



## **User manual and systems documentation**

Generation 1.0 December 2021

### **DignaCare Solution**

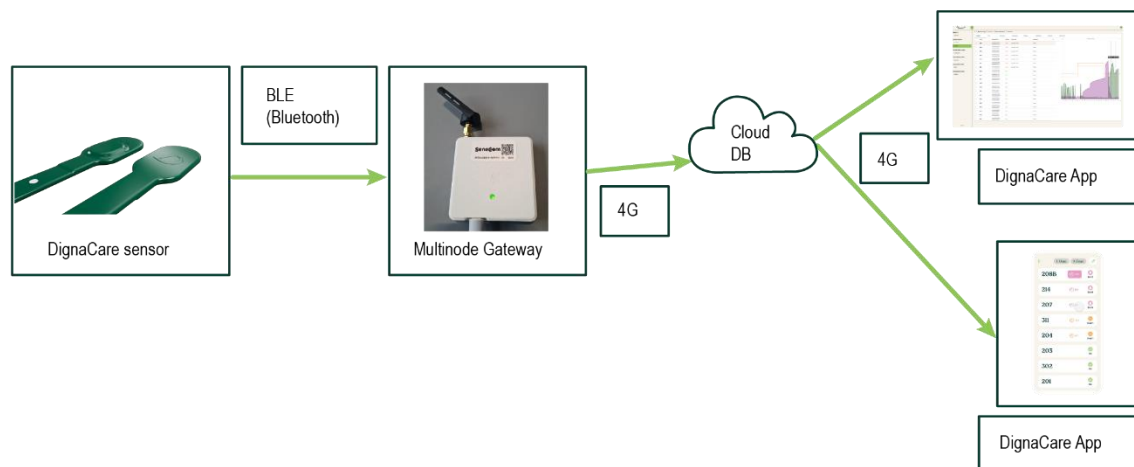
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# 1 Introduction to DignaCare

DignaCare is a welfare solution. The system is built from several independent units and components, connected by signaling and data transportation systems, using wireless communication. When connected, the units work as an integrated solution. The main components are the sensor devices, the Cloud solution, and the User App.

## 1.2 Systems Overview



## 2 DignaCare Sensor Device

The sensor device is designed to be mounted on the outside of any incontinence product. The sensor device contains four sensors, designed to monitor humidity, temperature, movement, and orientation of the sensor device. Data are collected by a micro controller (MC) located on the top of the sensor device. Data are sent wirelessly to a Gateway, by using BLE (Blue Tooth Protocol) communication.

### 2.1 Gateway

The Gateways have configuration to transmit data from multiple BLE devices by using mobile data (4G) to the DignaCare cloud (Database).

The Gateway is a standalone device and not a part of the DignaCare Solution. Gateways have not been developed and are not produced by SensCom. Gateways are standard products, but minor adjustments are required to establish communication between the sensor device and the open net. Gateways will have separate and independent user

manuals and product documentation, issued by the Gateway producer. Reference is made to any producer's user manual and web pages for more information.

Based on 4G coverage and customer preferences, Gateways will normally be delivered to the user by SensCom, when needed. When DignaCare is delivered as a service from SensCom, the Gateway according to customer preferences will be part of the services that SensCom provide to customers.

## 2.2 Database

The database contains sensor data and meta data. The sensor data are sent to the SensCom Cloud solution (Azure database) and then forwarded to the SensCom CouchDB (database) where all the data are stored together with the meta data from the Configuration manager, linking the users to data, collected by the sensors on the sensor device. The data will then be processed using one or more algorithms, designed to understand and monitor user data and to trigger alarms and notifications to care personnel.

## 2.3 DignaCare app

The DignaCare App will receive notifications and alarms from the database. Alarms and notifications are triggered and managed by parameters and algorithms defined and configured to match the preferences of everyone. Configuration is vital to secure correct and relevant use of the algorithms.

The DignaCare Application can be found in AppStore and Google Play. Before DignaCare can be used it will be necessary to download the application, to be connected to internet and to be able to access the application on a handheld device (mobile phone, tablet, or iPad).

*Google Play Store*

<https://play.google.com/store/apps/details?id=net.dignacare.prod>

*Apple App Store*

<https://apps.apple.com/no/app/dignacare/id1585769204>

## 2.4 DignaCare Management Application

The DignaCare solution has a management application interface (Superuser interface). The Superuser interface is normally defined as a restricted part of the system and developed for administrative users to influence parameters and configurations in the system. The Superusers can normally define specifications for relevant diapers that are in use and select individual alarm triggers for users in need of special care and attention.

Detailed descriptions and specifications relevant to the administrative solutions, can be found in the separate chapter **DignaCare Management Application**, or a short user manual can be found here: <https://dignacare.com/quickstart/slik-bruker-du-adminportalen/>

<https://portal.dignacare.net>

### 3 Safety and Warnings

DignaCare is not designed to be used as a standalone product. DignaCare is developed to be used together with, and to be mounted on the outside of an incontinence product. DignaCare can only operate, and have the intended effect, when an incontinence product is used correctly, either during day and night, part of the day, at night or as a temporary assistance over a limited period. DignaCare will not work as intended if multiple incontinence products are used in layers and not according to manufacturer specifications.

DignaCare will monitor and make notifications and alarms when the incontinence product is defined to be ready to be changed.

**The sensor device should never be:**

- *Used inside an incontinence product*
- *Mounted directly on underwear*
- *Fixed directly to human skin*
- *Be placed in any openings of the human body*

DignaCare is designed to operate according to guidelines made by the Medical Device Coordination Group, Document MDCG 2021-24, The DignaCare Solution and the sensor device has been classified as a Medical Device class 1 product.

The classification of medical devices is a risk-based system considering the vulnerability of the human body and the potential risks associated with a device. The 'classification rules' can be found in Annex VIII of Regulation (EU) 2017/745 on medical devices (MDR) established by Article 103 of Regulation (EU) 2017/745. They correspond, to a large extent, to the classification rules established by the International Medical Device Regulators Forum (IMDRF) in the guidance document GHTF/SG1/N77:20121.

The DignaCare Solution is developed to be a supplement and improvement to existing routines and policies in institutions or environments run by trained and professional care personnel. The solution is simple to use and developed to be intuitive for the employee's care personnel. However, all employees care personnel must be trained and educated to secure correct use.

