and completion of radiation therapy together with and after standard of care maintenance chemotherapy.

For the treatment of recurrent GBM, Optune Gio is indicated following histologically- or radiologically-confirmed recurrence in the supratentorial region of the brain after receiving chemotherapy. The device is intended to be used as a monotherapy, and is intended as an alternative to standard medical therapy for GBM after surgical and radiation options have been exhausted.

3. Contraindications, Warnings and Precautions

IMPORTANT SAFETY INSTRUCTIONS:

SAVE THESE INSTRUCTIONS. THIS MANUAL CONTAINS IMPORTANT SAFETY AND OPERATING INSTRUCTIONS

Contraindications

- Do not use Optune Gio 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, or defibrillators. Use of Optune Gio together with implanted electronic devices has not been tested and may lead to malfunctioning of the implanted device.
- Use of Optune Gio together with skull defects or bullet fragments has not been tested and may possibly lead to tissue damage or render Optune Gio ineffective.
- Do not use Optune Gio 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 Gio may commonly cause increased redness and itching, and rarely may even lead to severe allergic reactions such as shock and respiratory failure.

Warnings

- Use Optune Gio 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 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 Gio 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.

- Optune Gio is not intended to be used as a substitute for chemotherapy but rather as an adjunct to treatment with TMZ for newly diagnosed GBM.

- Do not use Optune Gio if you are 17 years old or younger. It is unknown what side effects the device may cause in these cases or if it will be effective.

- Do not use Optune Gio 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 Gio 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.

- In case of skin irritation, which appears as redness under the transducer arrays (a mild rash), use high potency topical steroids (your doctor can prescribe this for you) 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.

- 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

- Keep Optune Gio out of the reach of children. If children touch the device, they could damage the device. This could cause a break in treatment. Breaks in treatment may lower your chance to respond to treatment.

- Do not use any parts that do not come with the Optune Gio 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. Breaks in treatment may lower your chance to respond to treatment.

- If your doctor used plates or screws to close your skull bone during your surgery, be careful when placing the transducer arrays. Make sure the round disks that make up the transducer arrays are not on top of the areas where you can feel the screws or plates under your skin. In other words, make sure the screws or plates under your skin are in between the round disks that make up the transducer arrays. If you do not do this, you may have increased skin damage which may lead to a break in treatment. Breaks in treatment may lower your chance to respond to treatment.

- Tell your doctor before using the device if you have an inactive implanted medical device in your brain (such as a stent, plastic drug delivery reservoir, aneurysm clip or coil or device lead). Use of Optune Gio in subjects with inactive implanted medical devices in their brain was not tested and could lead to tissue damage or lower your chance to respond to treatment.

- Do not use Optune Gio 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. Breaks from treatment may lower your chance to respond to treatment.

- 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 head. If this happens, the device will turn off and you will need to change the transducer arrays.

- Before connecting or disconnecting the transducer arrays, make sure that the Optune Gio 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.

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

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

Notices

- The Optune Gio device and transducer arrays will activate metal detectors.
- Do not use Optune Gio if your tumor is located in the lower parts of the brain close to the spinal cord. Ask your doctor if your tumor is located in this part of your brain. Optune Gio has not been tested in patients with tumors in these locations. It is unknown whether these tumors will respond to treatment.
- You should use Optune Gio for at least 18 hours a day to get the best response to treatment. Using Optune Gio for less than 18 hours a day lowers the chances that you will respond to treatment.
- Do not stop using Optune Gio before you finish at least four full weeks of therapy to get the best response to treatment. Stopping treatment before four weeks lowers the chances that you will respond to treatment.
- Do not stop using Optune Gio 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.
- 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.
- 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. Breaks in treatment may lower your chance to respond to treatment.
- 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 1.5 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.
- You should carry the Troubleshooting Guide (Section 25) at all times. This guide is necessary to ensure Optune Gio works properly. If you do not operate the system correctly you may have a break in your treatment. Breaks in treatment may lower your chance to respond to treatment.
- Do not block the device vents located on the front and back of the Electric Field Generator. 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.

- Do not block the battery charger vents located on the sides of the battery charger. Blocking the vents may cause the charger to overheat. This could prevent your batteries from charging.

- 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.

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

4. What Are the Risks of Treatment with Optune Gio

Skin irritation is often seen under the transducer arrays when using Optune Gio. This will look like a red rash, small sores or blisters on your scalp. 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 the clinical study of Optune Gio in GBM that reappeared after chemotherapy, headaches, weakness, convulsions and thinking changes were seen. In the device group, 18 out of 116 patients had headaches, 10 out of 116 patients had weakness, 11 out of 116 patients had convulsions and 6 out of 116 patients had thinking changes. These events are also seen in patients with recurrent GBM who do not use Optune Gio. However, there was a higher rate of these problems overall in Optune Gio patients (43.1%) compared to patients on cancer drugs (36.3%). Only skin redness and open sores are related to Optune Gio treatment itself.

By using Optune Gio instead of cancer drugs, patients would avoid many of the side effects due to cancer drugs. These include infections, nausea, vomiting, loss of appetite, and tiredness. Three times as many patients who used cancer drugs had these side effects compared to patients who used Optune Gio.

The table below shows the occurrence of medical problems in patients using Optune Gio after cancer drugs compared to patients on cancer drugs.

Occurrence of Medical Problems in Patients Using Optune Gio Compared to Patients on Cancer Drugs

Medical Problem	Optune Gio	Cancer Drugs
Lower white and red blood cell counts	5 out of 116 subjects (4%)	17 out of 91 subjects (19%)
Vomiting, nausea and diarrhea	9 out of 116 subjects (8%)	27 out of 91 subjects (30%)
General disorders	15 out of 116 subjects (13%)	14 out of 91 subjects (15%)
Infections	5 out of 116 subjects (4%)	11 out of 91 subjects (12%)
Rash under device transducer arrays and other injuries	21 out of 116 subjects (18%)	1 out of 91 subjects (1%)
Nutrition disorders	9 out of 116 subjects (8%)	12 out of 91 subjects (13%)
Brain disorders	50 out of 116 subjects (43%)	33 out of 91 subjects (36%)
Behavioral disorders	12 out of 116 subjects (10%)	7 out of 91 subjects (8%)
Breathing disorders	7 out of 116 subjects (6%)	10 out of 91 subjects (11%)

The table below shows the occurrence of certain events when Optune Gio was used correctly and incorrectly in the clinical study in patients whose tumor reappeared after cancer drugs.

Occurrence of Certain Problems with Correct and Incorrect Use of Optune Gio

Event	Likelihood of Event	Outcome/Harm	Likelihood of Outcome
Correct use			
Skin reaction	18 out of 116 subjects (16%)	Mild scalp redness (rash)	17 out of 18 subjects (95%)
Skin reaction	18 out of 116 subjects (16%)	Moderate scalp redness (rash with little sores and blisters)	6 out of 18 subjects (33%)
Incorrect use			
Skin reaction	1 out of 116 subjects (1%)	Open sore on scalp	1 out of 1 subjects (100%)
Use in a patient with a pacemaker	1 out of 121 subjects (1%)	Heart problems	0 out of 1 subject (0%)
Use in patients 21 years or younger	0 out of 120 subjects (0%)	Unknown	Unknown
Use in pregnant women	0 out of 120 subjects (0%)	Unknown	Unknown
Use in patients with implanted electronic devices or bullet fragments	0 out of 120 subjects (0%)	Unknown	Unknown
Known allergic reaction to electrode gels	0 out of 120 subjects (0%)	Increased redness and itching, (rarely may even lead to severe allergic reactions such as shock and breathing failure)	Unknown
Opening the device for service by untrained personnel	0 out of 120 subjects (0%)	Damage to the device and risk of electric shock	Unknown
Incorrect uses not predicted	Unknown	Unknown	Unknown

In a clinical study of Optune Gio together with temozolomide (before the tumor reappeared), the device led to skin irritation in about half of the patients (53%). Most of these cases were not severe and were treated with topical creams. Only a handful of patients (2%) had severe skin irritation.

