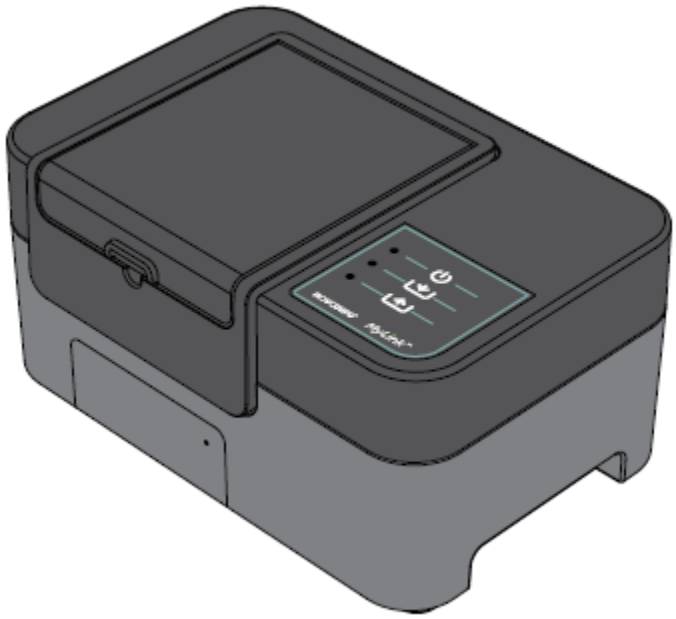
MyLink™ User Guide

MODEL OTU5000

Easier data collection from the Electric Field Generator with MyLink



Contents

This manual is intended for patients receiving Tumor Treating Fields therapy using one of the following electric field generators:

- Optune / Optune Gio device (TFH9100)
- Optune Lua device (TFT9200)

Please note: The color of the front face of your device may look different to the color shown in the diagram.

1. About MyLink – Device Description

Intended Purpose

MyLink enables the patient to upload the electric field generator's log files to a remote secured Novocure server from the comfort of his/her home.

Intended Users and Use Environment

The device is intended for use by the adult patients or their caregivers in the home health care environment.

Contraindications, Warnings, Precautions and Notices

WARNINGS

Warning — All servicing procedures must be performed by qualified and trained personnel. Attempting to open and service your MyLink unit may result in an electric shock by touching the inner parts of the equipment. It could also cause damage to the unit.

Warning — No modification of this equipment is allowed.

PRECAUTIONS

Caution — MyLink is to be used with the electric field generators listed on page 3 only.

NOTICES

Notice — your MyLink unit uses a cellular network for its operation. If you are trying to use it in a non-cellular reception environment, the unit will not work properly.

2. Principles of Operation

MyLink is a standalone technical unit which enables the easy upload of data from the electric field generators to a remote secured Novocure server from the comfort of the patient's home. The data uploaded contains only information about the usage of the device and any errors, it does not contain identifiable patient information.

MyLink connects to the electric field generator to download the data log files to an internal memory and then uploads the downloaded data to the remote secured Novocure server using the cellular network. Data integrity is maintained at all times even when the data transfer stops, loses signal or cannot be completed.

The download time should take 1-3 minutes while the upload time takes up to 15 minutes with a good connection. The data download mode must be finished before the upload mode can start. The separation between the two modes is done by disconnecting the data cable from the electric field generator.

3. Overview of MyLink

MyLink is comprised of the enclosure incorporating a cellular modem and custom software, a cable that connects the unit to the electric field generator and a power cord. It is powered from AC mains and is equipped with an internal backup battery.

