1 PURPOSE

This is the drawing for the User Manual in English (Product : ST0001)
The official reference for the UMA is:

ST0001-16.EU.E-**E** : for English

The reference used in the GPAO/Nomenclature is 230001E-**005**

Version E	November 2011	New software .NET
Version D	December 2010	New address Sensimed AG changed.

2 RESPONSABILITY

The drawing management is under Product Manager responsibility.

3 PROCEDURE

The User Manual (Print-Out) is attached. The electronic version pdf is included in the Quality Management System.
The source (working version) is under Adobe Illustrator (on Intranet Marketing)

4 REFERENCES

5 ANNEXE

ST0001-16.EU.E-E – Hard Copy

Written by			Approved by			Authorized by		
Date:	Name:	Signature:	Date:	Name:	Signature:	Date:	Name:	Signature:
01.11.2011	FS		01.11.2011	CM		01.11.2011	SC	

Revision	Date	Affected Pages/ Sections	Description
A	10.12.2010	All	Creation / ISO 13485:2003 implementation
B	01.11.2011	All	New software .NET (ST8000) – ECO-11-003

ST-UMA-230001E-B

SENSIMED Triggerfish

SENSIMED Triggerfish®
User Manual

Continuous IOP Monitoring

SENSIMED Triggerfish® User Manual

November 2011

Because of continuous improvement of the product, prices and specifications are subject to change without notice. Changes to this manual are accomplished through reissue, either in response to user input or to continuous improvement of the product. Should errors, omissions or incorrect data be noted when using this manual normally, please contact SENSIMED Technical Support or your local SENSIMED representative.

Issued by

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CE
0344

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Not approved for sale in the U.S.A.

Table of contents

Introduction

This manual is written for clinical professionals familiar with monitoring glaucoma patients and contact lens handling. You must read and understand this manual and all other information accompanying the SENSIMED Triggerfish®.

IMPORTANT This user manual is effective as of November 2011 and supersedes all prior manuals for the products described below.

WARNING Please read this manual carefully before attempting to use the SENSIMED Triggerfish® and keep this information for future use.

SENSIMED Triggerfish®

The SENSIMED Triggerfish® is a breakthrough solution to monitor fluctuations in intraocular pressure continuously up to 24 hours in order to aid the diagnosis and treatment of glaucoma.

SENSIMED Triggerfish® is:

- non-invasive and convenient,
- monitors IOP continuously up to 24 hours (i.e. during sleep and normal activities).

The patient wears the SENSIMED Triggerfish® up to 24 hours and performs normal activities including sleep periods. At the end of the 24 hours the data is transferred from the Recorder to the practitioner's computer where a qualified expert reviews and if necessary edits the data.

When purchasing the complete SENSIMED Triggerfish® Set, items 1-8 must be included:

1. SENSIMED Triggerfish® Recorder (the “Recorder”)
2. SENSIMED Triggerfish® Software (the “Software”),
3. SENSIMED Triggerfish® Data Cable (the “Data Cable”),
4. SENSIMED Triggerfish® Antenna (the “Antenna”),
5. SENSIMED Triggerfish® Sensor (the “Sensor”).
6. Recorder Sleeve
7. Battery Charger
8. Bluetooth USB Stick

WARNING The SENSIMED Triggerfish® is composed of the above elements. Only original equipment must be used to guarantee correct functioning of the device.

Code No., Specification, Item, Quantity

Product REF	Box REF	Name	Description	Shipping unit
ST1000	BO3SMF	Sensor ALL SIZES	Ocular Telemetry Sensor – STEEP, MEDIUM, FLAT	3
ST1001	BO3S	Sensor STEEP	Ocular Telemetry Sensor – STEEP	3
ST1002	BO3M	Sensor MEDIUM	Ocular Telemetry Sensor – MEDIUM	3
ST1003	BO3F	Sensor FLAT	Ocular Telemetry Sensor – FLAT	3
ST2001	BO3AL	Antenna – LEFT	Telemetry communication antenna with LEFT sticker	3
ST2002	BO3AR	Antenna – RIGHT	Telemetry communication antenna with RIGHT sticker	3
ST5000	BO1R	Recorder	Portable data Recorder	1
ST5010	BO1DC	Data cable	Data cable connecting the Recorder to the Antenna	1
ST8000	BO1SOF	Software	Software for Triggerfish data	1
ST4001	BO25SL	Recorder sleeve	Pocket for Recorder	25
ST6000		Battery charger	Battery charger	1
ST9000		Bluetooth USB stick	Bluetooth communication with computer	1
ST7001		Case	Starter set case – empty with foam	1
ST0001-16.EU.E		User manual	User Manual book	1
ST0001-17.EU.E		Patient booklet	Patient booklet	1
ST0001-18.EU.E		Quick guide	Quick guide insert	
ST0001-19.EU.E		Recorder guide	Recorder LED status guide insert	
ST0001-70.EU.E		Fitting guide	Fitting guide insert	

Symbols

Manufacturer:
SENSIMED AG
1007 Lausanne
Switzerland

Caution, Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.

SENSIMED Triggerfish® Sensor is delivered sterilised. Autoclave sterilised.

Do not re-use

Caution: see direction for use

CE Marking of conformity

Use by date (expiry date)

Batch code

REF

Catalogue Number

This product and package do not contain natural rubber latex.

	Non-ionizing electromagnetic radiation
SN	Serial Number
	Keep dry
	Recyclable product: Do not dispose this product as unsorted municipal waste. Prepare this product for re-use or separate collection according to local hospital or clinical requirements.
	Protection BF applied part
	Type of protection II
	Bluetooth® Wireless Communication Technology
BC	Base Curve
DIA ∅	Diameter
	Do not use when packaging is damaged
	Do not re-sterilize

Warnings and precautions

WARNING advises against certain actions or situations that could result in personal injury or death.

PRECAUTION advises against actions or situations that could damage equipment, produce inaccurate data or invalidate a procedure.

NOTE draws attention to useful information regarding a function or procedure.

Warnings

- The Sensor is not designed for vision correction. It may have residual optical power.
- The patient must be instructed not to drive vehicles, crafts or handle dangerous machinery while wearing the Sensor.
- The Sensor is intended for use on the surface of the eye. Do not implant the Sensor.
- The patient must be instructed to contact the health care professional if the Sensor is displaced.
- Only a trained health care professional should manipulate the Sensor.
- The Sensor, Antenna, Data Cable and Recorder must never be manipulated by the patient.
- To avoid complications the Sensor should not be used simultaneously with any kind of contact lens or other device applied in the same eye.
- Environmental fumes, smoke, dust, vapors or windy conditions should be avoided in order to minimize the chances of Sensor contamination.

- ⚠ Do not use a Sensor with exposed parts of the microchip.
- ⚠ Eye irritation or infection may occur if cosmetics, lotion, soaps, creams, hair sprays or deodorants come in contact with the Sensor.
- ⚠ Patients must be instructed to immediately contact the health care professional in case of complication.
- ⚠ The Sensor is not intended for extended wear.
- ⚠ Do not use a Sensor after the expiry date.
- ⚠ Do not use a Sensor if the sterile packaging has been opened or if the seal is damaged.
- ⚠ Do not re-sterilize the Sensor.
- ⚠ Do not re-use the Sensor. It will not be sterile and there is a risk of eye irritation or infection including epithelial damages due to degraded hydrophilic property. The Sensor may have intermittent loss of communication and compromise the sensing performance.
- ⚠ Do not use a damaged Sensor, Antenna, Data Cable or Recorder.
- ⚠ Do not use a Sensor, Antenna, Data Cable or Recorder with exposed electronic parts.
- ⚠ The patient must be instructed not to wet the Antenna, Data Cable or Recorder.
- ⚠ While wearing the SENSIMED Triggerfish® the patient must not take a shower and avoid rain, sauna, steam baths or similar. There is a risk of an electric shock.
- ⚠ Do not re-use the Antenna. There is a risk of contamination and diminishing the adhesive effect. It may fall from face or losing the signal transmission.
- ⚠ To avoid complications the Antenna should not be used simultaneously with another Antenna, tape or dressing on the same eye.
- ⚠ The Antenna is intended to be applied around the eye during IOP monitoring. Do not apply it on wounds.
- ⚠ Do not use the Antenna if the package is open or damaged.
- ⚠ The patient must be instructed to immediately 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 and Data Cable.
- ⚠ The health care professional is responsible for all data entry into the Software.
- ⚠ Protect the saved data in a secure folder.
- ⚠ Make sure that unauthorized third parties cannot access the patient's data.
- ⚠ Before using the Software version 2.0, you have to uninstall/ remove any previous versions of the Software application.
- ⚠ 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 with the SENSIMED Triggerfish® other than those specified may result in increased electromagnetic emissions or decreased electromagnetic immunity of SENSIMED Triggerfish®.
- ⚠ Portable and mobile Radio Frequency communication equipment may affect medical electrical equipment such as SENSIMED Triggerfish®.
- ⚠ The SENSIMED Triggerfish® should not be used adjacent to or stored with other equipment. If adjacent use is necessary, the SENSIMED Triggerfish® should be observed to verify normal operation.
- ⚠ Patients must be instructed not to rub their eye while wearing the Sensor.
- ⚠ Never wear the SENSIMED Triggerfish® while exposed to intense electromagnetic fields such as MRI (Magnetic resonance imaging) which could result in severe eye burn.
- ⚠ The health care professional is responsible for all files generated and information disclosed by the use of the SENSIMED Triggerfish® system.