The table below shows the occurrence of severe medical problems in patients using Optune Gio together with temozolomide compared to patients on temozolomide alone.

Occurrence of severe medical problems in patients using Optune Gio together with temozolomide compared to patients on temozolomide alone.

Medical Problem	Optune Gio with Temozolomide	Temozolomide
Lower white and red blood cell counts	59 out of 456 subjects (13%)	23 out of 216 subjects (11%)
Vomiting, nausea and diarrhea	23 out of 456 subjects (5%)	8 out of 216 subjects (4%)
General disorders	42 out of 456 subjects (9%)	13 out of 216 subjects (6%)
Infections	32 out of 456 subjects (7%)	10 out of 216 subjects (5%)
Rash under device transducer arrays and other injuries	24 out of 456 subjects (5%)	7 out of 216 subjects (3%)
Muscle disorders	21 out of 456 subjects (5%)	9 out of 216 subjects (4%)
Nutrition disorders	16 out of 456 subjects (4%)	10 out of 216 subjects (5%)
Brain disorders	109 out of 456 subjects (24%)	43 out of 216 subjects (20%)
Behavioral disorders	17 out of 456 subjects (4%)	6 out of 216 subjects (3%)
Breathing disorders	24 out of 456 subjects (5%)	11 out of 216 subjects (5%)
Bleeding and clotting disorders	19 out of 456 subjects (4%)	5 out of 216 subjects (2%)
Heart disorders	5 out of 456 subjects (1%)	3 out of 216 subjects (1%)

The table below shows the occurrence of certain events when Optune Gio was used correctly and incorrectly together with temozolomide in the clinical study in patients whose tumor has not yet reappeared.

Occurrence of Certain Problems with Correct and Incorrect Use of Optune Gio Together with Temozolomide

Event	Likelihood of Event	Outcome/Harm	Likelihood of Outcome
Correct use			
Skin reaction	235 out of 456 subjects (52%)	Mild or moderate scalp redness (rash with little sores or blisters)	235 out of 242 subjects (97%)
Use in patients with implanted shunts in the brain	4 out of 437 patients (1%)	Shunt malfunction or infection	0 out of 4 subjects (0%)
Incorrect use			
Skin reaction	7 out of 437 subjects (2%)	Open sores on scalp leading to treatment breaks and hospitalization	7 out of 7 subjects (100%)
Use in a patient with a pacemaker	0 out of 437 subjects (0%)	Heart problems	Unknown
Use in pregnant women	0 out of 437 subjects (0%)	Unknown	Unknown
Use in patients with implanted electronic devices or bullet fragments	0 out of 437 subjects (0%)	Unknown	Unknown
Known allergic reaction to electrode gels	0 out of 437 subjects (0%)	Increased redness and itching, (rarely may even lead to severe allergic reactions such as shock and breathing failure)	Unknown
Opening the device for service by untrained personnel	0 out of 437 subjects (0%)	Damage to the device and risk of electric shock	Unknown
Incorrect uses not predicted	Unknown	Unknown	Unknown

5. What Are the Benefits of Treatment with Optune Gio

Patients using Optune Gio 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 every 100 patients lived for one year or longer.

Patients using Optune Gio after their tumor reappeared had a better quality of life (see Section 7).

Below 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 Gio

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 Gio 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 Gio with temozolomide were observed to be alive longer than patients who used temozolomide alone.

	Benefit of Optune Gio + 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 Gio with temozolomide were alive after 2 years than patients using temozolomide alone:

	Patients Alive 2 Years after the Start of Treatment (Optune Gio + 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. What Studies Have Been Conducted with Optune Gio

A clinical study tested Optune Gio against the best standard of care chemotherapy (cancer drugs). The study included 237 subjects with recurrent GBM (120 Optune Gio subjects and 117 cancer drugs subjects).

Subjects who used Optune Gio lived a similar amount of time compared to subjects who were taking cancer drugs. Optune Gio subjects and cancer drugs subjects lived for an average of 6.4 months after treatment was started. In addition, the same portion of subjects who used Optune Gio or cancer drugs were alive one year after starting treatment. That is, 22 out of every 100 subjects were alive at one year when using Optune Gio or cancer drugs. Finally, when subjects used Optune Gio, the tumor shrank to at least half of its original size in 14 out of 100 (14%) Optune Gio subjects compared to 7 out of 73 (10%) cancer drugs subjects. Optune Gio was similar to cancer drugs in other measures of treating GBM. Quality of life was better in Optune Gio subjects compared to cancer drugs subjects.

The number of subjects with digestive problems, blood problems, or infections was three times lower in the Optune Gio group than in the cancer drugs group. That is, 17 out of 91 subjects on cancer drugs had blood problems compared to 5 out of 116 subjects using Optune Gio. 27 out of 91 subjects on cancer drugs had digestive problems compared to 9 out of 116 subjects using Optune Gio. 11 out of 91 subjects on cancer drugs had infections compared to 5 out of 116 subjects using Optune Gio.

18 out of 116 Optune Gio subjects had mild or moderate skin reaction under the transducer arrays (red rash, small sores or blisters). This was expected. None of these cases of skin irritation caused damage to the skin that could not be fixed. The reaction went away after being treated with steroid cream and moving the transducer arrays. In all cases, the rash went away after stopping treatment. One subject had a larger open sore under his transducer arrays, which healed after moving the transducer arrays to another place.

The clinical study found that Optune Gio was similar in effectiveness to cancer drugs in treating recurrent GBM. Optune Gio subjects as a group had a better quality of life without many of the side effects of cancer drugs.

A second clinical study tested Optune Gio together with temozolomide compared to temozolomide alone. The study included 695 subjects with newly diagnosed GBM (466 subjects with Optune Gio and temozolomide and 229 subjects with only temozolomide).

In the clinical study using Optune Gio 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 695 patients had joined the study.

The table below shows the amount of time that patients who used Optune Gio with temozolomide were observed to be alive longer than patients who used temozolomide alone.

	Benefit of Optune Gio + Temozolomide	
	Half of Patients in Study	All Patients in Study
Correct use	Almost 5 months longer	Almost 8 months longer
All subjects	3 months longer	Almost 5 months longer

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

	Patients Alive 2 Years after the Start of Treatment (Optune Gio + Temozolomide vs. Temozolomide Alone)	
	Half of Patients in Study	All Patients in Study
Correct use	48% vs. 32%	44% vs. 25%
All subjects	48% vs. 34%	43% vs. 31%

The number of subjects with digestive problems, blood problems, or infections was similar in the group treated with Optune Gio and temozolomide compared to the group treated with temozolomide alone.

