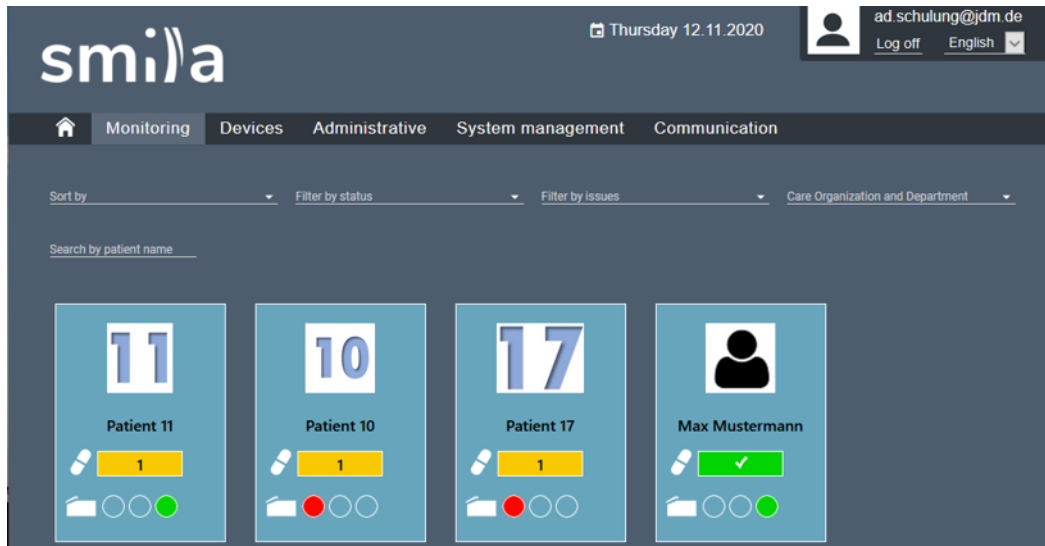


User Manual Cloud SMILA



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Document status

Rev.	Description	Date
1	Document created and approved	15.01.2021
8	3.6 Time based SMS-Altering added 3.7 new function Adjustable Taking Time window 7. Temperature display removed 7. Photo scan only visible for super admins 10. Conformation when deleting a roll	19.01.2024

0. Introduction

This medical device conforms to the Medical Device Regulation MDR 2017/745, as well as its revised versions. The medical device, hereinafter referred to as the device, has been classified in class 1 in accordance with regulation I and 13, Annex VII, (EU) 2017/745.

0.1. Cloud provider

The provider (in accordance with the Medical Device Regulation MDR 2017/745 and its revised versions) of the cloud is:

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Carl-Benz-Straße 16
71711 Murr, Germany
Tel.: +49 (0)7144 8121 0
Website: <http://www.jdm.de>
E-Mail: info@jdm.de

0.2. Publication details

Published by the provider.

The provider reserves the right to make changes to this user manual and the cloud described herein. The cloud specifications can be changed without prior notification. Nothing in this manual can be considered an offer, guarantee, promise or contractual condition, and shall not be intended as such.

0.3. Copyright

No part of this manual may be reproduced or transmitted in any form without the written approval of the provider.

The software belongs to the manufacturer. The user shall obtain only the right to use the software.

This right shall be neither exclusive nor transferable.

Furthermore, written approval must be obtained from the provider before making changes to the use of the cloud for other purposes besides those stipulated.

0.4. Information on the user manual

The purpose of this user manual is to provide a valid aid to ensure the safe and efficient use of the cloud described.

Please read the user manual before using the cloud.

The user manual is a significant component of the cloud. **It must be stored so that it is available for use and access at all times.**

0.5. Compatibility

The cloud platform is compatible with the following web browsers:

- Mozilla Firefox
- Google Chrome
- Microsoft Edge

The Internet explorer web browser is not supported.

If the page is not displayed correctly when the cloud platform is opened, please empty your browser cache. Delete the browser cache by pressing the key combination: [Ctrl] + [Shift] + [Del]

The cloud platform can also be operated using a smartphone or tablet.

0.6. Training

Cloud users must be sufficiently trained to ensure secure and effective use of the cloud, before attempting to use the cloud described in this user manual.

The user is responsible for ensuring that they have received the right training in accordance with applicable laws and local standards.

0.7. Proper use

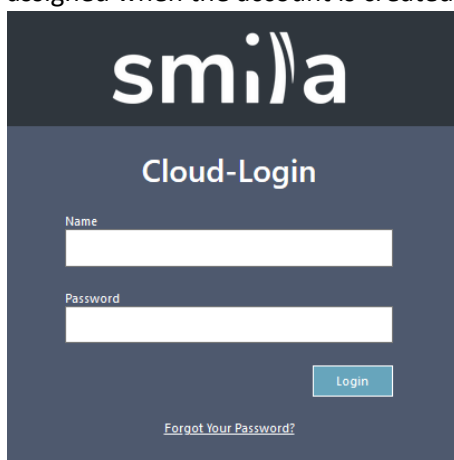
The cloud is designed to support and document monitoring of compliance with the medication plan. Furthermore, it simplifies monitoring of the medical devices.

The cloud shall only be used in conjunction with the medical device SMILA. The cloud is used to exchange data with the SMILA device. The platform contains all important information that the device needs to dispense medication.

Nurses and service employees can monitor the technical function of the device using the cloud platform and complete service and maintenance work on the SMILA device.

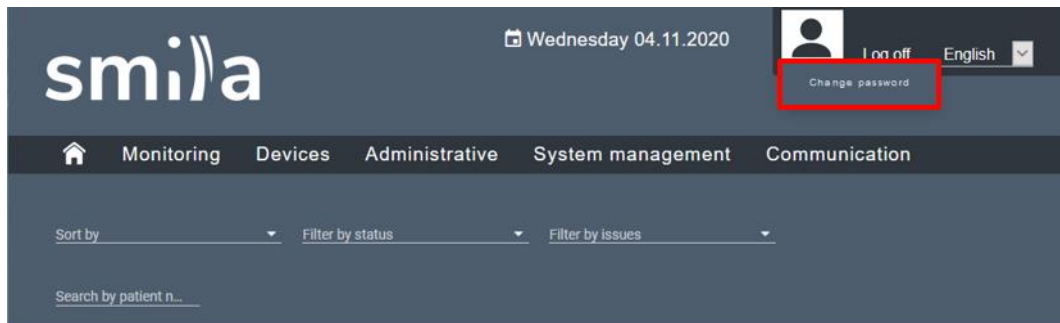
1. Login to the cloud

- To login to the cloud, access the following link: <https://smilaservice.fi>
- The cloud user must enter their user name and password to log in (an initial password is assigned when the account is created, for use during initial log in).



- If the user forgets their password, they can set a new password using the “Forgot your password” function.
- The initial password should be changed after the first log in.

- To change the password, hover over the user image with the mouse, then click “Change password”



- Enter the current and new password into the fields provided.

A screenshot of the 'Change password' form within the Smila application. The form is a dark grey rectangle with a white border. It has a title 'Change password' at the top. Below the title are three input fields, each with a label and an asterisk: 'Current password*', 'New password*', and 'Repeat password*'. Below these fields is a small text note: '*Indicates required field'. At the bottom right of the form is a blue button labeled 'SAVE'. The form is set against a background of the application's navigation bar, which includes a home icon and the menu items 'Monitoring', 'Devices', and 'Administrative'.

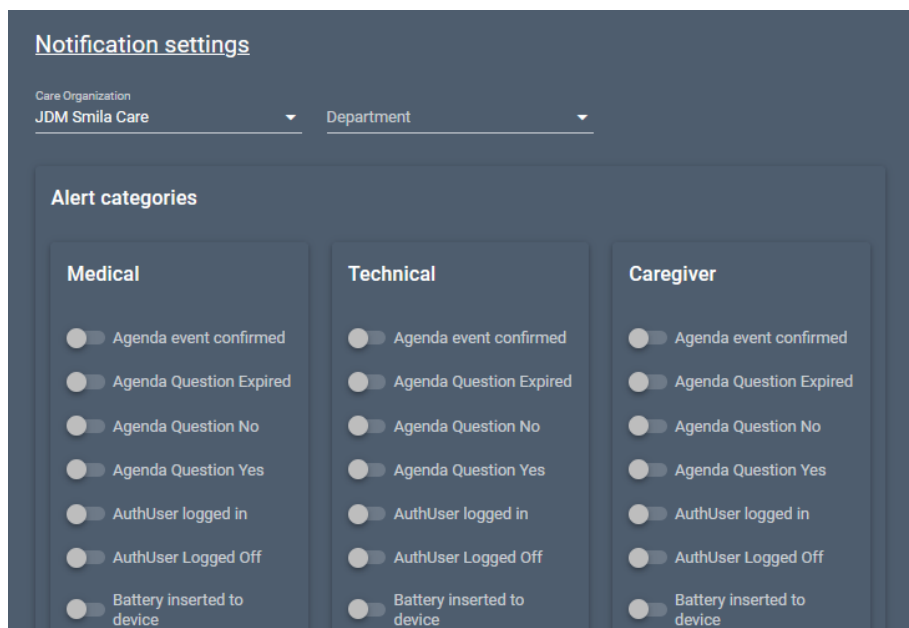
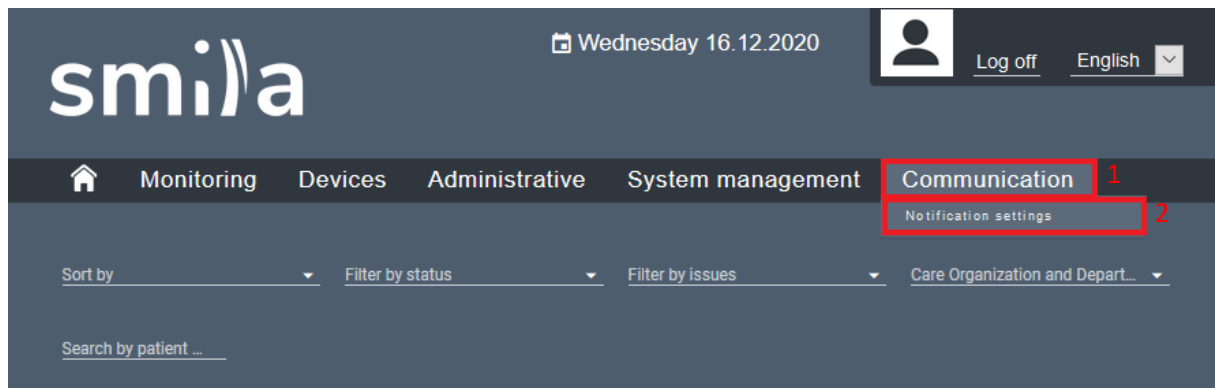
You can login to the Smila cloud using single sign on. Currently we are supporting Microsoft Azure Active Directory. Set up instruction can be found here: [Single-Sign On – Smila \(zendesk.com\)](https://smila.zendesk.com/entries/2020/01/21/Single-Sign-On-Smila)

2. Alarm configuration

2.1 Notification settings

Alarm notifications can be individually adapted. To access the alarm settings, complete the following steps:

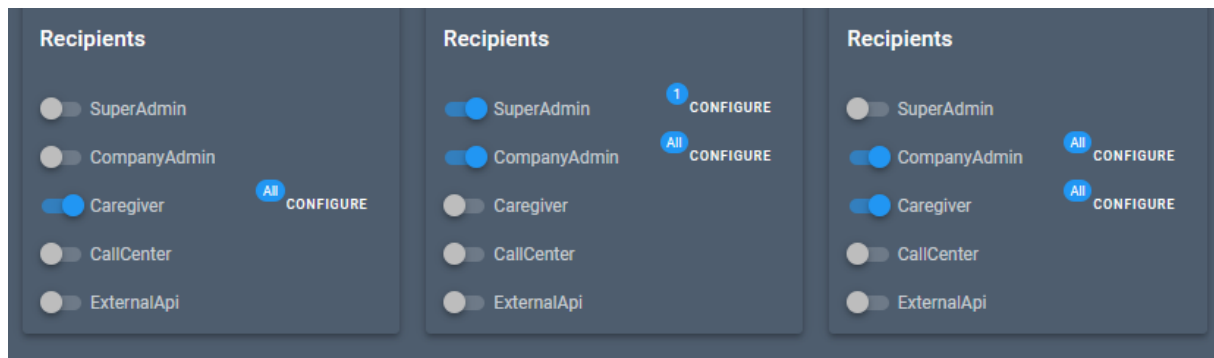
- Select “Communication” (1)
- Select “Notification settings” (2)



