User Manual Dispenser SMILA

Model: SMILA-MD1

JDM Innovation GmbH

Carl-Benz-Strasse 16

DE - 71711 Murr, Germany

+49 - 7144 – 81 21 0

www.jdm.de

info@jdm.de

Contents

Document status

Rev.	Description	Date
1	Document approval	18.03.2019
15	New declaration of conformity	05.12.2022

0. Introduction

0.1. Compliance

This medical device is in compliance with the Medical Device Regulation MDR 2017/745 and its revised versions. The medical device, hereafter called device, has been classified in class I according to rule I and 13, annex VIII, (EU) 2017/745 of the regulation mentioned above. It is also necessary to seek a written permission of the manufacturer before making changes for the use of the equipment for purposes other than those established.

0.2. Manufacturer

The manufacturer according to (Council Regulation MDR 2017/745 and its revised versions) of the equipment is:

JDM Innovation GmbH
Carl-Benz-Straße 16
71711 Murr, Germany
Tel.: +49 (0)7144 8121 0
Web: http://www.jdm.de
e-mail: info@jdm.de

Information about the compliance can be required from the manufacturer.

0.3. Distributor

The distributer of the equipment is:

JDM Innovation GmbH
Carl-Benz-Straße 16
71711 Murr, Germany
Tel.: +49 (0)7144 8121 0
Web: http://www.jdm.de
e-mail: info@jdm.de

0.4. Publishing details

Published by the manufacturer.
The manufacturer reserves the right to modify this User's Manual and the device here described. The device specifications are subject to variations without notice. Nothing written in this User's Manual can be considered as an offer, warranty, promise or contractual condition, nor should it be so.

0.5. Copyright

The software included in the device belongs to the manufacturer. Upon receipt of the device, the user acquires only the right to use the software.
This right is neither exclusive nor transferrable.
It is also necessary to seek a written permission of the manufacturer before making changes for the use of the equipment for purposes other than those established.

0.6. Information about User's Manual

The purpose of this User's Manual is to provide a valid help in order to ensure a safe an efficient use of the described device to the user.
Before starting up the device, it is necessary to read the User's Manual and strictly respect all notices indicating warning and precaution messages.
Pay particular attention to information and procedures in paragraph "Safety".
User's Manual is an integral part of the device. **It must be kept near the device**, so that it is possible to consult it at any time.

0.7. Compatibility

The device described in this User's Manual must not be used in combination with any other products or components, except in case they are explicitly indicated as compatible by the manufacturer.
A list of these products and components can be obtained from the manufacturer.
Device changes and/or additions must be performed by the manufacturer or by any third party explicitly authorized by the manufacturer.
These changes and/or additions must be in compliance with all effective laws and local rules and must be performed with the highest technical capability.

Changes and/or additions on the device performed by not properly skilled people and/or by people who use not approved spare parts, can nullify the equipment warranty.
As for all complicated technical products, maintenance performed by not qualified people and/or by people who use not approved spare parts can cause serious damages to the device and risk personal injuries.

0.8. Training

Users of the device must be properly trained for a safe and effective use before trying to start up the equipment described in this User's Manual.
It is up to the user to assure to be to have received the proper training in compliance with effective laws and local norms.

0.9. Intended Use

The SMILA device is intended to support and improve the medication adherence of individual or several homecare clients.
The SMILA device is meant for homecare clients who have to take several medications over an extended period of time, and for whom homecare clients individual blisters are made. The blisters are produced based on a medication plan.
The SMILA device is designed for home-use as well as for the use in nursing homes or hospitals. The device is intended to be operated by the homecare client himself or a caregiver (nursing staff, hospital staff or caring relative).
However, the device is not intended to be used for life sustaining activities. Blisters that content medications with the purpose of life sustaining measures must not be used with the SMILA device.
The homecare client needs to be able to recognize either optical or acoustical signals, needs to be sufficiently mobile to get to the SMILA device, which is placed in his apartment independently and needs to be able to grip well enough in order to remove the pouches from the SMILA device.
The SMILA device can hold one or multiple homecare client individual medication blisters. A medication blister consists of a sequence of single pouches. Each homecare client individual pouch contains the medication for one specific taking time.

Based on the medication plan the SMILA device cuts off one pouch and delivers it to the homecare client. Blister pouches that are not taken at the predetermined taking time can be discarded into a storage container and stored safely.
The SMILA device is connected to a cloud-platform. That way the SMILA device can exchange data with the cloud. Caregivers can configure settings for their homecare clients through a Web-Frontend of the Cloud-Platform.
The medication plan is generated independently by a doctor or a pharmacist. The manufacturing of the homecare client individual blisters is carried out by pharmacies or blistercenter. The SMILA device uses the data from the medication plan and the data printed on the pouches to deliver the right pouch to the right homecare client at the right predetermined time. Any error notification indicating a non-dispensed taking time must be sent within 12 hours after the planned taking time.
The SMILA device itself does not make any decisions concerning diagnostic or therapeutic purposes nor provides information based on which the medication plan might be changed.
Caregivers and service employees can monitor the technical functionality of the devices through the cloud-platform and perform service and maintenance work on the SMILA device. Administration employees can handle administrative processes like billing through the cloud.

1. Safety

1.1. Warnings and precautions

	**Maintenance and defects** Do not use the device for any application before the user correctly performs all regular checks and updates the periodical equipment maintenance. If it is sure (or probable) that any part of the equipment is defective or wrong adjusted, don't use it before performing all reparations.
	**Importance of safety** Do not use the device for any application before reading, understanding and assimilating all information about safety, safety and emergency procedures specified in the current chapter about Safety.
	**Proper training** Do not use the device for any application unless you have a proper and adequate training to a safe and efficient use. If you aren't confident to be able to use this device in a safe and efficient way, don't use it.
	**Safety systems** Never try to remove, modify, exclude or obstruct any safety element on the device.
	**Expected use and compatibility** Do not use the device for purposes other than those for which it is intended. Do not use the device with other products than the ones whose compatibility has been recognized by the manufacturer. The use of the device for purposes other than the ones expected or with an incompatible product, can cause damages to the device or non-serious injuries to the homecare client. This equipment must be used only in compliance with the safety instructions specified in this User Manual and exclusively for intended purposes.

The manufacturer is responsible for safety features of its own products, only provided that maintenance, repairs and modifications are performed exclusively by the manufacturer's personnel or by personnel expressly authorized by the manufacturer.
As for all technical equipment, this medical device must be used properly and subject to regular maintenance and care, as described in "Maintenance, cleaning and disposal" paragraph.
The manufacturer can't be considered responsible for any error, damage or injury caused by improper use or lack of maintenance of the equipment.
It is necessary to contact the assistance service authorized by the manufacturer even in the case no error messages are displayed, but the device doesn't work as usual (first symptoms of a fault).
Do not modify or remove in any way the safety elements or other components.

1.2. Residual risks

Even if all safety regulations are fulfilled, a residual risk described below remains when operating the SMILA blister dispenser. All people working on and with SMILA must be aware of these residual risks and follow the instructions that prevent these residual risks from causing accidents or damage. Even if the product is used according to the instructions, it is not possible to eliminate all risks associated with its operation.

- The blister dispenser does not control the content of the medication pouch. If the content of the medication pouch is incorrect, the medication pouch may still be dispensed to the patient.

- Operating errors, e.g. incorrect insertion of the roll, may lead to an error that prevents the pouch from being dispensed to the patient within the taking time window.

- Due to technical or electronic errors, the medication pouch may not be dispensed to the patient within the taking time window.

- Problems with pouch dispensing may result in a medication pouch being cut open.

1.3. Electrical safety

This equipment is in compliance with safety class II in accordance with IEC 60601-1 standard.

Do not use the device near or leaned against other devices.
Do not remove protections or cables from this equipment, unless it is expressly required in this User's Manual. The removal of protections or cables can cause damage to the device or injuries to the homecare client or user.
Protections or cables must be removed only by qualified and authorized technical personnel.
Always unplug the device from the power supply before proceeding with cleaning or disinfection operations in order to avoid electric shocks.

Caution while handling fluids around the device!

1.4. Mechanical safety

Be sure that parts of the body or clothes aren't stuck among moving components of the device.
It is not possible to transport this device while it is working. For a safe transport, switch off the device before transporting it and ensure that all system peripherals (cables) are disconnected.
Do not remove protections or cables from this equipment, unless this operation is expressly requested in this User's Manual.

1.5. Fire safety

Do not use this device in areas where there is a risk of fire.
Do not cover the ventilation openings while the device is turned on.

1.6. Electromagnetic compatibility (EMC)

This device complies with international and national laws and regulations relating to electromagnetic compatibility (EMC) in force for this type of product, if it is used for the intended purposes. Such laws and regulations define the electromagnetic emissions level coming from the product and the requested immunity against electromagnetic interferences from external sources. Other electronic products that exceed the limits defined by EMC standards can, in unusual situations, affect the device working.

