Instructions for use – EU.

Intelligent **M**onitoring **P**atch (**IMP**)

Manufacturer

INFO@IMPScandinavia.com

Tel.: +45 42683551

IMP Scandinavia®

INSTRUCTIONS FOR USE

Read this instruction carefully before use of the product.

DESCRIPTION

IMP Scandinavia produces **I**ntelligent **M**onitoring **P**atches (**IMP**) for the healthcare sector. The product consists of an intelligent electronic part that tracks pulse and activity level. The purpose of the patch is to remove the manual nightly surveillance using remote monitoring, which helps to increase safety without disturbing patients' sleep.

The IMP system operates throughout the healthcare sector by the following setup:
Set up the computer and charger in the room where the healthcare staff is mainly located.
Set up beacons so the network covers the entire department.
The healthcare professional unpacks a patch from the bag and places the electronic device, in the pocket designed for that purpose, in the middle of the patch. The patch is then applied to the patient's skin where it is most convenient, but to the chest below the collarbone or forearm is preferable.
Healthcare professionals can monitor all patients wearing an electronic device through the application.
After use, healthcare professionals remove the patch from the patient. The electronic device is taken out of the patch and disinfected napkins before it is put in the charger, the rest is thrown out in the rubbish bin.

Software minimum requirements:

- **OS:** Windows 10 or MacOS Version 10.8: "Mountain Lion"
- **Processor:** 1 gigahertz (GHz)
- **RAM:** 2 gigabytes (GB)
- **Hard disk space**: 2 GB
- **Resolution:** 800 x 600

CONTENTS

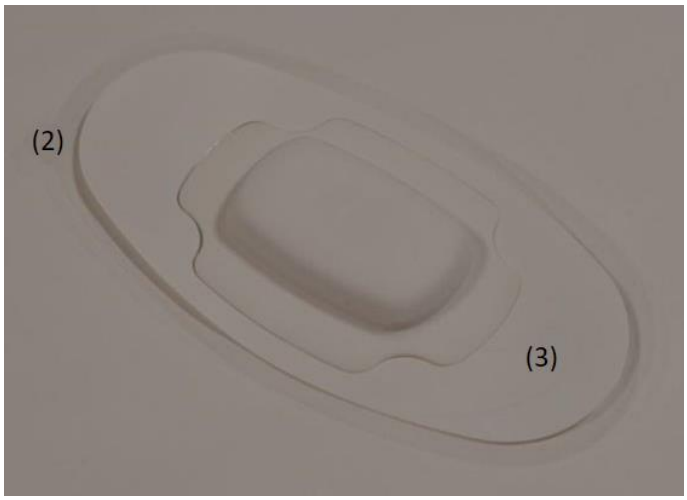
The Product contains:

An electronic device (1) that measures the patient's values, it is rechargeable and must be disinfected after use.

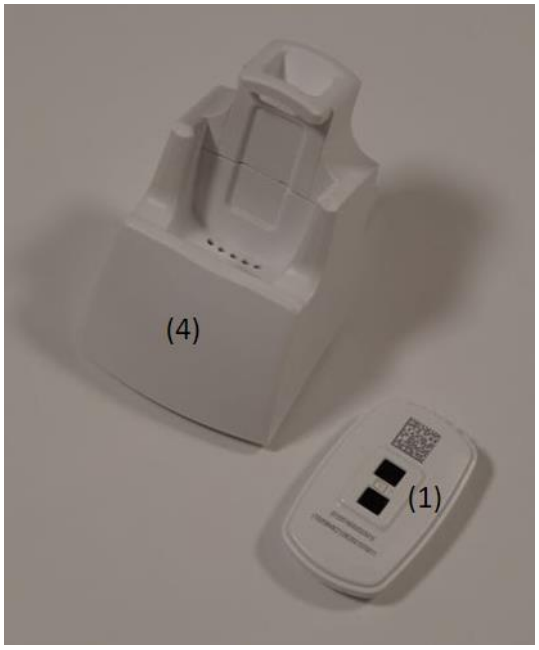
A protective plastic (2) on the underside of the patch that protects the adhesive surface that should have contact with the skin.

A protective paper (3) on top of the patch. In addition to protecting the patch itself, it also helps to stabilize the adhesive surface so that the patch can be easily mounted on the skin.

Note:
The electronic part **(1)** is not waterproof so it should only be cleaned with disinfecting napkins.
When the electronic part **(1)** is inside the patch and applied on a patient it reaches IP44 and is now protected against water splashes from all directions.



