



# User manual

# EPI901S





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## Warnings and safety instructions



- Read the operating instructions before use.
- Evaluate the EPI901S sensor each time it is used.
- The user/relatives must always be aware that situations may arise where no seizure can be detected and therefore no alarm is triggered, 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, meaning that the tremors are not detected by the sensor. Always ensure that the bed is set up correctly for the user – see page 7 for more information.
- The EPI901S **must not** be used for diagnosis!
- The EPI901S **must not** be used in cases where a seizure requires life-saving action or medical treatment.



## **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, ensure 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 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 a touch (e.g. a touch with a 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 EPI901S is intended solely as an external sensor for the EPI901 to detect 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 EPI901S detects a seizure, a signal is sent to the EPI901, which then sends an alarm to a receiver – operated and monitored by, for example, parents or care staff.

However, it is important to be aware that medical treatment may be required.

The EPI901S and/or EPI901 are **not** intended for the diagnosis or monitoring of individuals with serious medical conditions.

EPI901S is the same as EPI900S, but updated and improved.

The updated and new version of EPI900S has the following improvements:

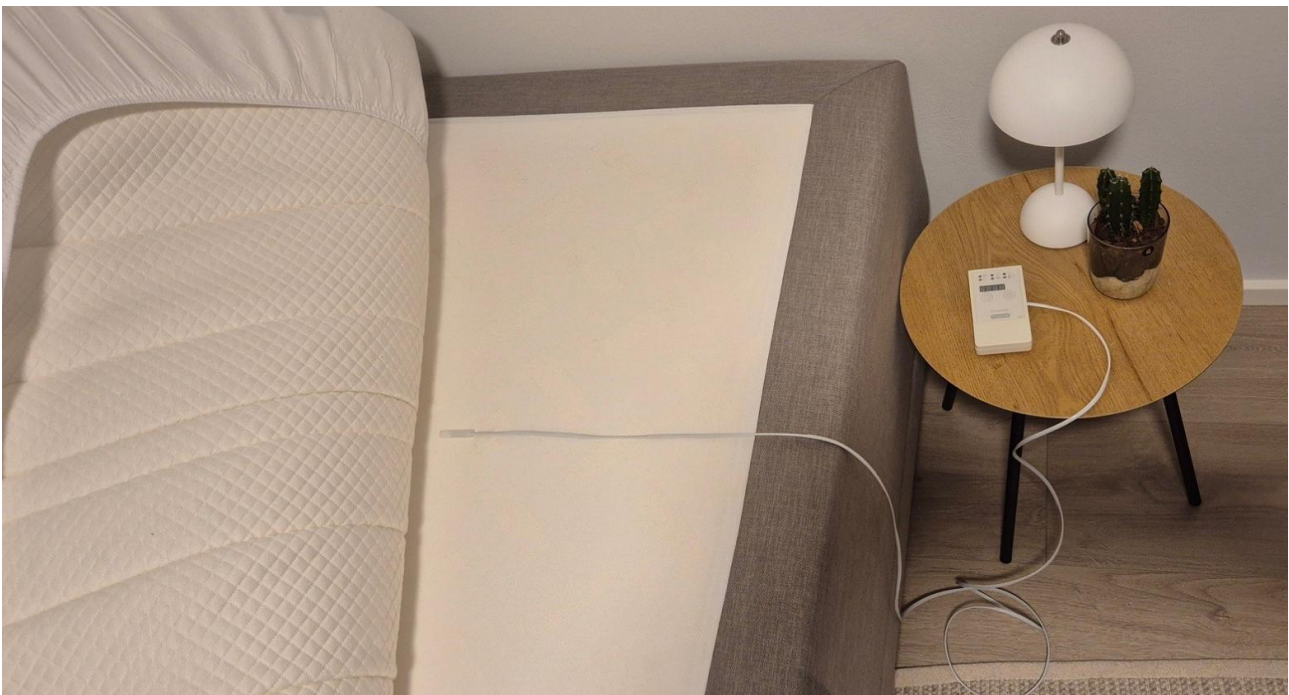
- Lower power consumption
- 3-way register

## Commissioning

When installing the EPI901S, there can be a big difference depending on whether the patient/client is using a hospital bed or a more standard bed.

The difference is simply that mounting under a regular bed can weaken the vibrations and thus make it more difficult to pick up signals. To solve this and optimise the signal, the external sensor EPI901S is placed on top of the mattress – but under the top mattress.