All other electrical devices placed in the immediate surrounding must comply with the EMC Directive 2014/30/EU and the Low Voltage Directive 2014/35/EU. This device must not be stacked on any other devices or vice versa.
The use of accessories and cables other than those specified can cause a higher emission or a lower immunity level.

1.6.1. Warning and safety precautions for electromagnetic compatibility

Increased emission or reduced interference immunity.
Exclusive use of the listed accessory or line with the exception of internal original spare part components**.**

Electric medical units are subject to special precautionary measures with regard to EMC and may only be installed and put into operation in compliance with the EMC information contained in the Operating Manual.
Portable and mobile radiofrequency communication devices can influence electric medical devices.

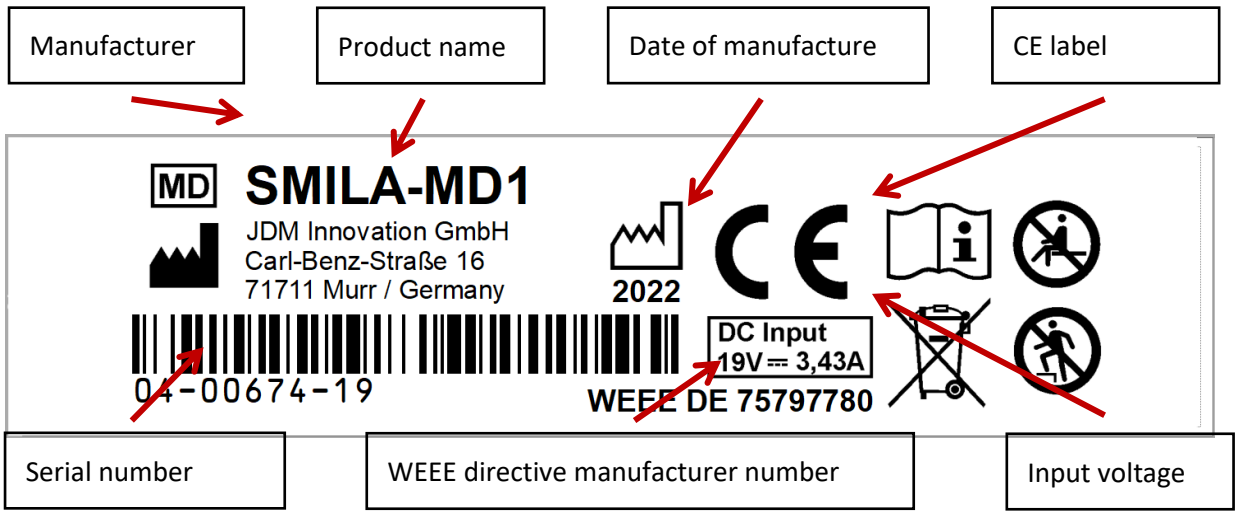
1.7. Laser light source

Radiation is potentially dangerous for eyes and skin.
Do not stare directly or through optical instruments at the laser beam.

1.8. Labeling

1.8.1. Product label

The product label is located on the back of the device.



Consider the user manual before use of the SMILA device	
Device is a Medical Device	
Waste of electrical and electronical equipment must not be disposed in domestic waste	
Do not sit on the device	
Do not step on the device	

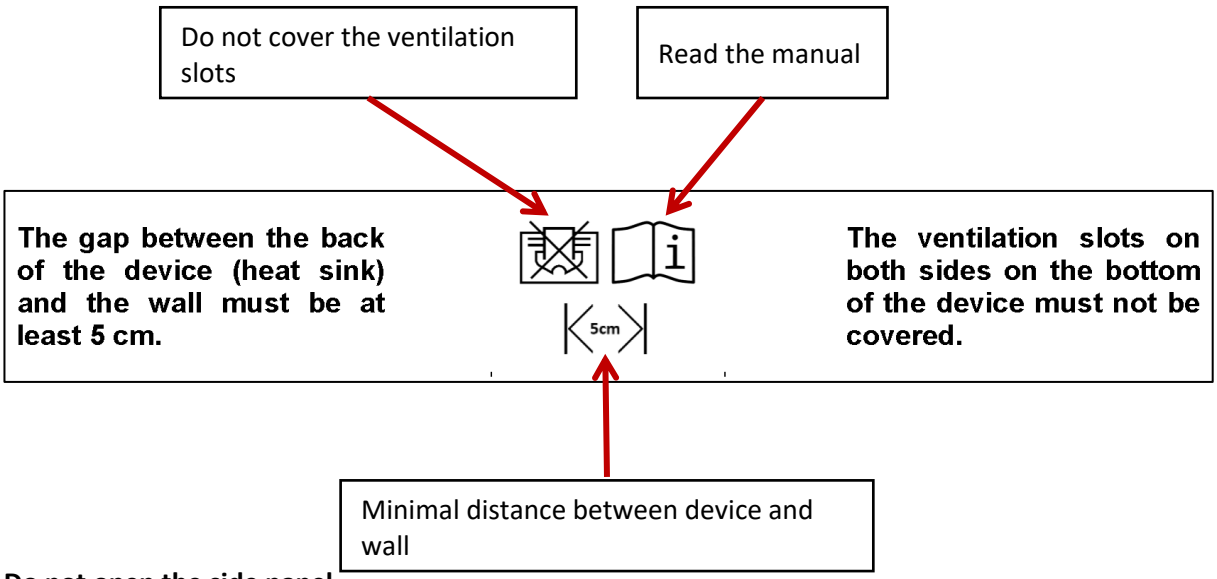
1.8.2. Further labeling

Label on battery

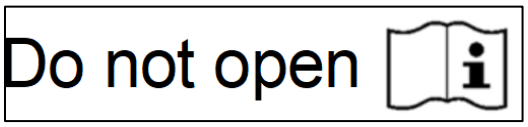
Do not remove the battery during operation!

Read **manual** first before replacing the battery.
Improper change or removal of the battery may be dangerous.

Cooling conditions



Do not open the side panel



Do not open the side panel. Only trained technical service personnel is authorized to open the side panels.

Labeling of smoker devices

If the device was placed with an in-house smoker and has a smoking odor the device must be marked as a “smokers device” The label is placed on the inside of the lid on the upper left side. The label is in the accessory bag.

2. Start up, Maintenance, cleaning and disposal

2.1. Start up

Plug in and switch on the device. The Installation Control Document is automatically shown in the AUM when first assigning a patient to a device. After filling it out, it is stored in the cloud. The user is guided step-by-step through the protocol. When reaching the last side, sending the report is only possible when all boxes are checked or filled out.

2.2. Scheduled maintenance

It is essential for this device to work safely, efficiently and reliable that the user regularly performs scheduled maintenances and checks.

Scheduled maintenance plan

The scheduled maintenance can be performed only by trained and authorized personnel and it is widely described in the service documentation.

2.3. Regular checks performed by the user (caregiver)

2.3.1. Obligations of the user

The user of the equipment must perform the program of regular checks. Such checks are described in the table below.

The user of the equipment must ensure that all checks and their actions are performed satisfactorily before using the equipment for its intended purpose.

Interval	**Object**
Monthly	Damp wipe the outside of the device
Inserting a new blister roll	Visual check if there are any objects in the blister storage or the transportation lane

2.3.2. Approved cleaning supplies

See chapter 2.4 Cleaning and disinfecting

2.3.3. Battery

The device is provided with a battery to ensure the functionality of the device in case of a power loss.

In case a battery is defective, it must be replaced by an original spare part.

2.3.4. Repairs

The device includes mechanical parts subjected to wear due to mechanical movement. All mechanical parts are designed to last throughout the entire lifetime of the device. Nevertheless in case any repairs are required, the manufacturer recommends that all repairs must be performed by trained and authorized service personnel. Defective components must be replaced with original spare parts.

2.4. Cleaning and disinfecting

The device can be cleaned with any common household cleaning agents.

Do not use any aggressive chemicals or abrasive products to clean the device.
Do not use scouring powders or the like.
Do not use any sharp cleaning materials or implements.

Only personnel trained in the management of cleaning and disinfection of medical devices is authorized to conduct such activities. Perform cleaning and disinfection operations of the equipment when preparing the device for a new homecare client.

Clean and disinfect the following party by using disinfecting tissues:

- Housing
- Screen
- Drawer
- Blister roll compartment

Always disconnect the equipment from the power supply before proceeding with cleaning and disinfection operations in order to avoid electrical shocks.
Avoid the seepage of water and liquids because it can cause short-circuits or corrosion of metallic parts.

All cleaning and disinfection operations must be in compliance with all laws and standards in force in the county where the device is installed.

2.5. Removing homecare client data

In between homecare clients the solid disc will be erased and a new image will be installed.