Precautions

△ Do not use solutions for hard contact lenses with the Sensor.
△ Sterile artificial tears are recommended while using the Sensor.
△ Do not use tap water on the Sensor.
△ According to surgeons, patients should not be monitored with the Sensor during the immediate post-operative period until the eye has completely healed.
△ Tweezers or other tools should not be used to hold or remove the Sensor.
△ Exposure to extreme heat or cold during the monitoring can disturb monitoring and/or can damage the electronic parts.
△ Do not use acetone, ether, Freon, petroleum derivatives, or other solvents to clean the Data Cable or Recorder.
△ Use only the appropriate medical grade battery charger provided by the manufacturer to charge the Recorder.
△ Do not freeze the Sensor.
△ Do not crush or flip the Sensor.
△ For a proper fit of the Sensor, refer to the "Fitting Guide" section in this manual.
△ The Sensor may reduce or delay absorption of eye drugs during the 24 hours monitoring.
△ Some patients may wear glasses under certain conditions to correct their nearsightedness, farsightedness or to offset refractive astigmatism.
△ Patients must not wear glasses with full metal frame.
△ Facial creams and make-up should be removed from parts of the face that will be covered by the Antenna. This will optimize the comfort and the adhesive effect of the Antenna.
△ Only a trained health care professional should manipulate the Antenna.
△ Do not crush or fold the Antenna, Data Cable and Recorder.
△ Do not sterilize the Antenna.

△ Do not place the Antenna upside-down on the patient's face.
△ Do not crush or twist the Data Cable or the Recorder.
△ Do not submerse, autoclave or steam clean the Data Cable or Recorder.
△ The Recorder and the Data Cable should only be handled and connected by a health care professional.
△ Do not use the Recorder and the Data Cable under extreme conditions (e.g. direct sun, snow, sauna, etc).
△ Do not charge the battery with a charger not indicated for use with the Recorder.
△ Store the Recorder and the Data Cable in a dry place at room temperature.
△ Patients must be instructed to contact the health care professional if the Antenna, the Recorder or the Data Cable are damaged or disconnected.
△ Make sure that the patient number and the Sensor ID are correctly entered into the Software before you start recording.
△ Do not change any part of the Recorder. The manufacturer is not responsible for the consequences of misuse. The Recorder would lose its warranty.
△ Please note that the monitoring data cannot be downloaded from the recorder more than once, so make sure the downloaded file is backed up or is saved in a safe location.
△ Check that the computer indicates the correct date and time.

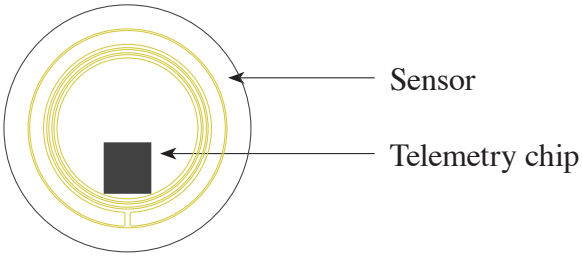
Product Description

SENSIMED Triggerfish® Sensor

The SENSIMED Triggerfish® Sensor "the Sensor" is a disposable silicone soft contact lens with a chip embedded in it, allowing the monitoring of changes in corneal curvature induced by intraocular pressure variation wirelessly.

The Sensor has the following properties:

- Diameter: 14.1 mm
- Base Curves: 8.4 (STEEP); 8.7 (MEDIUM); and 9.0 (FLAT)
- Lens material: Silicone
- Specific Gravity: 1.05
- Refractive Index: 1.43
- Light Transmission: Measures greater than 85% – dry
- Surface Character: Hydrophilic
- Water Content: Approximately 0.2%

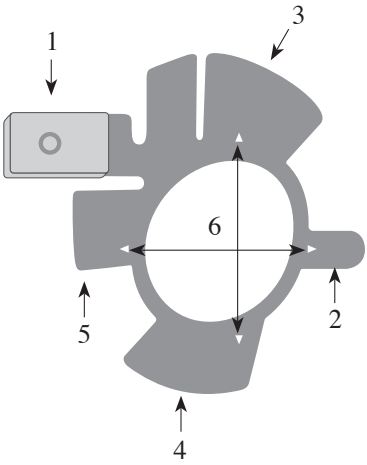


Packaging and Sterility

Each SENSIMED Triggerfish® Sensor is supplied sterile in a medical grade glass vial in a buffered saline solution. The vial is labeled with the Sensor parameters, expiry date, the manufacturing Lot Number, the Sensor ID and the product catalogue number.

SENSIMED Triggerfish® Antenna

The SENSIMED Triggerfish® Antenna "the Antenna" is the telemetry communication antenna for intraocular pressure monitoring. It is comfortably cushioned with a soft breathable medical grade material and an elastic breathable tape. The Antenna is easy to apply and to remove from the patient. The antenna is nickel-free.



1. Connector
2. Nasal tape
3. Forehead tape
4. Cheek tape
5. Temple tape
6. Marks stamped in the tape for exact horizontal and vertical centering of the Antenna around the patient's eye

SENSIMED Triggerfish® Recorder

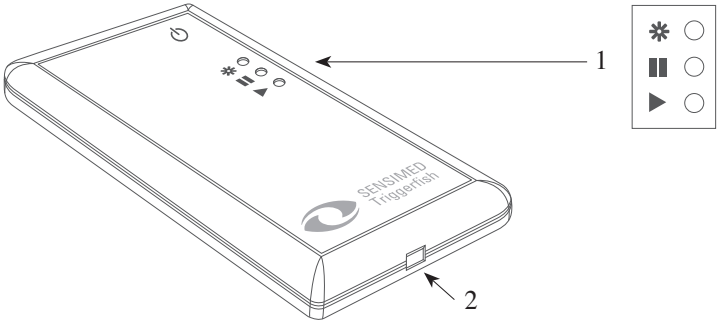
The SENSIMED Triggerfish® Recorder “the Recorder” is a portable external unit which contains a battery and records monitoring data. The integrated battery is rechargeable via a medical grade charger provided by the manufacturer.

Front side of the Recorder

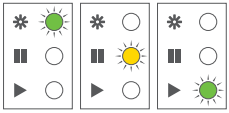
1. Three operation indicator lights
2. Battery charger connector

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	

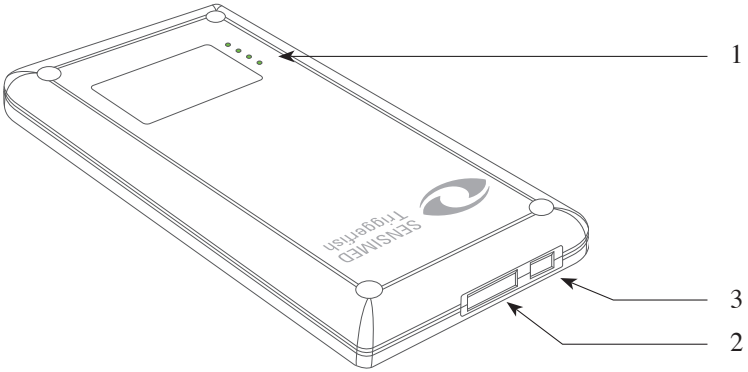
Recorder connection to the Sensor
(Fitting mode configuration – min.2 minutes)

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	

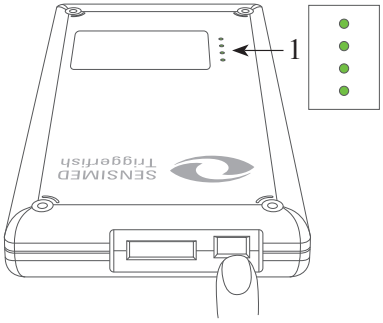
Back side of the Recorder



1. Four battery status lights
2. The connector for the SENSIMED Triggerfish® Data Cable
3. On/off Button

Battery Status

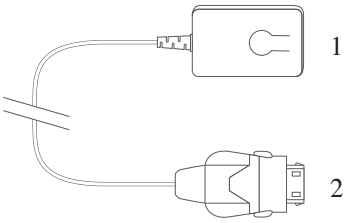
The Battery is fully charged when all four green lights (1) are glowing while pushing briefly the on/off button.



