# User manual

# EPI901



Fabriksvej 20 ● DK-7600 Struer ● knop@knop.dk ● knop.dk ● +45 97840444

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## *Warnings and safety instructions*

- Batteries used must comply with the relevant IEC safety standards.
- Read the intended use before using.
- Do not ingest/eat battery(ies), chemical burn hazard. Batteries can cause serious injury or death if swallowed.
- Keep new and used batteries away from children.
- If the battery compartment cannot be closed securely, the product must be discarded and kept away from children/patients and animals.
- The battery for the watch is permanently installed and not intended to be removed by the user.
- If the product is damaged, batteries may become accessible; the product must be discarded and kept away from children/patients and animals.
- Evaluate the EPI901 and any external sensors each time they are used.
- The user/relatives must always be aware that situations may arise where no seizure can be detected and therefore no alarm is given, e.g. in the case of weak tremors and in cases where the person has a seizure and loses consciousness without any tremors.
- There will be cases where the user, e.g. a child, is lying in a large adult bed and is too far away from the sensor, preventing tremors from being detected by the sensor. Always ensure that the bed is set up for the user.
- The EPI901 uses a wireless transmitter at 869 MHz, which in some cases may interfere with other approved equipment with 869 MHz transmitters/receivers, just as the EPI900 may be interfered with by other 869 MHz transmitters.
- The EPI901 ***must not*** be used for diagnosis!
- EPI901 ***must not*** be used in cases where a seizure requires life-saving action or medical treatment.
- The product is not water-resistant and must not be exposed to moisture/water.

## *Notes before use*

General considerations regarding the use of KNOP products:

In general, products must not be used if the client (patient) is mentally or critically ill.

Before use, it must be ensured that the patient in question is capable of operating the product.

The product must not be used for diagnostic purposes under any circumstances.

## *Lifespan after installation/use of the device*

The product is designed to have a long service life of 5 years.

However, please note that the battery must be replaced when the indicator lights up.
See the user manual for more details.

## *Battery operating time*

The operating time of the batteries is calculated by Knop – see specifications in the user manual under technical data.

## *Intended use*

The various versions of KNOP's medical equipment consist of a combination of aids (transmitters and receivers) designed to call for help for frail/disabled patients/clients.

The transmitter-receiver systems can be activated in different ways:

- E.g. clients who actively activate the device in question and are thus aware that they are calling for help. E.g. people with walking difficulties who need help going to the toilet.
- Or disabled clients who are unaware that they are inadvertently pressing the transmitter, e.g. during a seizure.
- Or clients with intellectual and/or cognitive impairments who are unaware that a mounted receiver receives a signal when the patient leaves a house or room.

# *General product description*

KNOP Elektronik products consist of several variants of transmitters and receivers that can be combined with each other. In addition, these products are used in combination with positioning and repeater systems.

These products are medical devices intended to call for help for people, e.g. those with walking difficulties, who need help going to the toilet.

The transmitters are activated, for example, by a sound or pressure (e.g. a touch of the finger or a breath from the mouth).

The receiver is monitored by healthcare professionals or lay persons in private homes.
The system is not designed for critically ill or mentally ill people.

| **Part of the product** | **Function in the product system** |
|---|---|
| Transmitter | The transmitter can send the signal from the patient to the receiver, which is monitored by healthcare professionals or lay persons.<br>A button, sound, breath, or movement can activate the transmitter products. |
| Receiver | The transmitters can be coded to all receivers and to several receivers at the same time.<br>Some receivers also have a call button so that they can call for help from their colleagues. |
| Repeater system | If there is a need to cover a more extensive and larger area, a repeater system is used. The repeater system also provides increased functionality, such as an alarm being automatically received first by the healthcare professional closest to the client. |
| Positioning system | If a transmitter is equipped with a position receiver, it can be used in conjunction with a position system. Not all product variants include position receivers. This is typically seen in connection with nursing homes and safety for dementia patients.<br><br>The receivers can be portable or stationary. |

## *Product*

The EPI901 is intended for people who may experience seizures. The product is designed to detect seizures when the person is lying in bed. This could be children sleeping in their own rooms or residents in healthcare institutions.

When the EPI901 detects a seizure, an alarm is sent to a receiver, e.g. to parents or care staff.

Please note the range of the alarm, which is described in the section ***"Checking the coverage area".***

However, you should be aware that medical treatment may be necessary.