2.6. Transport and storage

Keep away from heat	
Keep dry	
Temperature limitations during transportation **-20°C to 60°C max.**	
Marking for transportation of batteries	
CE marking	

2.7. Disposal

The manufacturer wants to make a contribution to the environmental defense and wants to guarantee a constant safe and efficient use of this device by using a proper support, maintenance and training program.

If the device is used correctly and always subjected to proper maintenance, it doesn't represent an environmental risk. However, it can include materials that can be potentially harmful for the environment if they are not properly disposed. The use of such materials is essential for carrying out the device functions in compliance with legal requirements and so on.

Final disposal of the device
The final disposal is effected when the equipment has been used so that it is no longer usable for the intended purposes.
The return, proper disposal or recovery of this medical device must be done in compliance with the European WEEE (Waste Electrical and Electronic Equipment) and / or national requirements.

WEE-Reg.-No. DE 75797780

The device or its parts must be collected separately as special waste. The separate collection for the subsequent forwarding for recycling, treatment and environmentally compatible disposal, helps to avoid possible negative environmental and health effects and to promote recycling of the parts included in the device.
Illegal disposal of the equipment involves the application of administrative sanctions according to the current regulations of the country where the equipment is installed.
For information on how to dismantle and / or dispose inoperative devices in compliance with local legislations, contact local authorities or an authorized representative of the manufacturer.

3. Package content

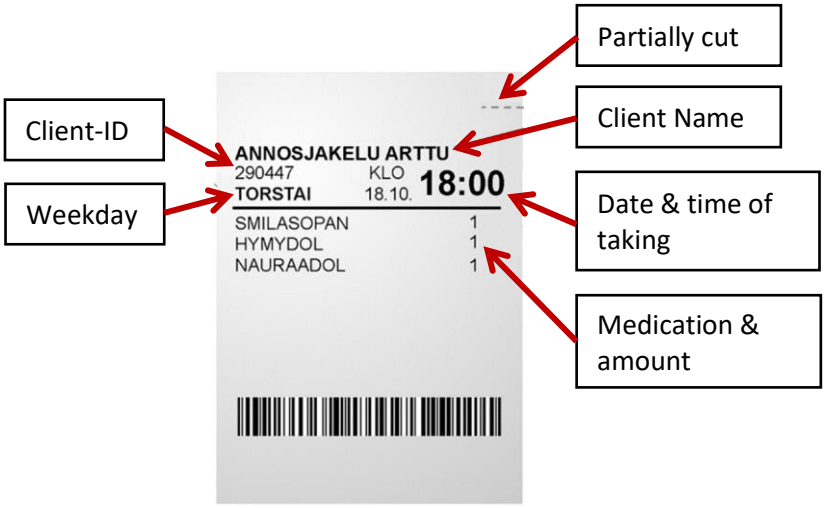
1. SMILA device
2. Battery
3. Power Supply Unit

4. Accessories

4.1. Blister roll

The blister roll is provided by a blister center. The blister center manufactures the blister roll according to a medication plan provided by a doctor or care facility. The manufacturer of this device (JDM) is not responsible for the content of the blister roll.

The information on a blister pouch might be arranged differently depending on the blister center manufacturing the said blister roll. See below for an example of a blister pouch.



The blister roll is inserted into the SMILA device by authorized personnel. The SMILA device processes the blister roll according to the medication plan and transports the separated blister pouches to the output slot. The blister pouch is partially cut in order to simplify the opening of the pouches.

5. Description of the SMILA device

5.1. Installation

- The device must only be operated in a closed space
- The ventilation slots on both sides on the bottom of the device must not be covered.
- The gap between the back of the device (heat sink) and the wall must be at least 5 cm.
- The device must not be placed right above a heat source (for example a heater).
- The device must not be placed in direct sun light.
- The device must not be placed in explosion proofed spaces.
- The device must be positioned in a way that the main power supply can be disconnected effortlessly by pulling the power cord out of the outlet.

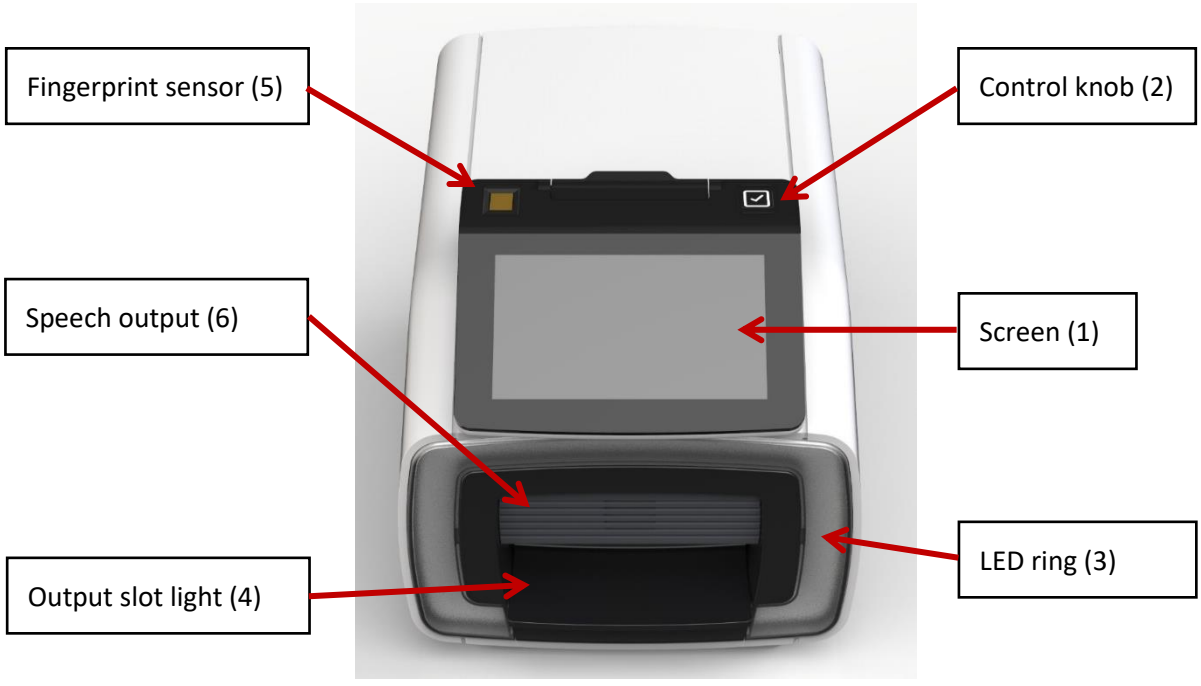
- The external power supply must be plugged in.
- The device must have sufficient reception. Whether the device is online or not will be indicated on the initial home screen in the upper left corner.

5.2. Visual signals in general

Color	Signal	Meaning
Green	Constant	No further action of the user is necessary at this point Everything is okay
	Flashing	User action has to be done → flashing element indicates at which part of the device the action has to take place Planned user action is necessary
Blue	Constant	Device is working, no user action is necessary Please wait
Yellow	Constant or flashing	Extraordinary user action is necessary to set back to fault-free state, e.g. connect the external power Main function (dispensing medication) can still be performed
	Flashing	Medication was not requested right away
Red	Constant or flashing	Device can no longer fulfill its main function (dispensing medication) without an extraordinary user action

5.3. User interface

The LCD Panel is plate glass. Do not subject the panel to mechanical shock or to excessive force on its surface.



5.3.1. Screen with touch

The screen is a 7 inch Amorphous-TFT-LCD (Thin Film Transistor Liquid Crystal Display) module. This module is composed of a 7” TFT-LCD panel, LED backlight, LED driver unit, Projective Capacitive Touch and power circuit unit. The screen has a resolution of 1024 x 600 pixels.

5.3.2. Control knob

The control knob is an illuminated push button to request blister pouches. The control knob also serves as an indication for the state of the device.

Color	**Signal**	**Meaning**
Green	Constant	User action has been completed successfully After the insertion of a blister roll was successful
	Flashing	Indication that one or more pouches are to be taken at this time When there is no external power supply and the device fall asleep
Blue	Constant	Device is working During the insertion of a new blister roll
Yellow	Flashing	Pouch has not been requested within the first time span (2 minutes) until medication is taken or taking time window is over One or more pouches are to be taken when there is no external power supply and the device fall asleep → double flashing
Red	Constant	Barcode not found during the insertion of a blister roll The first pouch is already expired / skipped during the insertion of a blister roll

5.3.3. LED ring

The LED ring illuminates the front of the device to indicate the medication intake.

