



OPTUNE GIO™

Quick start guide

Before you begin

Getting to know Optune Gio™

Familiarizing yourself with the components of the treatment kit will help ensure you are setting it up correctly each and every time you use Optune Gio.



Optune Gio components:

- A** Connection cable and box (also referred to as “CAD”)
- B** Easy-access sleeve bag*
- C** Electric field generator with battery (also referred to as “the device”)
- D** Plug-in power source
- E** Power cords
- F** Four (4) single-use transducer arrays
- G** Battery sleeve with extra battery
- H** Portable battery charger (holds up to 3 batteries)

*** NOTE: You will also be receiving an additional backpack-style carrying bag. Only use the carrying bags provided by Novocure®.**

For more detailed information on the Optune Gio components, refer to the Optune Gio Instructions For Use (IFU) or the *Optune Gio Patient Information and Operation Manual*.

Starting a treatment session

The following shows you step-by-step how to prepare for and begin treatment with Optune Gio™.

1 Applying the transducer arrays



- Remove each of the 4 transducer arrays from the sterile packaging
- Place the arrays on your clean-shaven scalp. **Refer to your transducer array layout (or map that your doctor gave you) for correct placement**

2 Connecting the arrays to the device



- Firmly insert the black and white transducer array wire ends into the corresponding black and white sockets on the connection box



- Insert the cable from the connection box to the connection cable socket on the device. **Note: Be sure the device is powered off before connecting arrays**

INFECTION PREVENTION

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

Refer to *A Guide to Scalp Care and Proper Transducer Array Placement* provided in the Starting Optune Gio Resource Kit for more information on preparing the scalp and applying your arrays.

Starting a treatment session (continued)

3 Powering on the device 2 ways

There are 2 ways to power the device: 1) using the plug-in power source OR 2) using a fully charged portable battery.

Option 1: Plug-in power



- Press the power switch on the bottom, or back, of the device
- **IMPORTANT!** Even if you are using the plug-in power source, a battery should always be in the device

Option 2: Fully charged battery power



- Insert a fully charged battery into the battery slot on the device until you hear a click
- Press the power switch on the bottom, or back, of the device
- On average, a battery lasts about 2 to 3 hours

Note: The device will automatically perform a self-test

You'll know the self-test has started because the device will beep and the "Power," "Battery," and "Error" lights will illuminate.



Battery power self-test is complete and the device is turned on when:

The red "Error" light turns off and **BOTH** the "Power" and the "Battery" lights are green.



Plug-in power self-test is complete and the device is turned on when:

The red "Error" light turns off and **ONLY** the "Power" light is green.

4 Initiating treatment

It is important to note that turning on the device does not initiate treatment.



- To begin treatment, push the "TTFields" button on the top, or front, of the device

Additional information

“No-Stop Swap” for switching power sources

“No-Stop Swap” enables you to swap batteries or power sources without disrupting delivery of Tumor Treating Fields, or TTFIELDS.

Switching from battery to plug-in power source



Make sure to plug the device into the plug-in power source and the power source into a wall outlet. Also ensure the “Battery” indicator light turns off and the “Power” light turns green **BEFORE** removing the battery so delivery of TTFIELDS is not disrupted.

- If you are staying in one place for a while (for example, working at a desk or going to sleep), simply connect the device to the plug-in power supply source and plug it into a nearby wall outlet to continue powering the device without disrupting treatment

Swapping batteries



If you are switching batteries using the “No-Stop Swap,” always do so when the battery gauge light is yellow and **BEFORE** the “replace battery” alarm sounds. **IMPORTANT!** If the battery gauge light turns yellow and you are not near an outlet, you will need to power off the device before switching batteries.