MyLink (front)

Electric field generator

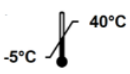
MyLink (back)

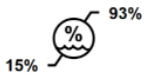
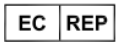
On/off indicator

Download indicator

Upload indicator

4. Glossary of symbols

	Follow instructions for use
MD	Medical Device symbol
	Manufacturer information Novocure GmbH, Neuhofstrasse 21, 6340 Baar, Switzerland
#	Model number
REF	Catalogue number
SN	Serial number
UDI	Unique Device Identifier symbol Indicates a device carries Unique Device Identifying information.
	Date of Manufacture
	Caution — Consult the instructions for use for important cautionary information
	WEEE; Waste Electrical and Electronic Equipment
	Protect from heat and radioactive sources
IP22	Ingress Protection: Protects persons against access to hazardous parts with fingers. Protects the equipment inside the enclosure against ingress of solid foreign objects of 12.5 mm in diameter or greater. Protects the equipment inside the enclosure against ingress of vertical falling water drops when enclosure is tilted up to 15°.
	Do not wet the device
	For indoor use only
	Class II electrical equipment
	Do not expose to temperatures below -5°C or above 40°C

	Do not expose to humidity below 15% or above 93%
	Fragile – handle with care
	CE mark symbol
	Authorized representative in the European Community
	Importer details: Novocure Netherlands B.V., Prins Hendriklaan 26, 1075 BD, Amsterdam, The Netherlands
	Power ON / OFF switch
	On/off indicator
	Download indicator
	Upload indicator

5. General Information

You should download your usage data from your electric field generator to the MyLink unit every month and when in need of technical assistance.

6. Instructions

MyLink

1. Plug the power cord into the back side of the MyLink unit and connect the unit to a wall outlet.

2. Locate the main power switch on the back side of the MyLink unit. Press the switch to "I" to power up MyLink.

   Result: The ⏻ indicator on the top of your MyLink unit will blink green, indicating MyLink is performing a self-test. **Wait until the light stops blinking and turns steady green.**

MyLink Electric field generator

3. Stop TTFields treatment by pressing the TTFields therapy ON/OFF button on your electric field generator, and unplug the connection cable from your electric field generator.

MyLink

4. Open the lid of your MyLink unit. Release enough cable to connect to the electric field generator.

MyLink Electric field generator

5. Plug the cable of your MyLink unit into electric field generator.

   Note: to ensure proper connection, align the arrow on the cable of your MyLink unit with the arrow on the socket on the front panel of the electric field generator.

6. Make sure your electric field generator is on.
   The “POWER” indicator on the front of the electric field generator is illuminated in green.

If a battery is installed and the plug-in power supply is not in use, the “BATTERY” indicator is also illuminated in green.

7. Download the usage data from your electric field generator.

Result: The ⬇ indicator on the top of your MyLink unit will blink green. This means that the MyLink unit is downloading your usage data from your electric field generator.

Important: After a few minutes, the ⬇ indicator stops blinking and turns steady green, indicating that the download process is complete. Your MyLink unit will beep to indicate completion of the download process. The beeps will continue until you disconnect the MyLink cable from your electric field generator (see next step).

Important: MyLink will beep for both successful and failed data collection. This beeping notification signal tells you to disconnect the MyLink unit and go back on treatment, even if data collection failed. In the case of download failure, the ⬇ indicator of your MyLink unit will show red. For more information, see the MyLink troubleshooting tips section of this manual.

8. Disconnect the MyLink unit cable from the electric field generator.

   Result: The beeping notification signal from the MyLink unit will stop.

9. Turn the electric field generator to OFF by switching the power switch to “O”. Wait a few seconds until the indicator “POWER” turns off and switch the power back on to “I” on the electric field generator.

   Result: The electric field generator performs a self-check. A successful self-check completion is indicated when the electric field generator “POWER” indicator light is showing steady green.

MyLink **Electric field generator**

10. Plug the electric field generator connection cable into the device and push the TTFields therapy ON/OFF button to resume TTFields treatment.

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

11. Automatic upload of the usage data from MyLink to the remote secured server.

    Once  starts blinking green, the MyLink unit is uploading your treatment data directly to the remote secured server.

    Wait up to 15 minutes for the uploading process to be completed.

12. Once all 3 MyLink indicator lights stop blinking and turn steady green, the upload has been successful.

    The data are now available to your Novocure representative.

MyLink

13. Turn off your MyLink unit using the main power switch on the back.

Note: The unit may take up to 10 seconds to turn off.

