Grasp

(EN) OPERATING MANUAL

Manufacturer – Contact details
Grasp AS
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www.grasp.global

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1. Introduction

Thank you for purchasing the GRASP device. The product purchased by you is a high class medical device meeting relevant European standards, which is confirmed by the relevant certificates and the "CE" mark. To fully use the possibilities offered by this device, and to minimise the possibility of its failure, please read this Operating Manual carefully.
By adhering to warnings included in the Operating Manual, you can prevent possible risks to patients' health and life.

Before you start to operate the device, read this Operating Manual carefully. The Operating Manual should be kept for possible consultation in the future.

1.1. Symbols

A tip facilitating operation of the device and enabling the full use of its possibilities.

Note prevents damage to the device or incorrect performance of the procedure.

Warnings against hazards of a serious damage to the equipment or to health and life of people.

Name and address of the manufacturer.

Name and address of the authorised representative in the EU.

Marking and type of the application part - appropriate for the BF part.

CE mark.

Follow the Operating Manual.

Label "DO NOT DISPOSE WITH UNSORTED WASTE".

Serial number with the production date encoded.

Operating Manual.

IP protection rating ensured by the casing of the electrical device, as per EN 60529:2003.

1.2. Protective equipment and warning

- Do not squeeze the device with any tools. The device is intended to be squeezed solely by hand.
- Do not use the device in a hands with skin abrasions, injuries or during treatment.
- Do not use the device together with any other medical equipment.
- Do not modify the device in any way.
- Do not open the silicone case of the device or modify its design. It is a battery-powered electrical device, therefore, any interference with its design poses a risk to the patient and the personnel operating the device.
- The device contains a lithium-ion rechargeable battery. Do not unseal the device casing or unseal and puncture the battery. Do not charge the battery that is removed from the device.
- Do not use the device in water or expose it to any contact with moisture and water.
- Do not use extension cords, adapters, USB adapters for connection with the battery.
- Do not leave the device unattended. The small size of the device and the power supply cable pose a risk of suffocation to newborns and infants.
- The operating manual should be kept near the device.
- Pay attention to the technical condition of the device silicone casing. If the casing is damaged or deformed, the device cannot be used.
- The production date is a part of the serial number provided on the nominal plate: the first 4 digits represent the year of manufacture, and the successive 2 digits mean the month of manufacture.

1.3. Electromagnetic Compatibility (EMC) Performance Statement

The presence of other electronic devices such as PCs and mobile telephones in the vicinity of an operating medical device may result in electromagnetic interference. This interference may result in an incorrect operation of the medical equipment and lead to a potentially hazardous situation. Medical devices also should not interfere with the operation of other devices.

To prevent a possibly hazardous situation resulting from electromagnetic interference, technical solutions meeting requirements of EN 60601-1-2:2014 have been used in the GRASP device.

WARNING: Any use of accessories, transducers and cables other than those specified or supplied by the manufacturer of this device may result in an increase of electromagnetic emissions or in the reduction of electromagnetic resistance of this device and its incorrect operation.

Do not use any devices generating strong electrical or electromagnetic field (e.g., diathermy machines during operation, HF surgical equipment during operation, a screened room with a system for magnetic resonance imaging) near this medical device. They may cause an incorrect operation of the device.

WARNING: Concerning interference of WiFi communication. The product operates in an unlicensed ISM band of 2.4 GHz. When the product is used near other wireless devices, including microwave ovens and wireless LAN networks which operate in the same frequency band that the device, it is possible that interference might occur in the operation of the product and those devices. If any such interference should occur, the operation of other devices must be stopped or the device must be moved to another location before it is used or it should not be used in vicinity of wireless devices.

The device meets the requirements of EN 60601-1-2:2014 concerning resistance and emissions of electromagnetic radiation.
EMISSIONS characteristics of this device enable it to be used in industrial areas and professional health care facilities (CISPR 11 class A) and in the environment of medical care provided at home (CISPR 11 class B).

2. Description of the device

2.1. Intended use

GRASP is a manual electrical device intended to be used by a patient squeezing it to register the duration and/or intensity of subjective symptoms, feelings, moods and/or behaviours. The device is equipped with an in-built memory to record events which can then be sent via a wireless connection to a smartphone application, to be saved. GRASP is a device that can help to identify stress, pain, and other subjective symptoms. It can be used in mental health therapies and in palliative care. GRASP is based on the therapeutic principle called the “transitional object”.

2.2. Indications

- Support in treatment of pain during dental procedures, with or without local anaes-thetic, to signal pain.
- Support in treatment of mental disorders, e.g., depression or anxiety, by recording intensity of subjective symptoms, feelings, moods and behaviours.
- Support in communication between the patient and the physician when the patient suffers from various neurological conditions.

Scenarios for possible use of GRASP are provided in advertising materials attached to the manual.

2.3. Contraindications

The device should not be used in the direct vicinity of exposed blood vessels, anastomoses, organs and nerves, or any breaks in skin continuity. In the event of any skin reactions at the place of contact with the device, the use of GRASP should be discontinued.
GRASP must not be used by children or people who cannot read and understand the operating manual, unless they are under supervision of a responsible person to ensure it is used safely.

