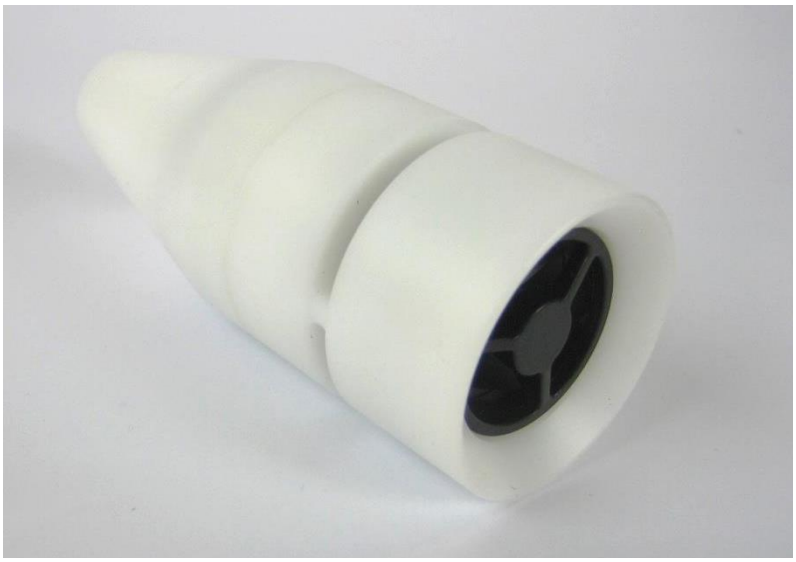
User manual

PU101



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

Table of contents

Warnings and safety instructions

- The battery in this product must compile with the relevant IEC safety standards for batteries.
- Do not consume or eat the battery as there is a risk of chemical burns.
- Keep new and used batteries away from children.
- If the battery compartment cannot be closed properly, discard the product, and keep it away from children.
- Read the intended use before using.
- 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.

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

The product is designed to send codes to KNOP wireless receivers when the user blows on it.

PU101 can be used where the user is unable to activate an alarm with a pull cord or push button.

PU101 must be used in conjunction with a KNOP Elektronik transmitter or existing call systems.

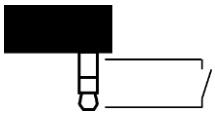
Testing and commissioning

After installation, it is important that the user tests the product by blowing against the propeller.

Staff shall receive an alarm on their alarm system/receiver. Please refer to the user manual of the transmitter or paging system used.

Connection

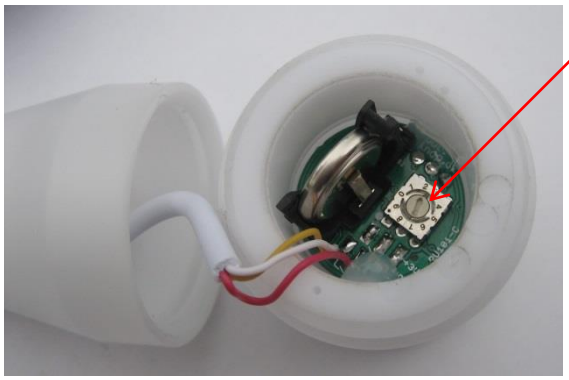
PU101 has a 3m cord with 3.5mm jack plug.
Potential-free contact between frame and tip.
Max. 36V/100mA.



Adjustment

PU101 has the possibility to set multiple sensitivities on the switch inside the product - see photo below.

PU101 can be disassembled without the use of tools. Use a small screwdriver to adjust the switch.



1 = High sensitivity:
Short weak puff.
2 = Medium sensitivity
Slightly longer and stronger puff.
3 = Low sensitivity.
Long strong puff.

0, 4-9: Reserved for other functions.

Location

PU101 should be positioned so that the user can easily blow straight into the propeller.

The push contact can be mounted on e.g. a gooseneck, contact your retailer for more information.

Service

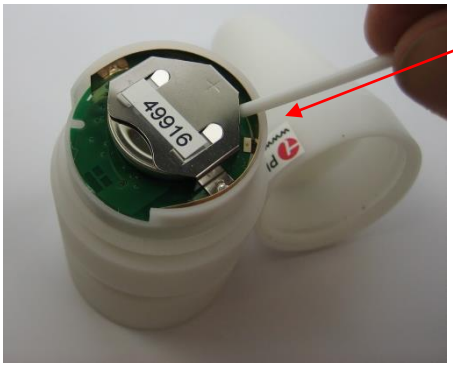
When the user blows against the propeller, strongly enough (depending on the sensitivity described earlier) to activate PU101, it will flash green.

Battery alarm

In case of low battery, a battery alarm with a red light appears through the propeller and on the sides when PU101 is activated with a puff.

Changing the battery

The top and bottom of PU101 can be unscrewed without tools.



The battery is gently pressed out of the holder, for example with a cotton swab or a match.
Never use a metal object.

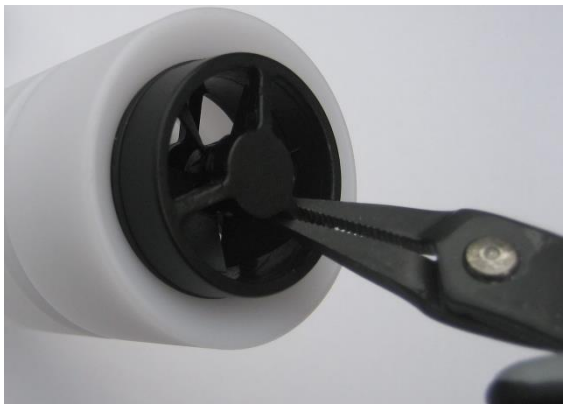
Carefully insert the new battery into the holder WITHOUT
using tools, as this may short-circuit the battery.

Use a CR1632 battery.
IMPORTANT + must be facing up.

After changing the battery, check PU901 as described under "Testing and commissioning". It takes about 1 minute after battery change before it can be activated.

Cleaning

The product can be cleaned with a moist cloth or disinfected wet wipe.
The propeller can be gently pulled out with pliers or other tools and cleaned.
The product is then thoroughly tested.
If necessary, the propeller can be replaced with a new one. See section "Spare parts and accessories".



Spare parts and accessories

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

Technical data

Battery type:	1 x CR1632, Lithium 3V 140mAh.
Battery life (expected):	Up to 1 year at 10 activations per day [(1)]
Low battery alarm:	At approx. 1/3 remaining capacity
Power consumption (inactive):	<1µA.
Power consumption (active):	<7mA for 3 seconds per activation.
Ambient environment:	Indoor use ≤ 90**% non-condensing**
Ambient temperature:	0°C to +40°C
Enclosure type:	White polyoxymethylene
Enclosure dimensions:	Ø: 43mm L: 106mm
Density:	IP40
Weight:	115g

The right to make changes is reserved.

[(1)] *Expected battery life depends on usage and battery quality.*

Explanation of symbols and approvals

CE	**This product complies with:** 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
	The product must not be used if the packaging is damaged.
MD	**Medical Device** Class 1, rule 1
	Manufacturer KNOP Elektronik A/S, Fabriksvej 20, DK-7600 Struer, Denmark
	Read the manual(s) before installation and commissioning at www.knop.dk.
	Interference may occur in an environment with equipment marked with this symbol.
	Must be protected against liquids.
	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** DK-MF-000025631
UDI	**Unique Device Identifier** PU101: 05744002852032
REF	**Product reference** PU101: Blow switch
SN	**Serial number** Placed on the product
IP	**Ingress Protection code** IP40