To assist care personnel and institutions DignaCare has developed a comprehensive collection of educational platforms to educate health care works in correct use of DignaCare. Education is available through SensCom, SensCom web pages

[www.dignacare.com](http://www.dignacare.com),

our partners and on the DignaCare App. Additional training modules can be found at SkillAid. The SkillAid Application can be downloaded at Google Play Store or Apple App Store. To use the app a user must be created, and a QR-code scanned to get started:

*Google Play Store*

<https://play.google.com/store/apps/details?id=no.drops.app&hl=no&gl=US>

*Apple App Store*

<https://apps.apple.com/no/app/skillaid/id1214505146>

### **3.1 Cleaning and Maintenance Policies**

When DignaCare is in use the sensor device must be kept clean and maintained. SensCom has issued policies and recommendations that can be found in the user manual and in the separate cleaning policy, issued and updated by SensCom. Cleaning and maintenance policies are also a part of the educational platform offered by DignaCare.

[www.dignacare.com](http://www.dignacare.com)

### **3.2 GDPR and Data Processing**

The European Data Protection Regulation (GDPR) is applicable as of May 25th, 2018, in all member states to harmonize data privacy laws across Europe. *(EU) 2016/679 (General Data Protection Regulation)*

The General Data Protection Regulation (GDPR) offers a uniform, Europe-wide possibility for so-called 'commissioned data processing', which is the gathering, processing, or use of personal data by a processor in accordance with the instructions of the controller, based on a contract.

SensCom is collecting data about users. In this context SensCom is defined as a data processor or data sub-processor under GDPR. As a data processor SensCom is only allowed to process personal data based on documented instruction ("Databehandleravtale") from the controller (client). The instruction describes what type of personal data that will be collected, stored, and processed, as well as the object and purpose of the processing. In addition, there are obligations for the processor with respect to storage, maintenance, and deleting of data at end of contract. The instruction used by SensCom is based on the template and recommendations issued by Direktoratet for e-Helse in Norway.

The processing of personal data is always associated with a certain degree of risk. Companies can reduce the probability of a data breach and thus reduce the risk if they use encryption of personal data. In general, encryption refers to the procedure that converts clear text into a hashed code using a key, where the outgoing information only becomes readable again by using the correct key. This minimises the risk of an incident during data processing. Encryption is the best way to protect data during transfer and one way to secure stored personal data. As far as possible and practical, SensCom use encryption and hashing to protect personal data. SensCom also encourage clients and customers to avoid using "real" names and personal identification to identify users of DignaCare. The DignaCare solution is design to operate based on the use of user "alias".

### **3.3 Warning**

DignaCare Solution and the sensor device has been classified as a Medical Device class 1 product. This classification means that data provided by the sensors should never be used to or used as bases for a diagnose, to start, stop or change any prescribed treatment or any other medical decision. The DignaCare Solution is not designed, classified, certified, or meant to treat any human condition. Any incidents or errors to the product or the service provided by SensCom should be reported to SensCom without delay.

### **3.4 Risk Analysis**

Before DignaCare was released to the market a risk analysis has been performed. Before new products and updates are released to market or if any changes are made to the product a new risk report will be performed. The risk management shall be performed according to *ISO 14971:2007 "Application of risk management to medical device"*.

### **3.5 General Considerations**

Where SensCom use suppliers and production partners they are required (if possible) to produce the product according to the standards for a medical device class 1 and the suppliers should have certificates for ISO 9001 and/or ISO 14000. DignaCare Cloud is produced and defined easy to use, clear, to display correct colours and show as correct and accurate information for the users of the DignaCare Cloud as possible.

#### **3.5.1 Disposal and Replacement Policies**

The Sensor device contain electronic components moulded in a plastic coating, sealing all electronic components to protect the sensors and to make the Sensor device waterproof and washable. Inside the sensor device is a battery, design to support the sensor device to operate for a minimum of 12 months. The battery is non-rechargeable.

After a 12-month period of operation the sensor must be replaced. SensCom will constantly monitor remaining battery capacity on all sensors and send replacement sensors to contractual customers before end of battery life.

Both sensors with empty battery and all other sensors in need of replacement shall be returned to SensCom disposal and recycling centre operated by our production partner:

**Norautron AS**  
**Nedre vei 8**  
**Bygg 25,**  
**3192 Horten, Norway**

Return address is also clearly indicated on the original sensor packaging.

## 4 How to Use DignaCare Sensor device



Place the sensor with the white dots faced down on the outside of the diaper



Cover the sensor with the tape, and tear it off gently



Press gently to make sure the tape is in place, and then the diaper is ready to be mounted

## 5 DignaCare Mobile Application

### 5.1 Distribution Channels

The DignaCare App is developed for iOS and Android and can run on any handheld device like mobile phone, tablet, iPad etc. The App can be found:

*Google Play Store*

<https://play.google.com/store/apps/details?id=net.dignacare.prod>

*Apple App Store*

<https://apps.apple.com/no/app/dignacare/id1585769204>

APK (Android application PackAge)

Provided on request

**DignaCare Management Interface:**

*URL*

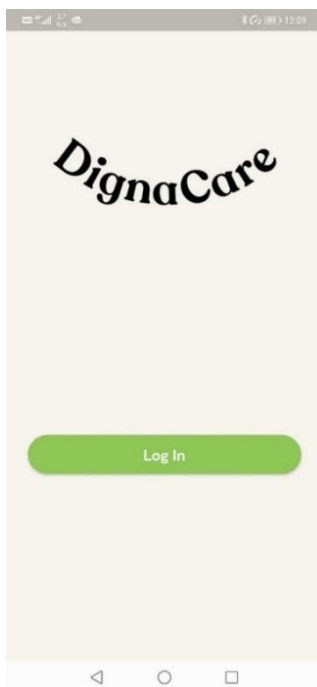
<https://portal.dignacare.net>

## 5.2 How to Use DignaCare App

- Download App from Apple Store or Google Play store
- Sign in with a common username and password for your department. You will receive this from the manager.
- Notifications: When you receive a notification, the service phone will vibrate and/or make a sound. The symbols in the app show the status of available sensors with color codes:
  - o Pink/red: Warning – Change within reasonable time
  - o Yellow: Soon – You need to start planning shifts
  - o Green: OK – There is no need to do anything
  - o Green: Recently changed – There is no need to do anything
  - o Blue: Snooze – The alarm has been delayed
  - o Grey: All inactive – All sensors is inactive
  - o Grey: One inactive – One sensor is inactive
  - o Grey: No sensors – No sensors linked to the Resident
  - o Grey: Unknown – Unknown problem

In the following section, the most important views from the DignaCare Mobile Application with description can be found.