- Plug the device into a wall outlet
- Simply remove the depleted battery and replace it with a fully charged one
- Once the battery has been replaced, unplug the device and go about your day

Charging batteries



Battery light meanings

- Blinking green light: battery is charging
- Solid green light: battery is fully charged
- Red light: an error has occurred

- The system comes with 4 portable batteries, each lasting about 2 to 3 hours when fully charged
- You can charge up to 3 batteries at a time
- Simply plug the charger into a wall outlet and insert batteries
- **IMPORTANT!** If you see a red light or if a battery is fully charged but lasts less than 90 minutes, call MyNovocure™ for 24/7 technical support or to request a replacement battery

Checking battery life



- To check the battery life, press the button on the top of the battery charger once. 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
 - 4 lights mean the battery life is “full,” or 100% charged
 - 1 light means there is only 25% battery life left
 - When the battery power indicator light turns yellow, it’s time to change the battery

What is Optune Gio™ approved to treat?

Optune Gio is a wearable, portable, FDA-approved device indicated to treat a type of brain cancer called glioblastoma multiforme (GBM) in adult patients 22 years of age or older.

Newly diagnosed GBM

If you have newly diagnosed GBM, Optune Gio is used together with a chemotherapy called temozolomide (TMZ) if:

- Your cancer is confirmed by your healthcare professional **AND**
- You have had surgery to remove as much of the tumor as possible

Recurrent GBM

If your tumor has come back, Optune Gio can be used alone as an alternative to standard medical therapy if:

- You have tried surgery and radiation and they did not work or are no longer working **AND**
- You have tried chemotherapy and your GBM has been confirmed by your healthcare professional

Who should not use Optune Gio?

Optune Gio is not for everyone. Talk to your doctor if you have:

- **An implanted medical device (programmable shunt), skull defect (missing bone with no replacement), or bullet fragment.** Optune Gio has not been tested in people with implanted electronic devices, which may cause the devices not to work properly, and Optune Gio has not been tested in people with skull defects or bullet fragments, which may cause Optune Gio not to work properly
- **A known sensitivity to conductive hydrogels** (the gel on the arrays placed on the scalp like the ones used on EKGs). When Optune Gio comes into contact with the skin, it may cause more redness and itching or may rarely cause a life-threatening allergic reaction

Do not use Optune Gio if you are pregnant or are planning to become pregnant. It is not known if Optune Gio is safe or effective during pregnancy.

What should I know before using Optune Gio?

Optune Gio should only be used after receiving training from qualified personnel, such as your doctor, a nurse, or other medical staff who have completed a training course given by Novocure®, the maker of Optune Gio.

- Do not use any parts that did not come with the Optune Gio Treatment Kit sent to you by Novocure or given to you by your doctor
- Do not get the device or transducer arrays wet
- 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

What are the possible side effects of Optune Gio?

Most common side effects of Optune Gio when used together with chemotherapy (temozolomide, or TMZ) were low blood platelet count, nausea, constipation, vomiting, tiredness, scalp irritation from the device, headache, seizure, and depression.

The most common side effects when using Optune Gio alone were scalp irritation (redness and itchiness) and headache. Other side effects were malaise, muscle twitching, fall and skin ulcers.

Talk to your doctor if you have any of these side effects or questions.

Please visit [OptuneGio.com/Safety](https://www.optunegio.com/safety) for Optune Gio Instructions For Use (IFU) for complete information regarding the device's indications, contraindications, warnings, and precautions.



Troubleshooting

Optune Gio™ is equipped with safety alarms to notify you of errors that may interrupt treatment. Should an alarm sound, please refer to your *Optune Gio Patient Information and Operation Manual* or call 1-855-281-9301 (toll free) for 24/7 MyNovocure™ technical support.

Possible causes for treatment interruptions may include:

- Low battery
- Disconnected cable
- Blocked vents
- Temperature threshold surpassed
- Poor transducer array contact
- Device malfunction

For more on troubleshooting, refer to the Troubleshooting section in the *Optune Gio Patient Information and Operation Manual* you received with your kit, or visit OptuneGio.com.

Questions?
Replacement parts?

MyNovocure offers 24/7
personalized support.



OptuneGio.com



**MyNovocure support at
1-855-281-9301 (toll free)**



support@mynovocure.com

Visit OptuneGio.com/safety to see the Optune Gio Instructions For Use (IFU) for complete information regarding the device's indications, contraindications, warnings, and precautions.