Color	**Signal**	**Meaning**
Green	Constant	User action has been completed successfully
	Flashing	One or more blister pouches are to be taken at this time
Blue	Constant	Device is working
Yellow	Constant	Blister pouch has been requested but not taken by the homecare client within 2 minutes One or more taking times has been missed and an extraordinary user action has to be carried out
	Flashing	Blister pouch is not requested within the first time span (2 minutes) of taking time schedule

5.3.4. Output slot light

LED light to illuminate the output slot as soon as a pouch is delivered and can be taken by the homecare client. The output slot is illuminated in a cold white color.

5.3.5. Fingerprint sensor

A capacitive fingerprint serves as distinct user identification. All authorized users can identify themselves via fingerprint to access the authorized user menu. It is possible to change the settings of the user identification menu depending of the circumstances of the surroundings. It can be required, that each homecare client has to identify themselves via fingerprint before delivering any medications.

5.3.6. Speech output

The indication of a medication delivery is supported by a speech output with clear instructions. The volume of the speech output is approximately 71 db.

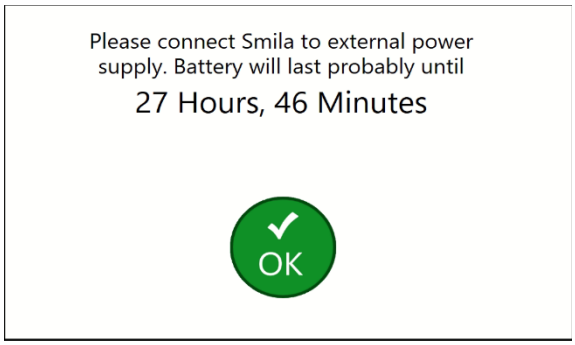
- "Please take your medication" → Reminder for the homecare client to request the medication.
- "Please withdraw your medication" → The pouch has been transported out of the output slot and the homecare client can take the medication.
- "You´re next medication is due in hh: min) → Information about next taking time, if it is not in the Pre-taking time window (see chapter 7.1.1 Pre-taking time)
- "You have missed your medication." → Previous medication has been missed. Homecare client needs to contact an authorized user who can decide which measures are to be taken.

5.3.7. Extraordinary states

If the device is not in a faultless state, the visual and audio signals will not work as described above.

Battery Mode

After the device has recognized battery operation, the control knob flashes yellow and shows the following screen. It will indicate for how long the device will last without external power.



The device falls asleep to save battery, the screen switches off and the control knob flashes green. The device only woken up when a taking time is coming up or the control knob was pressed. The control knob will flash green indicating that the device is in a standby mode but still working faultless. If the device is woken up the LED ring and the control knob briefly light up yellow and then flash yellow until the device falls asleep again. After the device is fall asleep again the control knob will flash green again.

If the taking time is due the device will wake up and the control knob is double flashing yellow, after 4 minutes the device falls asleep again. The device wakes up every 10 minutes to remind the homecare client if the medication is not taken. After the taking time window is over the device wake up and inform the homecare client that he/she missed the medication. After that it falls asleep again und flashes green. After connecting the external power, the device will wake up when a taking time is due or the control knob is pressed.

Offline
The “offline” sign on the initial home screen will indicate that device is not connected to the cloud at the moment.

Screen off
If the screen is off the indication of a taking time will only be shown by the green flashing of the knob and an acoustic signal (no speech output). To request the medication, the knop has to be pushed. The LED ring will flash green and the output slot illumination will go on to indicate that the medication can be withdrawn. Please contact the care center!

5.4. Audible signals

There are two different types of audible signals. Signals with the purpose of informing the homecare client that a taking time has come and that the medication can be requested. In addition, there is a signal that serves as a warning signal to inform the user that the device is not in a faultless state, e.g. the lid or the drawer is open.

5.4.1. Information signal

Information signals sound like a ship’s bell and will ring once as a reminder to request the medication. The ring lasts for approximately 2 seconds. The volume level of that signal is approximately 85 db. If the medication is not requested right away, the bell ring will be repeated after two minutes and then in 10-minute intervals until the medication is requested or the taking time window has elapsed.

5.4.2. Warning signal

In case the device is not in a faultless state the signal will be the ship’s bell sound ringing in shorter intervals several times until the device is back in a faultless state. The warning signal does not indicate any danger for the user. It only indicates that device is not in faultless state.

5.4.3. Acoustic signal

In case the speech output has a malfunction, the medication delivery is indicated by a simple sound instead of a speech output with instructions.

In case the device has a malfunction, the information signal will be a simple beep in regular intervals that will last for 30 seconds instead of the ship’s bell sound. The volume level of that signal is approximately 80 db. If the medication is not requested right away, the beep sound will be repeated after two minutes and then in 10-minute intervals until the medication is requested or the taking time window has elapsed.

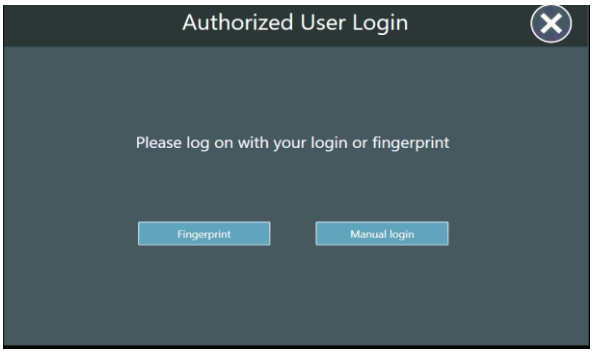
6. Core tasks authorized user

6.1. Start-up a new device

To start-up a new device, open the lid of the device with the designated key and turn on the device by pushing the main switch.

6.2. Login as an authorized user

To open the authorized users' menu, click on the user button on the top right corner of the screen. Login with your user name and password or your fingerprint. If the fingerprint is already enrolled.



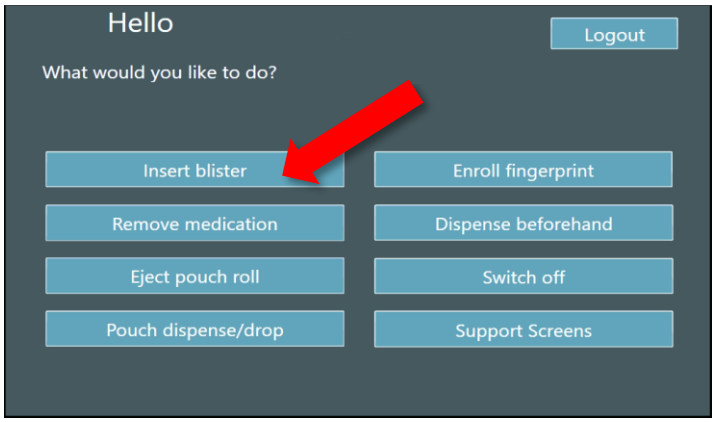
The login screen will be closed after 60 seconds without user action.

6.3. Inserting a blister roll

Do not insert a new blister roll with long, open hair or loose fitting clothes. The loose objects might be drawn into the transportation rollers.

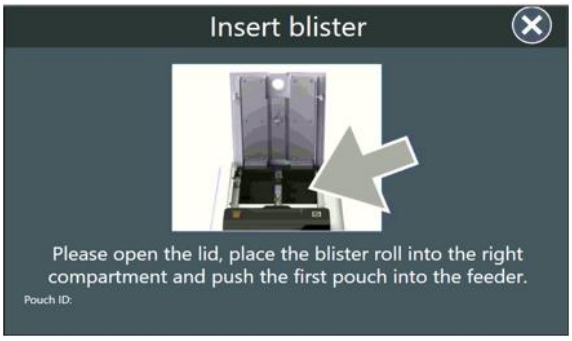
The drawer must be closed while inserting a new blister roll.

To insert a new blister roll, login as an authorized user via user name and password or fingerprint and select “Insert blister”.

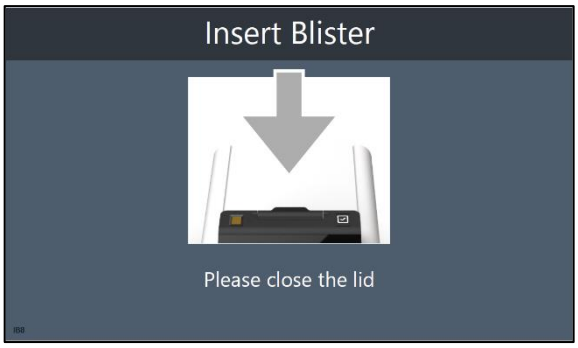


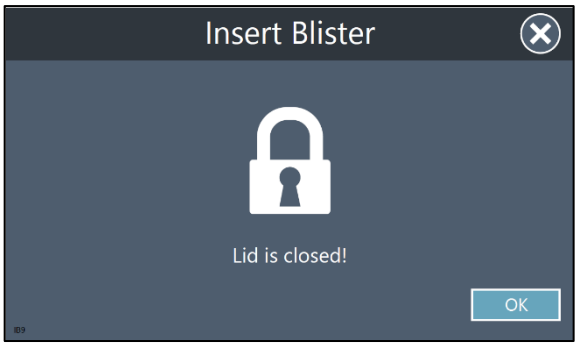
It will be indicated on the screen for which homecare client and for which period of time a blister roll should be inserted. In some cases, the blister roll might be held together by a glue point (green point). If the first pouch doesn’t contain any medication, the pouch must be removed from the roll. Please remove any stickers from the blister roll before you inserting the roll.