### 1.1 Log in - Screen



**Main purpose:** Splash screen/first screen that the user sees upon entering the application without being authenticated.

Clicking on Log In takes the user through Microsoft Authentication, see [1.2 MSAL Screen](#)



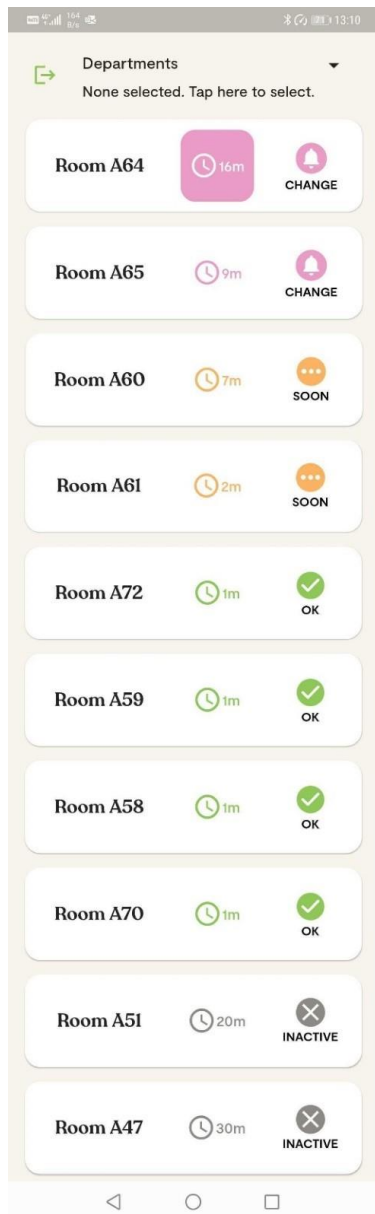
## 1.2 MSAL - Screen



**Main purpose:** Using Microsoft as an IDP (Identity Provider), the main purpose of this screen is to authenticate the users of the application.

Upon finishing the Authentication provided by the 3<sup>rd</sup> party, the user is presented with **2.1 Sensor Overview** screen.

## 2.1 Sensor Overview Screen



**Main purpose:** See the status of DignaCare Sensors.

The DignaCare Sensors are represented in a list view, showing the highest priority alarms and states at the top of the list. The priority is based upon time since alarm was triggered and/or status on the sensor.

The sensors are represented by an “Alias” – in this case, room numbers.

In the list view, the user can see when the alarm last changed state. If an alarm has reached the threshold level, and a threshold time duration, a box appears over the elapsed time to illustrate the time criticality of the alarm.

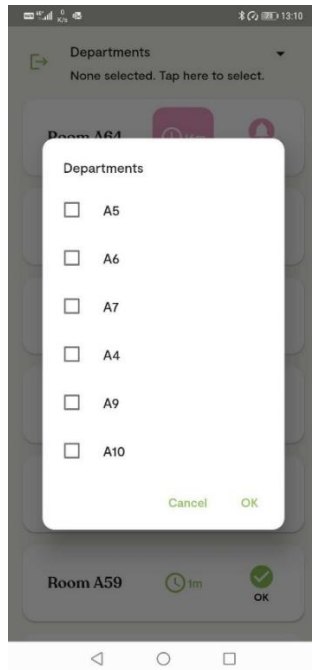
The icons change depending on the alarm state, to make it visually easier for the users to distinguish between the alarms. The icons are also represented by a color, that defines the different states:

- Pink/Red: Sensor has reached alarm level
- Yellow: Sensor is (about) reaching alarm level
- Green: Sensor is OK
- Green: Recently changed
- Blue: Snooze
- Grey: One is inactive
- Grey: All sensors inactive
- Grey: No sensors

The user can do three actions on this Screen

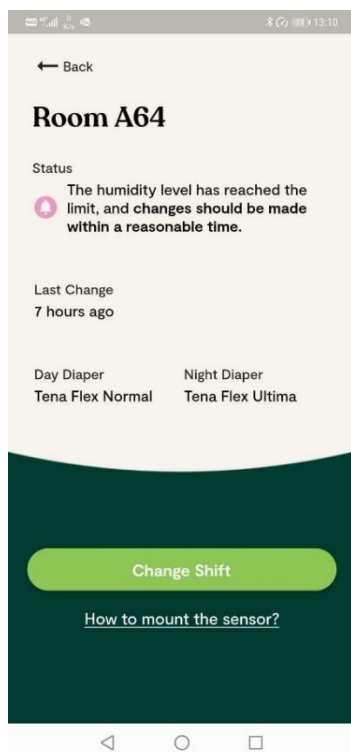
- Clicking on any item in the list takes the user to **2.2.1-4 Sensor Detail** screen depending on the state of the sensor
- Clicking on departments takes the user to **2.1.1 Department Selection** modal
- Clicking on the top left icon takes the user to **2.6 Log out** modal

### 2.1.1 Department Selection modal



**Main purpose:** Letting the user filter the **Sensor Overview** based on which department(s) the sensors are located.

### 2.2.1 Sensor Detail Screen – Alarm state



**Main purpose:** The following screen shows details about a sensor in an alarm state.

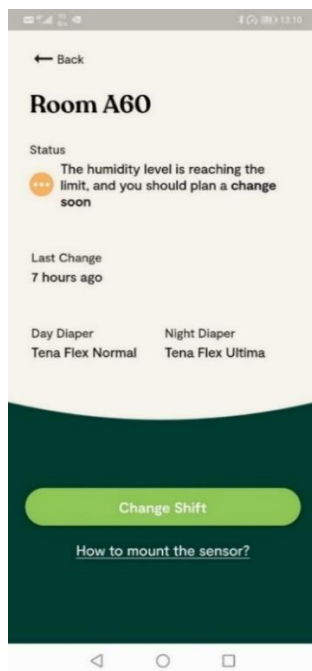
In general, for the views **2.2.1-2.2.4**, the user can see:

- A status messages
- Time since last change
- Diaper type
- Change button
- Guide on how to mount the sensor

The user can do three actions on this Screen:

- Clicking Back takes the user to **2.1 Sensor Overview**
- Clicking on *Change Shift* button takes the user to **2.3 Sensor Change** screen
- Clicking on “*How to mount the sensor?*” takes the user to **2.2.5 User Guide**