The alarms to be activated will be displayed in a list of three categories. The administrator can then individually decide for which category each alarm should be activated, or whether it should be activated in all categories. To do so, proceed as follows:

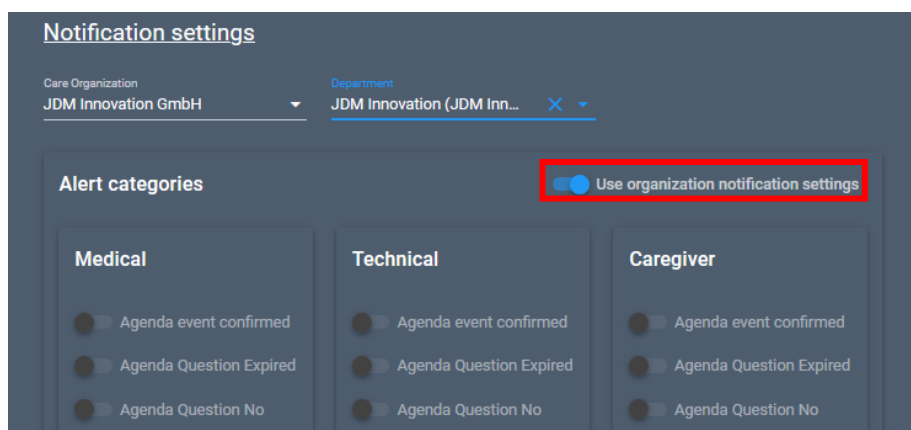
- Medical → all medical alarm notifications
- Technical → all technical alarm notifications
- Caregiver → all organizational matters

The recipients of the notifications are defined in the next step.



Notification recipients are defined for each category. You can either select the recipient groups as entire groups, or select individual recipients.

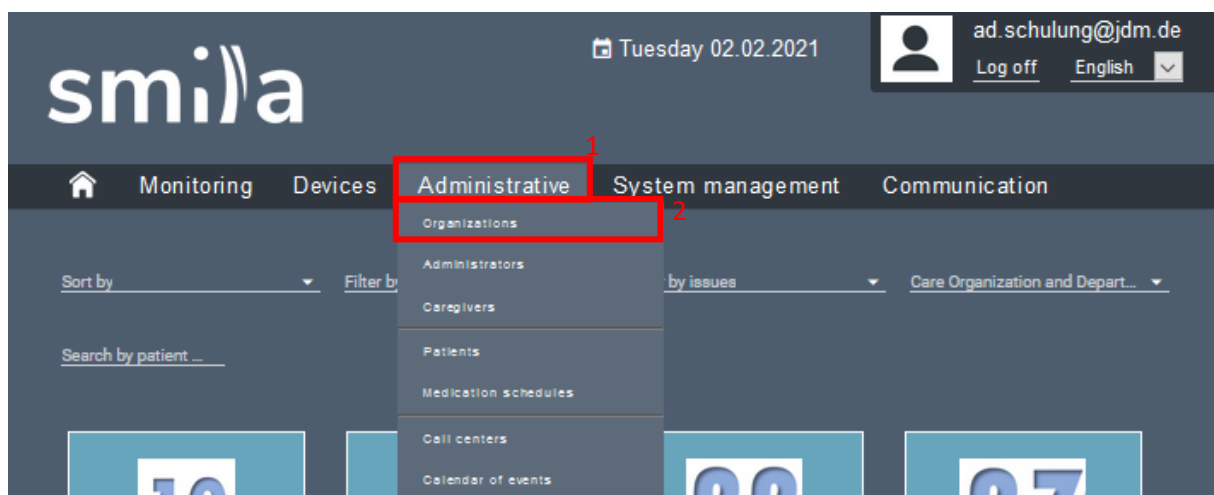
The notification channel is set individually for each recipient (see User management chapter, setting notification channels)



If an organization has sub-departments, the notification can be set individually for each department. Therefore, you have to select the department. When the checkbox “use organization notification settings” is activated, you cannot change the settings for the sub-department. First you have to deactivate the checkbox and then you can set the settings as described before.

The notification language can be set individually for each organization. To change the language, complete the following steps:

- Select “Administrative” (1)
- Select “Organization” (2)



- Select the organization and then Edit (as when editing an Account → see the User management section – Editing an account)

Edit organization Smila Training

Name*	Country*
Smila Training	Germany
City*	Street*
Murr	Carl-Benz-Straße
Zip Code*	Phone*
71711	00 49714481210
Fax	Email*
00 497144812133	info@jdm.de
Default Call Center*	
Smila Care-0049714481210	
Default language*	
English	

*Indicates required field

CANCEL UPDATE

- Click the down arrow to open a drop down menu with the available languages
- Select and “Update” to save

2.2 Gillie

Smila Cloud is supporting a customizable integration to the patient monitoring platform Gillie. The activation of the Gillie interface must be requested by the distributor organization via email. Local support then sets alerts in the section “external” that are sent to Gillie.

smila Thursday 03.08.2023 TrainingUser Log off English

Monitoring Devices Administrative System management Communication Reports

Notification settings

Care Organization: Gillie Test Organization Department:

Alert categories

Medical [ALL] [ALL] - Agenda event confirmed - Agenda Question Expired - Agenda Question No - Agenda Question Yes - AuthUser logged in - AuthUser Logged Off - Battery inserted to device - Battery removed from device - Call Center Call - Client about to miss medication	Technical [ALL] [ALL] - Agenda event confirmed - Agenda Question Expired - Agenda Question No - Agenda Question Yes - AuthUser logged in - AuthUser Logged Off - Battery inserted to device - Battery removed from device - Call Center Call - Client about to miss medication	Caregiver [ALL] [ALL] - Agenda event confirmed - Agenda Question Expired - Agenda Question No - Agenda Question Yes - AuthUser logged in - AuthUser Logged Off - Battery inserted to device - Battery removed from device - Call Center Call - Client about to miss medication	External [ALL] [ALL] - Client about to miss medication - Device Hibernate - Device Lid Open - Device Offline - Escalation Barcode Not Found - Escalation Barcode Wrong - Escalation Dropping Failed - Escalation Error In Beforehand - Escalation Not Coming Out - External Power Loss
---	---	---	---

3. User management

The following section shows the available cloud user accounts and their primary duties.

- Administrators = Manage users and data to monitor ongoing operations
- Caregiver = Nurses, home care of patients, operating the device and monitoring medical status
- Patients = No cloud access, but account required to use devices

User management works the same for all account types. The functions listed here are shown using the Administrator account type, as an example.

3.1 Rights of use

User rights can be adjusted based on organizational needs; the set user rights can be changed at any time, and are only valid for the account in question.

The following user rights are available for the Administrator account type:

- View care organizations: The administrator can view all organizations assigned to them, but cannot create new nor edit existing organizations.
- Edit care organizations: The administrator can view, edit and delete all organizations assigned to them, as well as create new organizations.
- View administrators: The administrator can view all other administrators within the same organization, but cannot create new nor edit existing administrators.
- Edit administrators: The administrator can view, edit and delete all other administrators within the same organization, and can create new administrators.
- View caregiver: The administrator can view all caregivers within the same organization, but cannot create new nor edit existing caregivers.
- Edit caregiver: The administrator can view, edit and delete all caregivers within the same organization, and can create new caregivers.
- View patient: The administrator can view all patients within the same organization, but cannot create new nor edit existing patients.
- Edit patient: The administrator can view, edit and delete all patients within the same organization, and can create new patients.
- Use Video Call: The administrator can make and receive video calls with patients
- Can login to device: The administrator can log into the patient devices as an authorised user

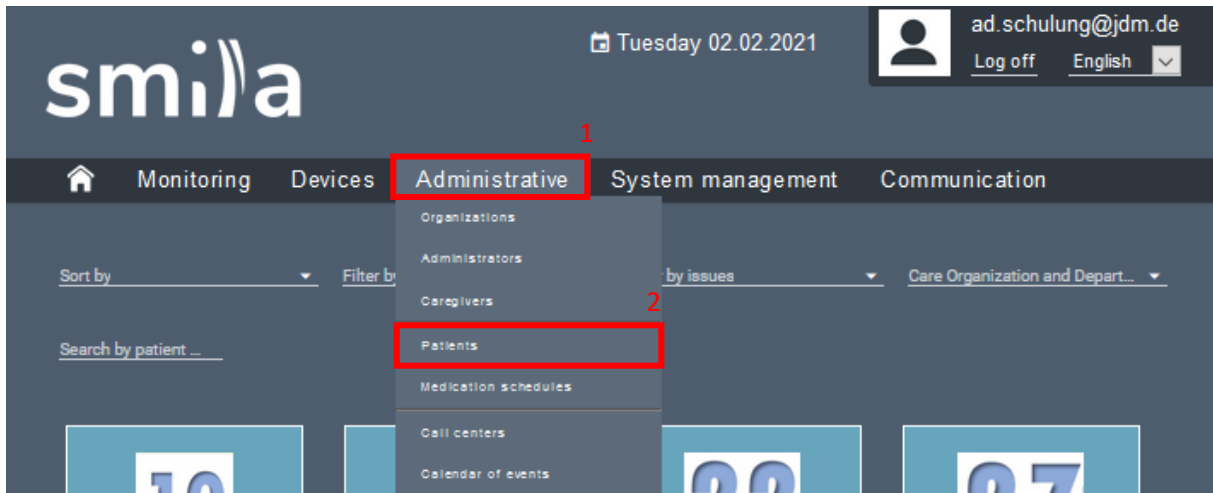
The following rights of use are available to the account type Caregiver:

- Can edit caregivers: The caregiver can edit other caregivers within the same organization.
- Can login to device: The caregiver can log into the patient devices as an authorised user
- Can assign devices to patients: The caregiver can assign devices to patients
- Can browse device: The caregiver can view all assigned devices within the same organization
- Can edit patients: The caregiver can edit patients within the same organization
- Use Video Call: The caregiver can make and receive video calls with patients

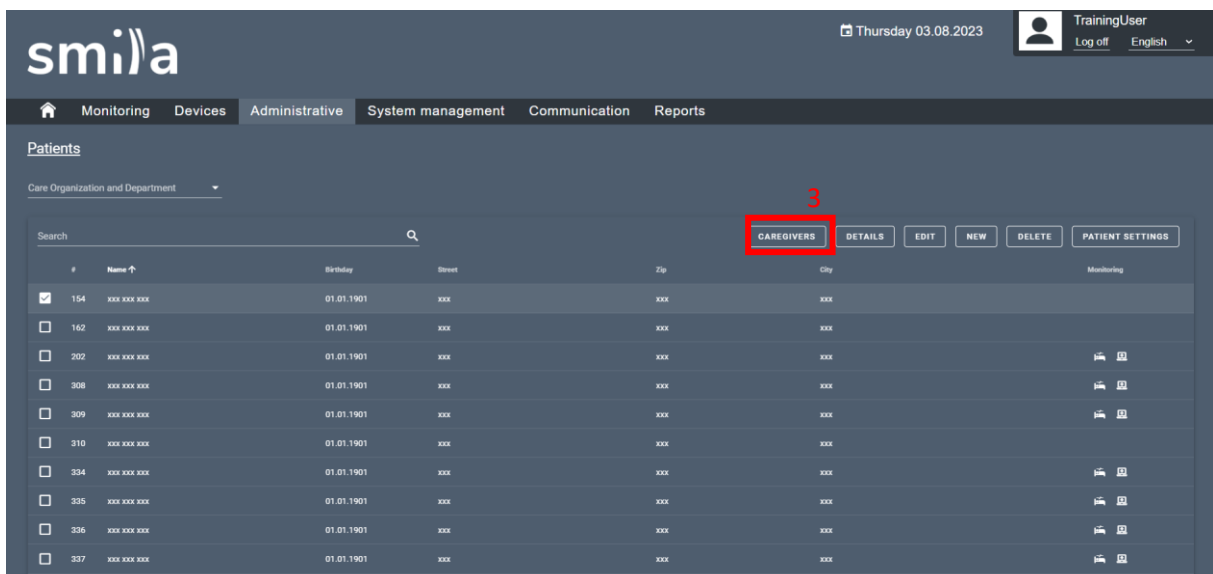
3.2 Patient overview

To get to the patient overview, complete the following steps:

- Select “Administrative” (1)
- Select “Patients” (2)



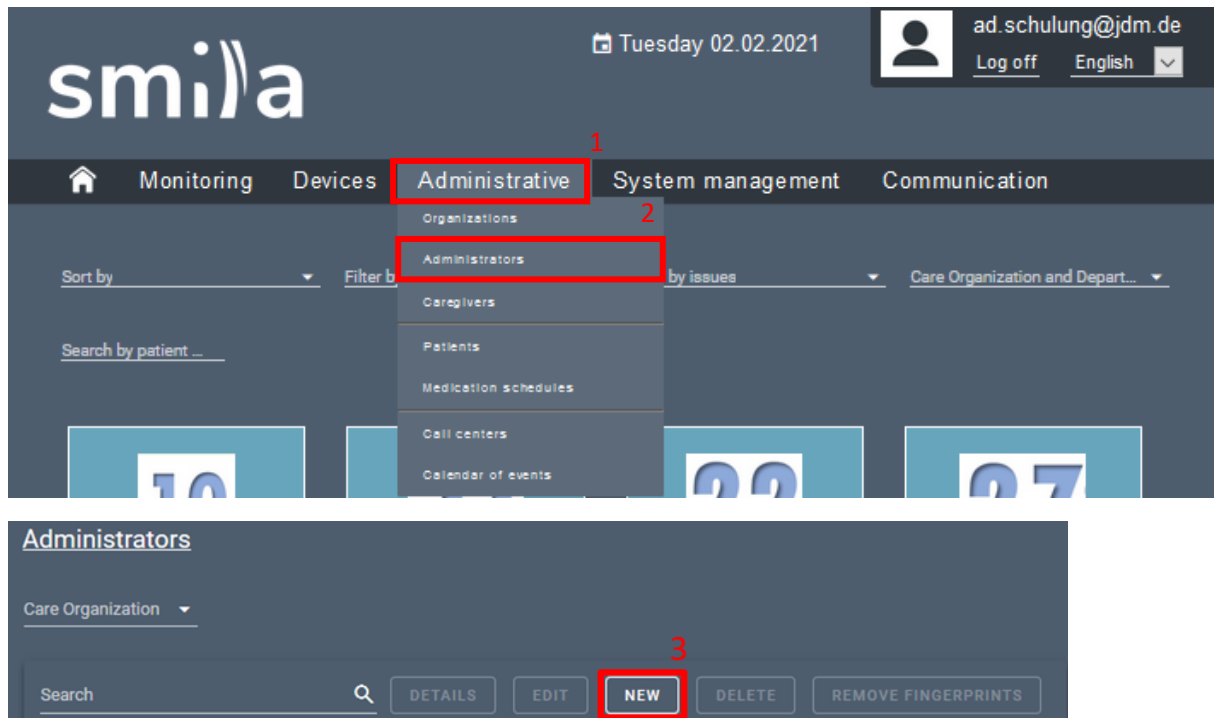
To see the caregivers, Select “Caregives” (3).



3.3 Creating a new account

To create a new account, complete the following steps:

- Select “Administrative” (1)
- Select the account type; in this example “Administrator” (2)
- Select “New” (3)



A pop-up window will open where information on the account can be completed and relevant user rights assigned.

Create new admin

Prenome

First name*

Last name*

Phone

Mobile phone

User Name*

Email*

Language*
English

Organization*

Password*

Confirm password*

☒ View care organizations

☒ Edit care organizations

☒ View administrators

☒ Edit administrators

☒ View caregivers

☒ Edit caregivers

☒ View patients

☒ Edit patients

☒ Use video call

☐ Can login to device

Notification channels

☐ Sma
☐ Telegram
☐ Email

*Indicates required field

CANCEL

CREATE

Create new patient



Prenome

Photo

Photo (jpg, png, bmp)

First name*

Last name*

Birthdate*

Language*
English

Social Security number*

Phone

Mobile phone

Country

City

Street

Zip Code

Email

Pre taking time window in minutes
30

Taking time window in minutes
60

All fields marked with (*) are mandatory fields and must be completed.

When an account is created, an initial password must be assigned. The initial password can be changed later by the account user. See the section “Logging into the cloud”.

3.4 Edit an account

To edit an existing account, complete the following steps:

- Select “Administrative” (1)
- Select the account type; in this example “Administrator” (2)
- Search for the name of the account (3)
- Select the account to be edited (4)
- Select “Edit” (5)

The screenshot shows the smila web interface. The top navigation bar includes 'Monitoring', 'Devices', 'Administrative' (highlighted with a red box and number 1), 'System management', and 'Communication'. A dropdown menu under 'Administrative' shows 'Organizations', 'Administrators' (highlighted with a red box and number 2), 'Caregivers', 'Patients', 'Medication schedules', 'Call centers', and 'Calendar of events'. Below this, a search bar is labeled 'Search by patient ...'. The main content area is titled 'Administrators'. A search bar contains the text 'Admin' (highlighted with a red box and number 3). Below the search bar, there are buttons: 'admin', 'DETAILS', 'EDIT' (highlighted with a red box and number 5), 'NEW', 'DELETE', and 'REMOVE FINGERPRINTS'. A table lists administrators with columns: '#', 'Administrator name ↑', 'Login', 'Email', and 'Fingerprints'. The first row is selected, indicated by a checked checkbox (highlighted with a red box and number 4).

#	Administrator name ↑	Login	Email	Fingerprints
☒	270 Admin 1	admin.1@admin.com	admin.1@admin.com	0
☐	271 Admin 2	admin.2@admin.com	admin.2@admin.com	0
☐	272 Admin 3	admin.3@admin.com	admin.3@admin.com	0
☐	273 Admin 4	admin.4@admin.com	admin.4@admin.com	0
☐	274 Admin 5	admin.5@admin.com	admin.5@admin.com	0

A pop-up window will open, like the one used to create a new account. All displayed information can be edited and updated in this window.

Edit admin Admin Schulung

Prenome	First name* Admin
Last name* Schulung	Phone
Mobile phone	User Name* ad.schulung@jdm.de
Email* ad.schulung@jdm.de	Language* English
Organization* JDM Smila Care, Smila Training X	
☒ View care organizations	☒ Edit care organizations
☒ View administrators	☒ Edit administrators
☒ View caregivers	☒ Edit caregivers
☒ View patients	☒ Edit patients
☒ Use video call	☒ Can login to device
Notification channels ☐ Sms ☐ Telegram ☒ Email	

*Indicates required field

CANCEL UPDATE

3.5 Change blister center

If the patient changes the blister center, the blister center settings must be changed in the cloud. First, follow the instructions to edit an account. Select “Patient” as the account type. Select the patient and then click “Edit”.

Edit patient Max Mustermann

Photo
Photo (jpg, png, bmp)

Prenom

First name *
Max

Last name *
Mustermann

Birthdate *
01.01.1950

Language* ▼

Social Security number

Phone

Mobile phone

Country
Germany

City
Murr

Street
Carl-Benz-Straße 16

Zip Code
71711

Email

Blister Center*
Pharmac X ▼

Department*
Smila Training X ▼

Call Center
Smila Care-0049714481210 X ▼

Client ID
264

Device ID
Smila-00017

*Indicates required field

CANCEL UPDATE

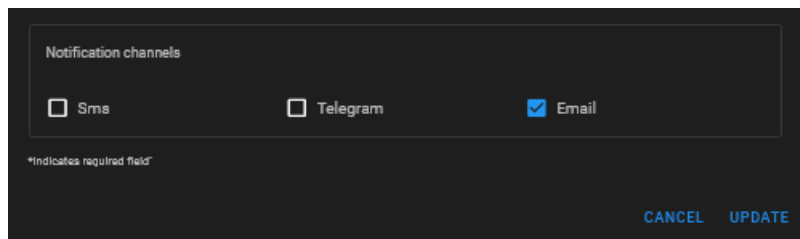
You can now set the right blister center in the drop down menu.

3.6 Set notification channel

The notification channel can be set when an account is created or when it is edited.

To do so, access the account type under the “Administrative” menu option and select the relevant account, or create a new account.

The boxes shown below for the notification channels are shown on the bottom of the pop-up window.



Notification channels

☐ Sms ☐ Telegram ☒ Email

*Indicates required field

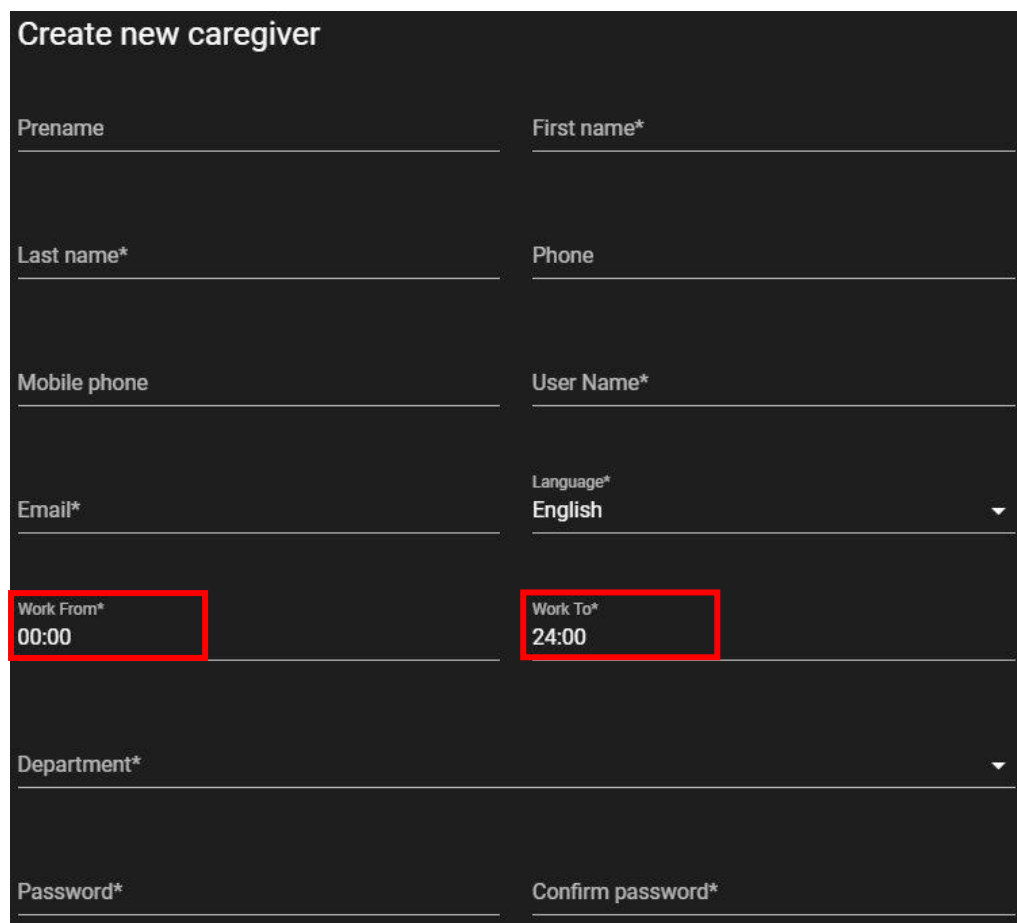
CANCEL UPDATE

For each account it can be decided whether the user wants to be notified via SMS, telegram or e-mail.