A charger (4), for the electronic part (1) which can be plugged into a USB port or a wall socket.



A Base / **Receiver (21),** which must be connected to a USB port on the computer.

A Beacon (27), which must be plugged into a power outlet. It ensures the network has coverage.

Product description:

Operational distance – maximum range from device to device or device to receiver is 60 meters.

Frequency between the electronic device and receiver – 868 Mhz.

Operational time of electronic part **(1)** – minimum 12 hours.

Electronic devices **(1)** connected – 1000 electronic devices **(1)** per receiver.

Receivers **(21)** per system – 128 receivers.

Receivers **(21)** per computer – 1 receiver.

PRINCIPLE OF OPERATION:

Before use:

The electronic part **(1)** must be put in the charging station before use as it will only display a **"Card"** on the computer or mobile device after this operation has been performed.

Identification of the electronics part:

When the electronic device **(1)** is in the charger, there will be a button on the screen **(26)** for each registered electronic device **(1)**. When the button is pressed, a light will flash on the corresponding electronic device **(1)**. It is also possible to do this by entering the setting icon **(5)** and pressing **"Ping" (25)**.

Activity level:

The activity level **(22)** indicates how much movement the electronic part **(1)** is detecting at the given

moment. There will be 5 stages of activity shown on the **"Card"** and the bar will fill up as the activity increases. The electronic part **(1)** will only register the movement on the part of the body where it is located.

Charging:

On each **"Card"**, there will be an indication of how much battery is left **(12)**. The electronic device **(1)** is placed in the charger **(4)** when the battery level is low or after use. The small holes in the electronic device **(1)** should face the corresponding holes in the charger **(4)**. When the electronic part **(1)** is in the charger **(4)**, the **"Card"** changes to **"Charging"**.

Numbering of room and bed:

Each **"Card"** on the screen can be assigned a room and bed number. This is done by clicking on the setting icon **(5)** and writing the room number in the field **"Room Number" (15)** and the bed number in the field **"Bed Number" (24)**. The bed number is only used if there are several beds in the room.

Set maximum and minimum pulse:

On each **"Card"** the maximum and minimum pulse should be set before use. This can be done by clicking the settings icon **(5)** and entering the preferred values in the respective fields with the words **"Pulse High Limit" (16)** and **"Pulse Low Limit" (17)**. It is possible to change the value for both maximum and minimum heart rate at any time.

Reset maximum and minimum pulse:

For each **"Card"** there will be two values. One value shows the highest pulse the patient has had while the patch has been applied **(11)**. The second value shows the lowest pulse the patient has had while the patch has been applied **(10)**. These values can be set to the current heart rate by clicking on the reset heart rate button **(6)**.

Notification:

If a patient's pulse drops below **"Pulse Low Limit" (17)** or goes above **"Pulse High Limit" (16)** the **"Card"** will change color and be highlighted in a special designed field on the screen. A new button will appear **(20).** Even if the patient's heart rate is subsequently within the range the alarm will still

be there until it is reset by clicking **(6)**.

Confidence:

Confidence (13) indicates how reliable the measurement of the heart rate is. If **Confidence (13)** is too low, the heart rate will not be displayed and the **"Card"** will switch to **"Too Much Movement"**. This can happen if **Activity level (22)** is too high. The measurement is displayed on a binary scale from 1-10

Trend Graph:

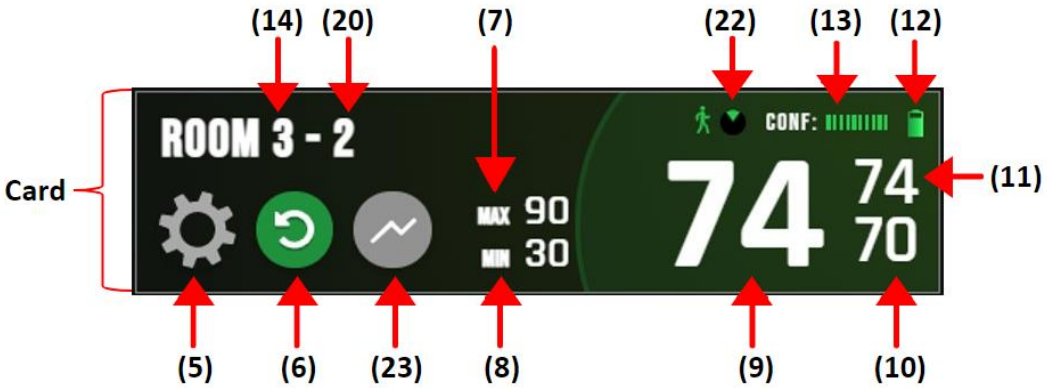
The patient's pulse can be read in the trend graph by clicking the graph icon **(23)**. The trend graph can show measurements for the last 24 hour.

