

SENSIMED Triggerfish® Recorder ST5000

Directions for Use

Carefully read these instructions for use and all contained warnings and precautions before using this product.

Product Description

The SENSIMED Triggerfish® Recorder (the “Recorder”) is a portable external unit which contains a battery and records monitoring data. The integrated battery is rechargeable via a medical grade charger provided by the manufacturer.

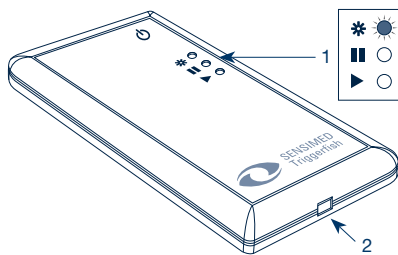
Shelf Life

The recommended shelf life is marked on each package. Storage beyond the recommended time may result in Recorder and battery deterioration.

The battery of the Recorder has to be charged within three months after purchase date

Symbols

Front side of the Recorder

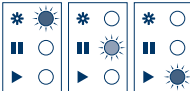



1. Three operation indicator lights
2. Battery charger connector

Symbols used


- ⏻ Stand-by
- * Power on
- ⏸ Action to be taken
- ▶ Monitoring


Recorder connection to the computer


A Three lights are flashing in succession	The Recorder is establishing a connection with the computer	
--	---	---

B One green light is glowing and one yellow light is flashing	The Recorder is connected to the computer	
--	---	---


Recorder connection to the Sensor (Fitting mode configuration – min.2 minutes)

C One green and one yellow lights are glowing	The Recorder is successfully configured and will establish communication with the Sensor	
--	--	---

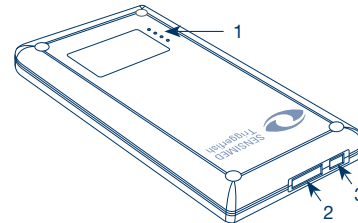
If all lights are flashing at the same time	The Recorder cannot find a connection with the Sensor. The Sensor is broken.	
---	--	---

One green and one yellow lights are glowing, plus one green light is flashing quickly	The Recorder is connected to the Sensor and is in the fitting mode process. It is not yet ready to monitor.	
---	---	---

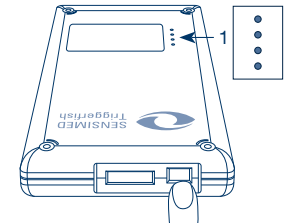
Recorder is monitoring

D Two green lights are glowing	The Recorder is now monitoring	
---------------------------------------	--------------------------------	---

Back side of the Recorder



1. Four battery status lights
2. Connector for the Data Cable
3. On/off Button



Battery Status

The battery is fully charged when all four green lights (1) are glowing when pushing briefly the on/off Button.

Safety

WARNINGS

- ▲ The patient must be instructed not to wet the Recorder (i.e avoid rain, sauna, steam baths, etc.). There is a risk of an electric shock.
- ▲ The patient must be instructed to contact the health care professional or emergency service in case of battery problem or dysfunction of the Recorder.
- ▲ The patient must wear the Recorder in an appropriate sleeve.
- ▲ Do not open any part of the Recorder.
- ▲ Patients must be instructed not to charge the battery themselves.
- ▲ Do not charge the battery while recording. The Recorder does not work while charging.
- ▲ The use of accessories and cables other than those specified may result in increased electromagnetic emissions or decreased electromagnetic immunity of the SENSIMED Triggerfish®.
- ▲ Portable and mobile Radio Frequency communication equipment can affect medical electrical equipment such as SENSIMED Triggerfish®.
- ▲ The Recorder should not be used adjacent to or stored with other equipment. If adjacent use is necessary, the Recorder should be observed to verify normal operation.
- ▲ Do not use a damaged Recorder.
- ▲ Do not use a Recorder with exposed electronic parts.
- ▲ Patients must be instructed not to manipulate the Recorder.