## 2.2.2 Sensor Detail Screen – Soon state

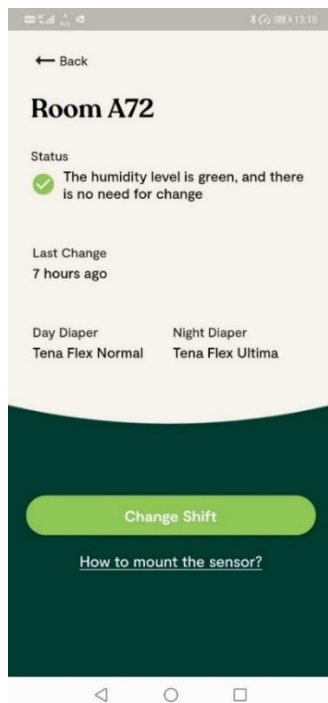


**Main purpose:** The following screen shows details about a sensor in a Soon state.

The user can do three actions, described in **2.2.1 Sensor Detail** Screen – Alarm state

The sensor does not change state if the user does not initiate the Shift-functionality.

## 2.2.3 Sensor Detail Screen – Clean state

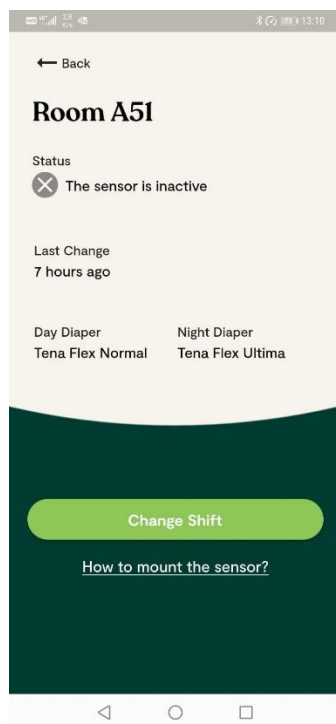


**Main purpose:** The following screen shows details about a sensor in a clean state.

The user can do three actions, described in **2.2.1 Sensor Detail** Screen – Alarm state

The sensor does not change state if the user does not initiate the Shift-functionality.

## 2.2.4 Sensor Detail Screen – Inactive state



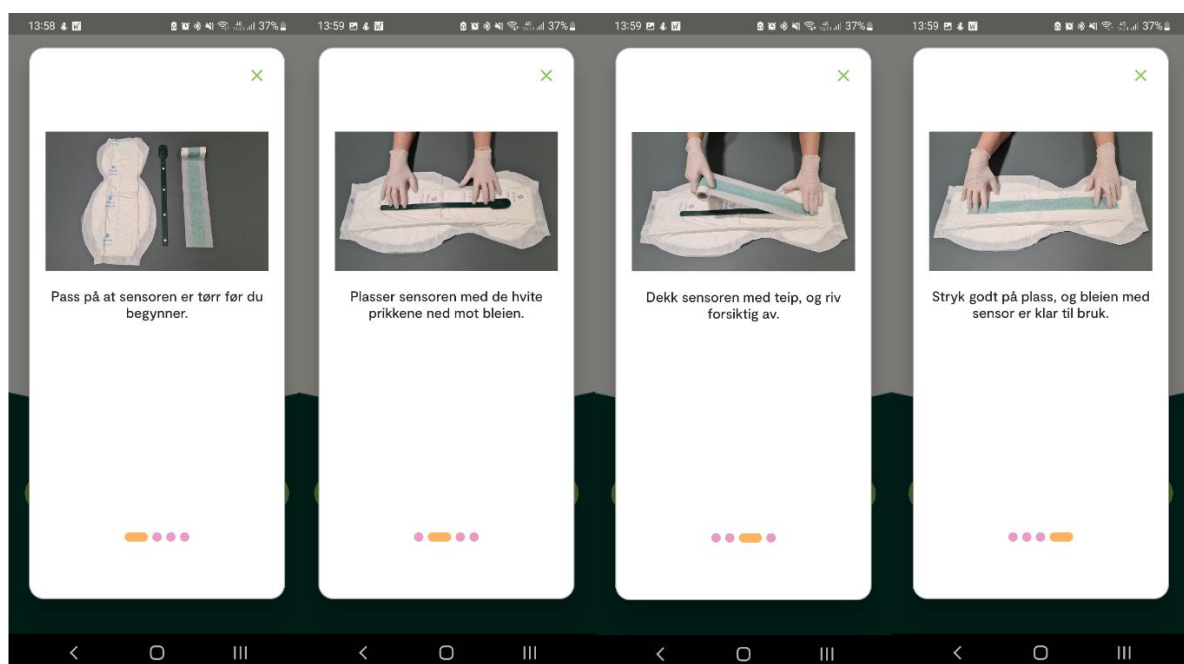
**Main purpose:** The following screen shows details about a sensor in an inactive state.

The user can do three actions, described in **2.2.1 Sensor Detail** Screen – Alarm state

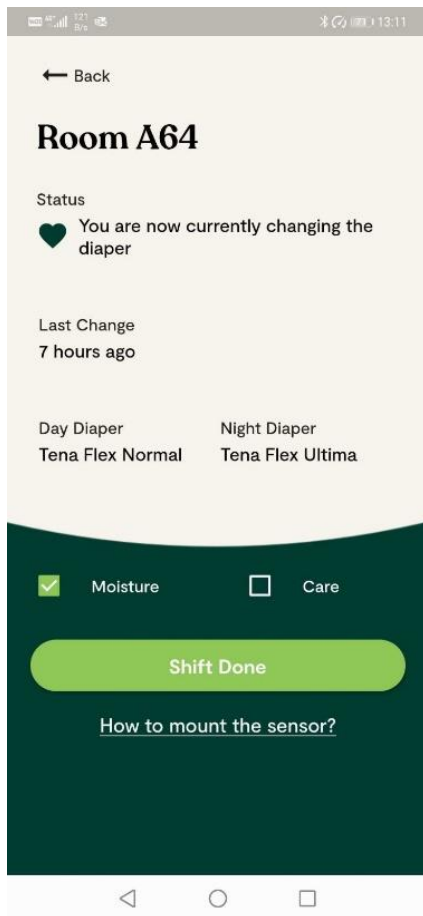
The sensor does not change state if the user does not initiate the Shift-functionality.