235 out of 456 Optune Gio subjects had mild or moderate skin reaction under the transducer arrays (red rash, small sores or blisters). This was expected. None of these cases of skin irritation caused damage to the skin that could not be fixed. The reaction went away after being treated with steroid cream and moving the transducer arrays. In all cases, the rash went away after stopping treatment. Seven out of 456 Optune Gio subjects had a larger open sore under their transducer arrays, which needed surgery to fix.

The clinical study in patients using Optune Gio with temozolomide before their tumor reappeared found that Optune Gio was more effective than temozolomide alone in treating GBM. Treatment with Optune Gio increased the time until the tumor reappeared and also increased the time patients lived.

A third study tested Optune Gio for recurrent GBM in a real life setting. The patients were using Optune Gio following the approval of the device for recurrent GBM as part of their standard of care treatment. The study results were compared to the best standard of care chemotherapy (cancer drugs) group from the first clinical study in recurrent GBM described above (historical control group). The study included 192 subjects with recurrent GBM in the Optune Gio group and 117 subjects in the cancer drugs group.

Subjects who used Optune Gio alone had a median survival time of 7.4 months and cancer drugs subjects has a similar median survival time of 6.4 months after treatment was started. In addition, subjects who used Optune Gio used it for a longer time compared to subjects who used cancer drugs. That is, the median Optune Gio treatment time was 3.3 months while the median cancer drugs treatment time was 1.6 months.

70 out of 192 Optune Gio subjects had skin reaction under the transducer arrays. This was expected. None of these cases of skin irritation caused damage to the skin that could not be fixed. The reaction went away after being treated with steroid cream and moving the transducer arrays.

This post-approval study confirmed the results of the initial study that led to the approval of Optune Gio for recurrent GBM.

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

7. About Optune Gio

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

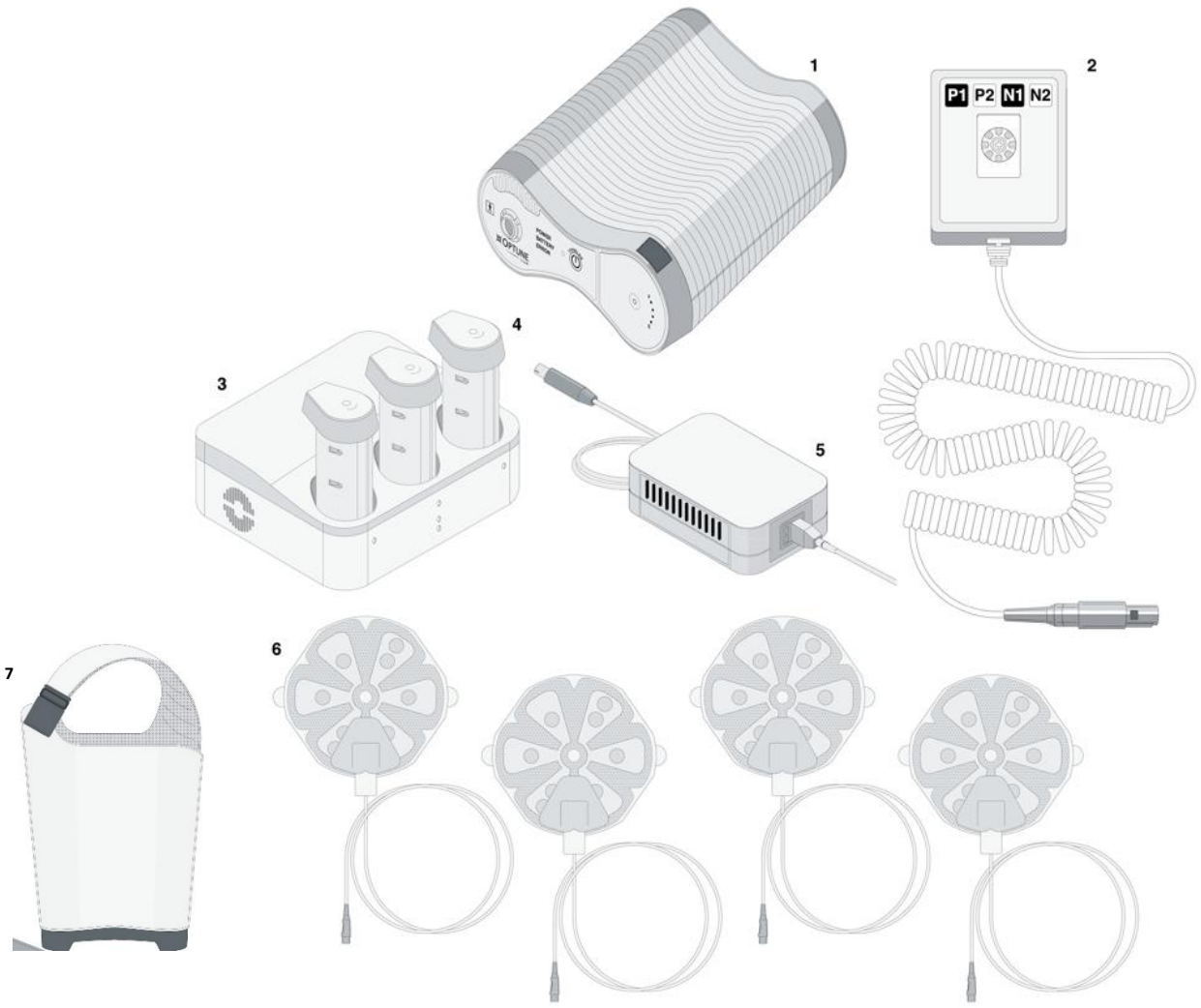
Your doctor has prescribed Optune Gio for use at home. You may be able to use Optune Gio on your own, or you may need help from a doctor, family member, or other caregiver. Use Optune Gio as many hours per day as possible. Only take short breaks for personal needs. Use the device for at least four weeks. When starting treatment at your doctor’s clinic, your doctor will tell you how to use the device, replace transducer arrays, recharge and replace batteries, and plug in the device. Your doctor 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 at the doctor’s office, with the help of a family member or care provider if needed, you will be able to properly work Optune Gio. 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 Gio Treatment Kit includes four rechargeable batteries. Each battery will last for two to three hours. 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 Gio does not need regular maintenance. Optune Gio 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 simple Troubleshooting Guide is provided in this manual (Section 25). You can also call the 24-hour technical support telephone number (Section 26).

Shave your scalp and change the transducer arrays at least twice a week. Keep treatment breaks 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 transducer arrays. To take a shower, unplug the transducer arrays from the device (leave the transducer arrays on your head) and put a shower cap on your head so it does not get wet. You can take a full shower and wet your head when you are not wearing the 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 transducer arrays, if you wish.