The sensor is held in place with a piece of tape or plaster. The EPI901S is connected to the EPI901, which is hung at the end of the bed or placed on a table or similar, next to the bed.



We recommend that the sensor is not placed under the bed, as experience shows that the best way to measure vibrations is as described in the instructions below:

Please note that if the patient changes position in bed, the position of the sensor must also be changed to ensure the best signal registration.

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.

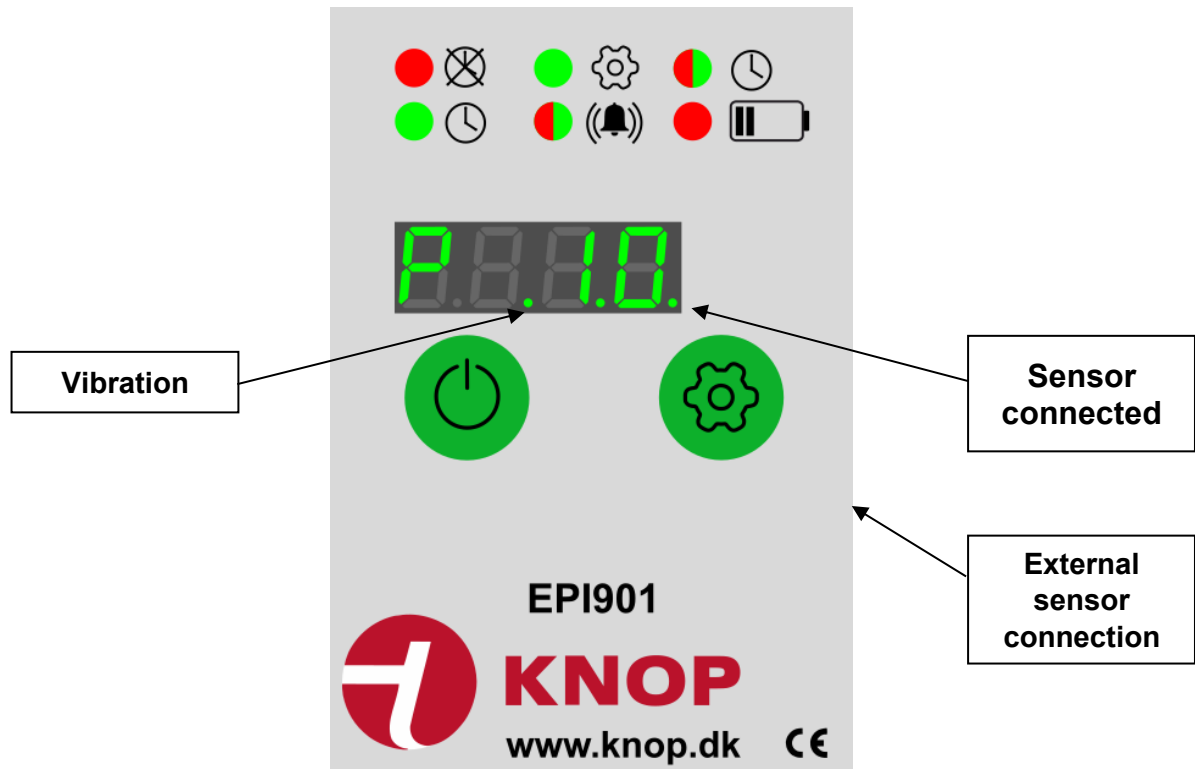
After installation, the system must therefore be evaluated by simulating a seizure with your hand on the mattress or by having a person lie down in the bed and simulate a seizure. Check that the signal is received correctly on the EPI901.

Remember to set the desired number of vibrations, see the section "**Setting the number of vibrations**" on the EPI901.



## Connecting the to the EPI901

Location of indicators and connections in the EPI901.





## Operation


The product does not include any direct operation. All settings are made on the EPI901 and must be connected to it. See the user manual for the EPI901.

**Info!** When a vibration is detected, this **dot** will be displayed on the EPI901 as illustrated in the image below. The dot will light up briefly.

**Remember** to check that the sensor is working by seeing if the LED is flashing.



### **How to check if the sensor is connected and detected.**

Press and hold the '  ' button for a few seconds – release the button when the display flashes.

If the dot appears on the right, the external sensor is active.