## 2.2.5 User Guide Modal

**Main purpose:** The modal shows the user information of the different steps needed to mount a DignaCare Sensor on the diaper. Clicking outside the modal (the black area) or the “X” takes the user to the previous screen **2.2.1 – 2.2.4 Sensor Detail** Screen.



## 2.3 Sensor Change Screen



**Main purpose:** Let the user select what type of shift they are currently conducting:

- Moisture detected and alarm triggered shift
- Regular care shift

In this screen, the status message has been updated to notify the user that they are in fact conducting a shift of the DignaCare Sensor.

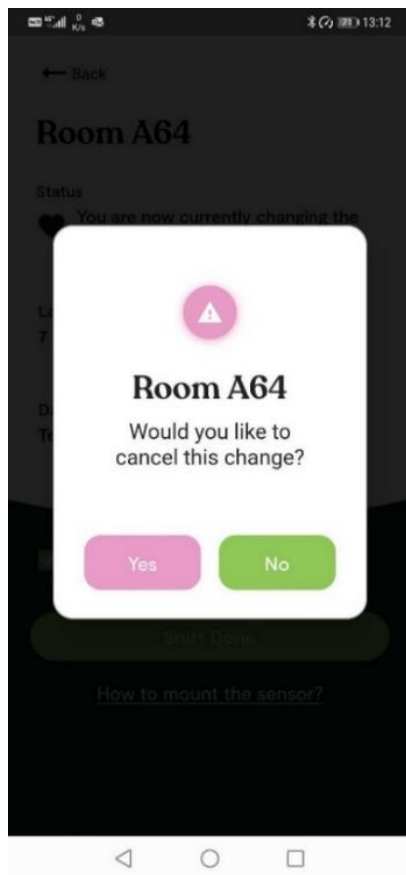
For other users of the application, the sensor updates state in the sensor list in **2.1 Sensor Overview** Screen.

After having initiated the change, the user can click "Back". Upon clicking "Back", the user is presented with **2.4 Cancel Change** modal.

The "Change Shift" button has changed to "Shift Done", and upon clicking this button, the user confirms that they have completed the change of diaper.

The states then change to "Clean", and the user is presented with **2.5 Change Success** Modal.

## 2.4 Cancel Change Modal

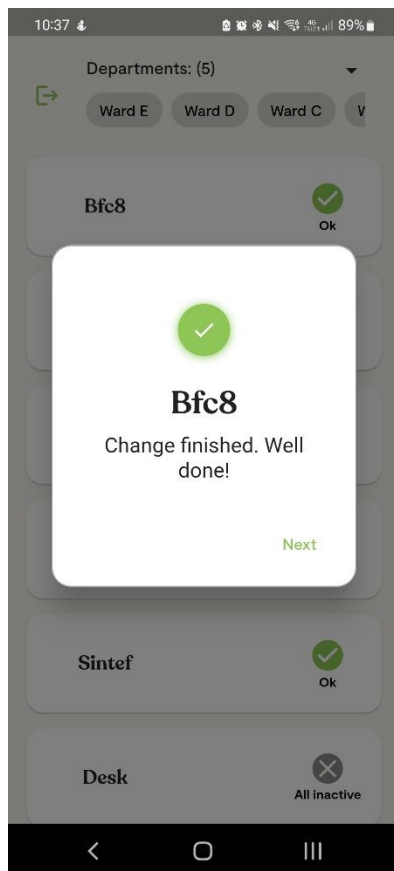


**Main purpose:** Letting the user cancel the ongoing change.

By clicking “Yes”, the change is canceled, and the user is presented with **2.1 Sensor Overview** screen.

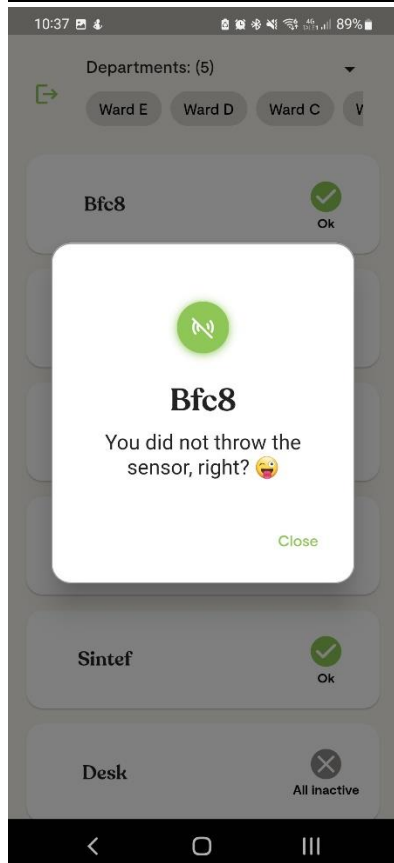
If the user clicks “No”, they are taken back to **2.3 Sensor Change** screen.

## 2.5 Change Success Modal



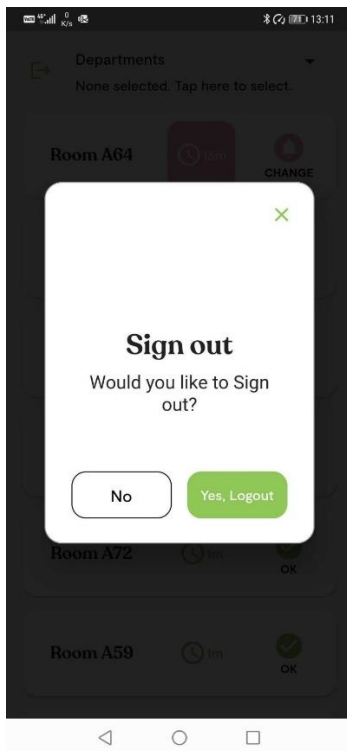
**Main purpose:** Providing visual feedback to the user that the change has been successfully registered.

The user can close the modal by clicking outside the box and is then presented with [2.1 Sensor Overview](#) screen. When clicking “next”, the user get a feedback to remind the user to not throw the sensor stripe.





## 2.6 Log Out Modal



**Main purpose:** Letting the user log out of the application.

If the user clicks “Yes, Logout”, they are taken to **1.1 Log In** screen.

## 6 DignaCare Management Application

### 6.1 How to Use DignaCare Management Application

DignaCare Management Interface Application is intended for department heads or other personnel with extended responsibilities (Superusers). The portal requires a login that is delivered with the solution. The portal is web-based and therefore requires internet access to open and retrieve data.