The EPI901 is ***not*** intended for the diagnosis or monitoring of persons with serious illnesses.

The EPI901 is the same as the EPI900, just updated and improved. The operation is also largely the same.

## *Commissioning*

Due to the sensitive sensor in the cabinet, hospital and institutional beds with spring bases are suitable for mounting the EPI901 under the bed without the use of an external sensor.

However, mounting under regular beds can make it difficult to pick up a signal. To solve this, the external sensor for EPI901S can be used, which is placed on top of the mattress – but under the top mattress. See illustration below. The sensor should be held in place with a piece of plaster or tape.

The external sensor is connected to the EPI901 and can, for example, be hung at the end of the bed or as shown.

Please note that if the patient changes position in bed, the sensor must also be repositioned to ensure the best possible signal reception.

There is no general rule for placement, but there are several things to consider. Today, there are many different mattresses that, due to their construction and use of materials, dampen the vibrations from seizures, making it impossible to register a reliable alarm.

Also consider the size and weight of the bed and the person. A small person can move around in bed and move away from the sensor, which may result in no tremors being detected.

After installation, the system must be evaluated by simulating a seizure with your hand on the mattress or by having a person lie down in the bed and simulate a seizure.

To set the desired number of vibrations, see the section ***"Setting the number of vibrations"***

*Continued on next page...*

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The EPI901 is evaluated together with a receiver from KNOP Elektronik.

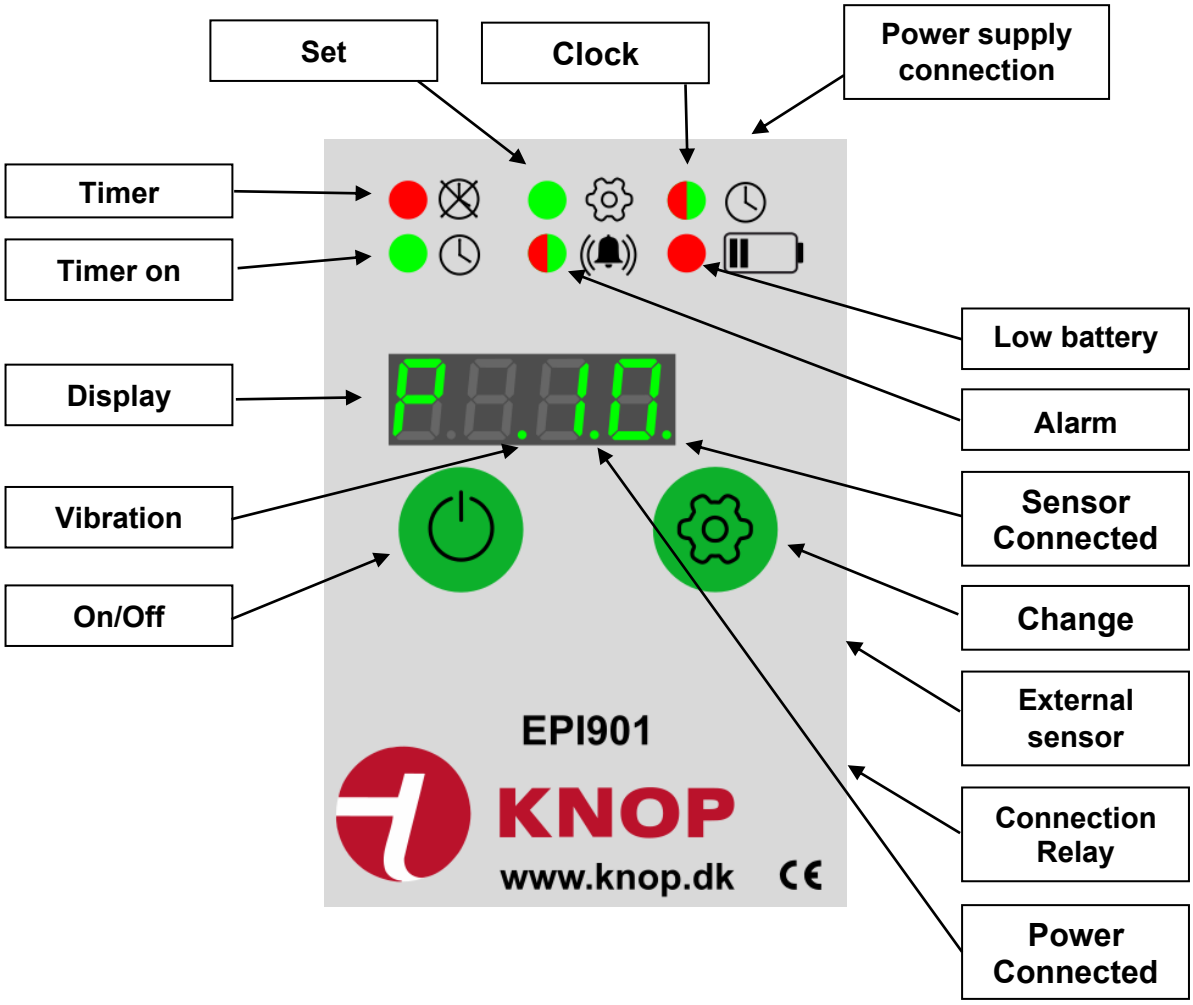
The EPI901 can also be connected to certain types of call systems via its relay output.