8. Overview of Optune Gio Treatment Kit



1 Optune Gio – Electric Field Generator (the device)
2 Connection Cable for Optune Gio (CAD)
3 Optune Gio Battery Charger
4 Battery for Optune Gio
5 Power Supply for Optune Gio
6 Optune HFE transducer arrays
7 Carrying bag

9. Overview of Optune HFE Transducer Arrays

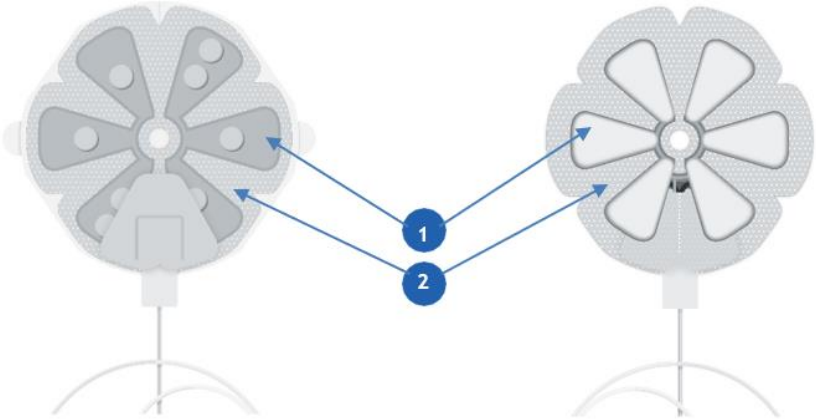
The Optune HFE transducer arrays are adhesive bandages that hold insulated transducers that are needed to deliver treatment. The Optune HFE transducer arrays should be used with Optune Gio only.

Four transducer arrays are used at one time. There are two different color transducer arrays, one type has a white connection end and one has a black connection end. You will need two transducer arrays with white connection ends, and two transducer arrays with black connection ends every time you change your arrays. In the clinical study in subjects whose tumor reappeared after cancer drugs, half of the patients used at least 36 transducer arrays each month. Most patients (95%) used between 20 and 60 transducer arrays each month. Put the transducer arrays on a clean, shaven scalp. Put them on your scalp in the place where your doctor told you, based on the location of your tumor.

The transducer arrays are disposable. Change them at least two times per week (every 4 days at most). Your hair growth will prevent good contact between the transducer arrays and your scalp. Shave the scalp again before you apply a new set of transducer arrays.

Please contact Novocure to arrange for proper disposal of used transducer arrays. Do not dispose of your used transducer arrays in household trash.

10. Before You Put on the Optune HFE Transducer Arrays



1. Segment
2. Tape

You will need to use four (4) Optune HFE transducer arrays at one time. Change the four Optune HFE transducer arrays twice a week to continue treatment with Optune Gio treatment kit. You may change the transducer arrays with the help of a doctor or caregiver if needed. You may change the Optune HFE transducer arrays with the help of a doctor, a nurse or caregiver if needed.

Make sure you have an adequate supply of the Optune HFE transducer arrays to keep you going until your next visit to your physician.

Before using the Optune HFE transducer array make sure its package is sealed. Do not use an Optune HFE transducer array package which has been opened previously.

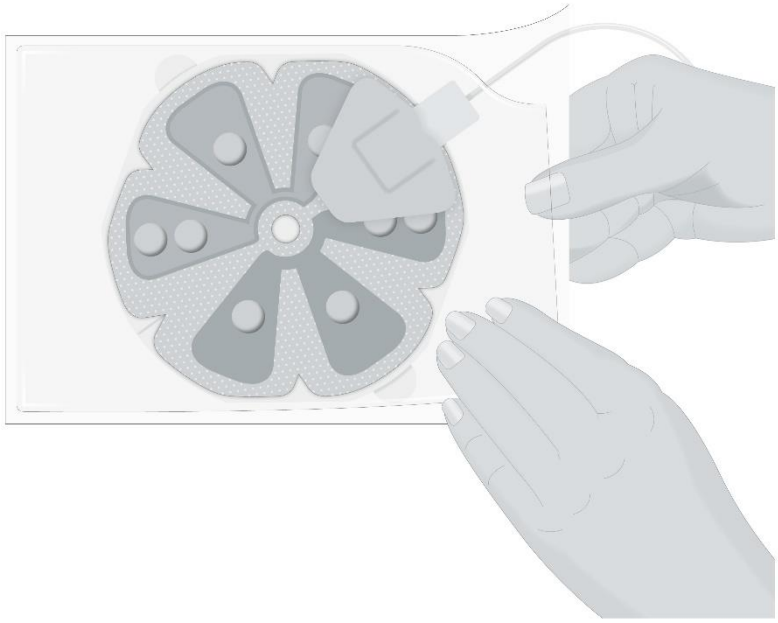
Although the transducer arrays are provided in individual sterile packages to minimize infection risk, you and/or your caregiver can take additional steps to further reduce the risk of infection: Always wash your hands prior to application and removal of the transducer arrays; Wash your scalp between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

The Optune HFE transducer arrays are provided sterile for single use.

11. Removing the Optune HFE Transducer Arrays from the Package

Wash your hands before opening the package with the Optune HFE transducer array.

Open the see through package of four (4) Optune HFE transducer arrays by gently pulling apart the opposing edges of the package as shown in the illustration.



12. Prepare Your Head for Transducer Array Placement

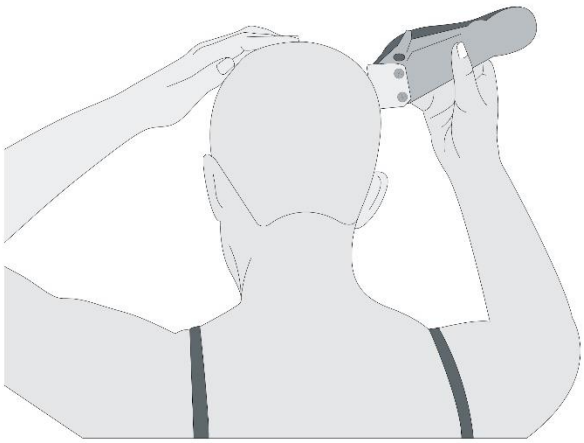
Wash your head with a gentle shampoo.

If this is the first time you have used the Optune HFE transducer arrays, ignore this step and skip ahead to the next step (shaving). If you are replacing the Optune HFE transducer arrays, you, or your doctor or caregiver if needed, should wipe the skin with baby oil to remove any old adhesive from previous Optune HFE transducer arrays. Baby oil is used to remove old 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 a high potency steroid cream if your scalp is red (your doctor will prescribe this for you). Treat open sores on your scalp following your doctor's instructions. If you use a cream or ointment, apply it to the scalp, wait at least 15 minutes and wipe your scalp again with 70% alcohol. Apply the Optune HFE transducer arrays after your scalp is dry.



13. Place the Optune HFE Transducer Arrays on Your Head

After you prepare your scalp (Section 12), put the Optune HFE transducer arrays on your head with the help of a doctor or caregiver if needed. Twice a week, remove the transducer arrays, prepare the scalp (as outlined in Section 12) and put on a new set of transducer arrays. You will know it is time to change the Optune HFE transducer arrays when the device alarm beeps consistently. This means that the device is not able to work properly because of hair growth. Hair growth keeps the Optune HFE transducer arrays from making good contact with your scalp.

To place the Optune HFE 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 are using the Optune HFE transducer arrays, ignore the first step (removal).

Remove the Optune HFE transducer arrays from your head by carefully and slowly peeling the medical tape away from your scalp.

In the treatment kit, there are Optune HFE transducer arrays with two connector colors – black and white.