**Note** There is no external indicator if the product is switched off.



## Typical error possibilities

- The batteries have not been replaced after the battery alarm.
- Both devices have not been switched on. (EPI901 and the receiver, e.g. RX901B)
- The receiver may be outside the coverage area.
- The EPI901S is positioned incorrectly in the bed.
- The EPI901 is set to too high a number of pulses/convulsions.

To ensure optimal operation and signalling, the following checks should be performed:

| <b>Checklist:</b>  | <b>Every week</b> | <b>Every month</b> | <b>Not in use</b> |
|--|-------------------|--------------------|-------------------|
| 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***

No maintenance is expected to be required.

## ***Cleaning***

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

## ***Spare parts and accessories***

EPI901S    Replacement unit (new)



## Technical

|   |  |
|---|--|
| <b>Operating voltage:</b>               | 3V   |
| <b>Power consumption standby:</b>       | <5 $\mu$ A   |
| <b>Power consumption sensor active:</b> | ~50 $\mu$ A  |
| <b>Environment (surroundings):</b>      | Indoor use. $\leq$ 90% non-condensing.<br>Do <i>not</i> use in oxygen-enriched areas or in conjunction with flammable materials. |
| <b>Ambient temperature:</b>             | 0 °C to +40 °C   |
| <b>Cabinet type:</b>                    | POM  |
| <b>Enclosure dimensions:</b>            | $\varnothing$ : 8.5 mm, L: 39 mm   |
| <b>Enclosure colour:</b>                | White  |
| <b>Density EPI901S:</b>                 | IP67   |
| <b>Connections:</b>                     | 4-pin modular plug   |
| <b>Weight incl. batteries:</b>          | 42g with cable   |
| <b>Expected service life:</b>           | 5 years, depending on use and handling.  |















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## Symbol explanation and approvals