SENSIMED Triggerfish® Data Cable

The SENSIMED Triggerfish® Data Cable “the Data Cable” is designed for data transmission during intraocular pressure monitoring. The maximal length of the cable is 0.6m.

The Data Cable has a top click connector on one end (1) and a device with two clips on the other end (2).

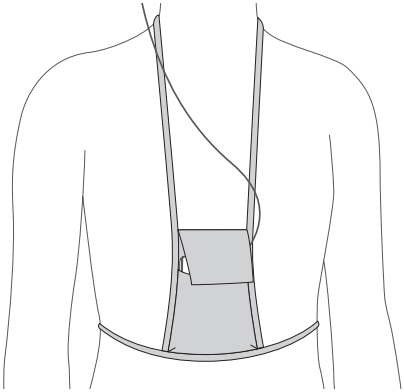


SENSIMED Triggerfish® Software

The SENSIMED Triggerfish® Software (the “Software”) is the support application to visualize the patient’s monitoring data obtained from the Recorder on the health care professional’s computer. It allows the health care professional to retrieve, view, and manage the monitoring data in a standard format.

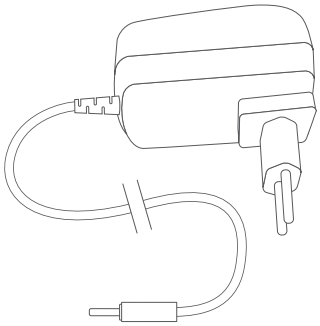
Sleeve

Tyvek disposable sleeve is intended to be used with the Recorder. It will protect the Recorder from damage and will allow the patient to move freely during normal day activities and during sleep.



Battery Charger

The medical grade battery charger is provided with the Recorder to charge the battery of the Recorder.



Directions for Use

The SENSIMED Triggerfish® 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

The SENSIMED Triggerfish® should not be used when one or more of the following conditions exist:

- Active eye disease, eye injury or eye abnormality affecting the cornea, conjunctiva, or eyelids
- Patient history of eye or eyelid infections including sties or history of adverse events associated with wearing contact lenses, or intolerance, or abnormal ocular response to contact lenses
- Active inflammation of the eye
- Active infection of the eye
- Corneal vascularisation
- Insufficiency of lachrymal secretion
- Corneal hypoesthesia
- Known allergy to silicone
- Patient inability or unwillingness to understand or comply with any warnings, precautions, restrictions or directions of the health care professional, because of age, infirmity, mental or physical conditions or an adverse working or living environment.

Although there are no absolute contraindications for the use of the Antenna, relative contraindications may include patients with skin irritations, certain allergies, skin eczema or other indications against the wearing of patches.

There are no absolute contraindications for the use of the Data Cable and the Recorder.

Complications

Usual contact lens complications

The patient must immediately contact a health care professional or an emergency health service (if after office hours), when one or more of the following events occur with the Sensor:

- Discomfort
- Dry eye sensation
- Foreign body sensation
- Excess tearing and/or other secretion
- Itching, burning, or gritty feeling
- Swelling of eyelids
- Pink eye (conjunctivitis)
- Eye infection
- Corneal abrasion
- Eye irritation
- Corneal ulcers
- Eye pain
- Contact lens related allergy
- Eye injury
- Allergy to silicone or allergic reactions to contact lens solution
- Blurred vision

The SENSIMED Triggerfish® may also include the following possible complications:

Antenna

- Electrical dysfunction or damaged connector can very rarely induce an electric shock.
- Antenna discomfort can be caused by local sweating and /or local feeling of pain while lying on the Antenna.
- Local skin irritation/inflammation/injury.
- Minimal skin abrasion after Antenna's removal.
- In rare conditions Antenna can cause skin infection.
- Unknown or known allergy to any material in the Antenna can provoke an allergic response.
- When removing the Antenna some hair may be pulled out.

Data Cable

- Data Cable discomfort as it may hinder some of the neck and head movements.

Recorder

- 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.

Preparations before using the SENSIMED Triggerfish®

IMPORTANT Before you place the Sensor in the patient's eye make sure that you have all the needed equipment ready. In addition to the SENSIMED Triggerfish® you will need standard ophthalmologic equipment to properly fit the Sensor in the patient's eye.

Required Accessories for Sensor Fitting

The fitting of the Sensor requires contact lens fitting equipment. To measure the central corneal radius of the patient's eye a topograph or a keratometer must be used. Moreover, a slit lamp and a reference tonometer are recommended. Sterile artificial tears are recommended to rinse the Sensor. Do not use tap water on the Sensor.

Minimum Computer Configuration for SENSIMED Triggerfish® Software

System requirements

- Windows XP (SP3 or later), Windows Vista SP1, Windows 7, Internet Explorer 6 or later

Hardware requirements

- At least 1 GB of memory or more
- Recommended Minimum: Pentium 1 GHz or higher (x86 or x64)
- A USB port to install a Bluetooth key

Software 2.0 Installation

NOTE Please read the system and hardware requirements below before you proceed with the installation of the Software 2.0

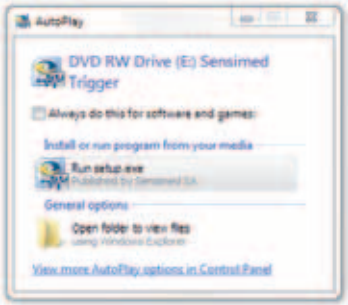
NOTE Administrator rights are required to install the Software on your computer. If you do not have such rights please consult your system administrator.

PRECAUTION It is strongly recommended that you exit all programs before running the installer. Applications such as virus-scanning utilities that run in the background might cause the installer to take longer than expected to complete.

PRECAUTION Connect the Bluetooth USB key to your computer only when the Software prompts you during the installation.

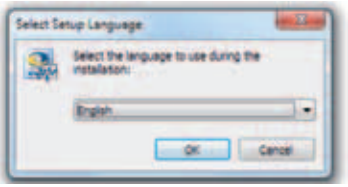
WARNING Before using the Software version 2.0, you have to uninstall/remove any previous versions of the Software application.

To install the Software 2.0 follow the instructions:

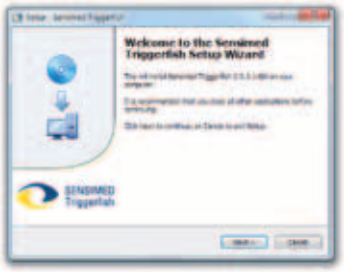


1. Insert the Software CD into the CD ROM drive. If AutoPlay is not enabled, open the CD in Windows Explorer and click on “Setup.exe” file.

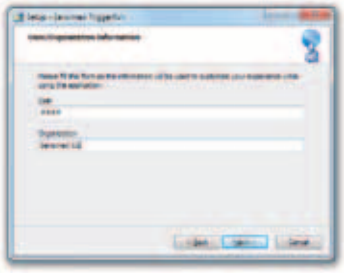
   If AutoPlay is enabled click on “Run setup.exe.” on the pop up window.



2. Select the language installation

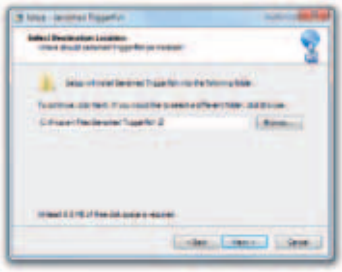


3. The setup window will open. Choose “Next” to continue the download.

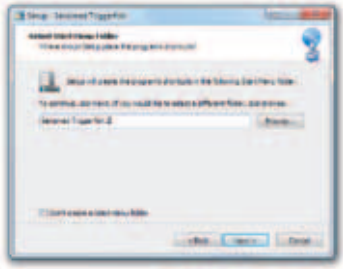


4. Fill in the user information. It will be used to customize your experience while using the application.

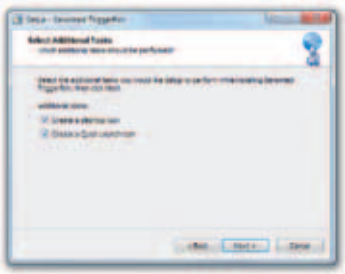
5. Make sure to read and accept the License Agreement to continue to install the software.



6. If you wish to accept the directories offered to install the software, click on the "Next >" button. If you wish to install the program to a different place, click on "Browse" to define a new directory. Select this as the destination.