Note on the Optune HFE transducer array layout the location where each Optune HFE transducer array color should be placed on your head. The Optune HFE transducer array locations and colors are: front & back (black), left & right (white)

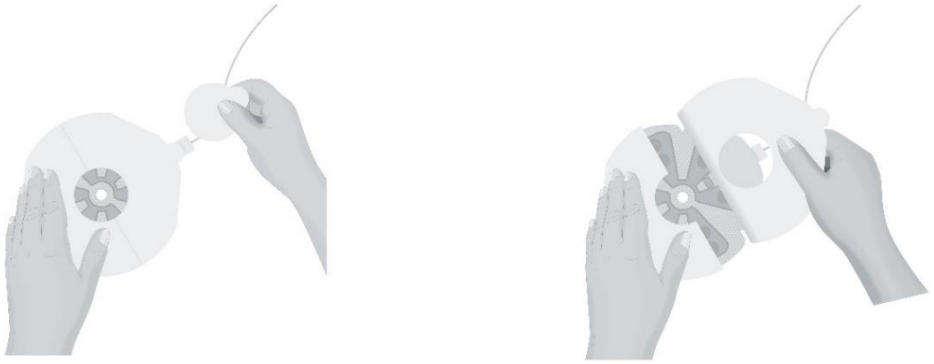
Prepare your skin for the Optune HFE transducer arrays, as described in Section 12.

Peel off the three (3) white l liners covering the gel from the first Optune HFE transducer array.

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

Pull the tabs on each side of the Optune HFE transducer arrays and press them firmly to your scalp. Press the entire edge of the Optune HFE transducer array tape to your scalp.

Optune HFE transducer array liner removal



Remove the white outer liners.

The flexible segments can be damaged on the Optune HFE transducer arrays.

Do not use the Optune HFE transducer arrays if the gel is damaged or the flexible segment is damaged on the top or back of the Optune HFE transducer arrays.

Remove all liners covering the gel areas before applying the Optune HFE transducer arrays to the scalp.

Put the Optune HFE transducer arrays on your head as shown in the Optune HFE transducer array layout or the map that you received. Placement is based on the location of your tumor.

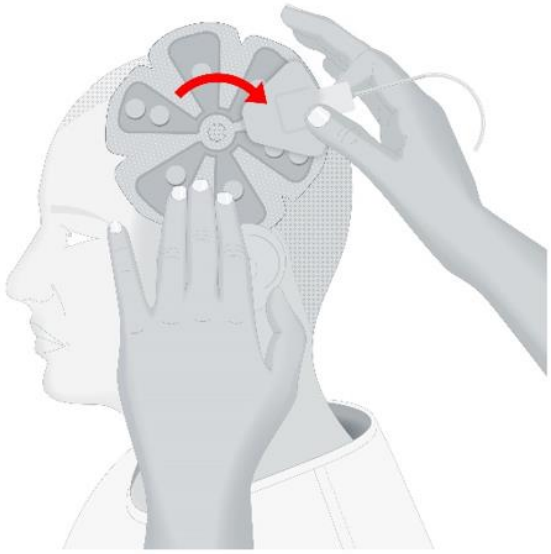


The Optune HFE transducer arrays should have approximately 2cm separation from each other (one finger width) during application to reduce the likelihood of skin irritation.

To reduce skin irritation under the Optune HFE transducer arrays, move or rotate the Optune HFE transducer arrays slightly.

Place the other three Optune HFE transducer arrays in the same way.

Press the Optune HFE transducer array firmly to your scalp. Press the entire edge of the Optune HFE transducer array tape to your scalp.

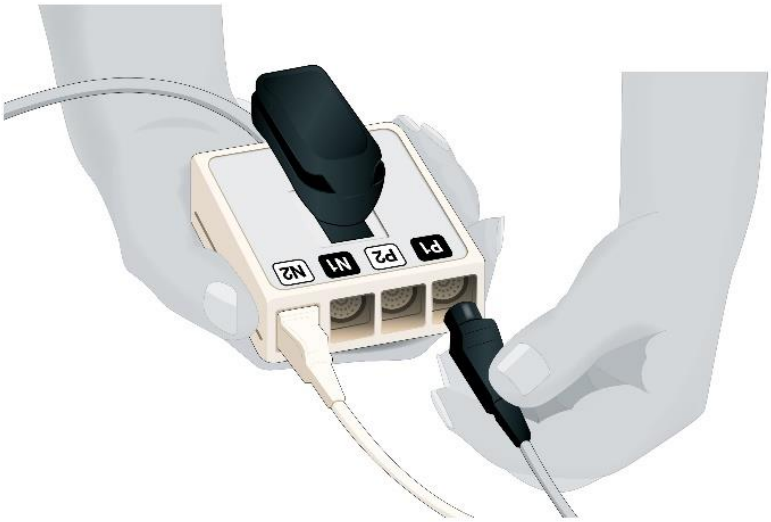


14. Connect the Optune HFE Transducer Arrays to the Device

Connect each of the four transducer array connectors with black and white connection ends to the matching sockets on the connection cable. Plug the transducer array connectors with the black connection ends into the two black sockets (there will be one labeled “P1” and one labeled “N1”) and the two white connection ends into the white sockets (there will be one labeled “P2” and one labeled “N2”) (see diagram).

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

You may clip the connection cable to your belt.



15. Disposal

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

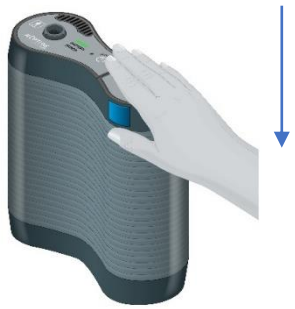
16. Connecting & Disconnecting the Battery

TO REDUCE RISK OF BATTERY EXPLOSION, FOLLOW THESE INSTRUCTIONS AND THOSE MARKED ON THE BATTERY

Optune Gio treatment kit comes with 4 rechargeable batteries. Batteries slide into the device. The battery should be inserted until you hear a “click”, indicating the battery is in place. Take care not to drop the battery in place or force it into the battery slot. Optune Gio uses one battery at a time. The other three 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 illuminated, as described in Section 17). If you plan to be away from home for more than 2 hours, carry spare 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 lift up



Recharge the batteries in the charger (see Section 17) 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 light illuminates and the alarm beeps) will get shorter. If the time from treatment start with a full battery to low battery alarm falls below 90 minutes contact technical support (see 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 light illuminates. Once this happens the treatment will stop and the device must be turned off and the battery replaced.

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 alarmed, using the following steps:

1. Plug in the wall power supply to bottom of the Optune Gio device. (See Section 18). The lights on the display panel will indicate you are no longer running on battery power.
2. Remove the battery from the battery slot by pressing the blue buttons on the side of the battery and lifting the battery cartridge out of the slot.
3. Select a fully charged battery from the charger or device bag.
4. Slide the fully charged battery in the battery slot, gently push down to lock the battery in place.
5. Remove the power cord from the bottom of the device.

The battery light on the display panel will illuminate indicating you are no longer running on wall power. To check the battery gauge see section 17.