The difference between EPI900 and EPI901 is that EPI901 now has a clock that continues to run, even when the batteries are removed. Battery life has also been improved.

***Important:*** The EPI900S sensor cannot be used with the EPI901 or vice versa.

## *Buttons, indicators, and connectors*

Location of buttons, indicators, and connections.



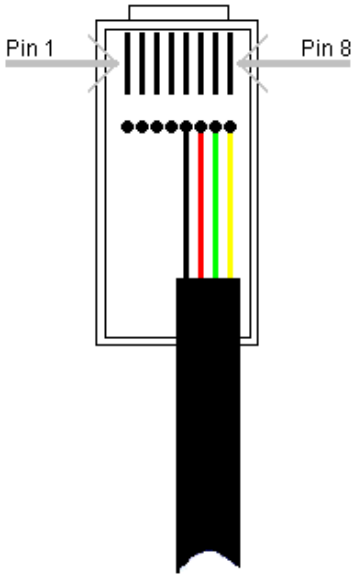

***Please note:*** Do not connect anything, other than what is described in this document, to the connectors.

## *Relay output*

The relay output on the EPI901 is a potential-free output connected to an 8-pin modular connector on pins 7 and 8 for connection to other equipment, e.g. call systems, etc.

Various adapter cables are available to order; these are not included.

Max load: 30V/20mA



## *External power supply*

A power supply can be connected at the top of the product.

A standard USB-C cable and mains adapter must be used; see accessories.

The adapter must be approved according to Electrical Safety Class II and marked: ⧈

USB-C:

The display shows the connection of an external power supply as shown below; this is only shown when the product is not in use.

# *Operation*

The product is a transmitter designed to collaborate with wireless receivers in the KNOP 901 series. Please note the range described in the section ***"Checking the range"***.

There are only two buttons for daily operation and several possible independent settings/programmes – see the following pages.

The user/staff should only switch the EPI901 on and off daily using or the product's timer function.

It is advantageous to use the product's timer function. When the person is not in bed, the EPI901 can switch itself off to save power.

The EPI901 remembers the settings, even when the batteries are removed.

When starting up the EPI901, set the number of tremors/convulsions required before the alarm is activated.
This is done by pressing

Please note that the EPI901 registers even exceedingly small tremors during convulsive seizures. The factory setting is the second highest sensitivity. However, it is possible to adjust this in the expert settings; see the section on this. Alternatively, contact the technical department for changes. However, experience shows that this is rarely necessary.

The only adjustment that needs to be made by the user is to set the number of tremors required to activate the alarm.

After an alarm has been sent, the product will *not* detect vibrations/convulsions for 5 seconds.

***IMPORTANT:*** To access the controls, hold the button down for 1 second, after which it will appear on the display. This is to minimise accidental presses.

The indicators show the status of the transmission in the following ways:

The indicators show the status of the transmission

Green flashing, alarm sent.

Then it shows whether the alarm has been received or not.

Green flashing, alarm received

or

Red flashing light, alarm ***not*** received.

## *Checking settings*

EPI901 is set to 6 vibrations. The time is 13:40, timer on is set to 16:00 and timer off is set to 08:00.

Press and hold the ' ' button for one second to view the settings for the EPI901 in sequence

The display turns off automatically.

❶ Number of pulses/vibrations, e.g. 10, required to trigger an alarm.

❷ The current time, e.g. **14:40,** and symbols.

❸ Timer switch-on time, e.g. **16:00,** and symbols.

□ Timer switch-off time, e.g. 08:00 a.m., and symbols.