7. Environmental Conditions

Conditions for operation

Mainly for home use.

For indoor use only.

Data Integrity

The integrity and availability of the usage data are assured:

- Usage data remain in the electric field generator until MyLink “confirms” all data have been received intact (successful download), and
- Usage data remain in your MyLink unit until the remote secured server “confirms” all data have been received intact (successful upload).

Storage

The MyLink unit should be stored in a dry area away from extreme temperature conditions.

Transportation

Traveling with MyLink

Transportation of MyLink shall be 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.

Cleaning

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

8. Expected Service Life

The MyLink device expected service life is 5 years.

9. Disposal

Please contact your Device Support Specialist for proper disposal. Do not throw in the trash.

10. MyLink troubleshooting tips

Follow the instructions provided if your MyLink is experiencing the following:

The On/off ( ) Indicator is OFF

1. Make sure your MyLink unit power cord is plugged into the AC port and a standard power source (wall outlet).
2. Make sure your MyLink unit power switch is in the "I" position. If not, push the power switch to "I".
3. If the indicator is still OFF, please contact your Device Support Specialist for further support.

The On/off ( ) Indicator is RED

1. Push the power switch of your MyLink unit to "O".
2. Wait a few seconds until the indicator turns OFF.
3. Then, switch your MyLink unit back to ON (power switch in "I" position).
4. If the indicator is still RED, please contact your Device Support Specialist for further support.

The Download ( ) Indicator does not turn ON

1. Make sure the indicator on your MyLink unit is green.
2. Make sure your electric field generator is connected to your MyLink unit, and that the arrow on the cable of your MyLink unit is aligned with the arrow on the socket on the front panel of the electric field generator.
3. Make sure your electric field generator is switched ON. If not, push the device power switch to "I".
4. If the indicator is still OFF, please contact your Device Support Specialist for further support.

The Download ( ) Indicator is RED

This indicates that the transfer of data from your electric field generator to your MyLink unit was unsuccessful.

PART A: Free up storage space on your MyLink unit for data transfer:

1. Disconnect your MyLink unit cable from the electric field generator.
2. Switch your MyLink unit to OFF (power switch in "O" position). It may take a few seconds for the indicators to turn OFF.
3. Switch your MyLink unit to ON (power switch in "I" position).
4. Wait for the indicator to turn steady green.
5. Wait for about 20 seconds and then check if the indicator starts flashing green.
   If it stays OFF, continue with "**PART B**."

6. Wait for the  indicator to be steady green.
7. Switch your MyLink unit to OFF (power switch in “O” position). It may take a few seconds for the indicators to turn OFF.
8. Switch your MyLink unit to ON (power switch in “I” position).
9. Wait for the  indicator to turn steady green.
10. Connect your MyLink unit cable to the electric field generator.
11. Power ON your electric field generator.
12. Make sure the  indicator is flashing green.
13. Wait a few minutes until it turns to steady green.
14. **NOTE:** If the  indicator turns steady green the failure is fixed. If the failure is still occurring ( indicator stays red), please contact your Device Support Specialist for further support.

PART B: If there is enough storage space on your MyLink unit:

1. Make sure the  indicator of your MyLink unit is steady green.
2. Make sure your MyLink unit cable is properly connected to the electric field generator.
3. Switch your MyLink unit to OFF (power switch in “O” position). It may take a few seconds for the indicators to turn OFF.
4. Switch your electric field generator to OFF (power switch in “O” position).
5. Switch your electric field generator back to ON (power switch in “I” position).
6. Then, switch your MyLink unit back to ON (power switch in “I” position).
7. Wait a few seconds until the  indicator turns to steady green.
8. Make sure the  indicator is flashing in green, and wait a few minutes while your MyLink unit is downloading data.
9. You will know the data download to your MyLink unit is successful when:
   a. The  indicator stops flashing and is steady green.
   b. Your MyLink unit is beeping.
10. If the  indicator stays red in one of the above steps, please contact your Device Support Specialist for further support.