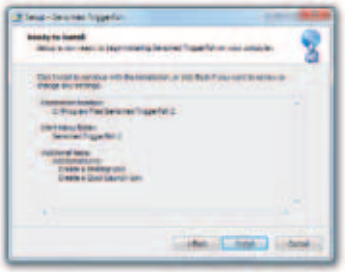


7. The setup will automatically create a shortcut access in the Start Menu folder of your computer. If you wish to install the shortcut to a different place, click on "Browse" to define a new directory. Click on the "Next >" button to continue.



8. The setup can create additional shortcut icons to open the Software on your computer.

   Please select “Create a desktop icon” and/or “Create a Quick launch icon” if you wish to add this additional task. Click on the “Next >” button to continue.

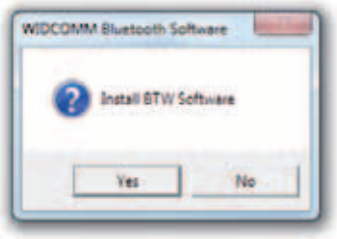


9. The Setup is ready to begin the installation. Click on “Install” button to continue.

10. To finalize the process, the setup needs to install the Bluetooth driver. Please click on “Install Bluetooth driver” and insert the Bluetooth key in the computer.

    You can also start the Software directly after finishing the installation. Please click if you wish to open the Software.

    Click on “Finish” to exit the setup.



11. The Software prompts you to insert the Bluetooth USB key provided by the manufacturer.

    Click on “Yes” to continue to install the Bluetooth software.

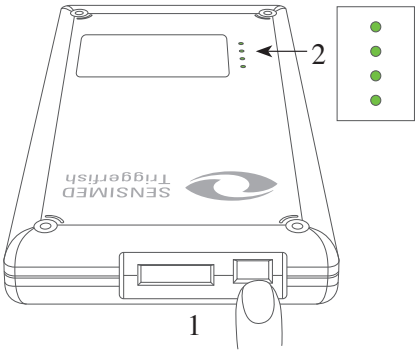
How to Perform a Monitoring Session

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 and illustrations:

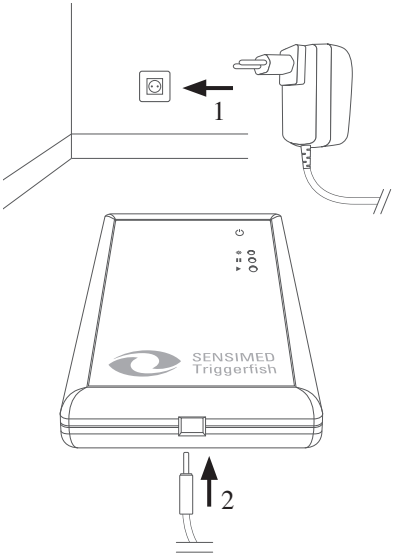


1. **Briefly** push the on/off button of the Recorder.
2. Refer to the four green lights on the back side of the Recorder.
   - All four battery level indicator lights must glow, indicating that the battery is fully charged.
   - If less than four battery level indicator lights are glowing, recharge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

IMPORTANT A new monitoring session can only be initiated if the Recorder is fully charged (four glowing lights).

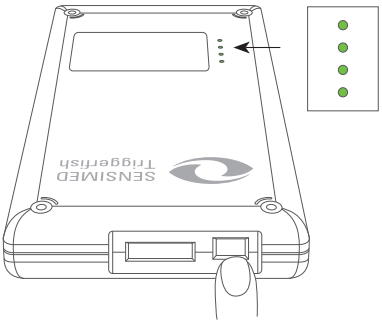
Charge the Battery of the Recorder

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.

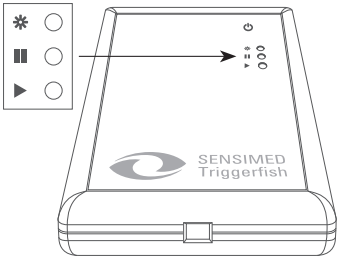


3. Charge the battery until all four battery level indicator lights are glowing. It may take up to 4 hours.

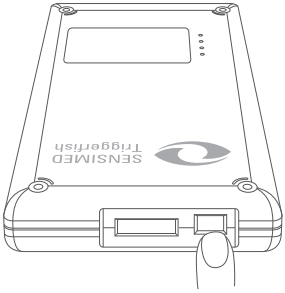
IMPORTANT Only use the battery charger provided by the manufacturer. Do not use other battery chargers.

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



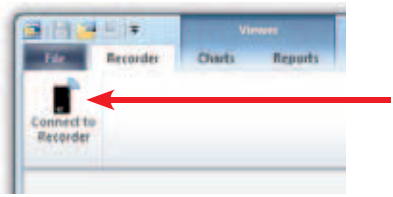
If the Recorder was not switched off switch it off by pushing the on/off button for **at least five seconds**.

Prepare your Computer and Configure Patient Data

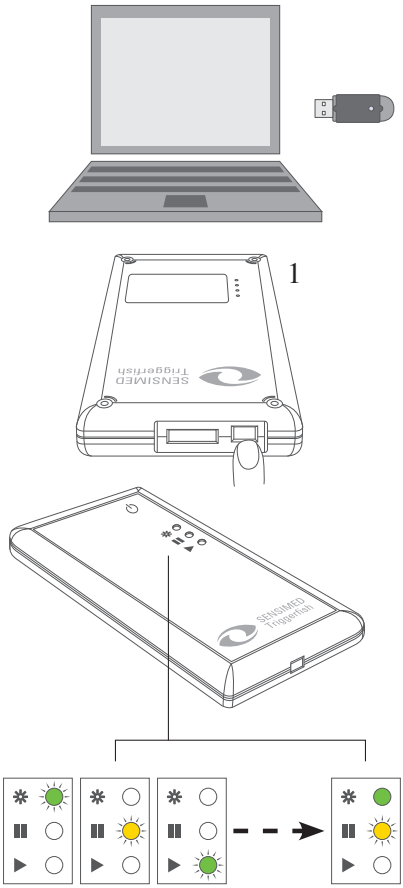
Before placing the Sensor in the patient's eye, prepare your computer, check the battery status of the Recorder and configure the patient data.

Make sure that the Software is installed on your computer and that Bluetooth USB key is connected and the driver is properly installed.

1. To open the Software, click in the Windows start menu, choose "All programs" and navigate till you find the SENSIMED Triggerfish® Software program. You can also open the Software directly from your desktop if you chose to have the shortcut icon.



2. To start a new monitoring, switch on the Software application, open the tab "Recorder" and click on the icon "Connect to Recorder".



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

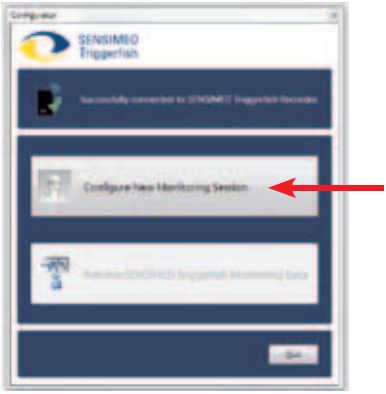
Refer to the three lights on the front side of the Recorder.
While the Recorder establishes the connection with your computer, the three lights are flashing in succession. It can take a few minutes until the connection has built up.
Once the Recorder is successfully connected with your computer, one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

NOTE If the Recorder already contains patient monitoring data, follow the instructions in this User Manual section "Retrieve Patient Monitoring Data".

PRECAUTION Avoid using portable and mobile Radio Frequency communication devices, they may interfere with communication between the Recorder and the computer.

Configure Patient Data and Enter Sensor ID

1. This will start a process which will look for and connect to a Recorder device. This process might take a few minutes.



2. Once the Recorder is connected, click on “Configure New Monitoring Session”.

3. To monitor a new patient, enter the patient's information data into the fields:
   - Patient's last name
   - First name
   - Patient ID
   - Date of Birth (click on the month & year field to change the date)
   - Race
   - Gender
   - Right or left eye
   - Sensor ID *
   - The reference tonometer IOP (mmHg) value

IMPORTANT Enter alphanumeric Sensor ID printed on the vial in the 'Sensor ID' field of the configuration window.

PRECAUTION Check if the Software shows the correct date and time in the field "Current Date / Time". It is based on the time of your computer. This will be the reference time of the monitoring session when synchronized with the Recorder.

NOTE Keep the vial of the Sensor until you retrieve the patient's data on your computer.

PRECAUTION Make sure that the patient name and the Sensor ID are correctly entered into the Software before you start recording.

4. Once all the fields are filled in, make sure to click on the "Start" button.

5. We recommend entering the initial IOP tonometer value in the 'Initial IOP' field for your records at this point. If you have not already done so, a message window will pop up. Press "Yes" to introduce the value or "No" to ignore and continue with the configuration.