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

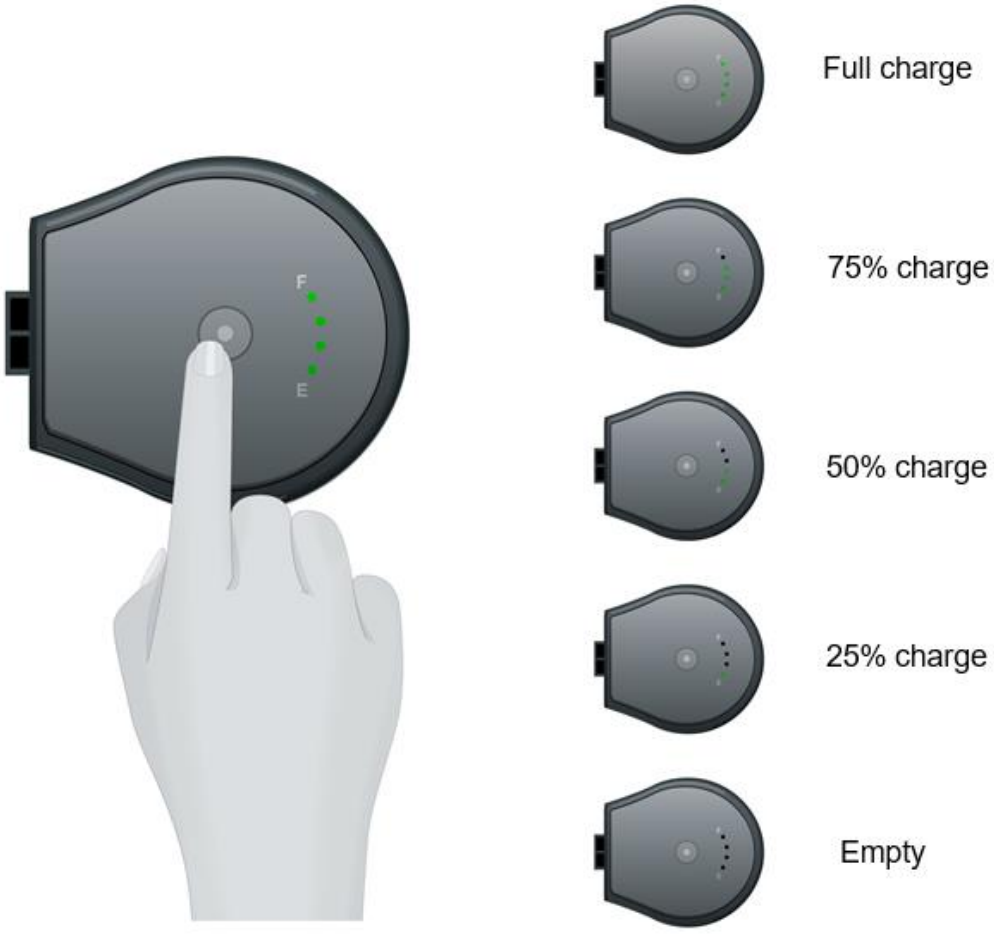
1. Press the TTFields button to stop the treatment.
2. Turn off the device using the power switch (on the bottom of the device).
3. Remove the battery from the battery slot by pressing the blue buttons on the side of the battery and lifting the battery cartridge out of the slot.
4. Select a fully charged battery from the charger.
5. Slide the fully charged battery in the battery slot, gently push down to lock the battery in place.
6. See the next section to check the battery gauge.
7. Turn ON the device using the power switch and wait for the system to run a self-check (this takes about 10 seconds). To start treatment press the TTFields button (see Section 21).
8. Insert the used battery into the charger for recharging (see Section 17).

17. Charging the Battery

Checking the Battery Gauge

While you are using Optune Gio 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 life, press the button once on the top of the battery cartridge. The battery life will be indicated by the lighted gauge to the right of the button. The gauge reads from full to empty, 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.

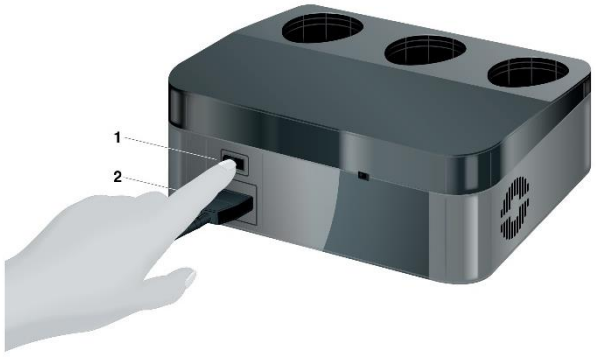
Before charging the batteries, plug the charger power cord into a standard wall outlet and turn on the power switch at the back of the charger. The front lights of the charger will come on during a self-check then the small light in the center of the front panel will light up green indicating power is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

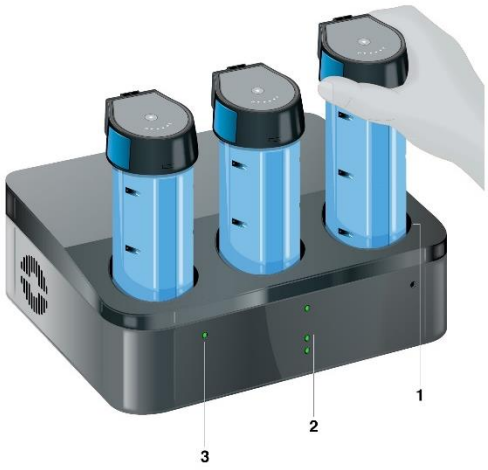
Keep the batteries in the charger even after they are fully charged. This will not harm the batteries.



1 Charger Power Cord
2 Power Switch

Back view of Battery Charger illustrating the power switch and Power Cord connection.

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



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

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

Caution: Do not expose the charger to rain.

18. 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/ CA (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 26).

When the device has a battery and is also connected to the wall power supply, the device will utilize the wall power supply as the preferred power source. When the wall power cord is plugged in while the device is running on 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 to a standard wall outlet using the power cord that comes with it.
2. You do not need to remove the battery from the device to use the wall power supply. Note that a battery in the device will not charge while the device is plugged into the wall power supply. Depleted batteries must be placed on the battery charger to recharge. If the TTFields are activated you do not need to turn them off to plug in the wall power supply.
3. Plug the connector of the wall power supply into the AC port on the back panel of the device (next to the power switch).
4. If the TTFields are running, the device will automatically switch to wall power supply 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 21).

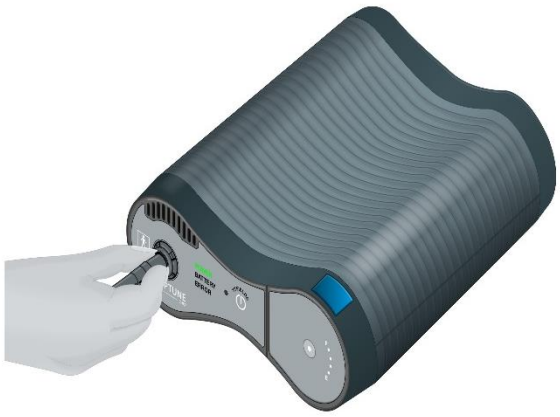
To Disconnect the Plug-In Power Supply and Go Back to Battery Power

1. Ensure that a charged battery is properly inserted in the device before removing the wall power supply. If the TTFields are running, you do not need to turn them off before removing the wall 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 back panel 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.

19. The Connection Cable & Connection Box

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

The connection cable plugs into the device in the port on the left of the front panel. The connection cable port has a picture of a person next to it. The connection cable plugs into the socket with the arrows facing up. Push in the connector until you hear a click. The click means it is secure.



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 switch.

Unplug the connection cable from the socket by holding the gray collar and pulling back. 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 using the power button. Wait for self-check to be completed (about 10 seconds).
3. Turn on the TTFields using the TTFields button.