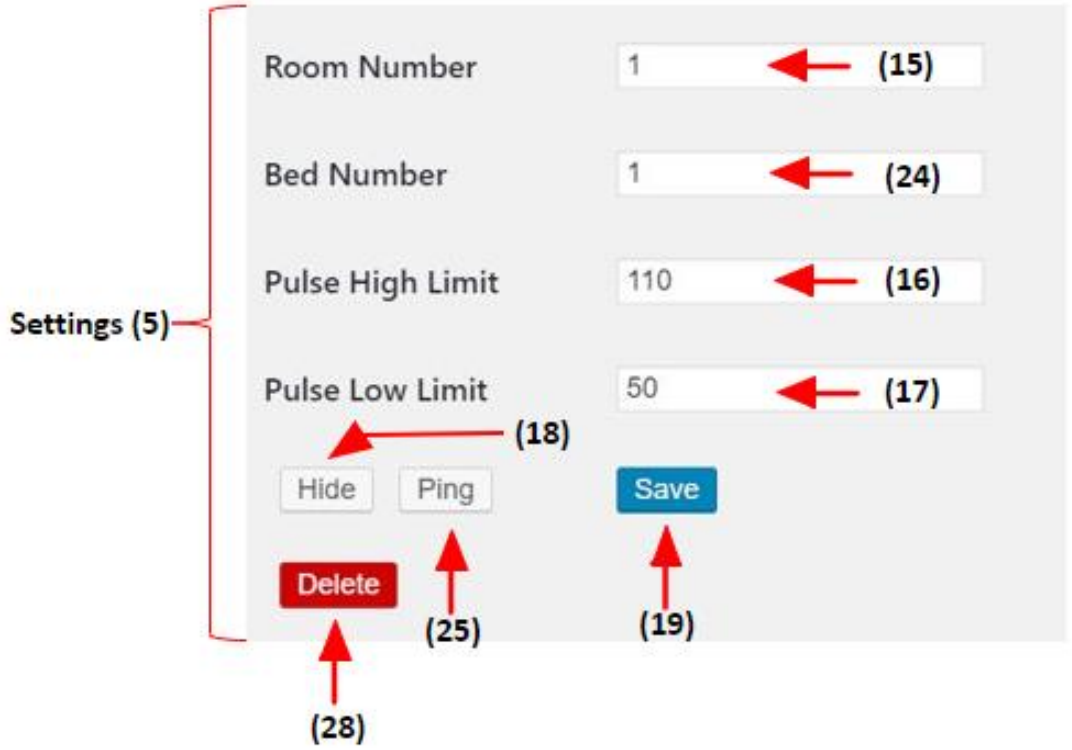
Awaiting Heart Rate:

The first time the electronic device **(1)** is placed on a patient, there should be three measurements in a row with a high **Confidence (13)**. This may take some time, as the electronic device **(1)** spends time calibrating to suit the patient and the place where it is attached.

Too Much Movement:

If there is too much movement, **Confidence (13)** may drop below an acceptable level. When this happens, the **"Card"** changes to **"Too Much Movement"**. When the **Confidence (13)** again is at an acceptable level, it will switch back to **"Card".**