If no channel is selected, no notification can be sent.

For caregivers SMS-alerting can be adjusted to the working hours. Time based SMS –Alerting is accessibly using Administrative → Caregivers. It can be considered when creating a new caregiver or edit an existing one. To adjust the worktimes, you need to enter a starting time (*work from*) and an end time (*work to*).

Both fields are mandatory. They are prefilled with working shifts from 00:00-24:00 o'clock. This ensures that existing caregivers and the ones which aren't adapted will receive their notifications as usual: 24/7.



Create new caregiver

Prenome	First name*
Last name*	Phone
Mobile phone	User Name*
Email*	Language* English ▼
Work From* 00:00	Work To* 24:00
Department* ▼	
Password*	Confirm password*

Time based alerting is only available for SMS alerts. It is possible to use email or telegram alone or in addition. This will lead to the following situation:

- Chosen channels: SMS, Telegram or/and Email. The caregiver will receive the alerts via SMS in the selected shift times. Email and Telegram alerts will be received 24/7.

- Chosen channels: Telegram or/and Email. Alerts will be received 24/7. Editing the work times has no effect.
- SMS- Alerts that are sent during non-working times, will not be received by the specific care giver.

3.7 Adjustable Taking Time Windows

Taking time windows can be defined individually for each patient. Taking time windows are accessible using Administrative → Patients. You can adjust it when creating a new care client or you can edit an existing one.



To adjust the taking time windows, enter a *pre taking time window* and a *taking time window*. Default values are 30 minutes (pre taking time window) and 60min (taking time window).

- Pre taking time window: Time before the actual taking time during which medication can already be requested. Available time windows: 0,15,30,45,60 minutes.
- Taking time window: Time after the actual taking time during which medication can still be dispensed. Available time windows: 10,15,30,45,...,180 minutes.

Create new patient

Photo (jpg, png, bmp)

Prenome

First name* Last name*

Birthdate* Language* English

Social Security number* Phone

Mobile phone Country

City Street

Zip Code Email

Pre taking time window in minutes 30

Taking time window in minutes 60

- Changing the *pre taking time window* will affect inserted as well as upcoming rolls.

- Changing the *taking time* window will only affect upcoming rolls. Workaround: Eject and Re-Insert the pouch roll.
- The notification "Client is about to miss medication" is not sent if the *taking time* window 10 mins.
- We do recommend the 10 minutes taking time window only to use for single taking times. If multiple pouches need to be dispensed and our support needs to intervene this can lead into pouches being missed.

3.8 Deleting an account

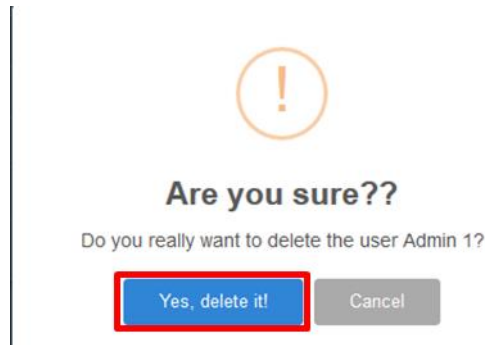
To delete an account, complete the following steps.

- Select "Administrative" (1)
- Select the account type; in this example "Administrator" (2)
- Search for the name of the account (3)
- Select the account to be edited (4)
- Select "Delete" (5)

The first screenshot shows the smila web interface. The top navigation bar includes 'Monitoring', 'Devices', 'Administrative', 'System management', and 'Communication'. The 'Administrative' menu is highlighted with a red box and labeled '1'. A dropdown menu is visible, showing 'Organizations' and 'Administrators' (labeled '2'). Below the dropdown, there are search and filter options. The second screenshot shows the 'Administrators' page. A search bar at the top contains the text 'Admin' (labeled '3'). Below the search bar, there are buttons for 'DETAILS', 'EDIT', 'NEW', 'DELETE' (labeled '5'), and 'REMOVE FINGERPRINTS'. A table of administrators is displayed below. The first row, 'Admin 1' (ID 270), is selected with a checkbox (labeled '4').

#	Administrator name ↑	Login	Email	Fingerprints
☒	270 Admin 1	admin.1@admin.com	admin.1@admin.com	0
☐	271 Admin 2	admin.2@admin.com	admin.2@admin.com	0
☐	272 Admin 3	admin.3@admin.com	admin.3@admin.com	0
☐	273 Admin 4	admin.4@admin.com	admin.4@admin.com	0
☐	274 Admin 5	admin.5@admin.com	admin.5@admin.com	0

A confirmation window will open asking whether the account should really be deleted. Confirmation will delete the account.



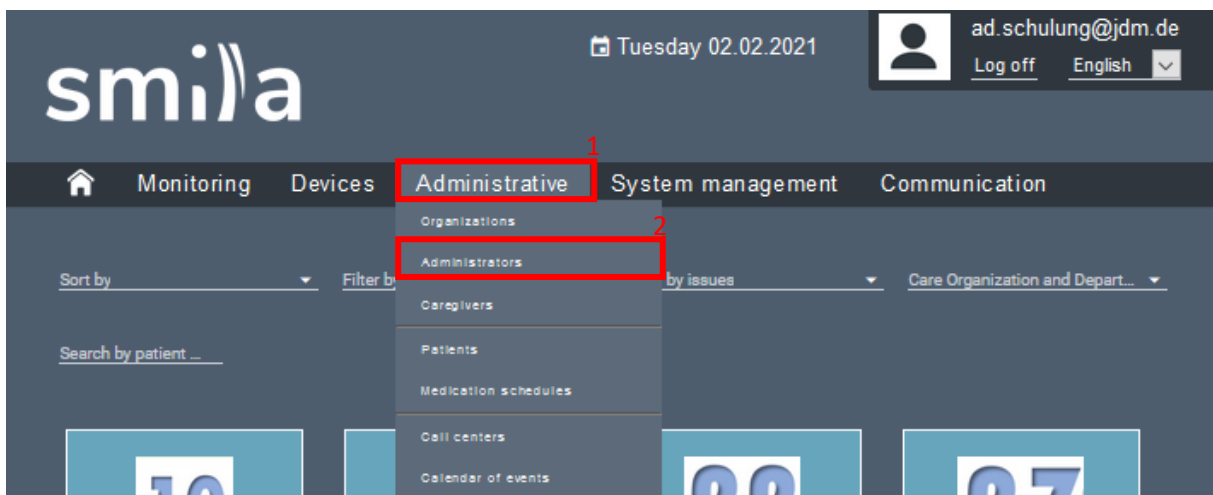
3.9 Removing fingerprints

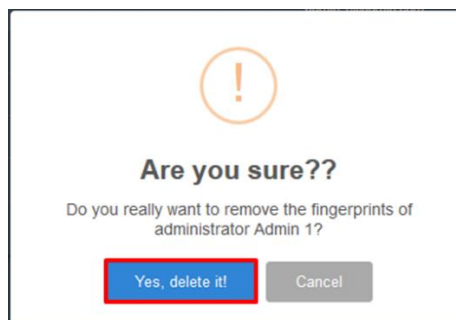
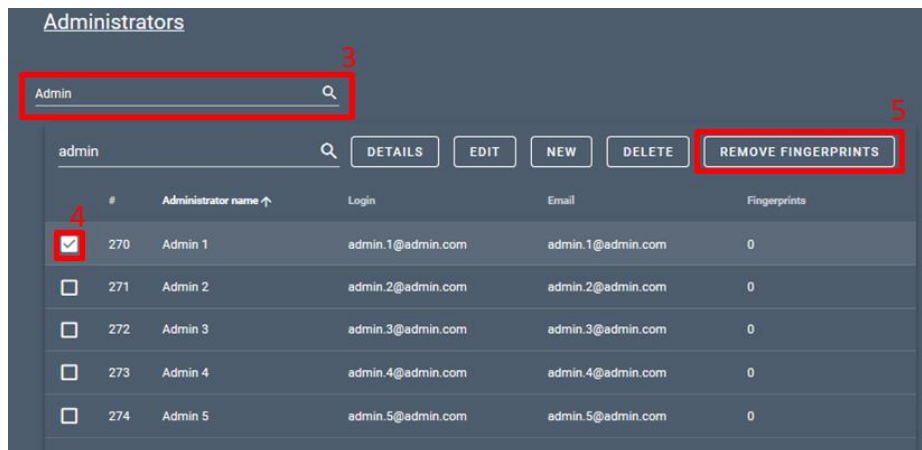
Caregivers and administrators can save fingerprints to simplify logging into the device. The instructions for saving fingerprints are provided in the user manual for the SMILA device.

If the saved fingerprints are deleted, the user will only be able to log into the device with their user name and password. If multiple fingerprints are saved, it is only possible to delete all fingerprints. It will not be possible to restore the saved fingerprints; they must be read in via the device once again.

To delete the fingerprints, complete the following steps:

- Select "Administrative" (1)
- Select the account type; in this example "Administrator" (2)
- Search for the name of the account (3)
- Select the account for which the fingerprints should be deleted (4)
- Select "Remove fingerprints" (5)

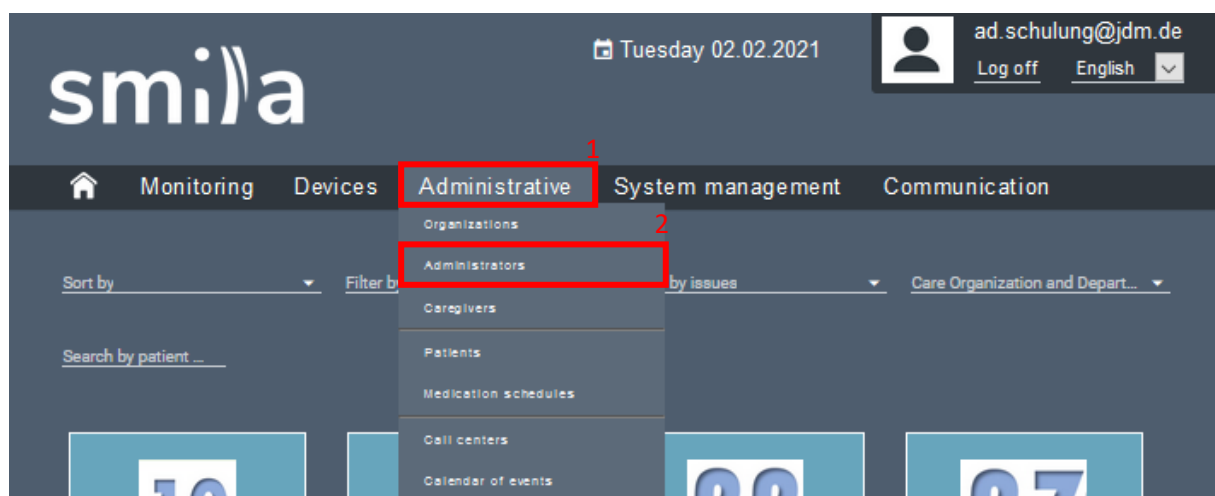


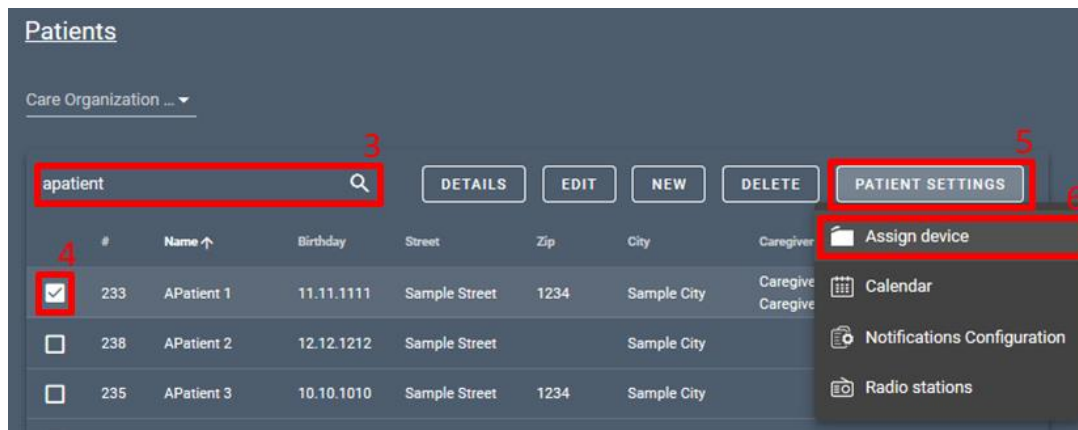


3.10 Assigning devices

To use the SMILA device, each patient must be assigned a device. To do so, complete the following steps:

- Select “Administrative” (1)
- Select “Patients” (2)
- Search for the name of the patient (3)
- Select the patient to whom a device should be assigned (4)
- Select “Patient settings” (5)
- Select “Assign device” (6)





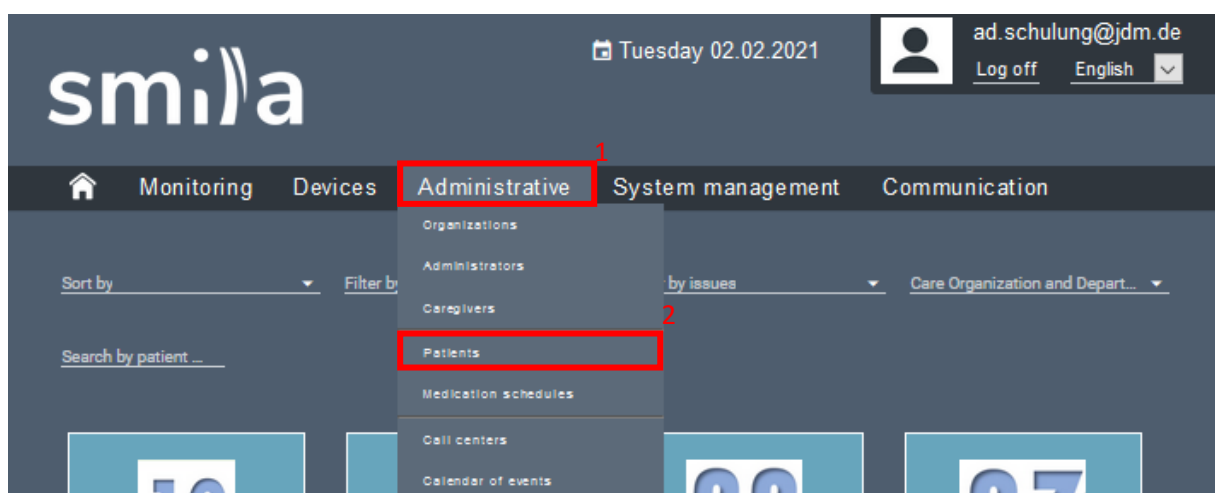
- Select the relevant device by choosing the serial number from a drop down list, and confirm the device assignment.

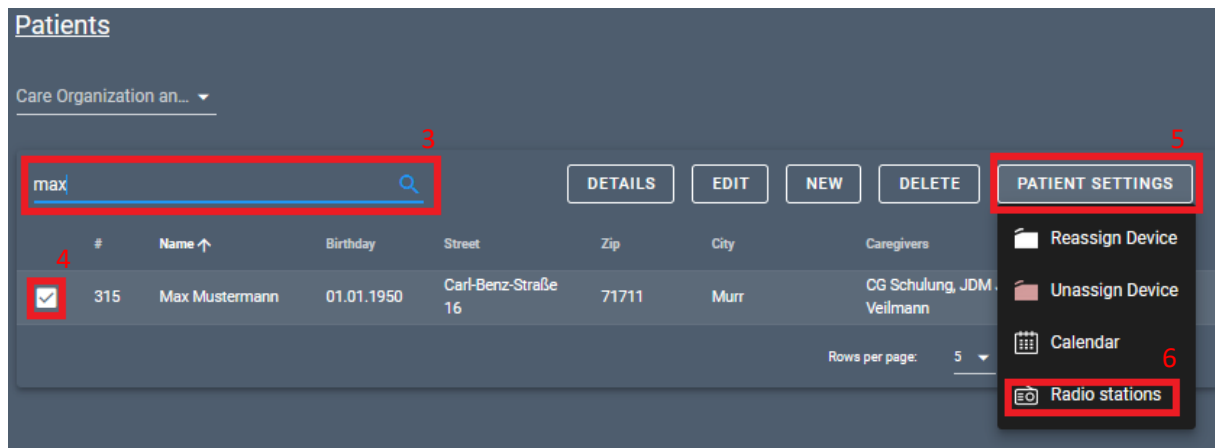


3.11 Setting the radio station

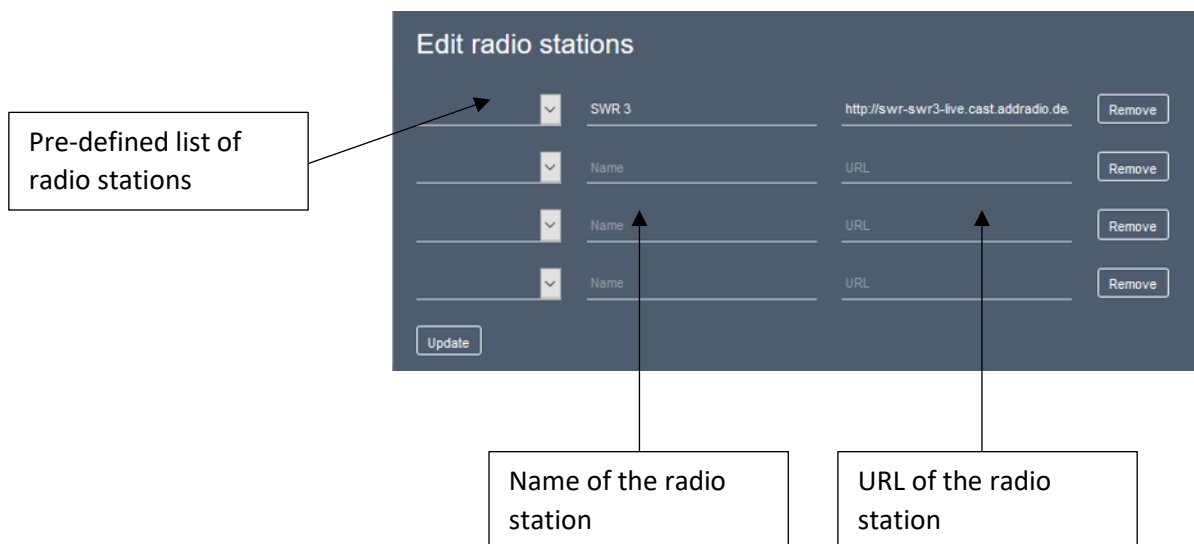
The patient can listen to the radio using the SMILA device. To do so, however, the radio station must be set in the cloud. The following steps are required to set a radio station:

- Select "Administrative" (1)
- Select "Patients" (2)
- Search for the name of the patient (3)
- Select the patient for whom the radio station should be added (4)
- Select "Patient settings" (5)
- Select "Radio stations" (6)





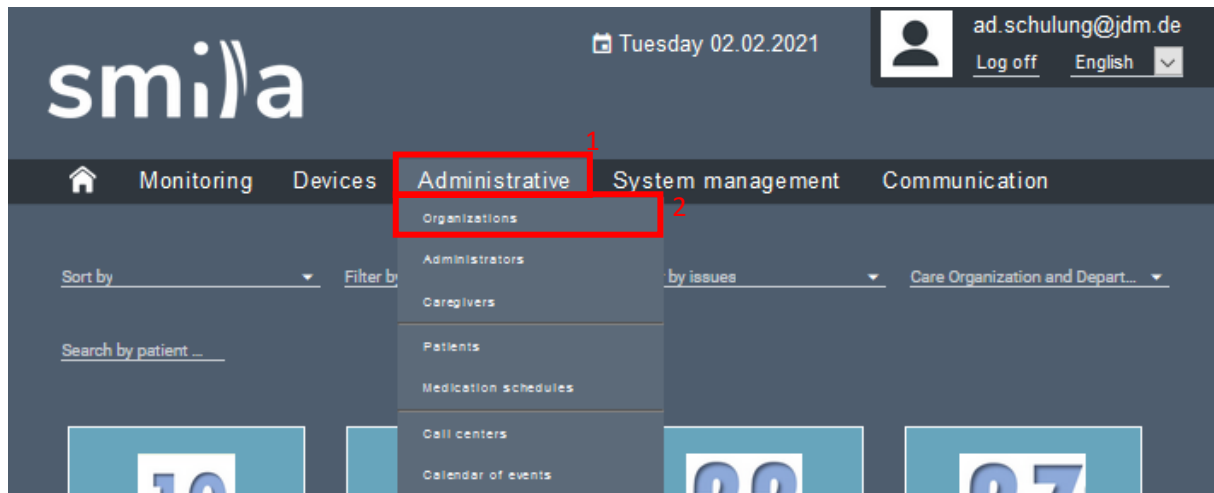
To set the radio station, select the desired radio station from a pre-defined list. Press “Update” to complete this step, after which the patient will be able to listen to the radio using the SMILA device.



3.12 Two Factor authentication

The two factor authentication can be activated individually for each organization. To activate the two factor authentication, complete the following steps:

- Select “Administrative” (1)
- Select “Organization” (2)



- Select the organization and then Edit

The screenshot shows the 'Edit organization Smila Care' form. The form has a dark background with white text. It contains several input fields with labels and values: 'Name*' (Smila Care), 'Country*' (Smila Land), 'City*' (Smila City), 'Street*' (Smila Street), 'Zip Code*' (12345), 'Phone*' (01 23456789), 'Fax', 'Email*' (Smila.test@jdm.de), 'Default Call Center*' (Vali 4.16.0.7-0000000000000000), and 'Default language*' (Finnish). At the bottom, there is a checkbox labeled 'TwoFactorAuthenticationEnabled' which is highlighted with a red box. Below the checkbox, there is a small text '*Indicates required field'. At the bottom right, there are two buttons: 'CANCEL' and 'UPDATE'.

- Select “TwoFactorAuthenticationEnabled”
- Select and “Update” to save

During login the user receives a SMS-Code to verify his identity.