6. You may now place the Sensor in the patient's eye and connect the Antenna to the Recorder. The Software configuration window will close automatically.

NOTE Please note the Sensor ID is not allowed to be registered twice in the Software. Make sure to use a new Sensor.

Place the Sensor in the Patient's Eye

The products and procedures in this manual are recommended by the manufacturer for handling the Sensor.

The Sensor must be rinsed with sterile artificial tears. The health care professional may recommend alternative products and procedures for contact lens handling. If other products and procedures are recommended under full liability of the health care professional, specific information for those products should be provided to the patient.

> **WARNING** Do not re-use the Sensor. It will not be sterile and there is a risk of eye irritation or infection including epithelial damages due to degraded hydrophilic property. The Sensor may have intermittent loss of communication and compromise the sensing performance.

Fitting Guide

The Sensor is fitted similarly to a soft silicone contact lens. The following minimum procedure must be followed when fitting a Sensor in a patient's eye:

1. Conduct a proper eye inspection to exclude all contraindications.
2. Conduct a keratometry or topography to measure the Central Corneal Radius. Use the Flat Meridian in millimeters (mm) or diopters (D) as reference.
3. Choose the adequate Base Curve according to the following table:

Central Corneal Radius (Flat Meridian)	≤ 7.53 mm > 44.75 D	7.54 - 8.44 mm 44.75 - 40 D	≥ 8.45 mm < 40 D
Base Curve	8.4 (STEEP)	8.7 (MEDIUM)	9.0 (FLAT)

Follow these recommendations to place the Sensor in the patient's eye:

- Inspect the vial and its seal to assure that it is not damaged.
- Wash your hands before handling the Sensor.
- Always handle the Sensor with care. Do not crush or flip the Sensor.
- To remove the Sensor from the vial pull out the holder and pull the lid to open it.
- Sterile artificial tears must be used to rinse the Sensor.
- Do not use tap water on the Sensor.
- Before placing the Sensor in the patient's eye, check that the Sensor does not show any damages on both sides.
- Carefully place the Sensor in the patient's eye.
- The Sensor should be well centered on the cornea and move about 0.5 mm with every eye blink and about 2 mm with a "push-up" test.
- Inform the patient about all risks associated with contact lens wear.
- Instruct the patient to immediately contact your office or the emergency service after office hours in case of incident.

Once you are sure that the Sensor is placed correctly, please prepare and connect all needed accessories as described in the following chapters.

Apply the Antenna

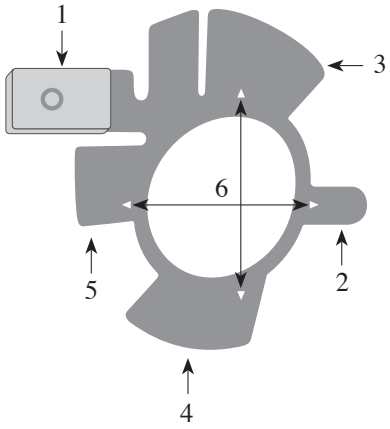
NOTE There are two different Antennas. One is specifically designed for the right eye and the other is specifically designed for the left eye.

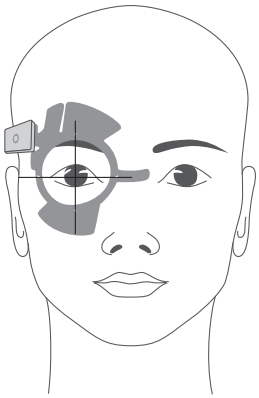
PRECAUTION Do not use the Antenna if the package is open or damaged.

WARNING Do not re-use the Antenna. There is a risk of contamination and diminishing the adhesive effect. It may fall from face or losing the signal transmission.

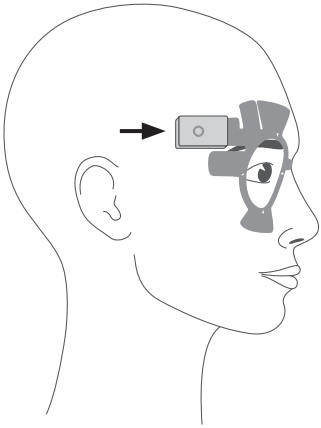
- Choose the left or right eye Antenna, depending on which eye the Sensor was placed.
- Carefully open and inspect the pouch to ensure that all parts of the Antenna are in a proper condition. Do not use a damaged Antenna or one with an exposed wire and/or electronics.
- Instruct the patient to look straight ahead. Apply the Antenna around the patient's eye following the instructions and illustrations:

1. Connector
2. Nasal tape
3. Forehead tape
4. Cheek tape
5. Temple tape
6. Marks stamped in the tape for exact horizontal and vertical centering of the Antenna around the patient's eye.

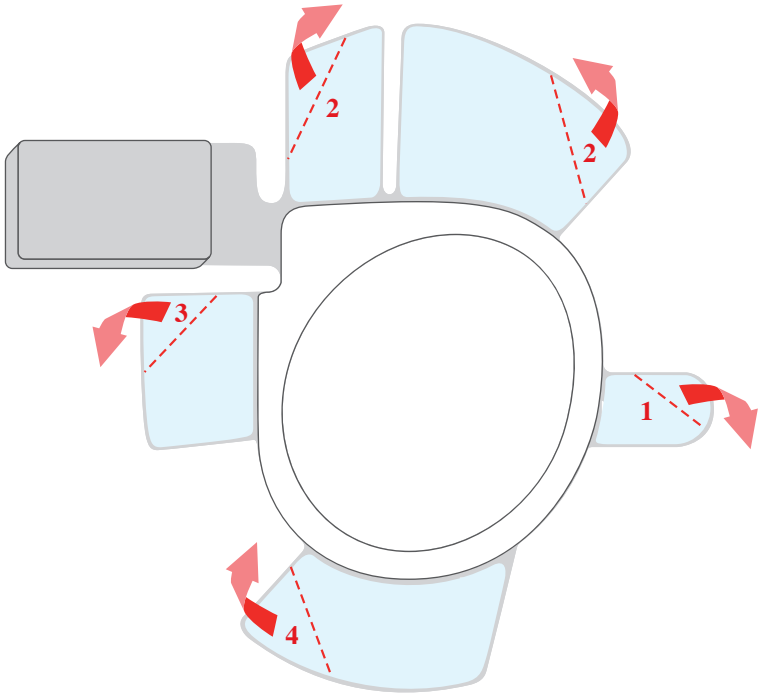




The Antenna must be applied around the patient's eye and centered according to the horizontal and vertical marks which are stamped into the tape.



The cable connector of the Antenna should be placed **horizontally** on the patient's temple.



1. Remove the cover paper from the nasal tape and place the adhesive part of the Antenna on the **patient's nose.**
2. Remove the cover paper from the forehead tape and place the adhesive part of the Antenna on the **patient's forehead**.
3. Remove the cover paper from the temple tape and place the adhesive part of the Antenna on the **patient's temple**.
4. Remove the cover paper from the cheek tape and place the adhesive part of the Antenna on the **patient's cheek**.

PRECAUTION Only a trained health care professional should manipulate the Antenna.

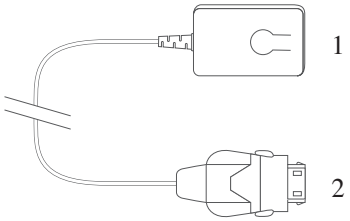
PRECAUTION Patients must be instructed to contact the health care professional if the Antenna is damaged or displaced.

WARNING Patients should not manipulate the Antenna.

NOTE Ensure that the Antenna is well applied and that the horizontal and vertical marks which are stamped into the tape are centered on the patient's eye when the patient is looking straight ahead. The cable connector has to be placed horizontally on the patient's temple. This will assure the patient's comfort and correct data transmission.

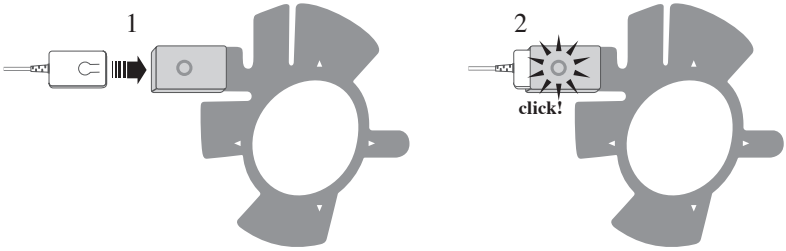
Connect the Data Cable

The Data Cable has a top click connector on one end (1) and a device with two clips on the other end (2).



> **WARNING** Do not use a damaged Data Cable or one with exposed wire and/or electronic parts.