PRECAUTIONS

- △ The Recorder should only be handled and connected by a health care professional.
- △ Do not charge the battery with a charger not indicated for use with the Recorder.
- △ Patients must be instructed to contact their health care professional if the Recorder is damaged or disconnected.
- △ Do not crush the Recorder.
- △ Do not submerge, autoclave, or steam clean the Recorder.
- △ Store the Recorder in a dry place at room temperature.
- △ Use only the appropriate medical grade battery charger provided by the manufacturer to charge the Recorder.
- △ Do not change any part of the Recorder. The manufacturer is not responsible for the consequences of misuse. The Recorder would lose its warranty.
- △ Do not use acetone, ether, Freon, petroleum derivatives or other solvents to clean the Recorder.
- △ Exposure to extreme heat or cold during the monitoring can damage the electronic parts and/or disturb monitoring. Do not use the Recorder under extreme conditions (e.g. direct sun, snow, sauna, etc.).

Direction for Use

The Recorder is indicated for continuous intraocular pressure monitoring up to 24 hours with glaucoma patients, patients at risk of glaucoma and/or patients with suspicion of high intraocular pressure.

Contraindications

There are no absolute contraindications for the use of the Recorder.

Required Equipment

The Recorder provides a means for continuous intraocular pressure monitoring using the SENSIMED Triggerfish® Set. This set consists of the SENSIMED Triggerfish® Software (the “Software”), the SENSIMED Triggerfish® Data Cable (the “Data Cable”), the SENSIMED Triggerfish® Antenna (the “Antenna”), and the SENSIMED Triggerfish® Sensor (the “Sensor”).

Complications / Adverse Events

Possible complications may include:

- Discomfort due to local sweating.
- Hindering of some daily activities.
- Breaking of the Recorder’s plastic case can cause injury.
- Exposed sharp parts of the Recorder case can cause bruising or cut the skin.
- Dysfunction of the battery can rarely induce an explosion of the battery which could lead to an injury or in very rare cases be fatal.
- Electrical dysfunction can induce overheat of the Recorder and induce a local skin burn.
- Electrical dysfunction or damaged connector can very rarely induce a light electric shock.

Operation

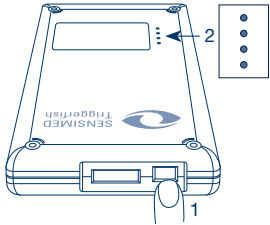
Before operating the Recorder follow the instructions in the User Manual section: “Preparations before using the SENSIMED Triggerfish®”. Make sure that the Software is properly installed and running on your computer and that the Belkin Bluetooth® USB Adapter F8T013 is connected and installed.

Activate the Recorder

Conduct a visual inspection to ensure that the Recorder is not damaged.

Recorder Battery Check

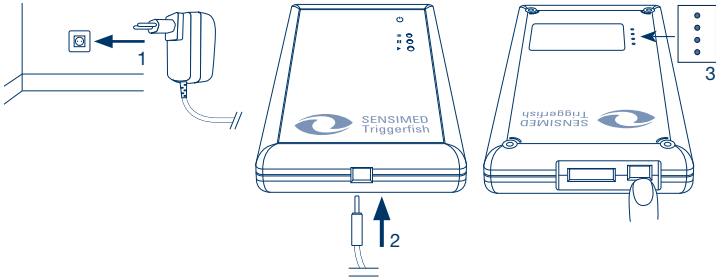
- Check the battery status on the back of the Recorder following these instructions:



1. Briefly push the on/off button of the Recorder.
2. Refer to the four green lights on the back side of the Recorder. All four battery level indicator lights must glow indicating that the battery is fully charged. If less than four battery level indicator lights are glowing, recharge the Recorder battery before proceeding.