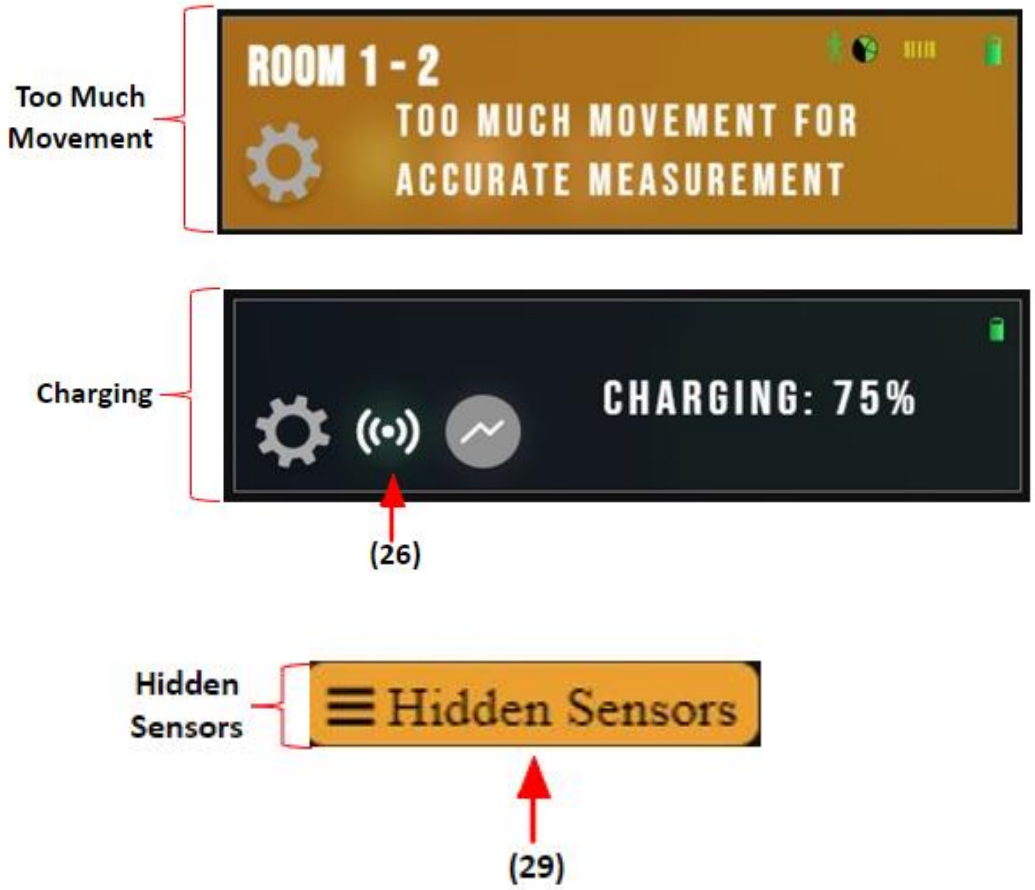



Settings (5)
Room Number
1
(15)
Bed Number
1
(24)
Pulse High Limit
110
(16)
Pulse Low Limit
50
(17)
(18)
Hide
Ping
Save
Delete
(25)
(19)
(28)


Pulse High Limit
ROOM 1 - 2
CONF:
MAX 65
MIN 44
93
95
78


Pulse Low Limit
ROOM 87 - 5
CONF:
MAX 80
MIN 55
49
63
46


Awaiting
Heart Rate
ROOM 1 - 2
AWAITING HEART RATE
CHECK SENSOR IF THIS CONTINUES



INTENDED USE:

IMP is a medical product designed to transmit patients' pulse and movements. The measurements are used by healthcare professionals to provide a better overview of patients' condition.

EXPECTED CLINICAL BENEFIT:

When used in accordance with the instructions for use, IMP claims to perform the following:

- Displays real-time pulse for clinicians at a distance from patients.
- Moves the patients **"Card"** on the display if the pulse moves outside the indicated range.

Safety claim:

IMP hereby confirms that the equipment in compliance with the applicable general safety requirements and performance in Annex I to the European Parliament Regulation (EU) 2017/745 and by the Council of 5 April 2017 on medical devices, apart from the aspects covered by the clinical study and that, with regard to these aspects, every precaution has been taken to protect the health and safety of the subjects. This includes, where appropriate, technical and biological safety testing and preclinical evaluation, as well as provisions in the field of occupational safety and accident

prevention, taking into account the latest technology;

The device's performance characteristics:

- Shorten the hospital stay by improving patients' sleep and well-being during hospitalization.
- Increased safety, due to continuous observations that do not disturb patients.
- Allows healthcare professionals to interact faster.
- Provides healthcare professionals with assurance about patients' well-being.
- Healthcare professionals can reduce the time spent on supervision and utilize resources more efficiently.

Specifications required for proper use of the device:

Read and understand the instructions for use before using IMP's products.

INDICATIONS FOR USE:

The product is designed to help healthcare professionals observe patients in need of daily supervision without disturbing them.

PATIENT MÅLGRUPPE:

- Elder care.
- Patients in psychiatry.
- Patients in need of observation.