**Sign in:** <https://portal.dignacare.net/>

In the following section, the views from the DignaCare Management Interface Application, pertaining to the logistical and managerial aspects of the medical devices, are described. The views are presented in Desktop Format, with a description of the main purposes and functionality.

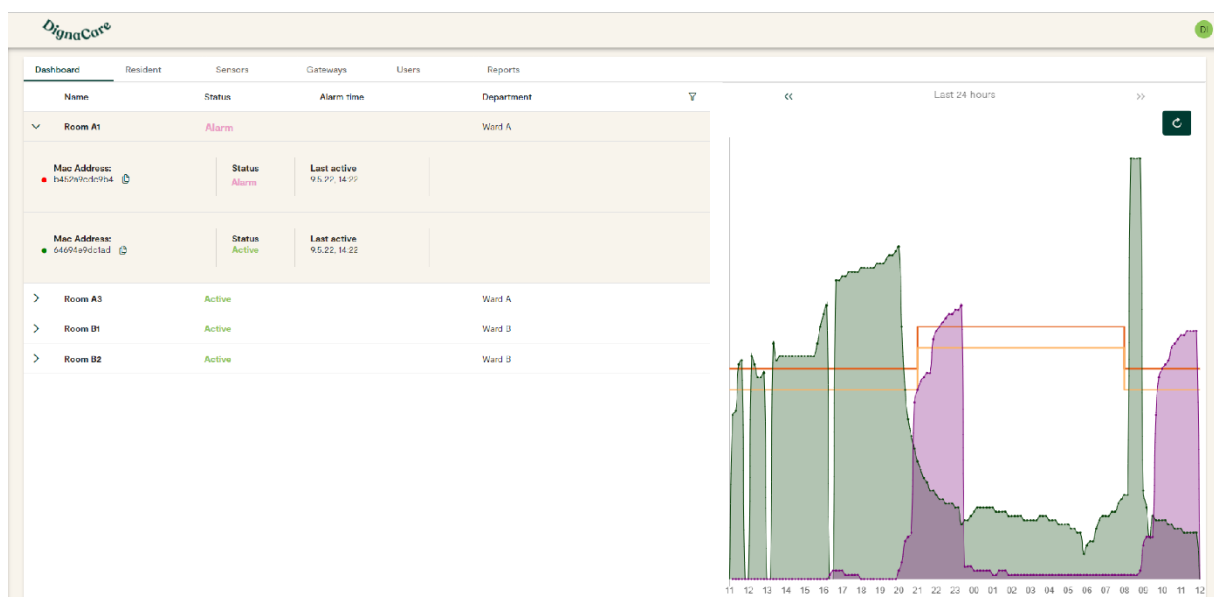
### 1 Customer Dashboard Screen

Each resident has two sensors. One sensor is on the incontinence product while the other is hanging or lying still. When a change is made, the sensor that has not just been used should be placed on the new incontinence product. This is so that the sensor has time to rest, and that the moisture level goes down completely before it goes on a incontinence product again.

One sensor is marked with a red stamp, while the other has no stamp. The sensor with a red stamp is called the red sensor, while the one without a stamp is called the green sensor from now on.

The colors of the horizontal stripes (red and yellow) in the graph denote the alarm thresholds that are set for each resident. The alarm thresholds can be set through the diaper type (each diaper type has its own alarm thresholds). The alarm thresholds can also be set to extra early, early, normal (default), late and extra late. When the red and yellow lines are higher in the graph, that indicates that it is daytime, and nighttime when the lines are lower on the graph. The green graph indicates the actual sensor values for the green sensor, and the purple/red graph indicates the values for the sensor with the red stamp. The events connected to a diaper change (with what kind of change(shift)) can be seen by looking at the vertical lines.

**Main purpose:** In the following screen, the user can instantaneously get an overview of the sensor status for the residents at the given customer. Upon entering this screen, the user can see the different statuses of the residents and click on different residents to see the sensors and to see their historic information in a graph on the righthand side of the screen.

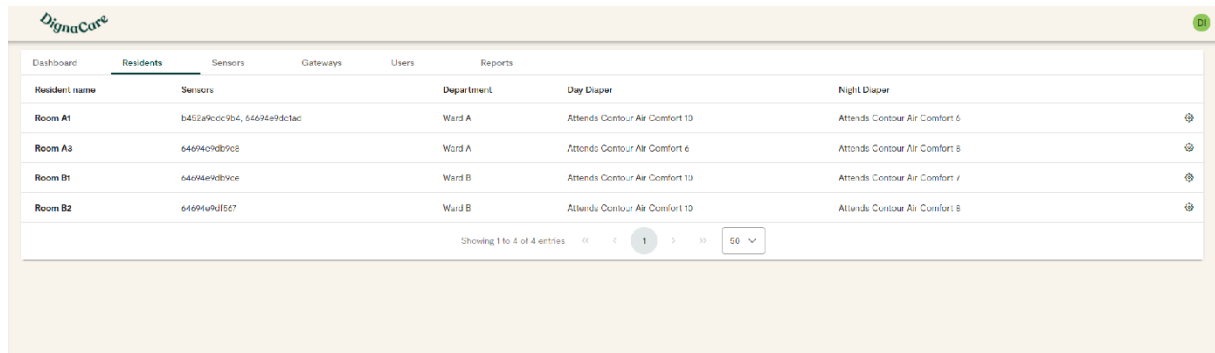


#### General navigation for all screens on Customer Level:

- Clicking “Residents”-tab takes the user to [2.1](#)
- Clicking “Sensors”-tab takes the user to [3.1](#)
- Clicking “Gateway”-tab takes the user to [4.1](#)
- Clicking “Users”-tab takes the user to [5.1](#)
- Clicking “Reports”-tab takes the user to [6.1](#)