Charge the Battery of the Recorder

- If the battery is not fully charged, charge it with the battery charger provided by the manufacturer:

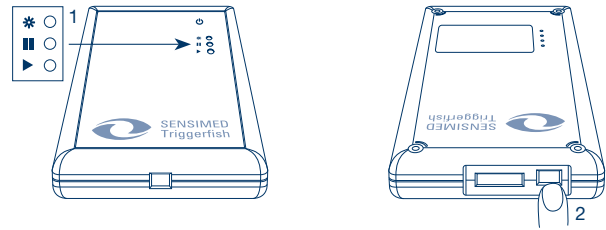


1. Connect the battery charger to a power supply plug.
2. Plug the power cord into the Recorder.
3. Charge the battery until all four battery level indicator lights are glowing. It may take up to 4 hours.

IMPORTANT Only use the battery charger provided by the manufacturer. Do not use other battery chargers.

Switch off the Recorder

- Before connecting the Recorder to your computer check that the Recorder is switched off:

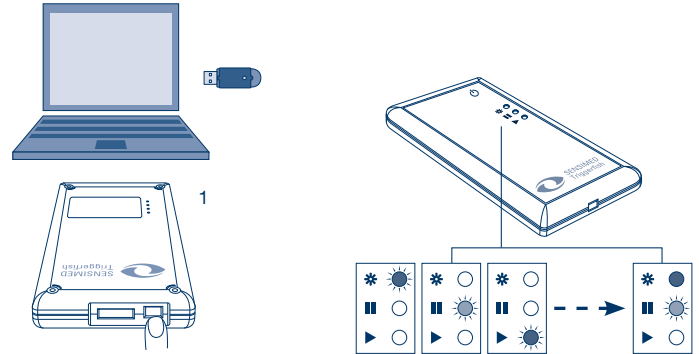


Refer to the three lights on the front side of the Recorder.

1. The Recorder is switched off when no lights are glowing.

2. If the Recorder was not switched off, switch it off by pushing the on/off button for at least five seconds.

Connect the Recorder to your computer



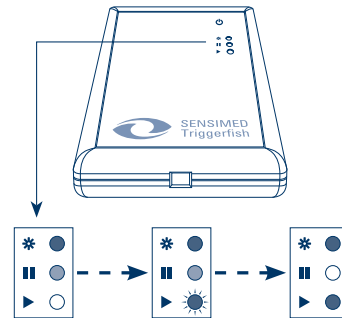
1. Once you have checked that the Recorder was switched off, place the Recorder within three meters of the Belkin Bluetooth® USB Adapter F8T013 of your computer and switch the Recorder on by pushing the on/off button for **two seconds**.

Refer to the three lights on the front side of the Recorder. While the Recorder establishes the connection with your computer, the three lights are flashing in succession. It can take up to one minute until the connection has built up. Once the Recorder is successfully connected with your computer, one green light will be glowing and the yellow light is flashing.

NOTE If the Recorder already contains patient monitoring data, follow the instructions in the User Manual section “Save Monitoring Data after a monitoring session”.

Start of Monitoring

- Make sure that the Antenna is correctly applied, that the Data Cable is connected and the patient data and the Sensor ID are entered in the Software.
- The Recorder automatically communicates with the Sensor and starts the configuration session. The lights on the Recorder indicate the status:



The green light indicates that the Recorder is switched on. The yellow light indicates that the Recorder will establish communication with the Sensor.

When the green and yellow lights are glowing, and the third green light is flashing, it indicates that the Recorder is in the fitting mode. It is not yet ready to monitor.

Once the fitting mode (min.2 minutes) is finished, the two green lights are glowing and the 24 hours IOP monitoring session starts.

NOTE If all lights are flashing at the same time every second, it indicates there is no connection from the Recorder to the Sensor (ie. Broken Sensor). The Recorder will switch off automatically after 2 minutes.



Follow the instructions in the User Manual sections “Save Monitoring Data” and “View New Monitoring Data after a monitoring session” to store and view monitored data using the Software.