Open the lid and place the blister roll in the right or left transportation lane as shown in the picture below. Once the blister roll is placed in the right transportation lane the rollers will automatically pull in the blister roll. After the blister roll was inserted the device will read the data and indicate once the data has been successfully read. As soon as the insertion was successful the control knob will light up green briefly.



Once the blister roll was inserted successfully, the lid can be closed. Please wait for an indication that the lid has been closed successfully!





If the blister roll is inserted and the taking time of the first pouch is already expired. The device will show the following the screens:

The roll is transported backwards and the pouch that have already passed have to be removed. The device will show you again on which side the roll has to be inserted. After reinserting the roll it is necessary to confirm that the passed taking time is skipped.

If the blister roll is inserted and the next taking time in the cloud does not correspond to the next taking time. The device will show the following the screen:

The device will skip the next taking time.

If the inserted roll does not match with the patient, because of a wrong barcode, the device will show the following screen:

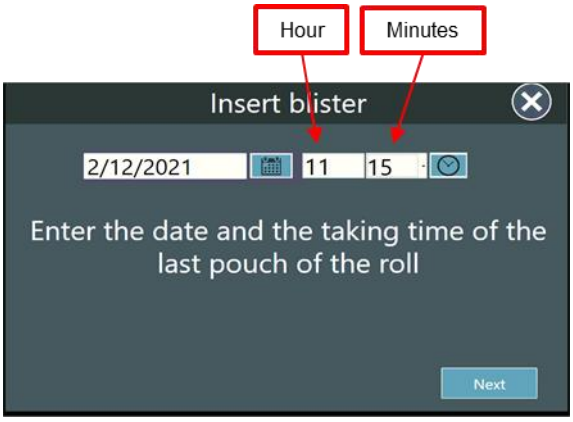
After pressing “ok” the blister will be transported backwards and the authorized user menu opens.

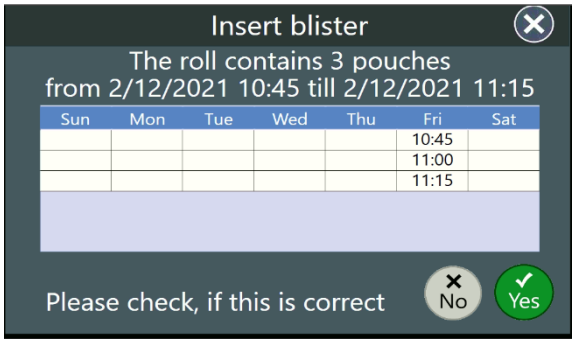
6.3.1. Insert after manual upload

The instructions for manually uploading the taking times can be found in the cloud user manual.

If no pouch ID is assigned during the uploading of the taking times, an intermediate step is necessary when inserting the roll.

Select the date and time of the last pouch of the roll and then confirm with “Next”. Please note that first full hours and then the minutes must be selected separately for the time. After confirming the date and time, the device display the number of available pouches and the medication schedule for one week. If all information is correct, please select “Yes”.

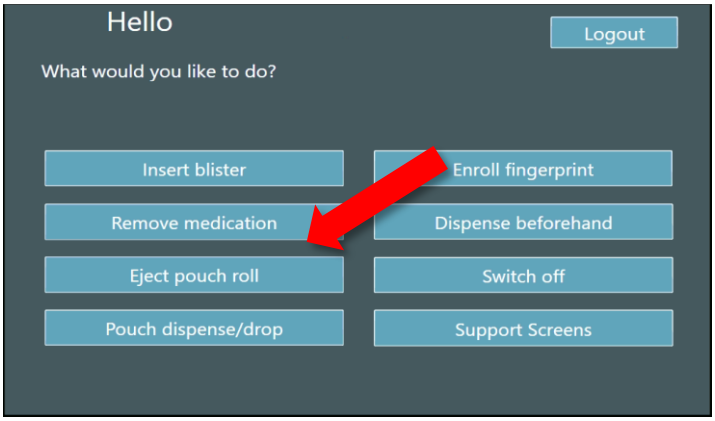




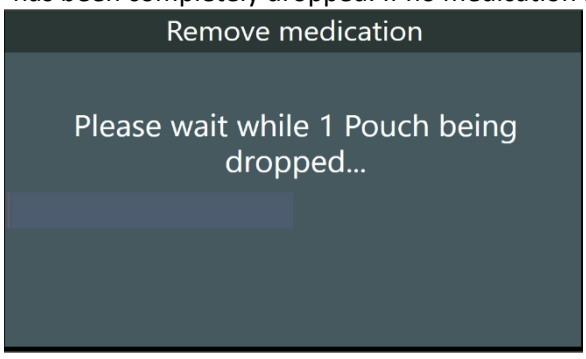
The roll is inserted as described in the chapter “Insert a blister roll”

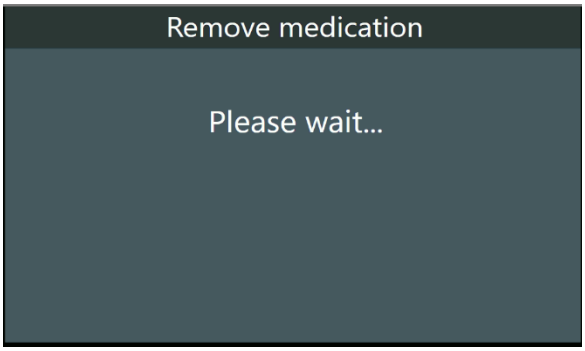
6.4. Remove missed medication

To remove the missed medication, login as an authorized user and press the “Remove medication” box in the authorized user menu.



If medication has been missed and has not yet been dropped, the lid only opens when the blister bag has been completely dropped. If no medication has been missed, the lid opens after a short time.





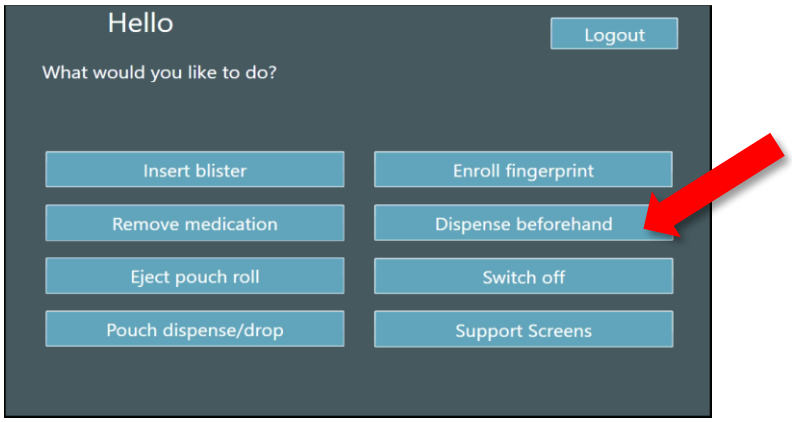
Open the lid and pull out the drawer to remove all medication pouches stored in the drawer. Once the drawer is pulled out, check the inside of the device for any missed pouches as well.

Please confirm that you have taken all pouches out of the drawer.

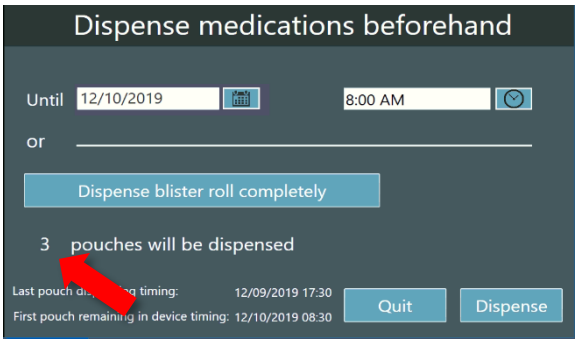
Please close the drawer and lock the lid! The device will light up green briefly once the drawer and the lid were closed successfully.

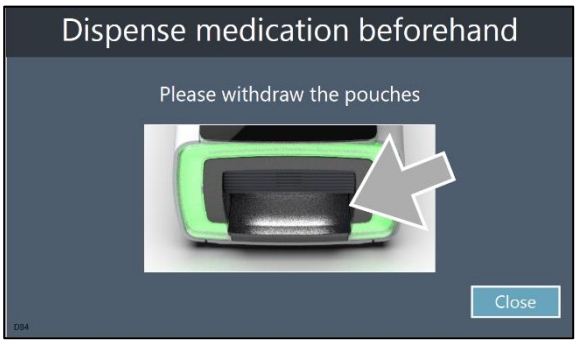
6.5. Dispense medication beforehand

To dispense medication beforehand, login as an authorized user and press the “dispense beforehand” box in the authorized users’ menu.