## 2.1 Customer Residents screen

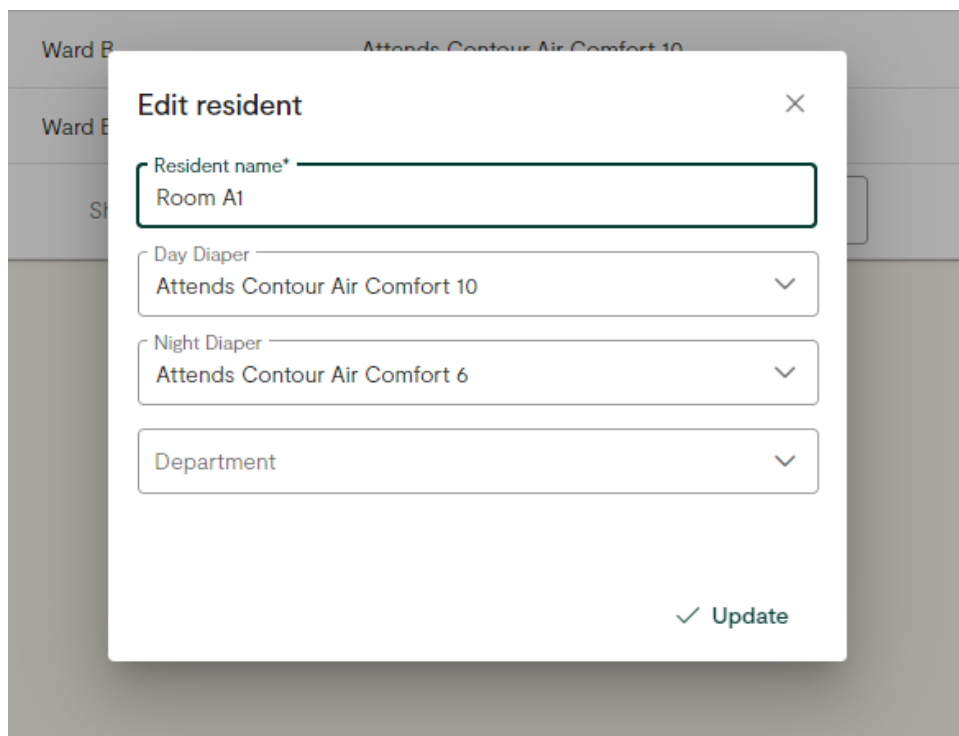
**Main purpose:** In the following screen, the user can see information about the residents linked to the customer – including the resident name (alias for the resident), MAC-addresses for the sensors linked to the resident, department name, and day- and night-diaper. By clicking on “**Edit**” in the cogwheel menu on one of the residents in the list, the user is presented with 2.2.



Resident name	Sensors	Department	Day Diaper	Night Diaper
Room A1	b452a9cc9b4, 54674e9d82ac	Ward A	Attends Contour Air Comfort 10	Attends Contour Air Comfort 6
Room A3	64674e9d82ac	Ward A	Attends Contour Air Comfort 6	Attends Contour Air Comfort 8
Room B1	64674e9d82ac	Ward B	Attends Contour Air Comfort 10	Attends Contour Air Comfort 7
Room B2	64674e9d82ac	Ward B	Attends Contour Air Comfort 10	Attends Contour Air Comfort 8

## 2.2 Customer Residents Edit modal

**Main purpose:** In the following screen, the user can change resident name, change diaper types and department. If the user does not click on «**Update**», the edits will not be updated.



### Edit resident

Resident name\*

Room A1

Day Diaper

Attends Contour Air Comfort 10

Night Diaper

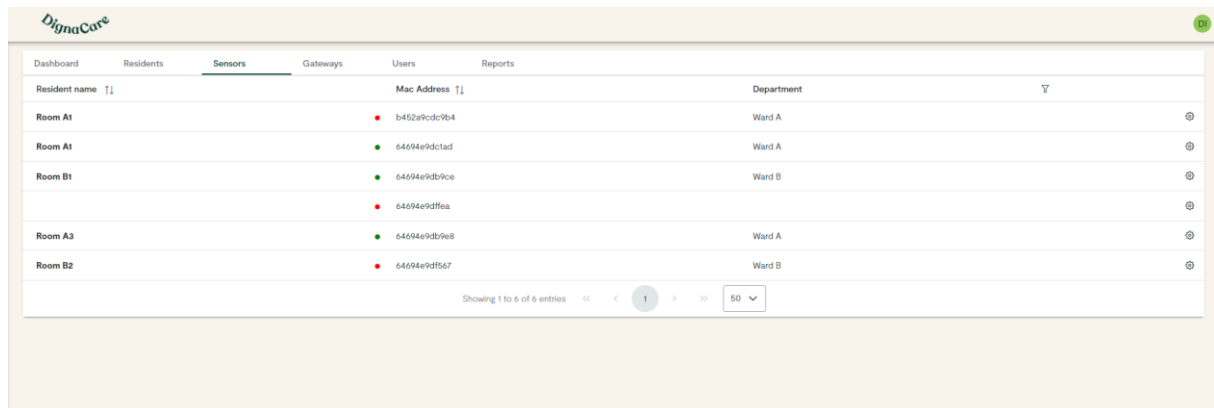
Attends Contour Air Comfort 6

Department

✓ Update

### 3.1 Customer Sensors screen

**Main purpose:** In the following screen, the user can see information about the sensors linked to the customer – including the resident name (alias for the resident), stamp color (green or red sensor), MAC-address and department name. By clicking on “**Edit**” in the cogwheel menu on one of the sensors in the list, the user is presented with 3.2.