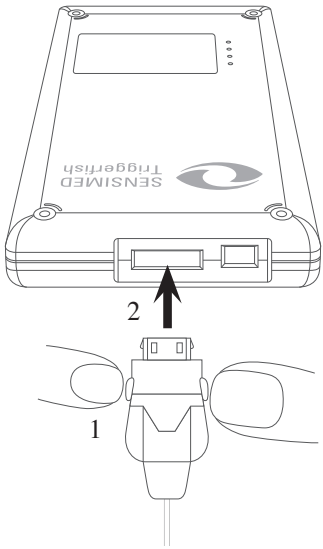
- Inspect the Data Cable.
- Make sure that the Antenna is applied correctly around the patient's eye.
- Ensure that the connector is placed horizontally on the patient's temple.
- Connect the top click connector to the Antenna (1). The plug is properly connected when you hear a "click" (2). Follow these illustrations:



WARNING The patient must be instructed to avoid letting the Data Cable get wet (the patient must not take a shower and avoid rain, sauna, steam baths or similar). There is a risk of an electric shock.

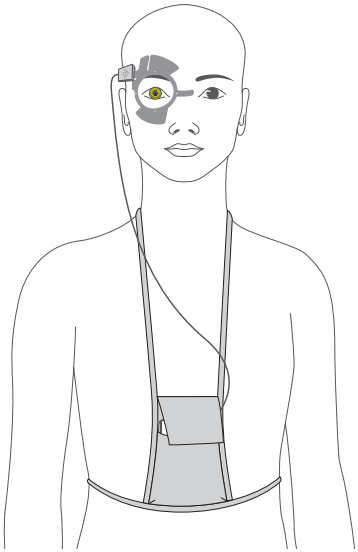
- Connect the Data Cable to the Recorder following the illustration:

Take the Data Cable's end which has the two clips. Press with your fingers the clips on both sides (1) and insert the Data Cable into the Recorder connector (2).



Tighten the Sleeve on the Patient

- Make sure to properly tie the sleeve on the patient's torso. First attach the upper part of the sleeve on the neck, then tighten the lower part around the waist.
- Place the Recorder into the sleeve after the monitoring session started.



Start of Monitoring

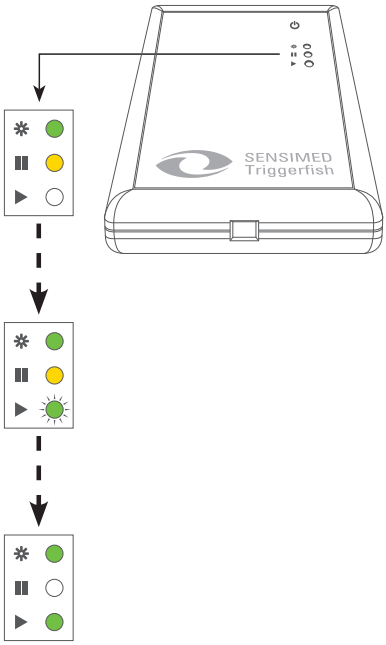
Make sure that the Antenna is correctly applied, that the Data Cable is connected and the patient data and the Sensor ID are entered in the Software.

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.

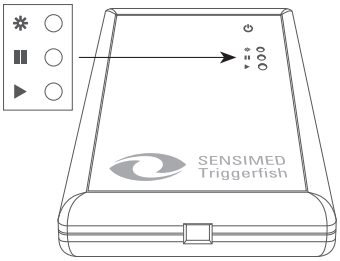
- Write down the date and the start time of the monitoring into the Log Book in the Patient Booklet. The effective monitoring starts when the two green lights are glowing.
- Instruct the patient about the warnings and precautions and give him / her the SENSIMED Triggerfish® Patient Booklet.
- Place the 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.

WARNING The patient must be instructed to avoid letting the Recorder get wet (i.e. shower, rain, sauna, steam baths, or similar). There is a risk of an electric shock.

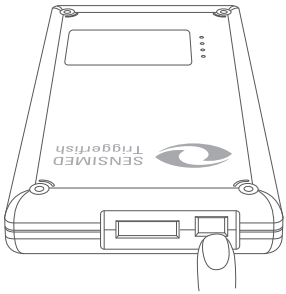
WARNING Patients must be instructed not to manipulate the Recorder.

PRECAUTION The Recorder should only be handled and connected by a health care professional.

End of Monitoring



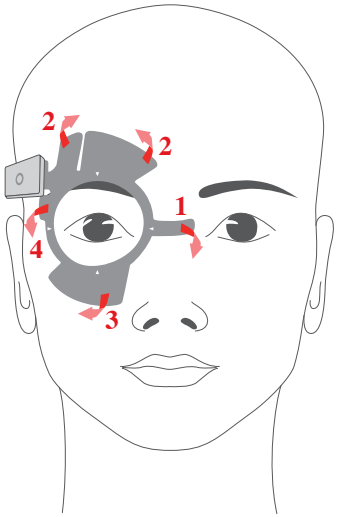
After completing a 24 hour monitoring session the Recorder turns off automatically. Refer to the three lights on the front side of the Recorder.
The Recorder is turned off when no lights are glowing.



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

Remove the Antenna

- After the monitoring session remove the Antenna from the patient's face. Carefully detach the tape starting from the nasal tape of the Antenna to the connecor tape following the instructions on this illustration:



1. Take off the nasal tape
2. Take off the forehead tape
3. Take off the cheek tape
4. Take off the temple tape

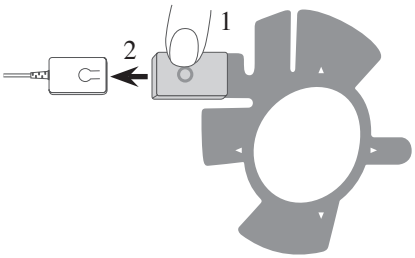
- Once the Antenna is removed, disconnect the Data Cable.

WARNING Do not disconnect the Data Cable from the Antenna while it is still on the patient's face.

NOTE The Antenna should be discarded according to local hospital/clinical practice requirements.

Disconnect the Data Cable from the Antenna

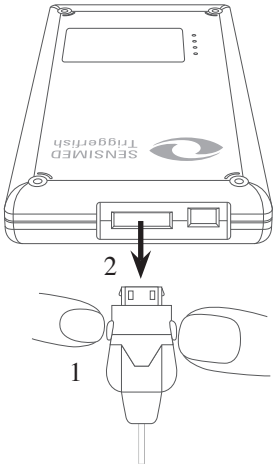
- Make sure that you have removed the Antenna from the patient's face before you disconnect the Data Cable.



Take the Antenna, press the round button of the top click plug (1) and disconnect the Data Cable (2) following the illustration.

Disconnect the Data Cable from the Recorder

- Disconnect the Data Cable from the Recorder following the instructions:



Press with your fingers the clips on both sides (1) and gently pull out the Data Cable from the Recorder's connector (2).

Remove the Sensor

The Sensor should only be removed by a trained health care professional. Refer to the recommended techniques generally used for the removal of soft contact lenses.

In case of emergency, the following removal procedure is recommended:

1. With the middle finger, pull down the lower eyelid
2. Place the index finger on the Sensor's edge
3. Slide the Sensor on the sclera and pinch it slightly between the thumb and the index finger to remove it.

A topical anaestesia can be used to make the process easier to remove the Sensor.

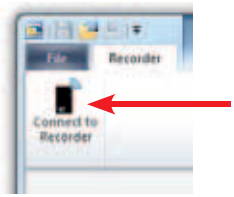
> **NOTE** The Sensor should be discarded according to local hospital/clinical practice requirements.

> **NOTE** Finger cots or surgical gloves may be used.

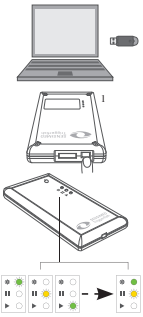
Retrieve Patient Monitoring Data

- Make sure that Bluetooth USB key is connected and installed on your computer.

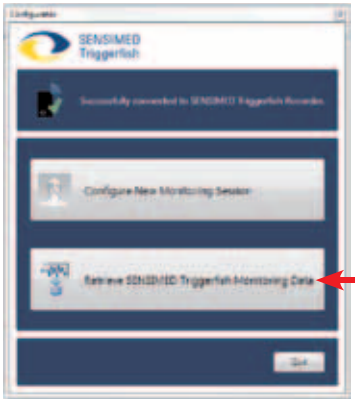
1. To open the Software, click in the Windows start menu, choose “All programs” and navigate till you find the SENSIMED Triggerfish® Software program. You can also open the Software directly from your desktop if you chose to have the shortcut icon



2. To retrieve data, start the Software application, open the tab “Recorder” and click on the icon “Connect to Recorder”

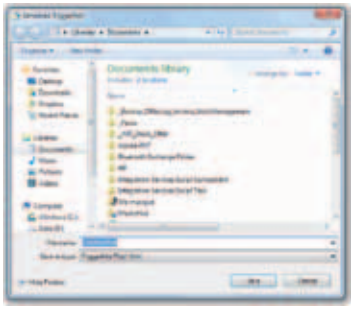


3. Switch on the Recorder and place it within three meters of the computer. The connection status of the Recorder is indicated by blinking lights; refer to the section “Prepare your Computer and Configure Patient Data”.