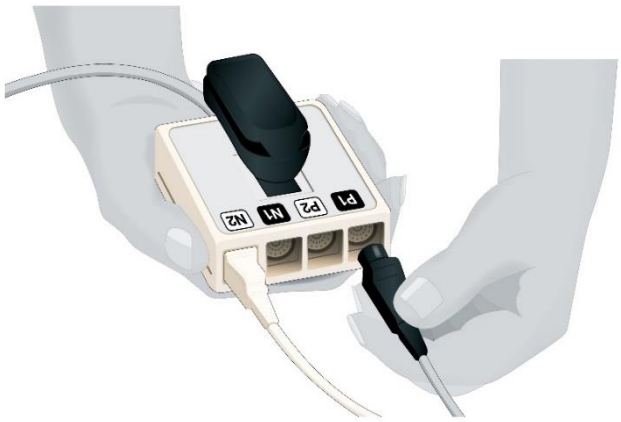
To Unplug the Transducer Arrays from the Connection Cable:

To take a break from treatment and completely disconnect from the device, unplug the transducer arrays from the connection cable box. The four transducer arrays are plugged into the connection cable box as described in Section 14. The connection cable is plugged into the device at the P1 (patient) socket.

1. Stop treatment by pressing the TTFields button.
2. Turn off the Optune Gio device using the power switch.
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 (as described in Section 13).

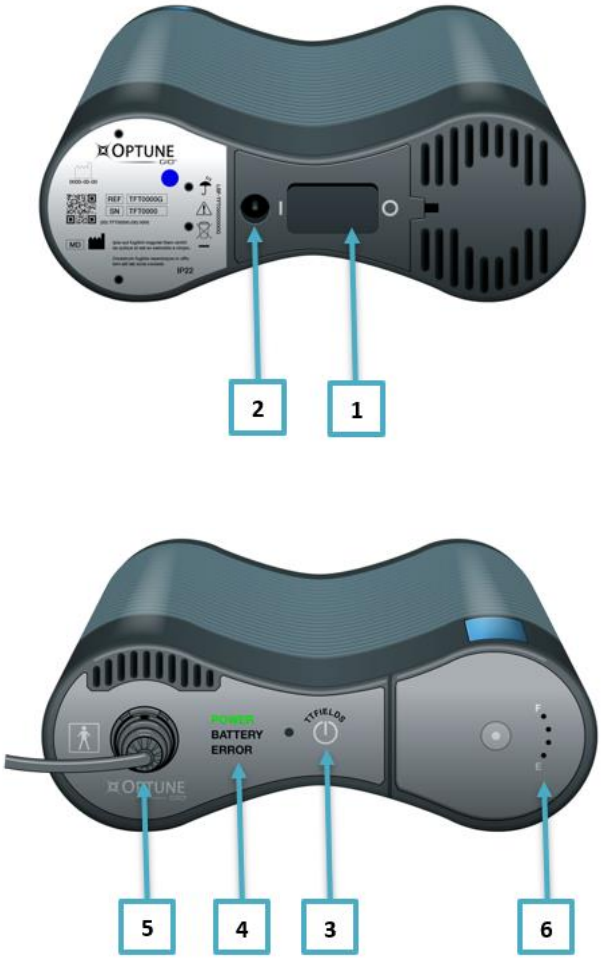
1. When all 4 transducer arrays are plugged in, turn on the power switch and wait for self-check to be completed (about 10 seconds). Push the TTFields button to restart treatment.



20. The Electric Field Generator

Keep the TTFields treatment on all the time, as much as possible, when awake and when sleeping. Keep breaks from treatment as short as possible.

The picture below shows the device controls to work the system. You do not need to adjust any settings. You only need to turn the device and the therapy off and on.



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

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

21. To Start & Stop the Device

To Start Treatment

1. Put the transducer arrays on the scalp (with the help of a caregiver if needed). Plug the transducer arrays into the connection cable box (Sections 14 and 15).
2. Plug the connection cable into the device with the arrows on the connector up (as described in Section 19).
3. Insert a charged battery into the device (see Section 17) or attach the wall power supply (Section 18).
4. Turn the power button on the bottom or the back of the device to the ON position.



5. Allow about 10 seconds for the self-check to be completed. The “Power” indicator on the front panel of the device will illuminate green.



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



If a wall power supply is plugged into the device the device will run using the wall power supply and the "Battery" indicator will not illuminate.

6. Press the TTFields therapy button once – this will start treatment.



The “TTFIELDS” above the TTFields therapy button will illuminate blue and stay on while the treatment is on. If the blue words are not illuminated, then the treatment is not running and you should check the setup and restart the procedure. If, after this, the indicator lights do not light up, consult the Troubleshooting Guide (Section 25). If you still have problems, contact technical support (Section 26).

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 10 minutes after the device is turned ON, an alarm 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 alarm and again to start the therapy. “TTFIELDS” will be illuminated blue when the patient is receiving treatment.

You may stop treatment if the following happens:

If the Device is running properly, but you need to stop treatment to take a break:

Press the TTFields button. The blue “TTFIELDS” lights around the button will turn off. This turns the TTFields therapy off, but the device power is still on.



Then, turn off the device by turning the power button on the bottom or the back of the device to the OFF position



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). In this case, once the red Error light illuminates, the treatment has stopped.

To turn off the device:

1. Press the TTFields button on the front of the device to stop the alarm. The red Error light will turn off. (If this does not silence the alarm, proceed to the next step of turning off the power switch to silence the alarm. A small number of alarm conditions cannot be silenced by the pushing the TTFields button).
2. Turn off the device by turning the power switch to the OFF position.
3. See the Troubleshooting Guide (Section 25) for instructions on fixing problems. Restart the device and restart treatment if no problem is found. If the alarm continues, contact technical support (Section 26).



If the Low Battery Indicator Lights Up:

When your battery runs out (after about 2-3 hours), an alarm will beep, the TTFields therapy will stop and both the yellow low Battery light and red Error light will light up. This alarm sound is the same alarm sound the device makes for an error. However, in this case both the yellow and red lights 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 alarm. The red Error and the yellow low Battery lights will turn off.
2. Replace the battery using the steps in Section 17.

22. Carrying the Device

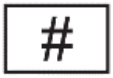


Both the electric field generator and the battery fit in a carrying bag. The bag can be carried in two ways: by the handle on top or over the shoulder/ cross-body with a carrying strap attached.

Note: Do not place the device in a different bag. Optune Gio 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

	Follow instructions for use
	Manufacturer Information: Novocure GmbH, Neuhofstrasse 21, 6340 Baar, Switzerland
	Model number
	Reference number
	Serial number
	Lot number
	Manufacture date
 YYYY-MM	Use-by date/Expiry date
	Caution Consult the instructions for use for important information such as warnings and precautions
	Waste Electrical and Electronic Equipment recycling “WEEEE disposal” Contact technical support to arrange for proper disposal of arrays that are used up or no longer in use.
	Batteries are Lithium Ion. Contact technical support to arrange for proper disposal of batteries that are used up or no longer in use
	Do not re-use. The transducer arrays are for single use and should not be re-used.
	Sterile/sterilization method. The transducer arrays are sterilized by Gamma irradiation

	Do not re-sterilize
	Do not use if package is damaged. Do not use the transducer arrays if their packaging is breached.
	Protect from heat and radioactive sources Optune Gio should be kept away from extreme heat and sources of radiation
IPxx	International Protection Rating (IP) code: A coding system to indicate the degrees of protection provided by an enclosure against access to hazardous parts or water.
	Keep dry. Do not enter rooms with high humidity or danger of direct exposure to water while wearing the device. Do not use the device if not within its carrying bag. Do not expose the device to direct rain.
	For indoor use only The charger and power supply are for indoor use only
	Class II equipment per IEC 60601-1
	BF type applied part Symbolizes the part which comes in contact with the patient
	Storage Temperature range Do not expose to temperatures below -5°C or above 40°C
	Storage humidity range Do not expose to humidity below 15% or above 93%
	Fragile, handle with care
	P1 P2 N1 N2 black and white coding on the connection box

	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
	MET Electrical Safety Mark

24. Storage & Transportation by the Distributor

Storage Conditions

- Temperature range: -5°C to +40°C for the device and additional parts.
- Temperature range: +5°C to +27°C for the transducer arrays
- Relative humidity range: 15-93% for the device and additional parts.