The Upload ( ) Indicator does not turn ON

This indicates that your data failed to be uploaded from your MyLink unit to the remote secured server.

1. Make sure that both the and the indicators are steady green.
2. Make sure your MyLink unit is disconnected from the electric field generator.
3. If the indicator stays OFF, please contact your Device Support Specialist for further support.

The Upload ( ) Indicator is RED

This indicates that your data were unsuccessfully uploaded from your MyLink unit to the remote secured server.

1. Make sure your MyLink unit has cellular reception (e.g. you are not in a basement).
2. Make sure your MyLink unit cable is disconnected from your electric field generator.
3. Switch your MyLink unit to OFF (power switch in "O" position). It may take a few seconds for the indicators to turn OFF.
4. Switch your MyLink unit back to ON (power switch in "I" position).
5. Wait about 20 seconds and check the indicator status:
   a. - Steady green
   b. - Steady green or OFF
   c. - Flashing green

   NOTE: If the data was already downloaded to your MyLink unit, then the indicator will be OFF.
6. Make sure the indicator is flashing in green and wait for the data to complete uploading.
7. You will know the data upload to the remote secured server is successful when the indicator stops flashing and turns to steady green.
8. If the indicator stays red in one of above steps, please contact your Device Support Specialist for further support.

   NOTE: MyLink will attempt to upload data for 15 minutes. You will know the upload of data has failed when the indicator becomes steady red.

11. Assistance and Information

TECHNICAL SUPPORT

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

SERIOUS INCIDENTS

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

12. Appendix A – Applicable Standards

The MyLink unit complies with the applicable standards in the IEC/EN 60601 series for medical electrical equipment.

13. Appendix B - Electrical specifications and cellular network specifications

MyLink is considered class II equipment according to IEC / EN 60601-1. It is connected to a standard power outlet and uses the cellular network.

100-240VAC, 50/60Hz, 0.5A

7.2VDC, 3350mAh from internal rechargeable battery.

14. Appendix C - Emitted radiation and electromagnetic compatibility

MyLink is intended for use in a home healthcare environment (such as domiciles [residences, homes, nursing homes], hotels, hostels and pensions).

Warning - Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Warning - The use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Warning - Portable and mobile RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm to any part of MyLink including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

MyLink needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided below.

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

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	MyLink 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	MyLink 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	

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

Immunity test	IEC 60601 level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD), IEC 61000-4-2	8 kV contact 15 kV air	8 kV contact 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 SIP/SOP lines	2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge, IEC 61000-4-5	1 kV line to line 2 kV line to earth	1 kV line to line 2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips and interruptions on power supply input lines IEC 61000-4-11	0 % U_T for 0,5 cycle 0 % U_T for 1 cycle 70 % U_T for 25/30 cycles 0 % U_T for 250/300 cycles	0 % U_T for 0,5 cycle 0 % U_T for 1 cycle 70 % U_T for 25/30 cycles 0 % U_T for 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.
Power frequency 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: U_T is the AC mains voltage prior to application of the test level.			

Table 3 – Guidance and MANUFACTURER'S declaration – ELECTROMAGNETIC IMMUNITY – for HOME HEALTHCARE ENVIRONMENT ME EQUIPMENT and ME SYSTEMS

Immunity test	IEC 60601 level	Compliance level
IEC 61000-4-6 Conducted RF	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands (6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz) and amateur bands (1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz)	[*V*] = 3 Vrms [*V*] = 6 Vrms
IEC 61000-4-3 Radiated RF	10 V/m 80 MHz to 2.7 GHz	[*E*] = 10 V/m
Proximity fields from RF wireless communications equipment	385 MHz	27 V/m
	450 MHz	28 V/m
	710 MHz	9 V/m
	745 MHz	
	780 MHz	
	810 MHz	28 V/m
	870 MHz	
	930 MHz	
	1720 MHz	28 V/m
	1845 MHz	
	1970 MHz	
	2450 MHz	28 V/m
	5240 MHz	9 V/m
	5500 MHz	
	5785 MHz	

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