4. Select “Retrieve SENSIMED Triggerfish Monitoring Data” to start the download of the monitoring data from the Recorder to your computer.

> **PRECAUTION** If this option “Retrieve SENSIMED Triggerfish monitoring Data” is unavailable then the Recorder does not contain any monitoring data.



5. Before downloading the data, select a file location and name to save it on your computer.

6. The monitoring session data will be downloaded and saved in the folder chosen previously. Once the download is complete, the Recorder device is automatically switched off and a confirmation dialog will pop up. Click “OK” to continue. The download process might take some time depending on the length of the monitoring session.

7. We recommend introducing the tonometer IOP value after the Sensor removal for your records at this point. A message window will pop up to remind you of this. Press “Yes” to enter the data or “No” to ignore and continue. This value can be entered at any time.

8. The software will open the file that the monitoring data has been saved to automatically.

PRECAUTION Please note that the monitoring data cannot be downloaded from the Recorder more than once, so make sure the downloaded file is backed up or is saved in a safe location.

NOTE The IOP Profile chart displays Fluctuation Profile in millivot equivalent [mV eq] (Y axis) against time in 24 hour format (X axis).

NOTE Do not forget to recharge the battery of the Recorder once the monitoring session is finished.

View Monitoring Data

Start the SENSIMED Triggerfish® application. To open a ".fish" file, open the "File" tab and click on "Open". Select a patient's file. Alternatively you can also open files by selecting them from a list of recently opened files in the 'Recent Files' section.

The SENSIMED Triggerfish® screen has the following features where healthcare professional can edit, superimpose curves or add patient's activity.

Legend

Section A "File" you can:

- Open a previous continuous monitoring IOP profile ".fish" file
- Save the changes to the ".fish" file
- Save the currently open file under a different name
- Close the current ".fish" file
- Open a recent ".fish" file
- Get additional help
- Options (change the Software language)
- Close the application

Section B "Recorder" you can:

- Configure a new monitoring session
- Retrieve patient monitoring data

Section C "Charts" you can:

1. Superimpose another curve
2. Show two curves side by side
3. Remove the superimposed curve
4. Shift the superimposed curve up (Only available when superimposing curves)
5. Reset the superimposed curve shift (Only available when superimposing curves)
6. Shift the superimposed curve down (Only available when superimposing curves)
7. Change chart scale to "Automatic": showing only the minimum to maximum [mV eq] of the current curve
8. Change chart scale to "Manual": changing manually the [mV eq] curve scale
9. Change chart scale to "Default": view the default curve scale
10. Show or hide patient activity records in the chart
11. Add a patient activity during the monitoring (ie: physical activity, medication, consumption, resting, other)
12. Remove a patient activity: Select the activity in the horizontal activity timeline and click on the icon "Remove Patient Activity".
13. Exclude a Burst: select a point in the main chart and click on the icon "Exclude Burst". The excluded point will appear in orange. To hide or show excluded burst in the curve, select "Excluded Points" box.

14. Add a point to the trendline: select a point in the main curve and click on the icon “Add a Burst to Trendline” to draw a trend line. The blue trend can be shown or hidden by selecting “Trendline” box.
15. Retrieve a Burst in the chart: select the excluded point in the main curve and click on the icon “Include Burst” to retrieve it.
16. Remove a point from the trendline: select a point in the main curve and click on the icon “Remove Burst from Trendline”.

Section D “Report” you can:

- Export the main curve to an image file (.png)
- Export all curves as individual images file (.png)
- Generate a summary report in PDF format

Section E “Patient information”

- In this section you can find the configured patients information (17) and the monitoring session information (18).
- All patient information can be modified manually except the Sensor ID, Monitoring start and end, Eye, Gender and Race fields.

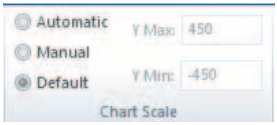
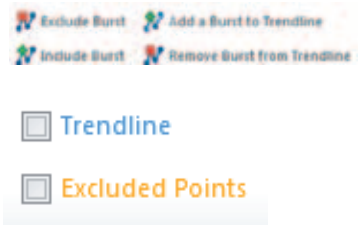
Section F “Continuous IOP Profile” main curve you can:

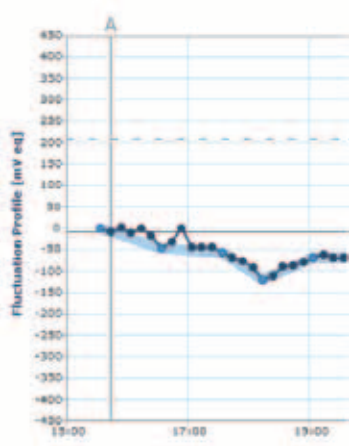
19. See the excluded burst.
20. Drag the vertical line (A) from a point to another to view the burst in details (see Zoom window A below).
21. See the trendline in blue.
22. Click on a point to see the time, the [mV eq] value, and to exclude or add it in the trendline.
23. Drag the vertical line (B) from a point to another to view the burst in details (see Zoom window B below).
10. See patient activity records.

Section G “Zoom A” and “Zoom B” you can:

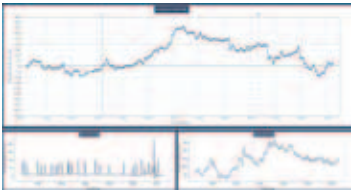
24. See individual monitoring fluctuations values in a burst of measurement.

Section C "Charts":

Features	Use
Superimposing IOP profiles 	It allows the healthcare professional to have a visual comparison of two curves in the main chart window or in two separate windows side by side which can be shift up or down on the [mV eq] scale.
Adapt the [mV eq] curve scale 	It allows the healthcare professional to choose the [mV eq] scale as "Automatic" which will show the minimum to the maximum scale of the current curve or as "Manual" which allows to adapt manually the value of the scale.
Add a patient activity 	It allows the healthcare professional to add relevant patients' activities occurred during the time of the monitoring such as physical activity, medication, resting, etc. Starting time and end time can be selected with additional comment. The Patient booklet will help to fill in this section and it allows keeping a complete record of the patient profile. Each activity is represented by a symbol shown under the main chart window.
Burst 	A burst is a median of points recorded during 30 seconds for every 5 minutes. To exclude a burst in the main curve, left click on it to select and click on the icon "Exclude burst". The point will change color to orange. To hide or show it, click on the icon "Excluded points". To retrieve a burst in the curve, left click on it to select and click on the icon "Include burst"

Trendline 	It allows the healthcare professional to draw a trendline in the main curve. To add a trendline, select a point by left clicking on it in the main curve and click on the icon “Add a Burst to Trendline”. Repeat the action on each point you would like to add as part of the trend. To hide or show the trendline in the curve, click on the icon “Trendline”.

Sections F “Continuous IOP Profile” & G “Zoom windows”:

Features	Use
Continuous IOP Profile window (main curve) 	It displays the Continuous Fluctuation Profile of the patient. Hovering the cursor on one point displays the [mV eq] value and time when measurements were taken. Double clicking on the curve will enlarge it and hide the zoom curves at the bottom
Zoom A & B windows 	It allows the healthcare professional to see the detail measurement points of each burst. In the main curve, move the vertical lines A or B from point to point to zoom on each burst. In the zoom windows you can see every points taken during a burst period. It allows identifying the IOP fluctuation. Double clicking on one of the two zoom windows will enlarge the particular zoom curve.

Cleaning Instructions

The Recorder and Data Cable 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. Make sure that the connectors are absolutely dry before re-using.

> **PRECAUTION** Do not use acetone, ether, Freon, petroleum derivatives, or other solvents to clean the Recorder or the Data Cable.

> **WARNING** The Sensor and the Antenna are for single use only. Do not re-use a Sensor or Antenna.

Disposal of the Recorder

Prior to disposing the Recorder and/or cables and to avoid contaminating or infecting personnel, the environment or other equipment, make sure that the Recorder and/or cables are appropriately disinfected and decontaminated in accordance with your country's law for equipment containing electrical and electronic parts.

For single use parts and accessories, when not otherwise specified, follow local regulations regarding disposal of hospital waste.

Preventive Maintenance

Periodically examine the exterior of the Recorder and Data Cable for general condition. Verify that the housing is not cracked, broken or dented. Inspect that there are no spilled liquids and that there are no signs of abuse.