NTENDED USER:

The intended user of IMP is healthcare professionals who have patients to observe.

CONTRAINDICATIONS:

- Hypersensitivity to silicone or silicone-based adhesive.
- People with special skin conditions e.g. open wounds, irritated skin etc. can be further damaged by the use of patches due to the skin condition.

WARNINGS AND PRECAUTIONS:

1. The electrical unit **(1)** is not waterproof and should therefore only be cleaned with disinfectant wipes. Once the electronic device **(1)** is inside the patch and attached to a patient, it achieves IP44 and is now protected from water spray from all directions.
2. The product is to be used only by healthcare professionals.
3. Make sure the skin area is clean and dry before applying the patch.
4. The measured data should not be the only basis for critical decisions.
5. Do not put the electronic device **(1)** in your mouth.
6. Do not apply the patch to areas of skin that are heavily covered with hair or to irritated skin.
7. If the packaging is broken on arrival, the product must be returned, as we cannot take responsibility for the hygiene or condition of the product.

INSTRUCTIONS BEFORE USE:

Prepare the computer

1. Turn on the computer.
2. Connect the receiver **(21)** to the USB port on the computer.
3. Turn on the application by clicking the IMP shortcut on the desktop

Prepare the charger

1. Unpack the charger **(4)**
2. Plug the supplied cord into the charger.
3. Plug the other end of the cord into a USB port or electrical outlet.

Prepare the electronic part

4. Unpack the electronic device **(1)**.
5. Insert the electronic device **(1)** into the charger **(4)**.
6. Click the settings icon **(5)** and insert **Room Number (15)**, **Pulse High Limit (16)**, and **Pulse Low Limit (17)**. **Bed Number** is only used if there are several beds in the room.
7. Click the **"Save"** button **(19)**.

Find the electronic device associated with a particular room and bed

1. If the electronic device **(1)** is in the charger: Click this button  **(26)** - a light on the electronic device **(1)** will now flash for 5 seconds.
2. If the electronic device **(1)** is not in the charger: Click on the setting button **(5)** and then click on **"Ping" (25).** - a light on the electronic device **(1)** will now flash for 5 seconds.

Apply the patch

1. Take the patch out of the package.
2. Insert the electronic device **(1)** into the appropriate pocket at the bottom of the patch. Diodes and sensors must face the skin.
3. Remove the protective plastic **(2)** from underneath the patch.
4. The patch should preferably be placed on the forearm or on the chest below the collarbone but can be placed elsewhere. Rub gently from the center of the patch and toward the edge to ensure the best possible contact between the skin and the adhesive surface.
5. Remove the protective paper from the top of the patch **(3)** by pulling on the small flap.

Remove the patch

1. Grasp the end of the adhesive part and pull the patch off. For the least possible discomfort, this is done in the direction of the hairs.
2. The electronic device **(1)** is removed from the patch and cleaned with disinfectant wipes.
3. The remaining part of the patch is discarded.

Reuse the electronic part

Place the electronic device **(1)** in the charger **(4)**. The settings will remain the same until manually changed.

Delete a Card

1. Find the **"Card"** you want to delete.
2. Click the setting button **(5)**.
3. Click the **"Delete"** button **(28)**.

Note:

Only use when the electronic device **(1)** is no longer active. If the electronic device **(1)** is still active it

will automatically appear again.

Hide a Card

1. Find the “Card” you want to hide.
2. Click the setting button **(5)**.
3. Click the **“Hide”** button **(28).**

Show hidden Card

1. Click the **“Hidden Sensors” (29)**.
2. Click the **“Card”** you want to show.

COMBINATION WITH OTHER APPLIANCES, INCLUDING ACCESSORIES:

- IMP’s software
- The Beacon **(27)**
- The receiver **(21)**

Complications:

The known potential complications related to the use of IMP include the following:

- Patients with paranoid schizophrenia may be afraid to use it.
- Patients may accidentally remove the patch while sleeping.
- Patients may intentionally remove the patch to contact healthcare professionals.

REPORTING OF ADVERSE EVENTS:

All serious incidents related to the product must be reported to IMP Scandinavia by filling out a reporting form on the website IMPscandinavia.com, or a descriptive email can be sent via Info@impscandinavia.com.

LEVERINGSPROCEDURE:

The patches, devices and chargers are provided by a delivery service.