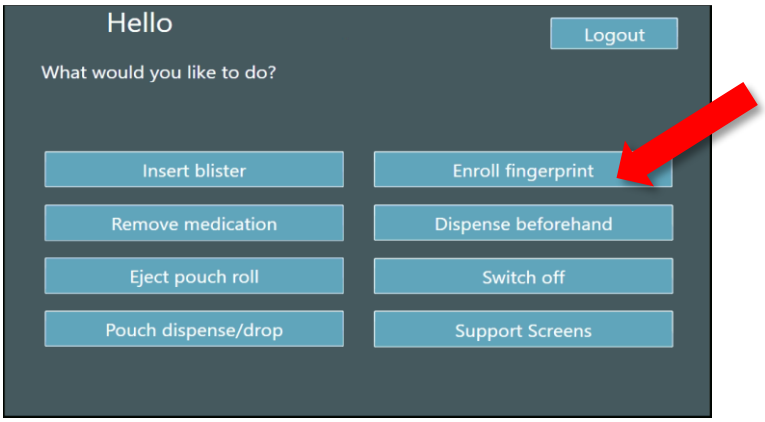
Select date and time up to which the pouches should be dispensed or select “Dispense blister roll completely to dispense the whole roll. The number of pouches that will be dispensed is shown on the screen. Furthermore, the device shows you the dispensing time of the last pouch and from the pouch which it will return to the standard process. During the dispensing of the pouches, the LED ring will light up blue. Once the medication is ready to be taken the LED ring will flash green and output slot will be illuminated.





6.6. Enroll a fingerprint

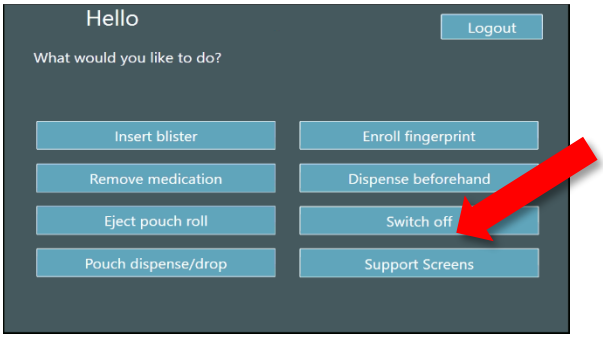
To enroll the fingerprint of a caregiver, press the “enroll fingerprint” box in the authorized users’ menu.

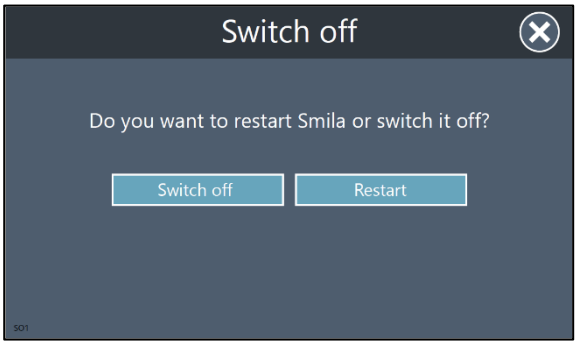


Place the desired finger on the fingerprint sensor in the top left corner of the device. Follow the instructions on the display until the scanning is completed.

6.7. Switch off the device

To switch off or restart the device press the “switch off” box in the authorized users menu and choose “switch off” or “restart”



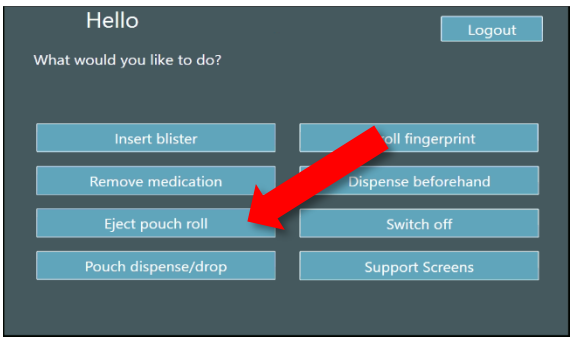


The device will then be restarted or switched off. If the device has been switched off by the main switch and the lid is closed it can only be restarted with a key!

If you want to switch off the device open the lid, press “switch off” on the screen, wait until the blue light goes off and press the main switch in the center of the device. The device can now be disconnected from the power supply by pulling the power cord out of the outlet.

6.8. Eject pouch roll

To remove the pouch roll please press the “Eject pouch roll” box in the authorized user menu. Always use the eject function in the authorized user menu for removing the blister roll. Never pull it out manually. It will be indicated for which homecare client you want to remove the blister roll.

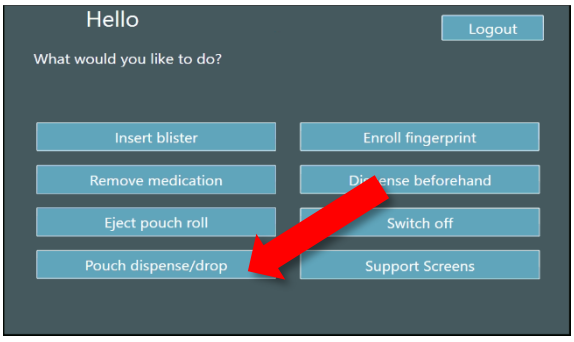


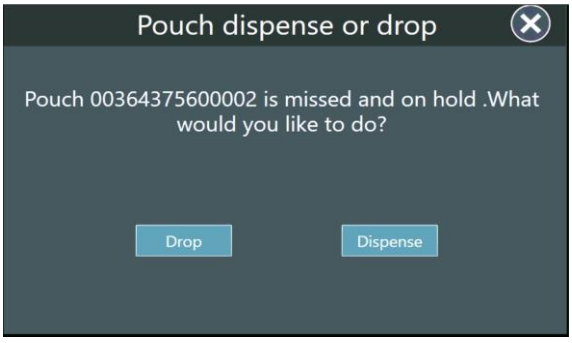
After confirmation the homecare client, you have to decide on which side the roll should be ejected. Only both sides were displayed if both sides are loaded. After you have selected on side, the lid will open automatically and the roll is ejected. After the blister roll is ejected please close the lid.

To enable dispensing after ejection a pouch roll, you have to use the “Insert blister” function.

6.9. Pouch dispense / drop

If the homecare client has missed one or more pouches and they are still on hold position then the medication can be dispensed or dropped through the authorized user menu.



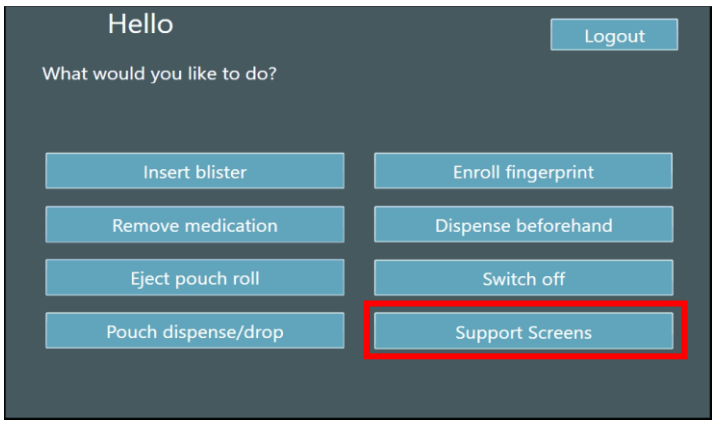


The caregiver can choose if the pouch should be dispensed or dropped. If more than one pouch is missed at the same time, the caregiver has to select for every pouch if the pouch should be dispensed or dropped. In both cases the caregiver receives a confirmation screen as soon as the action has been completed successfully.

If no pouch is on hold position the caregiver will get an information that no pouch can be dispensed or dopped.