In the above example, the EPI901 will automatically switch on between 16:00 and 08:00 the following day.

***Please note:*** If the timer on and timer off times are the same, the timer is not active.

## *Setting the number of vibrations*

When setting up the EPI901, you set the number of vibrations required before the alarm is activated. It may be necessary to adjust this if there are changes in the client's/user's pattern, e.g. cramps, weight, and the mattress on which the person is lying.

***Important:*** *If the client's mattress is changed, the number of vibrations may need to be changed.*

There are no rules for what the vibration setting should be, but it is important to check it as described in the section ***"Commissioning".***

There are two different ways in which the EPI901 measures the number of vibrations required to trigger an alarm:

- Consecutive tremors between 1 and 29
- And/or the frequency over a period of time – which can be set to, for example, 1, 5, 10, 13, 16 and 20 seconds.

Both methods have a reset time, but this can be changed under ***"Expert settings"*** – expected to be used rarely.

Press and hold  (approx. 1 second)

***Please note:*** The product must be switched on!

The current setting is now displayed, e.g. as shown 10 pulses.


Press the button once  to switch to the next setting, e.g.

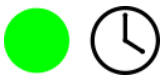

Press the button several times to increase the number; you can set between 1 and 29 vibrations.

*Continued on next page…*

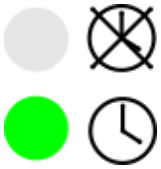
Press the button once to switch the setting to vibrations over a period, e.g. 10 seconds (S 10).

Once the desired value has been found, simply wait until the EPI901 displays the other settings (briefly).

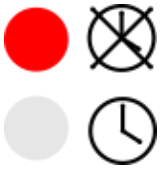
First, the clock is displayed:



Then the hours light up:



And finally, the timer off



***Tip!*** *Press the "symbol" to go directly outside.*

***Info!*** When a vibration is detected, the dot shown in the image below will briefly light up on both the internal and external sensors.

## *On/Off*

Press and hold the " ◯ " button. The display will then flash either "**On**" or "**OFF**".



Press the button before switching it from either **On** (on) or **OFF** (off).

If the product is switched on, either the indicator ● 🕒 or ● ⊗
This shows whether the timer is on or off.

***Please note*** that if the product is switched off or the timer is switched off, vibrations will ***NOT*** be registered!

***Tip!*** *After 5 seconds, the display switches off automatically.*

***Info!*** The timer is not activated at the factory.

This also shows whether an external sensor is connected and activated.


Internal sensor in EPI901 active.


External sensor in EPI901 active.

***Please note!*** No external indicator is displayed if the product is switched off.

## *Setting the clock/timer*

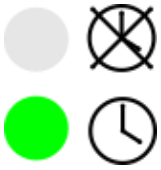
Hold down the ' ◯ ' and ' ⚙ ' buttons simultaneously for 5 seconds ● ⚙ will flash during this process.

***Please note!*** The product must be switched on!

Release the buttons when the display shows the clock and ● 🕒 is lit, e.g.:

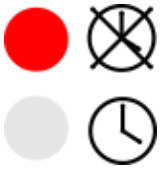

If you want to change the clock to, for example, 11:35

Press the " ⚙ " button or hold it down until "35" appears.

Press ◯ briefly and the hours will flash.

Press the " ⚙ " button or hold it down until "11" appears.

.

Press ◯

Then the hour on/off (subsequent) must be set and the current symbol will light up.
The setting is done in the same way as for the clock.

If you do not want to make any changes to either *the timer on* or timer off, simply press the " ◯ " button until you are finished.

***Remember!*** *The timer on* and timer off settings must be the same for the timer to be deactivated.

***Info!*** The clock in the product continues to run even if the batteries are removed.

***Important!*** *The clock* ***does not*** *automatically change to summer/winter time.*

If necessary, proceed to ***"Setting the timer function"***.

## *Expert settings*

The product has a few expert settings.

- Heart rate reset time for both heart rate and time.
- Sensitivity
- Show heart rate counter in display

The reset time is the time the product waits before the vibration counter is reset. It can be set between 0.2 and 4.0 seconds. The default setting is 2.0 seconds. When vibrations are used over time, this can be set between 0.5 and 2.0 seconds.

The sensitivity can be set to 4 levels, 1 to 4, where 4 is maximum sensitivity. The product is set to 3 by default.