|   |   |                        |     |                         |       |                      |      |                      |      |                      |                       |                |                                     |                     |                               |                     |                               |                               |   |                 |                   |               |                      |
|---|---|------------------------|-----|-------------------------|-------|----------------------|------|----------------------|------|----------------------|-----------------------|----------------|-------------------------------------|---------------------|-------------------------------|---------------------|-------------------------------|-------------------------------|---|-----------------|-------------------|---------------|----------------------|
|    | <p><b>This product complies with the following electrical safety and EMC directives:</b></p> <table border="0"> <tr> <td>Regulation 2017/745/EU</td> <td>MDR</td> </tr> <tr> <td>Regulation 1907/2006/EU</td> <td>REACH</td> </tr> <tr> <td>Directive 2011/65/EU</td> <td>RoHS</td> </tr> <tr> <td>Directive 2012/19/EU</td> <td>WEEE</td> </tr> <tr> <td>Directive 2014/35/EU</td> <td>Low Voltage Directive</td> </tr> <tr> <td>ISO 14971:2019</td> <td>Risk Management for Medical Devices</td> </tr> <tr> <td>EN 301 498-1 V2.2.3</td> <td>Electromagnetic Compatibility</td> </tr> <tr> <td>EN 301 489-3 V3.1.1</td> <td>Electromagnetic Compatibility</td> </tr> <tr> <td>EN 60601-1-2:2014 + 1-11:2015</td> <td>Electromagnetic compatibility (Medical)</td> </tr> <tr> <td>EN 62368-1:2020</td> <td>Electrical safety</td> </tr> <tr> <td>EN 63000:2018</td> <td>Hazardous substances</td> </tr> </table> | Regulation 2017/745/EU | MDR | Regulation 1907/2006/EU | REACH | Directive 2011/65/EU | RoHS | Directive 2012/19/EU | WEEE | Directive 2014/35/EU | Low Voltage Directive | ISO 14971:2019 | Risk Management for Medical Devices | EN 301 498-1 V2.2.3 | Electromagnetic Compatibility | EN 301 489-3 V3.1.1 | Electromagnetic Compatibility | EN 60601-1-2:2014 + 1-11:2015 | Electromagnetic compatibility (Medical) | EN 62368-1:2020 | Electrical safety | EN 63000:2018 | Hazardous substances |
| Regulation 2017/745/EU  | MDR   |                        |     |                         |       |                      |      |                      |      |                      |                       |                |                                     |                     |                               |                     |                               |                               |   |                 |                   |               |                      |
| Regulation 1907/2006/EU   | REACH   |                        |     |                         |       |                      |      |                      |      |                      |                       |                |                                     |                     |                               |                     |                               |                               |   |                 |                   |               |                      |
| Directive 2011/65/EU  | RoHS  |                        |     |                         |       |                      |      |                      |      |                      |                       |                |                                     |                     |                               |                     |                               |                               |   |                 |                   |               |                      |
| Directive 2012/19/EU  | WEEE  |                        |     |                         |       |                      |      |                      |      |                      |                       |                |                                     |                     |                               |                     |                               |                               |   |                 |                   |               |                      |
| Directive 2014/35/EU  | Low Voltage Directive   |                        |     |                         |       |                      |      |                      |      |                      |                       |                |                                     |                     |                               |                     |                               |                               |   |                 |                   |               |                      |
| ISO 14971:2019  | Risk Management for Medical Devices   |                        |     |                         |       |                      |      |                      |      |                      |                       |                |                                     |                     |                               |                     |                               |                               |   |                 |                   |               |                      |
| EN 301 498-1 V2.2.3   | Electromagnetic Compatibility   |                        |     |                         |       |                      |      |                      |      |                      |                       |                |                                     |                     |                               |                     |                               |                               |   |                 |                   |               |                      |
| EN 301 489-3 V3.1.1   | Electromagnetic Compatibility   |                        |     |                         |       |                      |      |                      |      |                      |                       |                |                                     |                     |                               |                     |                               |                               |   |                 |                   |               |                      |
| EN 60601-1-2:2014 + 1-11:2015   | Electromagnetic compatibility (Medical)   |                        |     |                         |       |                      |      |                      |      |                      |                       |                |                                     |                     |                               |                     |                               |                               |   |                 |                   |               |                      |
| EN 62368-1:2020   | Electrical safety   |                        |     |                         |       |                      |      |                      |      |                      |                       |                |                                     |                     |                               |                     |                               |                               |   |                 |                   |               |                      |
| EN 63000:2018   | Hazardous substances  |                        |     |                         |       |                      |      |                      |      |                      |                       |                |                                     |                     |                               |                     |                               |                               |   |                 |                   |               |                      |
|    | Do not use the product if the packaging is damaged.   |                        |     |                         |       |                      |      |                      |      |                      |                       |                |                                     |                     |                               |                     |                               |                               |   |                 |                   |               |                      |
|    | <p><b>Medical product</b><br/>Class 1, rule 1</p>   |                        |     |                         |       |                      |      |                      |      |                      |                       |                |                                     |                     |                               |                     |                               |                               |   |                 |                   |               |                      |
|    | <p><b>Manufacturer</b><br/>Knop Elektronik A/S, Fabriksvej 20, DK-7600 Struer</p>   |                        |     |                         |       |                      |      |                      |      |                      |                       |                |                                     |                     |                               |                     |                               |                               |   |                 |                   |               |                      |
|   | <p>Read the manual(s) before installation and use.<br/>Find the manual here: <a href="https://www.knop.dk">https://www.knop.dk</a></p>  |                        |     |                         |       |                      |      |                      |      |                      |                       |                |                                     |                     |                               |                     |                               |                               |   |                 |                   |               |                      |
|  | 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.  |                        |     |                         |       |                      |      |                      |      |                      |                       |                |                                     |                     |                               |                     |                               |                               |   |                 |                   |               |                      |
|  | <p><b>Single Registration Number</b><br/>DK-MF-000025631</p>  |                        |     |                         |       |                      |      |                      |      |                      |                       |                |                                     |                     |                               |                     |                               |                               |   |                 |                   |               |                      |
|  | <p><b>Unique Device Identifier</b><br/>05744002853473</p>   |                        |     |                         |       |                      |      |                      |      |                      |                       |                |                                     |                     |                               |                     |                               |                               |   |                 |                   |               |                      |
|  | <p><b>Product reference/item number/item text</b><br/>EPI901S, External sensor</p>  |                        |     |                         |       |                      |      |                      |      |                      |                       |                |                                     |                     |                               |                     |                               |                               |   |                 |                   |               |                      |
|  | <p><b>Serial</b><br/>The serial number is located on the label.</p>   |                        |     |                         |       |                      |      |                      |      |                      |                       |                |                                     |                     |                               |                     |                               |                               |   |                 |                   |               |                      |
|  | <p><b>Ingress Protection code</b><br/>EPI901S: IP67</p>   |                        |     |                         |       |                      |      |                      |      |                      |                       |                |                                     |                     |                               |                     |                               |                               |   |                 |                   |               |                      |