Transport Conditions

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

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

Transportation of the transducer arrays is possible using air/ground transportation in weather protected conditions as specified below:

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

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 light does not light up after turning ON the device	1. Device not connected to power source 2. If Battery – 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 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 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 866.320.2006
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 866.320.2006
Device dropped or wet	Incorrect use	1. Press TTFields button to stop therapy 2. Turn OFF power switch 3. Call technical support at 866.320.2006

Problem	Possible Causes	Actions to be Taken
Device alarm on	1. Low battery 2. Cable loose or disconnected 3. Device is too hot – vents on the device are blocked 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. Device malfunction 7. Device is turned ON, but the therapy has not been activated	If low Battery light is yellow: 1. Replace battery as described above in Section 18 2. Turn on treatment If the Error light lights up but the low Battery light 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 blue lights around the TTFields therapy button light up – the therapy has now 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-test is completed and press the TTFields button 4. Check vents on device to make sure they are not blocked 5. If lying down, move your head 6. Make sure transducer arrays are well stuck to the head, add tape if needed 7. Restart treatment 8. If alarm keeps going, turn off the device and call technical support at 866.320.2006
Notification alarm sounds 10 minutes after the device was powered on	1. Therapy Timeout	The notification alarm on the device will sound if it is powered on for 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 review the general "notification signal" section below

Problem	Possible Causes	Actions to be Taken
Low Battery indicator light 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 866.320.2006
When powering on the device a continuous notification alarm 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	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 contact technical support
Redness of the skin under the transducer arrays	Common side effect	Use over-the-counter 0.1% hydrocortisone cream when switching transducer arrays. 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: 1. 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: 1. See your doctor
Pain under the transducer arrays	Rare side effect	Stop treatment. See your doctor.

26. Assistance & Information

Technical Support:

For technical support call at 1-866.320.2006 (toll free)

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

Medical Support:

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

27. Traveling with Optune Gio

Optune Gio's portable 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. Contact Novocure Support if you have questions related to travel restrictions.

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

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

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

28. Brain Cancer

What Is Brain Cancer?

In simple terms, brain cancer is a growth of cells that form a tumor in the brain. Just like any other form of cancer, brain tumors can spread to other parts of the brain. They do not usually spread outside of the brain. Even before the brain cancer grows and spreads, the tumor could cause problems inside the brain. The brain controls the functions of the body. Any problem in the brain will affect normal functioning. Therefore, symptoms of brain cancer depend on where and how big the tumor is.

Can Brain Cancer Be Treated?

There are currently six main options to treat GBM:

- Operation – Treatment of patients with GBM usually begins with taking out all or some of the tumor
- Radiation – Following an operation, many patients have radiation therapy
- Stereotactic radiosurgery – This is a type of radiation therapy that uses focused radiation beams coming from different angles to deliver radiation to a specific area of the brain while sparing surrounding tissues
- Local Chemotherapy – During the operation, the surgeon can put a wafer that delivers cancer drugs to the site where the tumor was taken out
- Systemic Chemotherapy – Many GBM patients take cancer drugs. There are several approved drugs to treat GBM
- Optune Gio® together with systemic chemotherapy

Radiation therapy and cancer drugs can allow patients to live longer than if they had no treatment. Adding Optune Gio to temozolomide can allow patients to live even longer than with temozolomide alone. Radiation and cancer drugs have side effects. These side effects include hair loss, skin irritation, possible hearing problems, nausea, vomiting, loss of appetite, effects related to the brain, and tiredness.

When Brain Cancer Returns (Recurrence of Brain Cancer)

GBM can come back even with operations and the treatments described above. In these cases, some of the above treatments (operation, radiation and cancer drugs) may still work to treat the cancer. However, in some cases, operations and radiation will no longer work for the patient. In those cases, doctors may use a systemic cancer drug treatment, or, alternatively once a patient has had treatment with a cancer drug, Optune Gio.

29. Emitted Radiation & Electromagnetic Compatibility

The Optune Gio device (model TFH9100) 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 Gio Treatment Kit and the accompanying battery charger.

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

1. CAD9100 connection cable
2. IHEP9020 Optune HFE transducer array (Sterile)
3. IBH9100 battery
4. SPS9200 power supply
5. ICH9100 charger
6. Unshielded AC mains cables for indoor use only with a maximal length of less than 3.0 m

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

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

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

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

Table 2 – Guidance and MANUFACTURER'S declaration – electromagnetic IMMUNITY – for all ME EQUIPMENT and ME SYSTEMS

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
Optune Gio Treatment Kit, including the Optune Gio device, the ICH9100 charger and the SPS9200 power supply, is intended for use in the electromagnetic environment specified below. The customer or the user of Optune Gio Treatment Kit should ensure 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	Floors should be wood, concrete or ceramic tile. If floors 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 ±1 kV for input/output lines 100 kHz repetition	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° 0 % 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 AC mains voltage prior to application of the test level.			

Normal operation: The Optune Gio device is working properly when the blue LED surrounding the TTFields button are lit and no notification signal sounds. The ICH9100 charger is working properly when all the LEDs are lit. The SPS9200 power supply is working properly when the blue LEDs surrounding the TTFields button on Optune Gio 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 Gio® Treatment Kit is intended for use in the electromagnetic environment specified below. The customer or the user of Optune Gio Treatment Kit should ensure that it is used in such an environment.			
Emissions test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the Optune Gio treatment kit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \frac{6}{E}\sqrt{P}$ Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m. Field strengths from fixed RF transmitters, as deter-mined by an electromagnetic site surveya, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	10 V/m	10 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz	
Radiated fields in close proximity Standard IEC 61000-4-39	8A/m 30KHz CW 65A/m 134.2KHz pulse modulated 2.1KHz 7.5A/m 13.56MHz pulse modulated 50KHz	5cm distance	
NOTE 1 At 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 Gio Treatment Kit is used exceeds the applicable RF compliance level above, Optune Gio 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 Gio Treatment Kit b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m			

Guidance and manufacturer's declaration – electromagnetic immunity			
The ICH9100 charger and the SPS9200 power supply are intended for use in the electromagnetic environment specified below. The customer or the user of the ICH9100 charger and the SPS9200 power supply should ensure that they are used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the ICH9100 charger and the SPS9200 power supply, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \frac{6}{E}\sqrt{P}$ Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m.
Radiated RF IEC 61000-4-3	10 V/m	10 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz	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 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

Optune Gio Treatment Kit is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of Optune Gio Treatment Kit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Optune Gio 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**						
	380 – 390MHz	**430 – 470MHz**	**704 – 787MHz**	**800 – 960MHz**	**1700 – 1990MHz**	**2400 – 2570MHz**	**5100 – 5800MHz**
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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