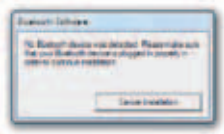
Routinely inspect the Data Cable and battery charger cables for fraying, cracks and recessed pins, and ensure that there are no exposed wires.

Troubleshooting

Use the diagnostic and instruction table below in case of dysfunction of the SENSIMED Triggerfish®.

Errors displayed in the Software

Error	Probable Cause and Solution
It is not possible to click on the start button in the Software window 	All required patient information and a valid Sensor ID have to be entered before the Software can start a new monitoring session. Refer to the section "Configure Patient Data" in this manual.
Device Bluetooth not found or not compatible 	No Bluetooth device was detected. Please make sure that your Bluetooth device is plugged in properly. Refer to the Bluetooth USB Adapter instructions.
Bluetooth not active because an integrated Bluetooth device is already running	Disable the integrated Bluetooth device in the Device Manager and restart the computer.
The Recorder is not connected 	The Recorder has to be activated to connect with the computer. Refer to the section "Activate the Recorder" in this manual. You may have to recharge the battery before the Recorder can be activated.
Retrieving of patient monitoring data is not possible 	Retrieving monitoring data is only possible if the connection to the Recorder is activated and the Recorder contains monitoring data. Refer to the section "Connect the Recorder to your computer" in this manual. If retrieving monitoring data is still not possible, the Recorder does not contain any monitoring data.

Error	Probable Cause and Solution
The Sensor ID is not accepted 	The Sensor ID is an alphanumeric code which is unique for every Sensor. It is printed on its vial. Refer to the section “Configure Patient Data” in this manual and double-check if there are any typing mistakes. Please note that the Sensor ID is not allowed to be registered twice in the Software. If it still doesn’t work contact your SENSIMED representative.
Bluetooth installation not successful 	To finalize the setup of the software you have to insert the Bluetooth key in the computer when prompted.
Not possible to start the monitoring session 	The Sensor ID is not allowed to be registered twice in the Software. Make sure you typed the correct serial number or the Sensor you are using has not been used in the past.
Not able to start a new monitoring session 	Make sure the Recorder does not contain any data. You can download the data onto your computer by clicking on “No” and then on “Retrieve SENSIMED Triggerfish Monitoring Data”. Once the monitoring data are erased or downloaded, the Recorder is empty and therefore ready to register new patient data.

Patient Preparation Errors

Error	Probable Cause and Solution
The Antenna does not remain on the skin	Greasy skin, sweat, facial creams or make-up may reduce the performance of the adhesive tape of the Antenna. Clean the patient's skin before applying an Antenna. See the instructions in section "Apply the Antenna" in this manual.
The Sensor does not fit in the patient's eye	Follow the Fitting Guide in section "Place the Sensor in the Patient's Eye" and choose the appropriate Sensor.
The Data Cable connector does not click	Follow the instructions in section "Connect the Data Cable" in this manual. If it still doesn't click, use a new Data Cable or contact your SENSIMED representative.
No power (Recorder)	Conduct a battery check as described in section "Activate the Recorder" in this manual. If the four lights on the back of the Recorder do not react, recharge the Recorder battery with the medical degree charger available from your SENSIMED representative. If it still does not work, contact your SENSIMED representative.
Charger cable breaks	Do not use the charger anymore. Contact your SENSIMED representative.
Fitting mode lasts more than 2 minutes	If the patient wears glasses test the communication between the Recorder and the Sensor while the patient is wearing their glasses. Full metal frame glasses will create interference. Patient should not wear them. The Data Cable is not properly connected. Check the cable connection from the Antenna to the Recorder. The fitting mode will be validated only if the two green lights stay on.

Compliance to Regulatory Standards

Characteristics of the SENSIMED Triggerfish®

Characteristics	Value
Radio Frequency used for SENSIMED Triggerfish®	27.12 MHz
Type of modulation	FSK
Field strength	43.6 dBuA/m at 3m (appr. 0.6 mW ERP)
Sampling rate	10Hz
Sampling duration	< 40ms
Burst duration	30s
Burst period	300s
Monitoring session duration (maximum)	24h
Type of current	dc
Battery current	600mA
Battery voltage	5 V max.

The SENSIMED Triggerfish® is a medical electrical equipment and requires special precautions regarding EMC. It must be installed according to the EMC information provided in this document. The SENSIMED Triggerfish® contains a RF receiver, it may interfere by other equipment, even if they complies with CISPR EMISSION requirements.

SENSIMED Triggerfish® is a portable intraocular pressure (IOP) fluctuations monitor. Information provided by this medical device relates to IOP fluctuations during the recording time. The device records IOP fluctuations up to 24 hours.

The SENSIMED Triggerfish® has no essential performance regarding IEC 60601-1-2: 2007.

Electromagnetic Emissions and Immunity Information

Guidance and manufacturer's declaration – electromagnetic emissions		
The SENSIMED Triggerfish® is intended for use in the electromagnetic environment specified below. The customer or the user of the SENSIMED Triggerfish® should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The SENSIMED Triggerfish® contains a RF transmitter (wireless communication). Adjacent electronic equipment may be affected.
RF emissions CISPR 11	Class B	The SENSIMED Triggerfish® is suitable for use in all establishments including domestic ones and those directly connected to public low-voltage power supply networks that supply buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	No power network input	
Voltage fluctuations / flicker emissions IEC 61000-3-3	No power network input	

Guidance and manufacturer's declaration – electromagnetic immunity			
The SENSIMED Triggerfish® is intended for use in the electromagnetic environment specified below. The customer or the user of the SENSIMED Triggerfish® should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with a synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 610004-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	No such connection during measuring	Main power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	No such connection during measuring	Main power quality should be that of a typical commercial or hospital environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	No such connection during measuring	Main power quality should be that of a typical commercial or hospital environment. If the user of the SENSIMED Triggerfish® requires continued operation during main power interruptions, it is recommended that the SENSIMED Triggerfish® is powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical industrial environment.

NOTE U_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity			
The SENSIMED Triggerfish® is intended for use in the electromagnetic environment specified below. The customer or the user of the SENSIMED Triggerfish® should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Com-pliance level**	**Electromagnetic environment – guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the SENSIMED Triggerfish® including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	NA	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE At 80 MHz and 800 MHz, the higher frequency range applies.

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 SENSIMED Triggerfish® is used exceeds the applicable RF compliance level above, the SENSIMED Triggerfish® should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the SENSIMED Triggerfish®.

b Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the SENSIMED Triggerfish®

The SENSIMED Triggerfish® is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SENSIMED Triggerfish® can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SENSIMED Triggerfish® as recommended below, according to the maximum output power of the communication equipment.

Rated maximum output power of transmitter, *W*	**Separation distance according to frequency of transmitter,** *m*		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	NA	0.12	0.23
0.1	NA	0.38	0.73
1	NA	1.2	2.3
10	NA	3.8	7.3
100	NA	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in metres (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.

NOTE At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Storage, Transport and Use conditions

The environment for ophthalmic instruments as specified by the EN ISO 15004-1 is:

	Condition of use	Storage condition	Transport condition
Temperature	+10°C to +35°C	+10°C to +55°C	+10°C to +70°C
Relative humidity	30 % to 90 %	10 % to 95 %	10 % to 95 %
Atmospheric pressure	800 hPa to 1060 hPa	700 hPa to 1060 hPa	500 hPa to 1060 hPa

NOTE The above storage and transport conditions apply only when in the manufacturer package and for a period not exceeding the given shelf-life of the product.

Limited Warranty

Sensimed AG warrants that the SENSIMED Triggerfish® Recorder is fit for the purposes and indications described in the labeling for a period of two (2) years after the date of purchase when used in accordance with the directions for use. If equipment is not used in accordance with such instructions, this warranty is void and of no effect.

No other express or implied warranty exists, including any warranty of merchantability or fitness for a particular purpose. This warranty does not include cables, battery charger or Bluetooth used with this SENSIMED Triggerfish® Recorder.

SENSIMED's sole obligation and purchaser's exclusive remedy for breach of any warranty shall be limited to repair or replacement of the SENSIMED Triggerfish® Recorder at SENSIMED's option.

SENSIMED shall not be liable for proximate, incidental or consequential damages. SENSIMED shall not be obligated under this warranty to repair or replace a damaged or dysfunctional SENSIMED Triggerfish® Recorder if such damage or dysfunction is caused by the customer's use of a battery charger or cables other than those recommended by SENSIMED.

IMPORTANT The medical degree battery charger is under separate warranty from its manufacturer. See the specific documentation for further instructions.

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, EP1401327, PCT/EP2007/061244. Prices, specifications, and model availability are subject to change without notice.