The patches are wrapped in a PMS Steripack. It is a heat-sealed sterilization bag that complies ISO

11140-1, ISO 11607 and EN 868-5 standards. There are 10 patches in each bag.

The software is installed manually by IMP staff, but can also be downloaded using a link if required.

SUPPLIER & CONTACT PERSON:

IMP Scandinavia ApS

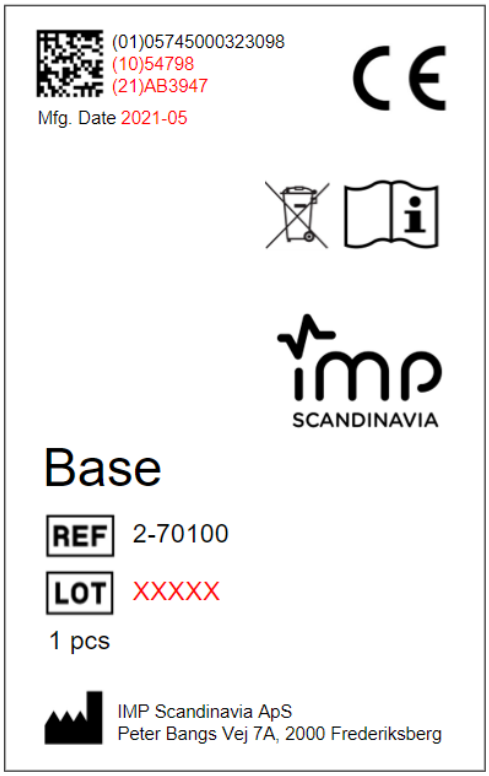
Mail: Info@impscandinavia.com

Tel: +45 42683551

LABELS:

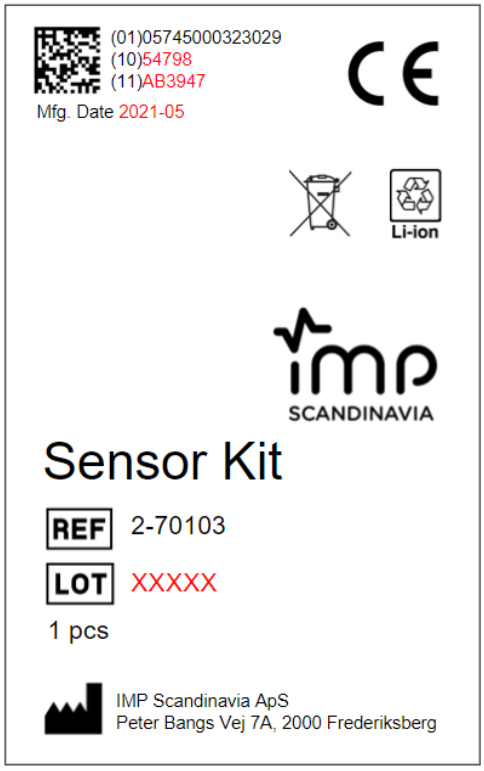
UDI-DI labeling for each component of the product:

Base:

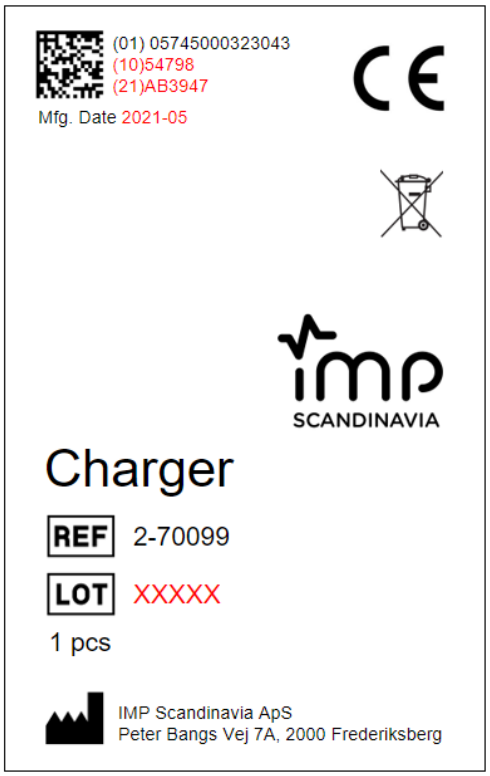


Beacon:

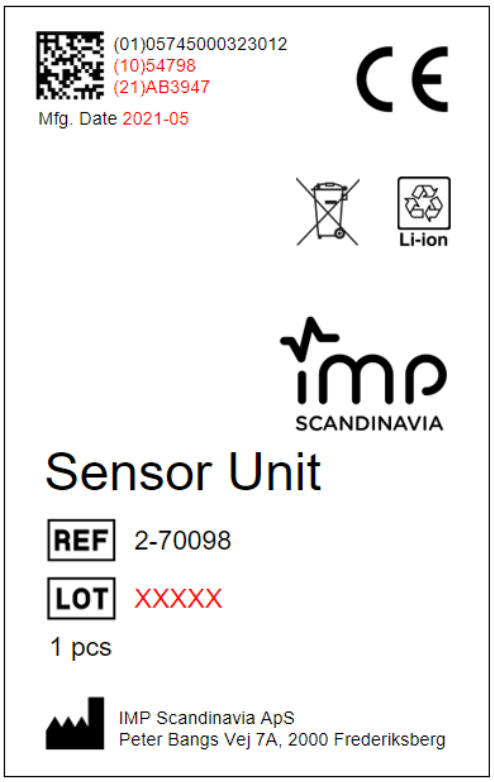
Sensor kit - Contains: Charger, power supply and electronic device:



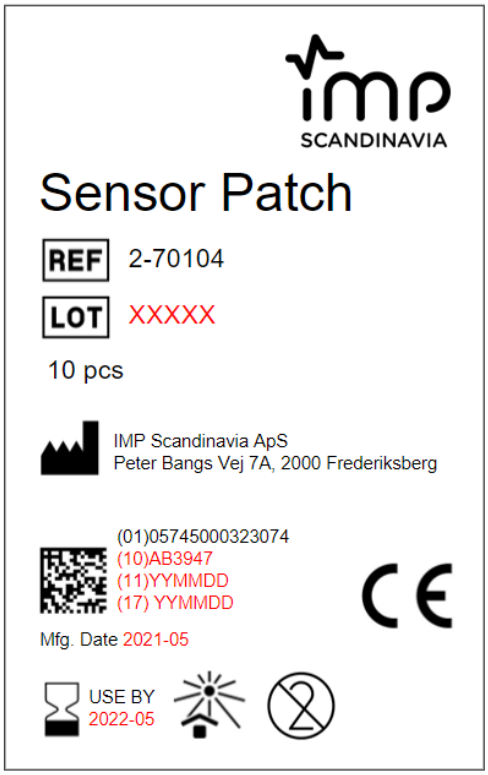
Charger and power supply:



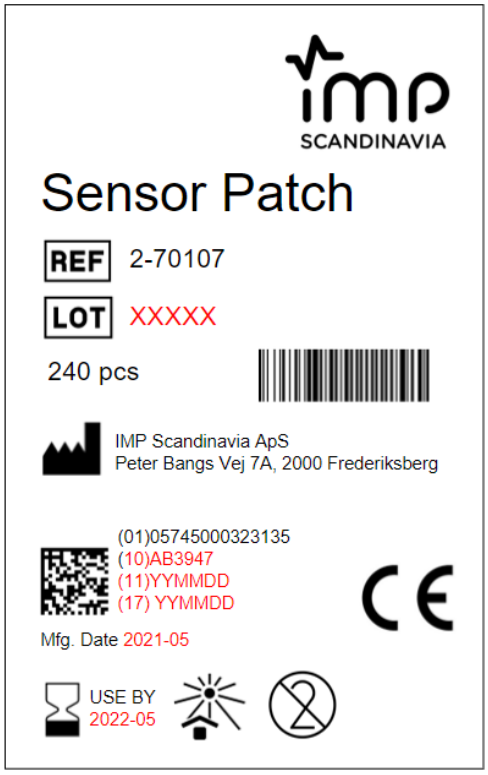
Sensor Unit:



Sensor patch 10 pcs.:



Sensor patch 240 pcs.:



STORAGE:

The products lifetime is 2 years when in use. The shelf life is 10 years. Store the device in a dry area. Do not store in direct sunlight.

MAINTENANCE AND REPAIR:

Cleaning and disinfection are necessary. This must be done after each use of the electronic device and for the charger in relation to the daily cleaning of the hospital.

Contact the supplier if the product needs a repair.

If the software crashes, restart the application.

MANUFACTURER:

INFO@IMPScandinavia.com
Tel.: +45 42683551