To access the expert settings, perform the following sequence:

Hold down the ' ◯ ' and ' ✿ ' buttons simultaneously for 30 seconds until, for example, **PU2.0** appears in the display.


The reset time (vibrations) is changed.

Press ✿ to change the time between 0.2 and 4.0 seconds.

Press ◯ briefly to continue.


The reset time (time) is changed.

Press and hold the " ✿ " button to change the time between 0.5 and 2.0 seconds.

Briefly press " ◯ " to continue.

*Continued on next page…*

Press ' ' to change the sensitivity between 1 and 4.

Press briefly to continue.

Press to select whether the counter should be displayed or not. Yes or no will be displayed.

Press briefly to continue.

The product's firmware version is displayed briefly in this case, version 1.0.0.

***Important!*** It is important to complete the entire process for the settings to be saved.

***Info!*** The display turns off after 5 seconds.

## *Battery alarm*

It is recommended that the battery be checked regularly.

When the batteries need to be replaced, "  " flashes every minute, accompanied by a short audible signal.

If a receiver with a display is used, *"Low battery"* will be displayed when an alarm is received from this product. 

If it flashes simultaneously, there is no more power in the internal lithium backup battery for the clock. The product must therefore be sent in, as the battery cannot be replaced. However, the product will function normally, but replacing the two AA batteries will reset the clock.

## *Battery replacement*

- Remove the battery cover on the back of the product with a suitable screwdriver.
- Insert 2 new **Alkaline LR-6 (AA)** batteries.
- Remember to insert them correctly. See the markings on the bottom of the battery compartment.
- Check that the product is working correctly.


If faulty batteries are inserted, the product will flash the indicators '  ' and  and emit a beep that repeats 10 times.

If the batteries are running low, the indicators will continue to flash as long as there is enough power for the functions. New batteries should be inserted as soon as possible.

## *Error indications*

- *  , and  indicators flashing simultaneously*

  An error has been detected on the external sensor. Replace the external sensor.

- *The indicators "  " flash intermittently*

  Replace the batteries, they are depleted.

- *The indicators  and  flash occasionally*

  The watch battery is depleted and must be sent in for replacement.
  However, the product is functioning normally, but replacing the two AA batteries will reset the watch.

- *No response when pressing either  or  *

  Replace the batteries. If this does not help, send the product in for repair.

- *The product flashes and/or beeps when batteries are inserted*

  The batteries are too weak and partially depleted. Use new batteries.

## *Fault causes*

- The batteries have not been replaced after the battery alarm.
- Both devices have not been switched on. (EPI901 and receiver, e.g. RX901B)
- The receiver may be outside the coverage area.
- The sensor is positioned incorrectly in the bed.
- The sensor is facing the wrong way; the red logo must face upwards.
- EPI901 is set to too high a number of pulses/convulsions.
- The sensor is not working; an EPI901S sensor has been used.

For inspiration, the following checks can be performed:

| **Checklist:** | **Every week** | **Every month** | **Not in use** |
|---|---|---|---|
| Check that the external sensor is positioned correctly in the bed. | X | | |
| Check that the cable on the external sensor is secure and has not been damaged by a bed rail or anything else. | X | | |
| Check that the logo on the external sensor is facing upwards. | X | | |
| Evaluate the EPI901 together with the receiver. | X | | |
| Keep an eye on LOW BATT on the EPI901. | | X | |
| Try different parts of the coverage area | | X | |
| Check the "PULSE" setting on the EPI901. | | X | |
| Simulate convulsions with one hand on the mattress each time a device has been turned off and the bed has been made. | X | | |
| Inspect and clean the devices with a soft, slightly damp cloth. | | X | |
| Ensure that new employees are thoroughly familiar with the appliances. | X | | |
| Ensure that the appliances are switched on. | X | | |
| Always remove batteries when the devices are not in use and will be stored for a long period of time. | | | X |

## *Maintenance*

It is possible to update the software in the EPI901. For a more detailed description, please refer to KNOPtool.

## *Cleaning*

The product can be cleaned with a damp cloth or alcohol wipe.

## *Checking the coverage area*

To ensure the intended coverage area, the following procedure is recommended:

- One person activates signals at short intervals while another systematically walks around the area.
- Mark where there is coverage on a floor plan of the area. Ensure that there IS coverage throughout the entire area.
- It is recommended that the floor plan with coverage area be available to all persons using the receiver system.

The coverage area can be increased by using KNOP's repeater system MR902/RP902.
Contact your dealer for more information.