The image shows a mobile application interface for SMILA Cloud-Login. At the top, the 'smila' logo is displayed in white on a dark blue background. Below the logo, the title 'Cloud-Login' is centered in a large, white, sans-serif font. A message in white text explains that an SMS-code was sent to the user's phone number '*****02' for security verification. Below this message, there is a label 'Enter SMS-code:' followed by a large, empty white rectangular input field. In the bottom right corner, there is a teal-colored button with the word 'Verify' in white text.

smila

Cloud-Login

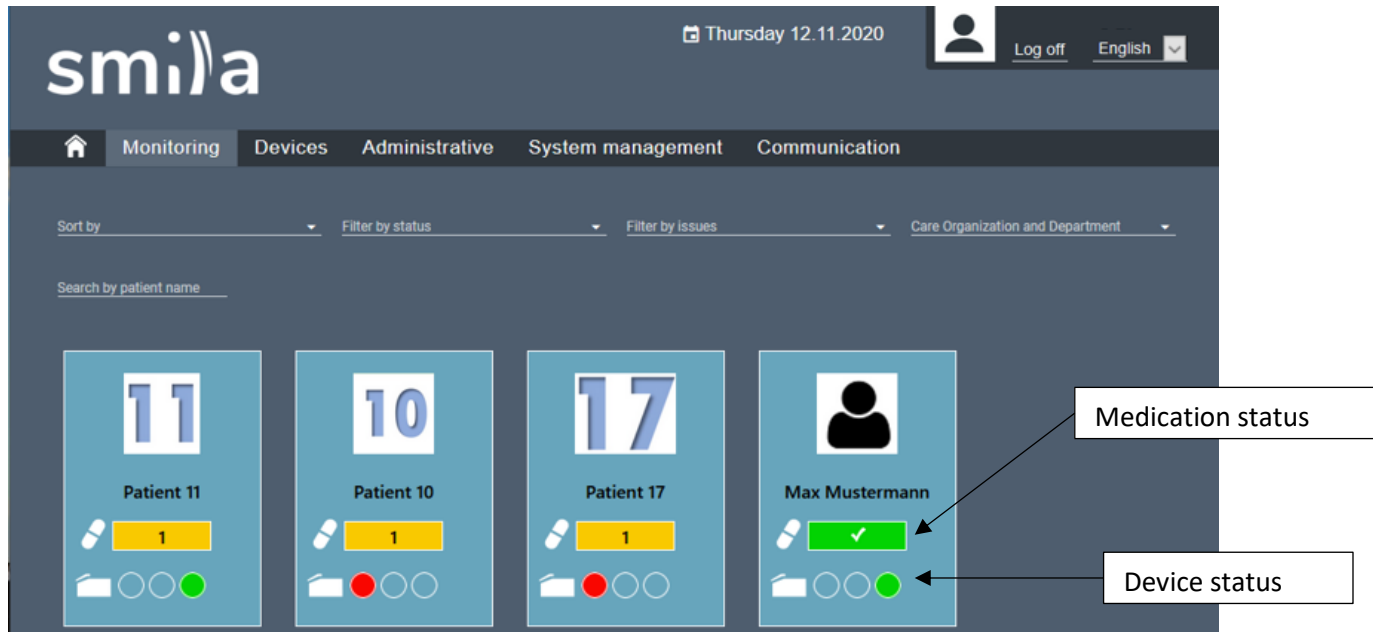
In order to keep your account safe, we sent SMS-code to your phone number: *****02. We need to be sure it was you who just tried to sign in.

Enter SMS-code:

Verify

4. Monitoring

The patient overview, also called Monitoring, displays all important information on the current medication status and device status for each patient at a glance.



The medication status indicates how many pouches have been missed since the drawer was emptied the last time.

- Green: No pouches missed
- Yellow: One pouch missed
- Red: 2 or more pouches missed

The caregiver or administrator can determine the number of pouches missed based on the colour and number displayed.

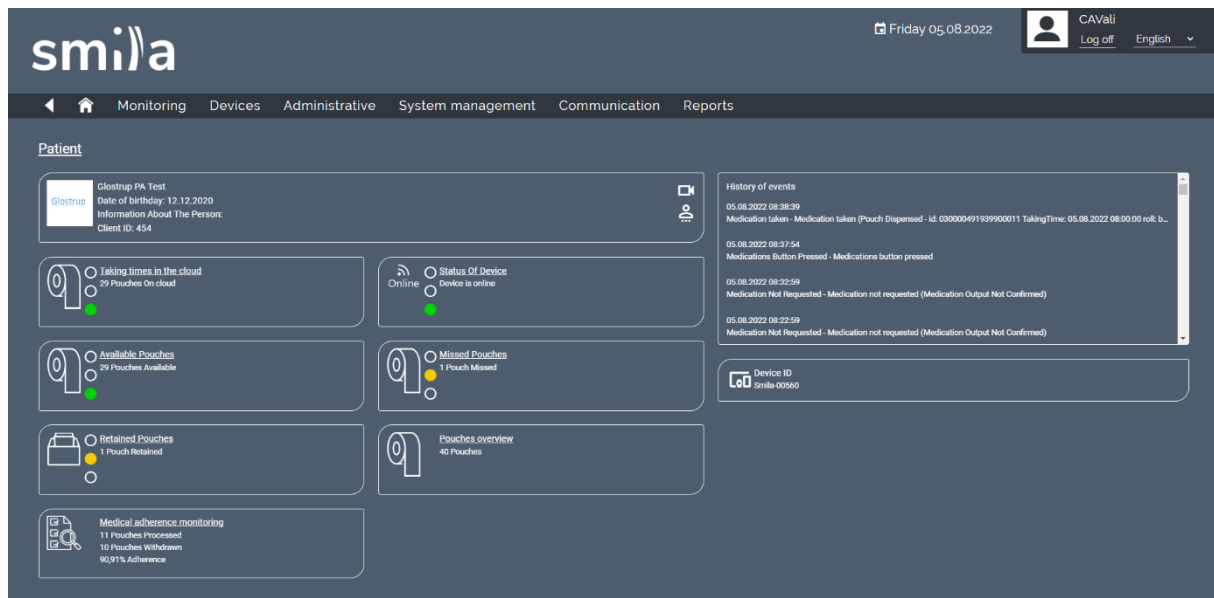
The device status indicates whether the device is free from malfunctions, or whether there is any fault and whether medications can continue to be administered.

- Green: everything OK
- Yellow: restricted functionality; however, the device is still able to dispense medications. One example of this status is that the device is in battery operation
- Red: there is a malfunction and the device is not able to dispense medications. However, red is also displayed when the device is switched off.

5. Patient details

The patient details open when the caregiver or administrator clicks on the patient in Monitoring.

Personal data such as the patient's name, address, date of birth, information on medication times, and various lists related to the pouches are displayed in the patient details. However, the device status is also displayed. In addition, the user can see which device is assigned to the patient and which last user or device actions were taken.



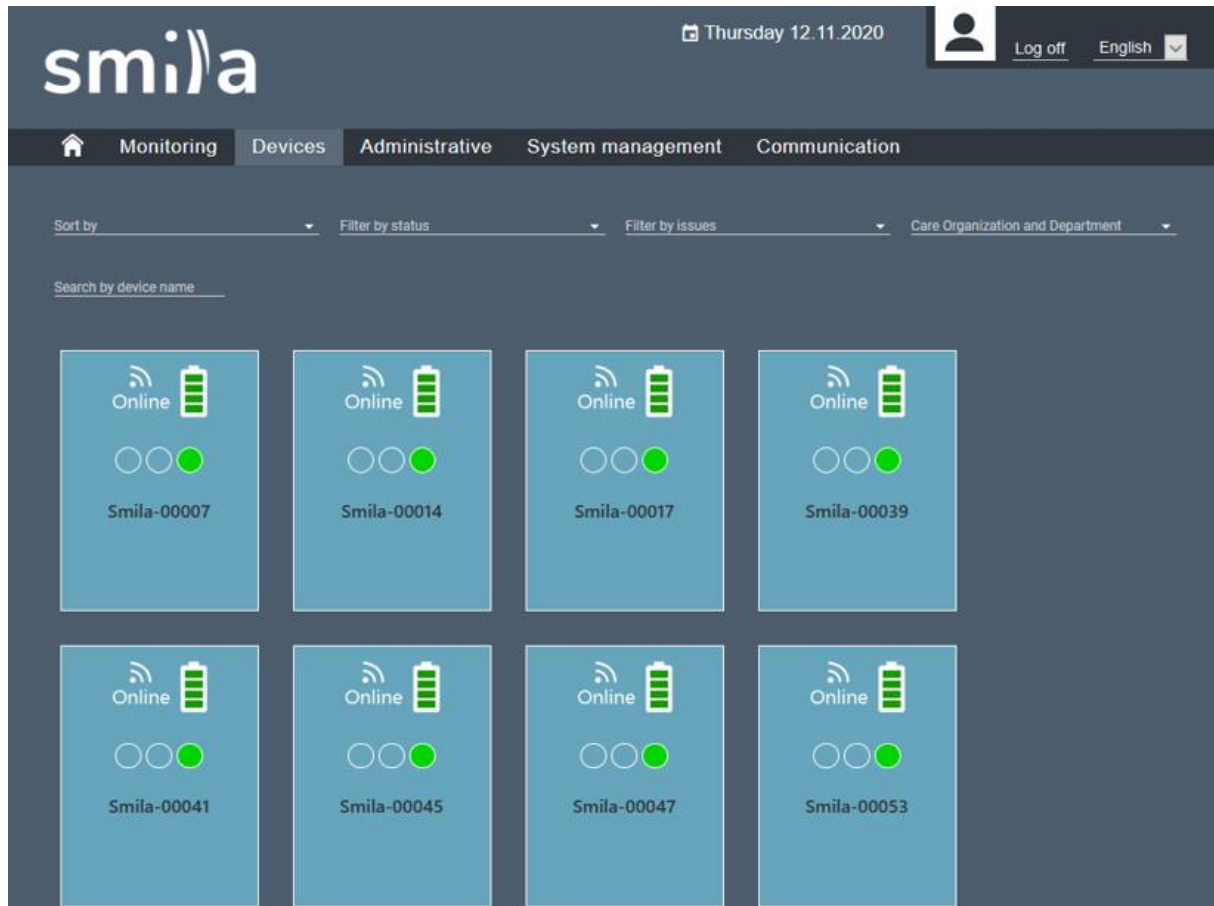
The following lists are included in the patient details:

- Taking Times in the cloud: Number of taking times saved in the cloud
- Available Pouches: Number of pouches inserted into the device
- Retained Pouches: Number of medications missed and dropped into the drawer
- Missed Pouches: Number of medications missed by the patient
- Medical adherence monitoring: Percentage calculated based on processed pouches and withdrawn pouches

Click the list to open an overview of all pouches, including the pouch ID and taking time.

6. Device overview

The device overview provides an overview of all devices within an . This view is used for technical information. It provides a direct overview of the device status and battery charge status. It also displays whether there is a connection between the device and the cloud, or whether the device is offline.



7. Device details

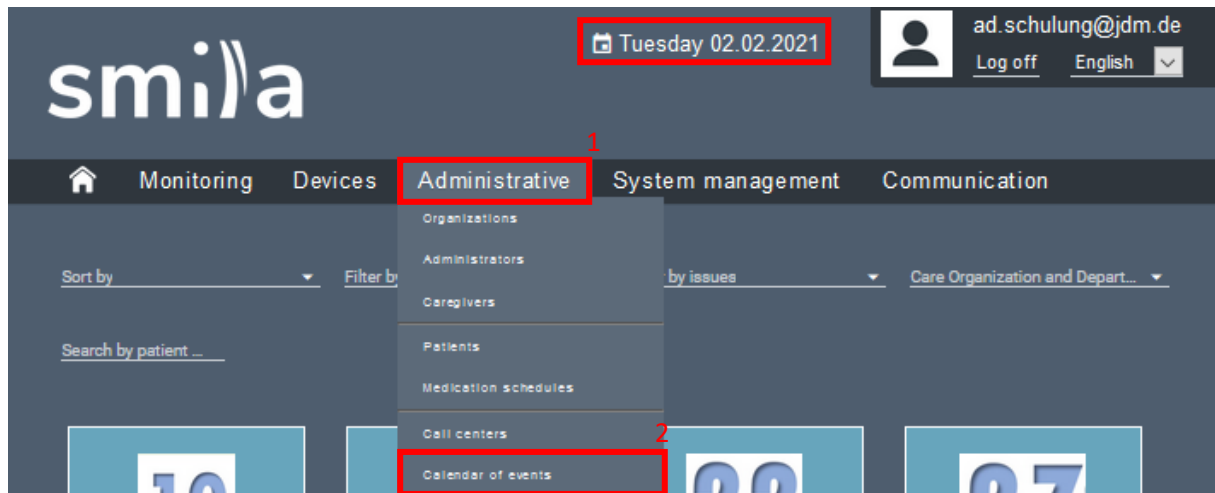
Same as for the patient overview, the user can access the device details by clicking on the device.

Like the patient details, this provides the user with information on the device itself such as the serial number, location and software version. However, it also displays various pouch lists.

Photo Scan is only visible for Super Admins.