3. Downloading and installing the apps

The GRASP device can be used with web and mobile applications available for Android and iOS operating system.

Visit the official website grasp.global where you can get the app and a setup guide.

4. Packaging contents

The packaging contains:
- Operating Manual.
- USB cable with A and C plugs.
- A box to be used for storage of the device and the USB cable.

5. Charging the GRASP device

The device should be charged with the USB-A charger conforming to IEC 60601-1, of the following parameters: DC 5V 1A with a USB port. For safety reasons, during charging place the device in a position in which the USB cable can be easily

disconnected from it. During charging, the device does not work as a recorder. To charge batteries in the device, locate the USB port on the side of the device. Connect one end of the USB cable to the GRASP device, and the other to the charger or to a computer that is switched on. The level of the device charging is signalled in the Grasp Connect application. The time needed to fully charge the battery is ca. 6 hours. When the charging is completed, disconnect the de-vice from the power source, disconnecting the USB cable from the socket in a secure way.

6. Disinfection

After each use the GRASP device should be disinfected, using the GRASP formula-tion recommended by the manufacturer of the device or any other formulation of the same composition (e.g., MEDISEPT MEDI Spray for cleaning and disinfection of surfaces of non-invasive medical devices). Spray the entire surface of the device from a distance of ca. 30 cm, making sure it is completely covered, and leave for the re-quired time - at least 60 s. The surface dries without any smudges.

7. Technical service and support

To receive technical support or flag up an incorrect operation of the device and other unforeseen circumstances, contact the local distributor or manufacturer of the GRASP device. Relevant contact details are available at: www.grasp.global.

USER RESPONSIBILITY
The GRASP device should be used in accordance with guidelines provided in this op-erating manual and in the labels. Do not use the device that is damaged. Missing, incomplete, damaged or worn parts should be immediately replaced in the authorised guarantee service (the details are available at grasp.global website). When necessary, any repairs or replacement can only be performed by qualified personnel at the au-thorised service. The manufacturer shall not be held responsible for any damages caused by a failure to observe the operating manual.

GUARANTEE
The GRASP device is covered by 24-month manufacturer’s guarantee. The guarantee is valid only when accessories and spare parts used are approved by company Grasp AS, and the device is operated in accordance with the operating manual. All repairs of the GRASP device must be conducted by the personnel of an authorised service. All repairs conducted by unauthorised persons may result in a loss of the guarantee. The guarantee does not cover:

- Costs of transports and transport-related hazards.
- Costs of repairs and/or defects resulting from repairs performed by unauthorised persons.

- Periodic inspections and maintenance.
- A failure or wear of optional parts other than the main device.
- Costs resulting from non-acceptance of the guarantee claim (a fee shall be charged in such case).
- Damages of any other kind, including personal injuries caused by an accident or incorrect operation

In the event of any guarantee claims, contact the seller from whom the device was pur-chased or an authorised distributor of Grasp AS. Contact details can be found on the device/documentation packaging or received from the seller.
Any repair or replacement during the guarantee period does not grant the right to an extended or renewed guarantee period. The guarantee will only be granted when a complete product with an original copy of an invoice/receipt issued by a seller to a customer is returned.

8. Technical and operating specification of the GRASP

Colour	The GRASP device is available in three colours: light blue, dark blue, orange and green 
Dimensions	65 mm × 45 mm × 35 mm
Storage conditions	Temperature between -20°C and +45°C, Air humidity: from 10% to 90% (with no condensation)
Transport conditions	Temperature between -20°C and +45°C, Air humidity: from 10% to 90% (with no condensation)
Operating conditions	Temperature between +5°C and +45°C, Air humidity: from 15% to 90% (with no condensation)
Mechanical durability	> 100 000 squeezes
Power supply	In-built rechargeable battery 3.7 V 120 mAh
Charging	Voltage of 5 V DC 1A (USB plug)
Battery charging time	6 hours

Battery operating time	90 days (standby mode) 30 days (regular use) 14 days (continuous use)
IP rating of the casing	IP22
Applied part type	BF
Weight	65 g

This device meets conditions specified in the European Commission Directive 93/42/EEC on medical devices.

This device meets conditions specified in the European Commission Directive 2014/53/EU (the radio equipment directive – RED).

9. Side effects and medical incidents

All undesirable effects or medical incidents which occurred while using the GRASP device should be notified to the manufacturer at the address provided in section **“Manufacturer – Contact details”**, and to a relevant body in the country of residence of the user.

10. Disposal

(Used electrical and electronic equipment)

This symbol indicates that at the end of its lifecycle the device should not be disposed of together with other household waste. To prevent possible environmental contamination or injuries to human health caused by an un-controlled disposal of waste, this type of waste should be separated from other waste and processed in a responsible waywith the aim of recycling. Private persons using the device at home should contact the seller from whom they purchased the product or a local government agency to receive detailed information where and how the product can be disposed of in a way that is safe for the environment.
Professional users should contact their supplier and check the terms and conditions of the purchase agreement. This product cannot be combined with any other product for disposal.