## *Resetting the product*

The EPI901 can be reset to factory settings:

- Remove the batteries for at least 30 seconds.
- Then hold down **the ON/OFF button** while inserting the batteries. Please note that new batteries must be used.
- The product will beep every second.
- Do not release the button until the indicator has emitted a beep-beep sound after approx. 10 seconds.

The EPI901 is now restored to factory settings.

## *Spare parts and accessories*

Spare parts and accessories can be ordered on our website www.knop.dk

| ***Item no.:*** | ***Product:*** |
|---|---|
| EPI901S | External sensor |
| MK202 | Cable, RJ45 6.3 mm mono angled, 3 metres. |
| ST903 | Power adapter with 1 m USBC cable |

## *Technical data*

| | |
|---|---|
| **RF frequency:** | 869.2125 MHz |
| **Range:** | Up to 1500m in clear line of sight to an RX901B (1) |
| **Battery type:** | 2 x 1.5V LR6/AA/E91 type ProAlkaline |
| **Operating voltage:** | 3V |
| **Operating time:** | 12 months at 5 transmissions per day (expected). |
| **Backup battery operating time:** | 10 years (expected) |
| **Expected service life** | 5 years |
| **Low battery alarm/indicator:** | ~1/4 remaining capacity. |
| **Consumption standby:** | <15µA |
| **Consumption internal sensor:** | ~110µA |
| **Consumption external sensor:** | ~120µA |
| Consumption active transmitter: | ~50mA average on a transmission. |
| **Ambient environment:** | Indoor use. ≤ 90% non-condensing.<br>Do *not* use in oxygen-enriched areas or in conjunction with flammable materials. |
| Ambient temperature: | 0 °C to +40 °C |
| **Cabinet type:** | White ABS |
| **Cabinet dimension:** | W: 65 mm, H: 128 mm, D: 22 mm. |
| **Density EPI901:** | IP20 |
| **Density EPI901S:** | IP67 |
| **Connections:** | 4-pin modular connector: External sensor<br>8-pin modular connector: Potential-free relay output<br>USB-C: External power supply (Electrical safety class II) |
| . | |
| **Weight incl. batteries:** | 146g |

Subject to change without notice.



1) Measured outdoors with clear line of sight between transmitter and receiver. In buildings, the range is reduced.

## *Symbol explanation and approvals*

| | |
|---|---|
| CE | **This product complies with the following electrical safety and EMC directives:**<br>Directive 2017/745/EU MDR<br>Directive 1907/2006/EU REACH<br>Directive 2011/65/EU RoHS<br>Directive 2012/19/EU WEEE<br>Directive 2014/35/EU Low Voltage Directive<br>ISO 14971:2019 Risk Management for Medical Devices<br>EN 301 498-1 V2.2.3 Electromagnetic Compatibility<br>EN 301 489-3 V3.1.1 Electromagnetic Compatibility<br>EN 50130-4:2011 + 2014 Immunity alarm systems<br>EN 300 220-1 V3.1.1 Short Range Devices<br>EN 300 220-2 V3.1.1 Short Range Devices<br>EN 300 220-3 V2.1.1 Short Range Devices<br>EN 60601-1-2:2014 + 1-11:2015 Electromagnetic compatibility (Medical)<br>EN 62133-2:2017 + A1:2021 Battery safety requirements<br>EN 62368-1:2020 Electrical safety<br>EN 50581:2012 Hazardous substances |
| | Do not use the product if the packaging is damaged. |
| MD | **Medical product**<br>Class 1, rule 1 |
| | ***Manufacturer***<br>Knop Elektronik A/S, Fabriksvej 20, DK-7600 Struer |
| | Read the manual(s) before installation and use.<br>Find the manual here: https://www.knop.dk |
| | Interference may occur in the vicinity of equipment marked with this symbol. |
| | Protect against liquids before installation. |
| | 0 °C to +40 °C, temperature limit for transport/storage and use. |
| | The product must not be disposed of with normal household waste. |
| SRN | **Single Registration Number**<br>DK-MF-000025631 |
| UDI | **Unique Device Identifier**<br>(01)05744002850472<br>(01)05744002853473 |
| REF | **Product reference/item number/item description**<br>EPI901, Seizure alarm<br>EPI901S, External sensor |
| SN | **Serial**<br>The serial number is located on the product. |
| IP | **Ingress Protection code**<br>EPI901: IP20<br>EPI901S: IP67 |