

User manual

MI901





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Warning and safety instructions



- Read intended use before putting into service.
- The product is not water-resistant unless noted in product specification.

Contraindications

In general, the product cannot be used if:

- The disabled client/patient is mentally ill.
- The disabled client/patient is critically ill.
- The client/patient is unable to use the transmitters.

Lifetime after mounting of the device

The battery, if applies, must be replaced when the battery replacement information appears on the display and according to the user manual.

Lifetime is evaluated in relation to the pressure button. This is made according to the supplier's specification.

Lifetime battery (products using battery, only)

KNOP calculates the life of the batteries. See specification in the user manual.

Intended use

In general, the different variants of the medical device (transmitters/receiver system from KNOP Elektronik) are made as assistive aid for impaired/disabled patients to be able to call for assistance.

The various variants of the medical equipment consist of a combination of products (transmitter and receiver) designed to call for help to impaired/disabled patients; The transmitter-receiver system can be activated in different ways:

- For example, patients who actively do this and are aware that they are calling for help, such as e.g., people with walking difficulties who need help going to the toilet.
- Or disabled patients who are not aware that they are inadvertently putting pressure on the sendere.g. during a seizure.
- Or patients with intellectual and cognitive deficits who are not aware that a receiver is receiving a signal from their transmitter when they leave a house or room.

The system is not designed for critically or mentally ill persons.

General product description

The products manufactured by KNOP elektronik 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.

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These products are medical devices intended to call for assistance and are used for disabled/mobile people, such as those with walking difficulties who need help going to the toilet. The transmitters are activated, for example, by a sound or by pressure (e.g. by pressure with a finger or a breath through the mouth). The recipient is supervised by health care personnel or lay people in private homes.

The system is not designed for critically or mentally ill people.

| Part of product | Function in the product system |
|-----------------|--|
| Transmitter | The transmitter can send the signal obtained from the patient to the receiver monitored by the healthcare personnel or lay person. The transmitter products can be activated by button, sound, blow or movements. |
| Receiver | The transmitters can be coded into all the receivers and to several receivers at the same time. Some receivers also have a summon button for calling assistance from their coworkers. |
| Repeatersystem | If it is needed to cover a more comprehensive and larger area a repeater system is used. The repeater system also gives an increased functionality as e.g. that an alarm automatically is received at first at the healthcare person closest to the client. |
| Positionsystem | If a sender is equipped with a position receiver it can be used in connection with a Position system. Not all product variants include position receivers. Typically, it is seen in connection with nursing homes and security for patients with dementia. The receivers can be portable or stationary. |



Product description

MI901 is an external microphone for LAK901. MI901 can be placed near the client so that it is easier for LAK901 to hear any sound.

Commissioning

Simply plug in LAK901 and position the microphone optimally without disturbing the client.

Cleaning

The product can be cleaned with a fruity cloth or wet wipe.

Spare parts and accessories

Spare parts and accessories can be ordered from Knop Elektronik A/S at www.knop.dk.



Technical data

| | |
|---------------------------------|----------------------------------|
| Cable length: | 4m |
| Power supply: | 2V |
| Power consumption, max: | 1mA |
| Surrounding environment: | Indoor use. ≤ 90% non-condensing |
| Ambient temperature: | 0°C to +40°C |
| Cable/Microphone colour: | Black |
| Density: | IP20 |















The right to make changes is reserved

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Symbol explanation and approvals

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|---|---|-----------------------|-----|------------------------|-------|----------------------|------|----------------------|------|----------------|-------------------------------------|---------------------|--------------------------------|---------------------|--------------------------------|------------------------|------------------------|---------------------|---------------------|---------------------|---------------------|---------------------|---------------------|--------------------------|---|-----------------|-------------------|---------------|----------------------|
|  | <p>This product complies with:</p> <table border="0"> <tr> <td>Directive 2017/745/EU</td> <td>MDR</td> </tr> <tr> <td>Directive 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>ISO 14971:2019</td> <td>Risk Management for Medical devices</td> </tr> <tr> <td>EN 301 498-1 V2.2.3</td> <td>Electro Magnetic Compatibility</td> </tr> <tr> <td>EN 301 489-3 V3.1.1</td> <td>Electro Magnetic Compatibility</td> </tr> <tr> <td>EN 50130-4:2011 + 2014</td> <td>Immunity alarm systems</td> </tr> <tr> <td>EN 300 220-1 V3.1.1</td> <td>Short Range Devices</td> </tr> <tr> <td>EN 300 220-2 V3.1.1</td> <td>Short Range Devices</td> </tr> <tr> <td>EN 300 220-3 V2.1.1</td> <td>Short Range Devices</td> </tr> <tr> <td>EN 60601-1-2:2014 + 2015</td> <td>Electromagnetic compatibility (Medical)</td> </tr> <tr> <td>EN 62368-1:2020</td> <td>Electrical safety</td> </tr> <tr> <td>EN 50581:2012</td> <td>Hazardous substances</td> </tr> </table> | Directive 2017/745/EU | MDR | Directive 1907/2006/EU | REACH | Directive 2011/65/EU | RoHS | Directive 2012/19/EU | WEEE | ISO 14971:2019 | Risk Management for Medical devices | EN 301 498-1 V2.2.3 | Electro Magnetic Compatibility | EN 301 489-3 V3.1.1 | Electro Magnetic Compatibility | EN 50130-4:2011 + 2014 | Immunity alarm systems | EN 300 220-1 V3.1.1 | Short Range Devices | EN 300 220-2 V3.1.1 | Short Range Devices | EN 300 220-3 V2.1.1 | Short Range Devices | EN 60601-1-2:2014 + 2015 | Electromagnetic compatibility (Medical) | EN 62368-1:2020 | Electrical safety | EN 50581:2012 | Hazardous substances |
| Directive 2017/745/EU | MDR | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| EN 50581:2012 | Hazardous substances | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | <p>The product must not be used if the packaging is damaged.</p> | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | <p>Medical Device Class 1, rule 1</p> | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | <p>Manufacturer KNOP Elektronik A/S, Fabriksvej 20, DK-7600 Struer, Denmark</p> | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | <p>Read the manual(s) before installation and commissioning at www.knop.dk.</p> | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | <p>Interference may occur in the environment of equipment marked with this symbol.</p> | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | <p>Must be protected against liquids.</p> | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | <p>0°C to +40°C, temperature limit for transport/storage and use.</p> | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | <p>The product must not be disposed of with normal household waste.</p> | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | <p>Single Registration Number DK-MF-000025631</p> | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | <p>Unique Device Identifier 05744002853466</p> | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | <p>Product reference/product number/warning text. External microphone for LAK901</p> | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | <p>Serienummer Placed on the product</p> | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | <p>Ingress Protection code IP20</p> | | | | | | | | | | | | | | | | | | | | | | | | | | | | |