8. Calendar

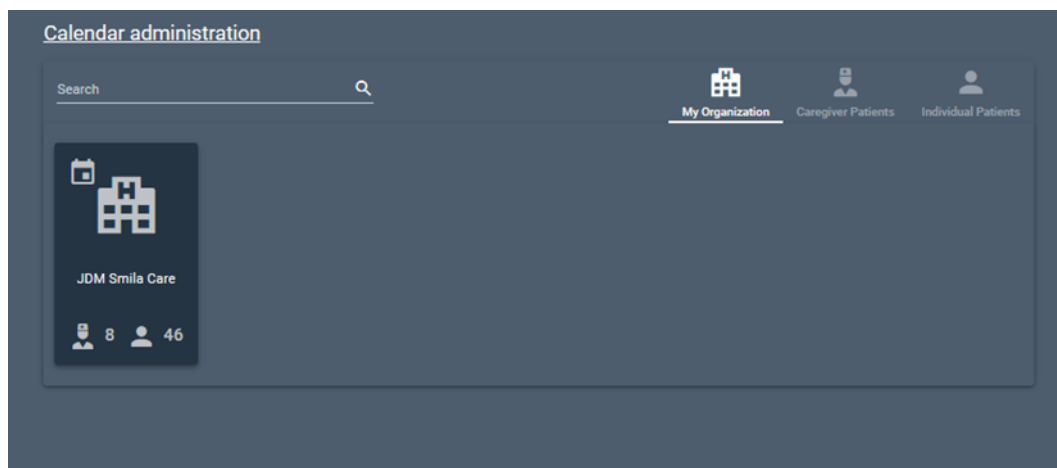
Access the calendar either by clicking the date in the cloud or selecting “Administrative” (1) and then “Calendar of Events” (2).



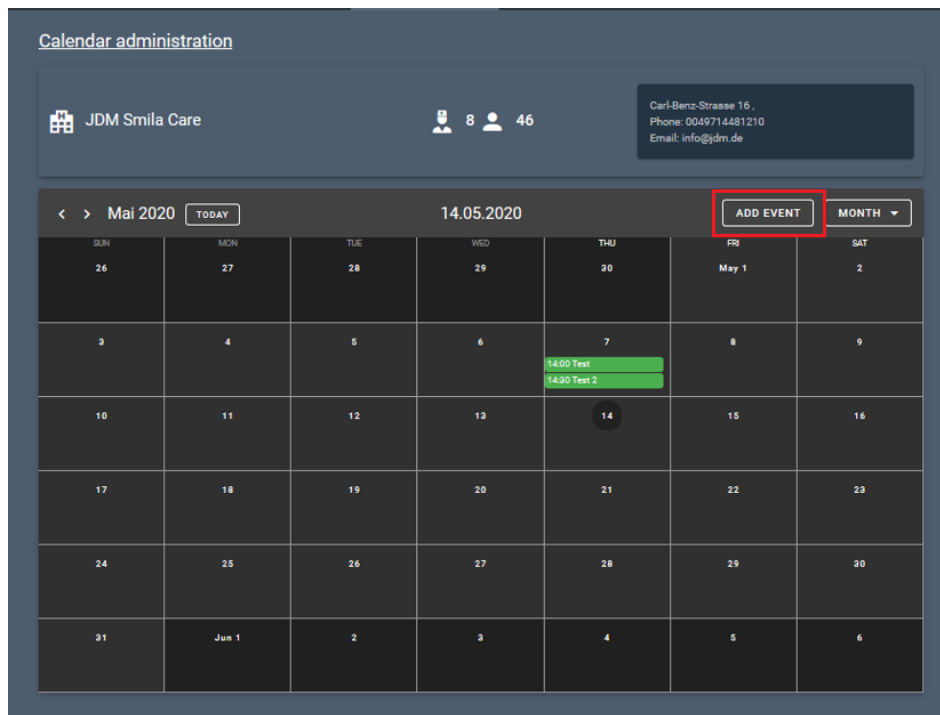
The calendar can be used to set events for the patient who is notified via the SMILA device.

Events can be set for the following categories:

- My Organization: Events are set organization-wide, meaning that all persons who belong to this organization will be reminded of this event
- Caregiver Patients: Events are only set for the patients assigned to the specific caregiver.
- Individual Patients: Events are only set for a specific patient.



To create a calendar event, select either the organization, caregiver or patient depending on the category. This example shows creating an event for the entire organization. The process for creating an event works the same for all categories.



If you want to create an event, first select the desired date and then “Add Event”. Another window will open where all information on the event can be entered.

The title is displayed both in the device app and in the calendar of the cloud. Further information can be added to the “Comment” field in addition to the title.

The person who creates an event can assign a category if it is desired that the event will be repeated or that a reminder will be sent. If it is necessary for the patient to actively confirm the event, this can also be shown. The confirmation will be shown in the patient history (see patient details).

9. Video communication

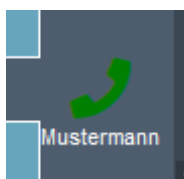
The cloud offers the option of contacting the patient via a video call. To do so, click the camera symbol in the patient details.



Access to the camera and microphone must be allowed for a successful video call. A notification window will appear on the computer, both for the camera and the microphone. The user must permit access to the camera and microphone.

It is possible to make both regular calls and video calls to patients. Please see the Smila device user manual for more information on how to make a video call with the device.

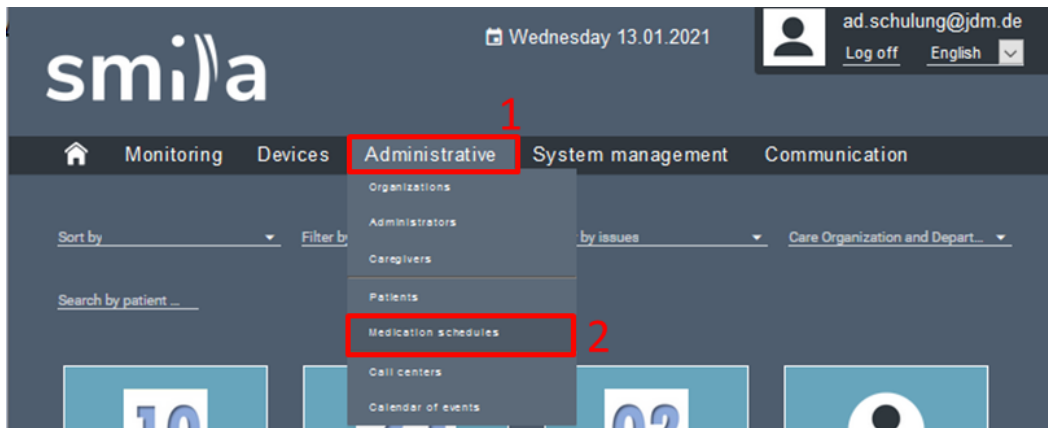
A phone receiver symbol and the last name of the patient are shown at the bottom left corner of the screen in the cloud when there is an incoming video call. Click this symbol to connect to the patient if access to the camera and microphone have been granted.



10. Manual data upload

It is also possible to directly upload medication taking times to the cloud. To manually upload data to the cloud, complete the following steps:

- Select “Administrative” (1)
- Select “Medication schedules” (2)



You will see all patients in your organization, and can view the following information at a glance:

- Patient information (patient ID, name, age, date of birth, blister center)
- Last taking time for the uploaded rolls
- Status:
 - Red: No data available
 - Yellow: Data available, but no roll added
 - Green: Data available and roll added.

Overview of medication schedules and pouch rolls

#	Name ↑	Age	Date Of Birth	Source	Blister Center	Roll end date and time	Status	Pouch Rolls/Medications
315	Max Mustermann	71	01.01.1950	Manual	Pharmac		●	
346	Patient 01	71	01.01.1950	Manual	Pharmac	30.01.2021 09:00	●	11.01.21 - 30.01.21 (60 TTs)

Select a patient for detailed information on their taking times, etc.

Select “Add pouch roll” to upload new data to the cloud.

Medication schedules and pouch rolls

MEDICATION SCHEDULES OVERVIEW PREVIOUS PATIENT NEXT PATIENT

Name: Max Mustermann Patient ID: 315 Birthdate: 01.01.1950 Blister Center: Pharmac Source: Manual

Pouch rolls

ADD POUCH ROLL EDIT POUCH ROLL DELETE POUCH ROLL

Roll ID Start date and time End date and time Taking Times Inserted

No data found

Rows per page: 10

Medication weekly template

Sunday Monday Tuesday Wednesday Thursday Friday Saturday

Pouches overview

Taking data and time ↑ Pouch ID Insert time Eject data

No data found

Rows per page: 10

Add pouch roll

Medication weekly template

SUNDAY MONDAY TUESDAY WEDNESDAY THURSDAY FRIDAY SATURDAY

Start date and time*
14.01.2021 06:00

End date and time*
26.01.2021 23:00

☐ With pouch id

*Indicates required field

CANCEL CREATE

Thursday

Time*
09:00

Time*
13:00

Time*
15:00

Time*
16:30

ADD ADDITIONAL FIELD +

☐ Apply template to each day

*Indicates required field

CANCEL **CONFIRM**

First, create a medication plan. To do so, click one of the weekdays shown and enter the taking times. If more taking times are required than those displayed, add as many fields as necessary. If not all taking times are required, remove the extra ones by clicking “Minus”.

If the taking times are the same for the entire week, you can transfer the entered taking times to all weekdays by selecting “Apply templates to each day”. If necessary, individual weekdays can also be edited. To complete the process, click “Confirm”.

Add pouch roll

Medication weekly template

SUNDAY MONDAY TUESDAY WEDNESDAY THURSDAY FRIDAY SATURDAY

15:00 09:00
16:15 12:00
15:00 15:00
16:30 16:30

Start date and time*
14.01.2021 06:00

End date and time*
26.01.2021 23:00

☒ With pouch id

First pouch id in roll*

Last pouch id in roll*

*Indicates required field

CANCEL **CREATE**

All entered taking times will be displayed, and you can enter the date and time of the first and last taking times. If the pouch IDs are available, you can also enter these, but this is not required. If you do not enter a pouch ID, an additional step will be required when inserting the roll (see the section Insertion after manual upload in the device user manual). Finally, confirm the entries by pressing “Confirm”.

You will return to the overview. When you select a roll, the individual taking times and (if available) the associated pouch IDs will be displayed.

Medication schedules and pouch rolls MEDICATION SCHEDULES OVERVIEW PREVIOUS PATIENT NEXT PATIENT

Name: Max Mustermann Patient ID: 315 Birthdate: 01.01.1950 Blister Center: Pharmac Source: Manual

Pouch rolls

ADD POUCH ROLL
EDIT POUCH ROLL
DELETE POUCH ROLL

Roll ID	Start date and time	End date and time	Taking Times	Inserted
☒ ec566368-e35c-41e8-b71c-95b0590f282f	14.01.2021 09:00	14.01.2021 16:00	3	☒

Rows per page: 10 1-1 of 1

Medication weekly template

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
				09:00	12:00	16:00

Pouches overview

Taking date and time	Pouch ID	Insert time	Eject date
14.01.2021 09:00	004309863000001	14.01.2021 14:40:16	
14.01.2021 12:00	004309863000002	14.01.2021 14:40:16	
14.01.2021 16:00	004309863000003	14.01.2021 14:40:16	

Rows per page: 10 1-3 of 3

In addition, you can also see when rolls are inserted and ejected in the overview. It is only possible to edit the roll before the roll is inserted for the first time. To edit, select a roll and then click “Edit pouch roll”. The entered data can also be deleted; however, the roll may not be inserted in the device at this time.

When deleting an existing roll the user gets a confirmation prompt. Only after confirmation, the roll is deleted.



Are you sure??

Do you really want to delete pouch roll for period from 03.11.2023 06:00 till 16.11.2023 06:00?