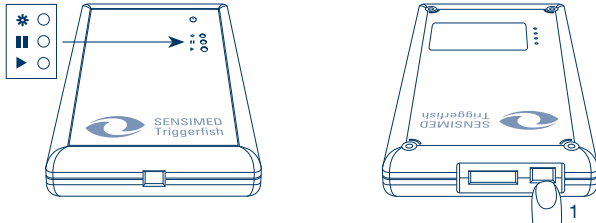
- Write down the date and the start time of the monitoring into the Log Book in the Patient Booklet. The effective monitoring starts when the two green lights are glowing.
- Instruct the patient about the warnings and precautions and give him/her the SENSIMED Triggerfish® Patient Booklet.
- The 24 hours IOP monitoring session has started.
- Place the Recorder in the Sleeve. To avoid patient’s discomfort and any damages to the Recorder, we recommend to pass the Data Cable through the smaller opening of the Sleeve and close it securely.

NOTE To maximize the battery life of the Recorder, frequently charge the battery. If the Recorder is not used frequently, a charge cycle should be completed at least once a month. A charge cycle means fully emptying the battery. It should then be charged completely. Storing the Recorder in a hot environment can irreversibly damage the battery. Please contact your SENSIMED Representative when the battery performance is limited.

Cleaning Instructions

The Recorder should be cleaned and disinfected after each use. It is recommended to wipe the Recorder with a damp cloth. Use mild detergent diluted in water. Dry with a clean, soft cloth or paper towel.

End of Monitoring



After completing a 24 hours monitoring session the Recorder turns off automatically. Refer to the three lights on the front side of the Recorder. The Recorder is turned off when no lights are glowing.

It is possible to abort an active monitoring session without losing the monitoring data by manually switching off the Recorder.
1. To switch off the Recorder push the on/off button for at least five seconds.

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

This product is manufactured and sold under one or more of the following global patents: US7137952, PCT/EP2007/061244, EP1401327.

Prices, specifications, and model availability are subject to change without notice.

Version ST5000-15.EU.E-C

Issued: June 2010

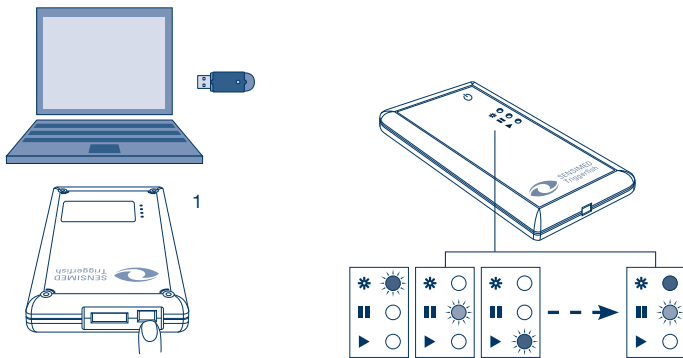
These Directions for Use supersede all prior instructions for this product.

Please read this information carefully and keep it for future use.

After the monitoring session follow the instructions in the User Manual sections “Remove the Antenna”, “Disconnect the Data Cable from the Antenna” and “End of Monitoring”.

Retrieve Patient Monitoring Data

- Make sure that the Recorder is switched off (see previous section “End of Monitoring”)
- Make sure that the Software is properly installed and running on your computer and that the Belkin Bluetooth® USB Adapter F8T013 is connected and installed.



1. Place the Recorder within three meters of the Belkin Bluetooth® USB Adapter F8T013 of your computer and push the on/off button of the Recorder for **two seconds** to switch it on.

Refer to the three lights on the front side of the Recorder. While the Recorder establishes the connection with your computer, the three lights are flashing in succession. It can take up to one minute until the connection has built up. Once the Recorder is successfully connected with your computer, one green light will be glowing and the yellow light is flashing.

SENSIMED AG

Route de Chavannes 37
1007 Lausanne
Switzerland

Telephone +41 21 621 9191
Fax +41 21 621 9193
www.sensimed.ch