6.10. Technical monitoring

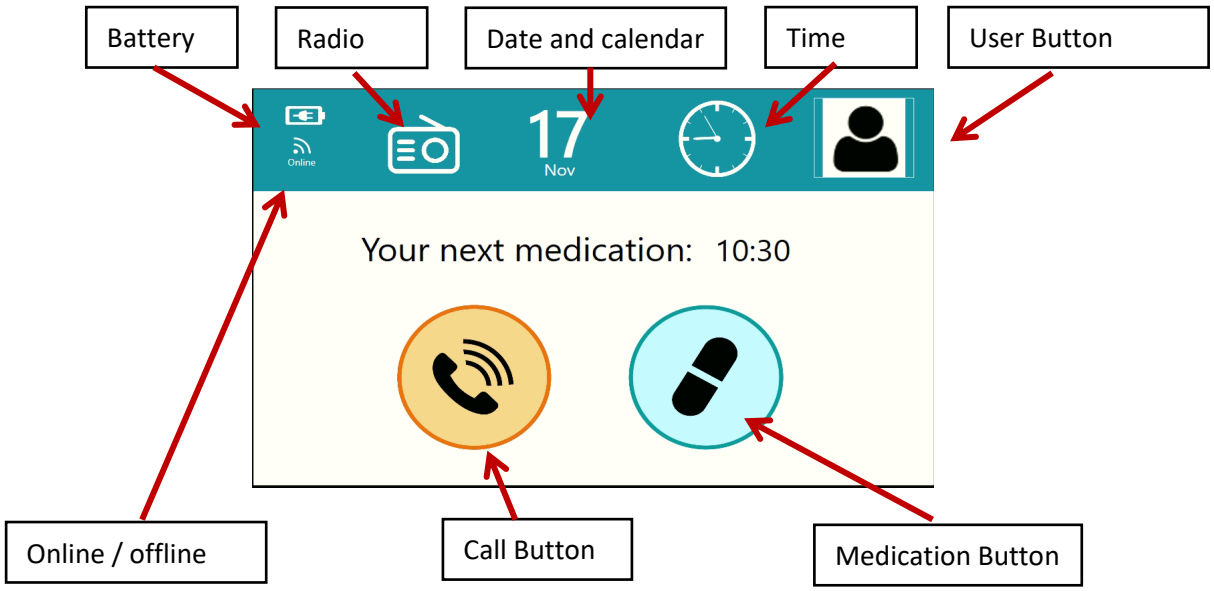
In the authorized user menu, there are two functions for technical monitoring of the device. These are protected by a password that is only known to support



7. Core tasks homecare client

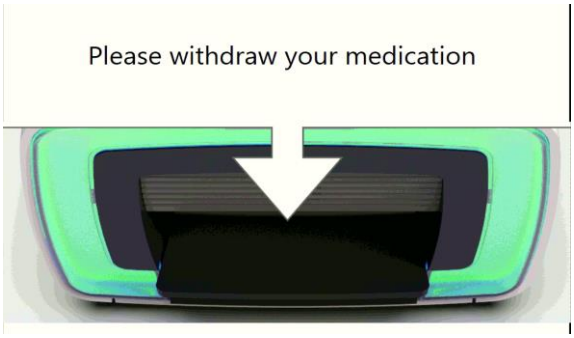
7.1. Information about medication

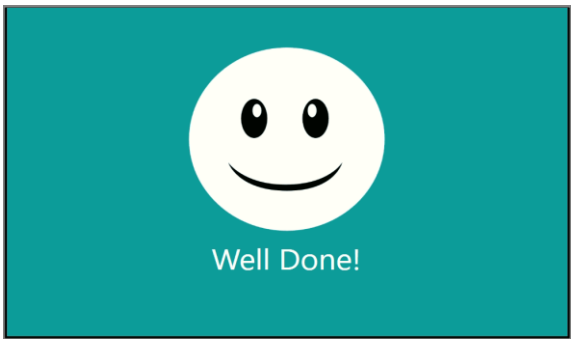
The initial home screen of the homecare clients' menu shows several information.



7.1.1. Pre-taking time

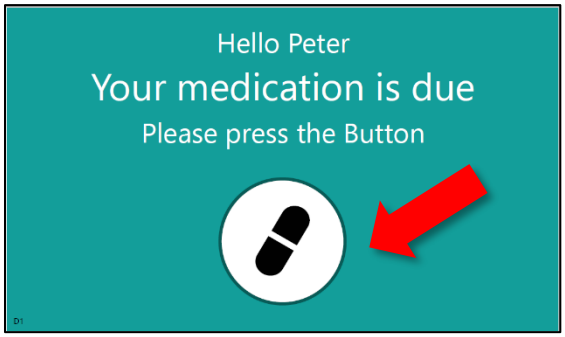
To get information about the next taking time press the medication button on the initial home screen. The screen will show at what time the next medication is due and whether the medication can already be requested. 30 minutes before the regular taking time the medication can already be requested. The homecare client press the "Yes" button to receive the medication. If the medication cannot be requested just yet the screen will only show at what time the next medication is due.
If the homecare client has pressed the "Yes" button the medication will be dispensed and the homecare client can take it.

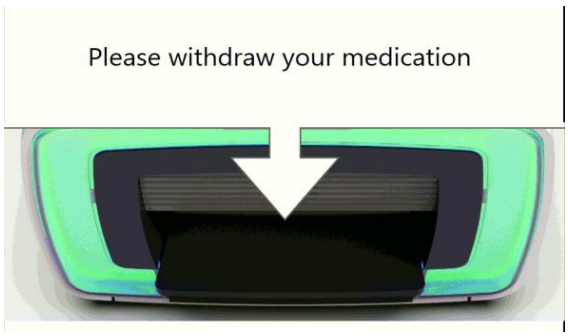




7.1.2. Regular taking time

If medication is due the screen will change and the lights of the device will flash green. Additionally, there will also be a speech output “please take your medication”. Please push the medication button or the knob on top of the device to request your medication. During the transportation of the pouch the device will light up blue. You can withdraw your medication once the output slot light goes on and the device flashes green.





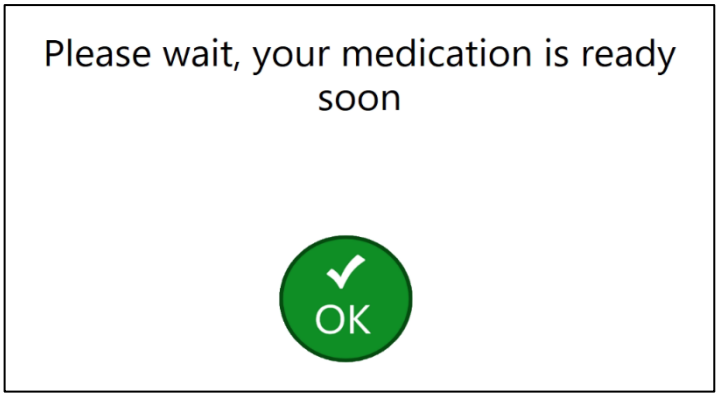
If the medication is not withdrawn or requested within 2 minutes, the device will flash yellow and the speech output “please take your medication” will be repeated every 10 minutes.

If the previous medication was missed the care center can be contacted to initiate a remote release or other actions. To contact the care center press the green “ok” button.

After 57 minutes, the taking time window is over. The device will inform the homecare client by the following speech output: “You have missed your medication” and the screen will change to the initial home screen.

To guarantee patient safety, in any case with evidence that there might be a deviation in pouch dispensing the system automatically starts a verification process.

During that verification process, that may take up to a few minutes, the following screen is displayed:

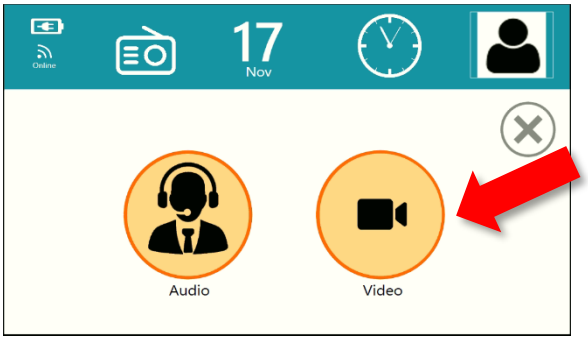


The device user does not have to do anything himself. As soon as the verification process is completed, the pouch can be regularly requested.

This screen is also indicated in cases when further intervention by the caregiver or remote support is necessary.

7.2. Communication with contact person

To communicate with a contact person, press the “Call Button” on the initial home screen. It is possible to call with or without video. To choose video-communication, press the video button.

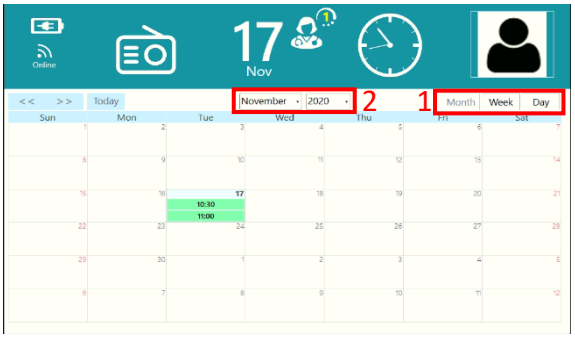


The homecare client will be connected automatically with one of his caregivers. The caregiver has to be logged in to the cloud.

To end the call, press the “x” button on the upper right corner. The call then will be disconnected and the standard screen will be shown.

7.3. Date and calendar

To open the calendar function, press the “date and calendar” button on the initial home screen. Calendar entries can be shown for a whole month, one week or one single day (1). The shown month and year can be selected separately (2).