Yes, delete it!
Cancel



Deleted

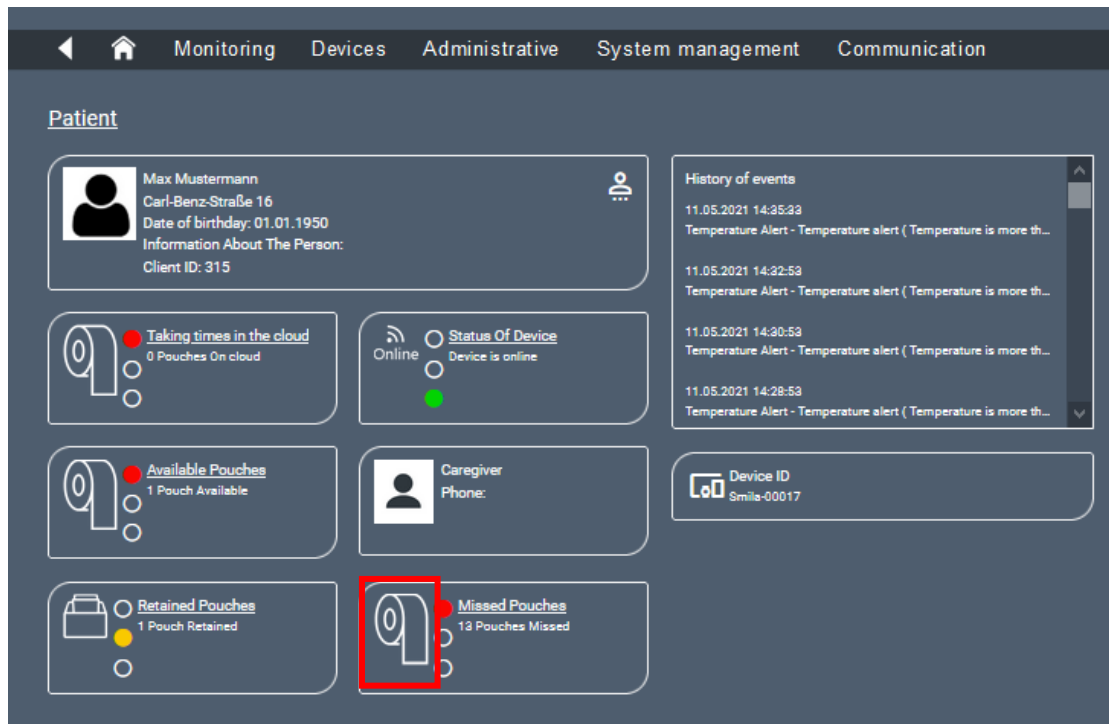
Pouch roll for period from 11.01.2024 06:00 till 24.01.2024 06:00 has been deleted successfully

OK

11. Remote dispense / drop

If the homecare client has missed one or more pouches and they are still on hold the medication can be remotely dispensed or dropped.

For remote dispensing and dropping we have two options, the caregiver can dispense or drop the pouch via the cloud or via the App on the device. For remote dispense via the App please look at the User Manual of the device. In this user manual we only describe how to dispense or drop the pouches remotely via the cloud.



For dispensing or dropping remotely, open the patient details and click on the roll in the field missed pouches.

Missed On Hold Pouches															
Pouch ID	Administer Date Time	Pharmacy Id	Pouch Provider Id	Take Status 1	Take Status 2	When Taken	Robot Status	Barcode Found	Before Hand	Happened Time	Time Requested	Time Withdrawn	Time Discarded	Roll I	
00364375600007	15.05.2020 13:00:00	8	3	past taking missed	on hold in robot		Too Long In Hold Position		False	15.05.2020 13:00:54				a6bcf4d8f4df360	

Click on the Pouch ID of the missed pouch.

Missed Pouch for : Max Mustermann
AdministerTime : 15.05.2020 13:00:00
Instruction :
Medications :
0 , Manual data upload
Total : 1
Pouch : 00364375600007
Pouch ID : 13711
Take Status 1 : past taking missed
Take Status 2 : on hold in robot
Robot Status : Too Long In Hold Position
PouchProvider : Pharmac
Time Retracted :

Drop
Dispense

Select if the pouch should be dropped or dispensed. If dispense is selected the patient has to request the medication before it is dispensed.

If more than one pouch is missed at the same time, the selected action will be taken for all missed pouches.

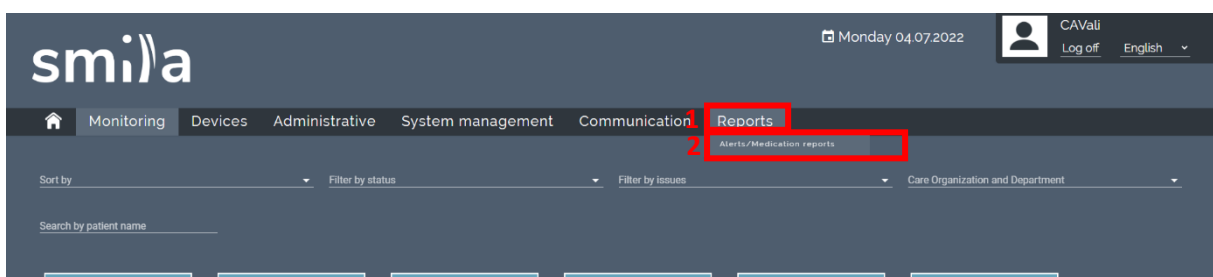
12. Reports

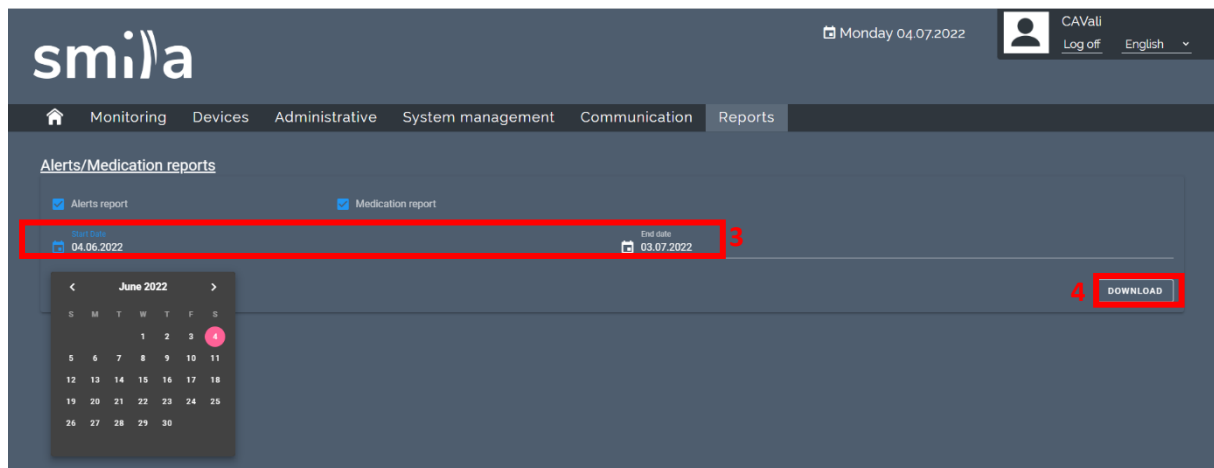
12.1 Medication Report

The reporting feature is visible for company admins. Reports contain information about how many pouches were taken by a patient over a selected time period.

To create a report, complete the following steps:

- Select "Reports" (1)
- Select "Alerts/Medication reports" (2)
- Enter a Start and End date (3)
- Select "Download" (4)
- Report is created as Excel file





Medication report.csv							
Suchen							
Datei Start Einfügen Seitenlayout Formeln Daten Überprüfen Ansicht Entwicklertools Hilfe							
Einfügen Ausschneiden Kopieren Einfügen Format übertragen Zwischenablage							
Schriftart Calibri 11 A A F K U Ausrichtung							
Zahl Standard Bedingte Formatierung Als Tabelle Zellenformatvorlagen Einfügen Löschen Formeln Zellen							
I11							
A	B	C	D	E	F	G	H
1	Device ID	Patient ID	Taken pouches	Not taken pouches	Given remotely pouches	Other given remotely pouches	
2	Smila-00015	434	0	0	0	0	0
3	Smila-00401	426	0	0	0	0	0
4	Smila-00406	424	0	0	0	0	0
5	Smila-00409	436	0	0	0	0	0
6	Smila-00412	421	0	0	0	0	0
7	Smila-00418	420	0	0	0	0	0
8	Smila-00422	425	0	0	0	0	0
9	Smila-00424	422	0	0	0	0	0
10	Smila-00434	428	0	0	0	0	0
11	Smila-00435	427	0	0	0	0	0
12	Smila-00554	435	0	0	0	0	0
13	Smila-00560	432	0	0	0	0	0
14	Smila-00561	433	0	0	0	0	0
15	Smila-00568	423	0	0	0	0	0
16							
17							

12.2 Installation Report

Installation report, that is created when assigning a patient to a device is stored in the cloud. The installation reports can be accessed by super admins in the cloud.

To download a report, complete the following steps:

- Select "System management"
- Select "Installation reports"
- Select "Download"
- Report is downloaded

Friday 05.08.2022

MSTJDM

Log off
English

Monitoring
Devices
Administrative
System management
Communication

UPDATE DEVICES
REBOOT DEVICES
SERVICE PACK
UPDATER PACK
INSTALLATION REPORTS
LOCK DEVICES

Filter by software package name

Organizations

SEND SECURE HASH TO ALL CLIENTS

SWITCH OFF DISPENSE BEFOREHAND

Select all

Search

SCHEDULE UPDATE

UPDATE UPDATER

	#	Device ID ↑	Time sent	Time scheduled	Update made on	Last update	Service pack name	App version	OS version	Firmware version	Updater Version
☐	1000003601	.									
☐	1000003591	*									
☐	1000003181	00090									
☐	1000003771	00238	25.11.2021 11:26	25.11.2021 11:26			4.11.0.0a				
☐	1000002641	avida mirak test 01						3.2.0.0			
☐	1000002881	avida mirak test 03	17.07.2020 04:43		✓			3.2.3.0			
☐	1000002891	avidsare mirak test 01									
☐	1000002321	Avidsare-Test-001									
☐	1000002811	Avidsare-Test-002									
☐	1000003351	Dfran									

Rows per page: 10

1-10 of 217

Friday 05.08.2022

MSTJDM

Log off
English

Monitoring
Devices
Administrative
System management
Communication

UPDATE DEVICES
REBOOT DEVICES
SERVICE PACK
UPDATER PACK
INSTALLATION REPORTS
LOCK DEVICES

Search

Q

#	Device ID	Creation date ↓	Download
51	Smila-00180	03.08.2022 15:54:13	
50	Smila-00180	03.08.2022 15:40:36	
49	Smila-00180	03.08.2022 15:33:35	
48	Smila-00180	03.08.2022 14:54:01	
47	Smila-00509	03.08.2022 13:44:09	
46	Smila-00180	03.08.2022 12:07:21	
45	Smila-00560	02.08.2022 15:14:11	
44	Smila-00561	02.08.2022 15:13:01	
43	Smila-00058	26.07.2022 11:10:34	
42	Smila-00436	26.07.2022 16:38:39	

Rows per page: 10

1-10 of 81

Inspection Report Installation SMILA-MD1

Person performing Installation	MSTJDM
Serial number of device	Smila-00180
Client-ID	464
Date of installation	03.08.2022

Installation instructions	Check
Device is not placed in a closed space such as cupboards	☒
Ventilation slots on both sides are not covered	☒
The gap between the device and the wall is at least 5 cm	☒
The device is not placed right above a heat source	☒
The device is not placed in direct sunlight	☒
The device is placed in a way that the main power supply can be disconnected effortlessly by pulling the power cord out of the outlet	☒

I hereby declare, that I checked all the tasks mentioned above and that the device is correctly installed according to these instructions.

13. Notification obligation

Patients or device users are obligated to contact the manufacturer and/or local agencies in case of a serious incident.

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

A ticket inquiry can also be created directly using the following link:

<https://jdm6121.zendesk.com/hc/en-us>

14. Declaration of conformity



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 <i>manufacturer</i>	JDM Innovation GmbH Carl-Benz-Str. 16 71711 Murr Germany
Produkt <i>product</i>	Medical Dispenser SMILA MD-1
Basis UDI-DI <i>Basic UDI-DI</i>	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 <i>Medical device</i>	Klasse I (Regel 1 und 13, Anhang VIII (EU) 2017/745) <i>class I (rule 1 and 13, Annex VIII, (EU) 2017/745)</i>
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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:

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