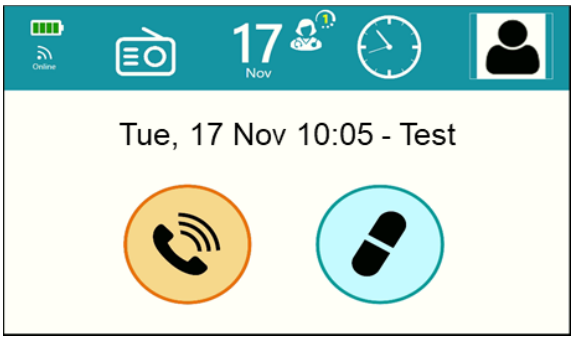
To close the calendar function, press the “date and calendar” button once again.

7.4. Radio

To listen to the radio, press the “radio” button on the initial home screen. The volume can be changed by pressing the (+) and (-) buttons. To turn the radio off again, press the exit (x) button. To increase the volume please push the plus (+) button. To decrease the volume please push the minus (-) button.

7.5. External Events

If events are configured for the homecare client you will find an indication next to the current date. This indication shows how many events are configured.



Shortly before the event is due, the announcement of the next taking time will be overwritten by the announcement of the event.

If a event is due you will see the information about the event. If a taking time and an event are due at the same time, you will see the normal taking time is due screen and after the taking time was taken the the announcement for the event. Announcements of events have to be confirmed.

8. Messages and signal lamps

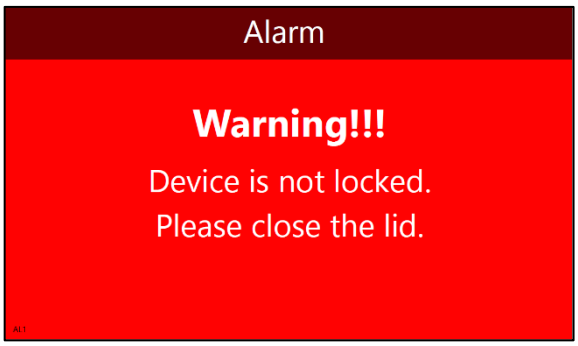
The following screens appear once a user action has been completed successfully. The device is ready for use once these screens appear.

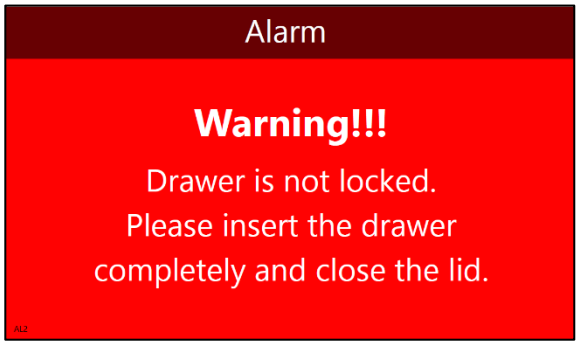
Blister roll has been successfully inserted

Dispensing of medication was completed successfully

Warning messages

If the lid or / and the drawer isn't locked the screen will show a warning message and a warning signal is given. The device will light up red. If the device is not locked correctly it cannot function efficiently. Please lock the drawer and the lid!





If the lid is not closed the warning signal is given every minute.
If the drawer is not closed the warning signal is given every 30 seconds.

9. Requirements for IT-network

If the device is connected via WIFI the following requirements must be fulfilled:

- SSID which must not directly lead to its purpose
- Password with at least 20 characters with letters, numbers and special characters
- Active encryption at least WPA2
- Router must have a firewall
- Cloud Server must be certified ISO/IEC 27001

10. Technical specifications

10.1. Electrical specifications

Specifications	**Data**
Power Supply unit	Primary 115 Vac / 230 Vac Secondary 19 Vdc
Frequency	50/60 Hz
Current max.	3,34 A (19 V)
Power consumption max.	65 W
Power consumption average	~ 15.3 W
Standard socket	16 A @ 230 Vac
Isolation class power supply cable	Class II
Use conditions	Continuous operation
Classification with respect to fluids and solid particles	IP00
Acoustic pressure max.	87 dB
Start-up time	1 min.
Estimated lifetime	5 years

10.2. Environmental specifications

Environmental factor	**In normal use**	**Warehouse and transport**
Temperature	10° C – 30° C	-20° C – 60° C
Relative Humidity	20% - 70%	20% - 70%

10.3. Mechanical specifications

Description	**Data**
Width	272,40 mm
Length	435,90 mm
Height	253,50 mm
Weight	11,5 kg

10.4. Radio communication

Mobile communication	**Bands and frequencies**
GSM	850/900/1800/1900 MHz
WCDMA	I, V, VIII
LTE	1, 3, 5, 7, 8, 20 ,28

Maximum Power: 33dBm (GSM) 23dBm (WCDMA, LTE)

Bluetooth	**Frequency**
Bluetooth V4.0	2,4GHz

Maximum Power: 8dBm

Wireless LAN	**Frequency**
b/g/n 2,4GHz	2,4GHz

Maximum Power: 17dBm

The device is developed and produced to meet the specifications for the European Union.

10.5. Batteries and battery charger

The device is able to run without an external power supply for 24 hours. The Smart Battery included in the device is a Lithium-ion battery pack RRC2054.

Battery type	Lithium-ion Battery Pack
Nominal voltage	14,4 V
Charge voltage	16,8 V
Capacity	3450 mAh
Estimated lifetime @23°C 1.6A Charge/1.6A Discharge	<300 cycles with min. 75% of initial capacity.

Do not take out the battery during operation!

11. Reporting obligation

The homecare client or user is obligated to contact the manufacturer or/and the local authorities in the case of a serious incident.

JDM Innovation GmbH
Carl-Benz-Str. 16
71711 Murr, Germany
Tel.: +49 (0)7144 8121 0
Web: http://www.jdm.de
E-Mail: info@jdm.de

You can also submit a ticket request by using the following link:
https://jdm6121.zendesk.com/hc/en-us

12. Declaration of conformity

JDM Innovation
a PHOENIX company

EU-Konformitätserklärung
(gemäß der Verordnung 2017/745 und der Richtlinie 2014/53/EU)

EU Declaration of Conformity
(according to the Medical Device Regulation 2017/745 and the radio equipment directive 2014/53/EU)

Hersteller *manufacturer*	JDM Innovation GmbH Carl-Benz-Str. 16 71711 Murr Germany
Produkt *product*	Medical Dispenser SMILA MD-1
Basis UDI-DI *Basic UDI-DI*	PP10483JDMI.04201901.1667

Zweckbestimmung
Intended purpose

Der Blister-Dispenser ist dafür bestimmt, die therapietreue Medikamenten-Einnahme einzelner oder mehrerer Patienten zu unterstützen und zu verbessern. Der Blister-Dispenser ist für die Nutzung bei Patienten zuhause, in Pflegeeinrichtungen oder Krankenhäusern konzipiert und wird sowohl von Patienten selbst wie auch von Pflegekräften bedient. Der Blister-Dispenser kann einen oder mehrere patientenindividuelle Medikamentenblister aufnehmen und gibt die einzelnen Medikamentenbeutel zu den vorgesehenen Einnahmezeitpunkten aus. Die Medikamenteneinnahme wird über eine Cloudplattform durch autorisiertes Personal überwacht.

The Blister-Dispenser is intended to support and improve the medication adherence of individual or several patients. The Blister-Dispenser is designed for home-use as well as for the use in nursing homes or hospitals. The device is intended to be operated by the patient himself or a caregiver. The Blister-Dispenser can hold one or multiple patient individual medication blisters. Based on the medication plan the Blister-Dispenser delivers the pouches to the patient. Caregivers and service employees can monitor the medication adherence through the cloud-platform.

Medizinprodukt Klassifizierung *Medical device*	Klasse I (Regel 1 und 13, Anhang VIII (EU) 2017/745) *class I (rule 1 and 13, Annex VIII,* (EU) 2017/745)

Wir erklären hiermit, in alleiniger Verantwortung, dass das oben genannte Medizinprodukt die Grundlegenden Sicherheits- und Leistungsanforderungen aus Anhang I der Verordnung MDR 2017/745 und die Anforderungen aus der RED 2014/53/EU erfüllt.

We declare under our sole responsibility that the product mentioned above is in conformity with the General Safety and Performance Requirements of Annex I of the Medical Device Regulation 2017/745 and with the RED 2014/53/EU.

Murr, 01.12.2022
(Datum/*Date*)

Dr. Martin Lafleur
(Geschäftsführer/*General Manager*)

Notes:

JDM Innovation GmbH
Carl-Benz-Str. 16
71711 Murr, Germany
Tel.: +49 (0)7144 8121 0
Web: http://www.jdm.de
E-Mail: info@jdm.de