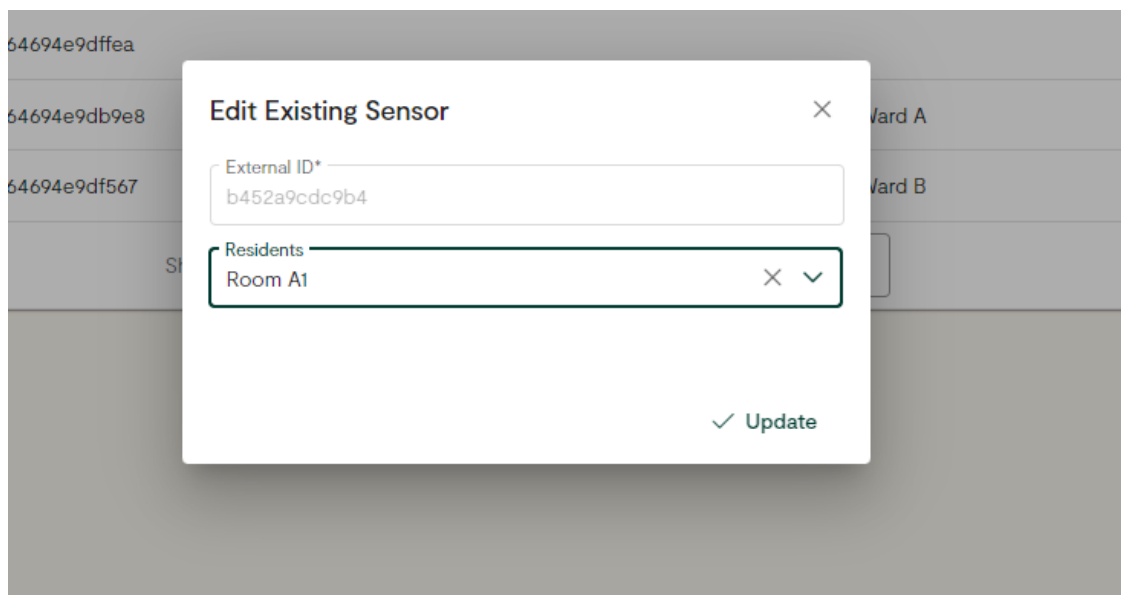


Resident name	Mac Address	Department
Room A1	b452a9cdc9b4	Ward A
Room A1	64694e9dctad	Ward A
Room B1	64694e9db9ce	Ward B
	64694e9dffe8	
Room A3	64694e9db9e8	Ward A
Room B2	64694e9df567	Ward B

Showing 1 to 6 of 6 entries << < 1 > >> 50

### 3.2 Customer Sensors Edit modal

**Main purpose:** In the following screen, the user can move a sensor between the residents of this customer. If the user does not click on «**Update**», the edits will not be updated.



**Edit Existing Sensor**

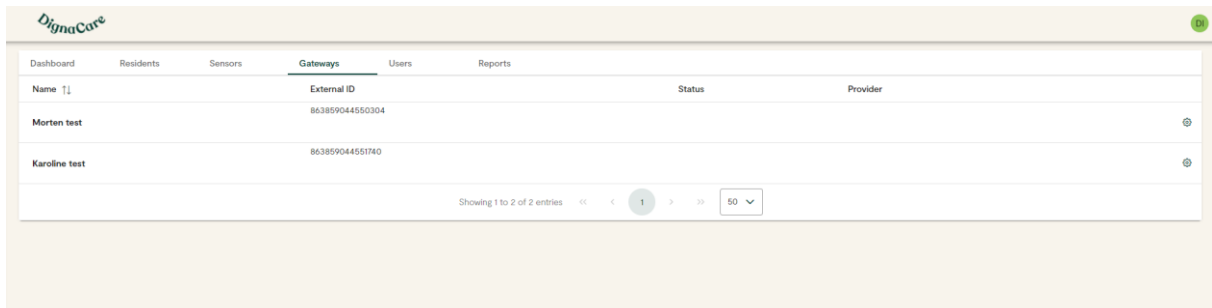
External ID\*  
b452a9cdc9b4

Residents  
Room A1

✓ Update

## 4.1 Customer Gateways screen

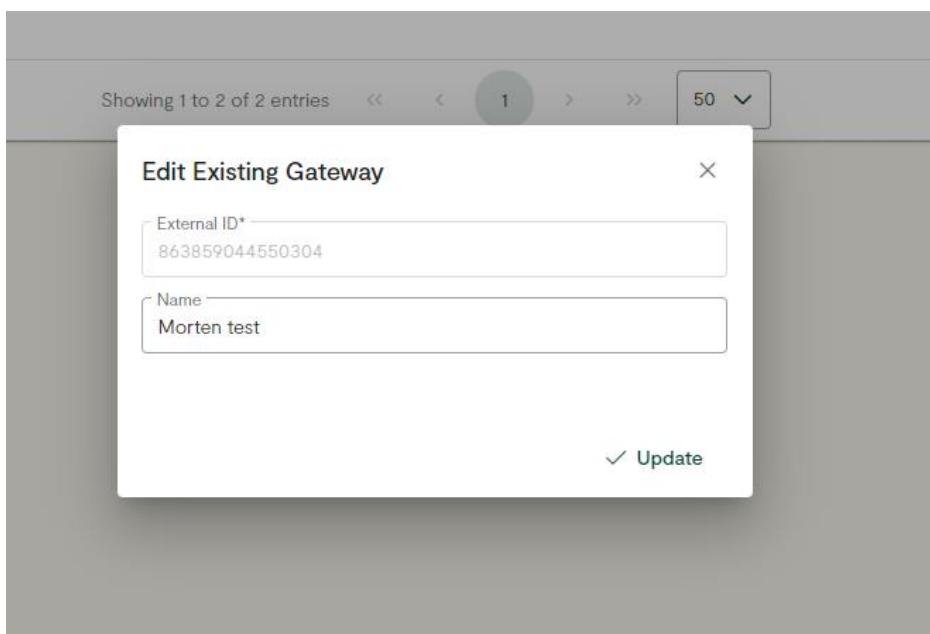
**Main purpose:** In the following screen, the user can see information about the gateways linked to a customer, including the name, External Id, status, and gateway provider. By clicking on **“Edit”** in the cogwheel menu on a list item, an information pane opens.



Name	External ID	Status	Provider
Morten test	863859044550304		
Karoline test	863859044551740		

## 4.1 Customer Gateways Edit panel

Main purpose: In the following screen, the user can change the name of the gateway.



Showing 1 to 2 of 2 entries << < 1 > >> 50 ▾

### Edit Existing Gateway

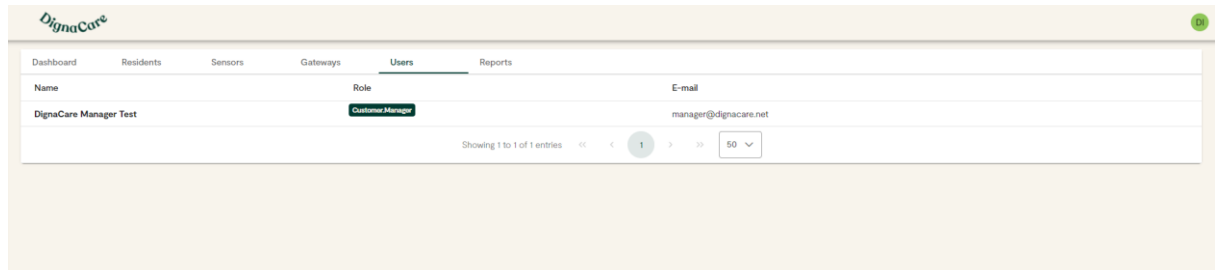
External ID\*  
863859044550304

Name  
Morten test

✓ Update

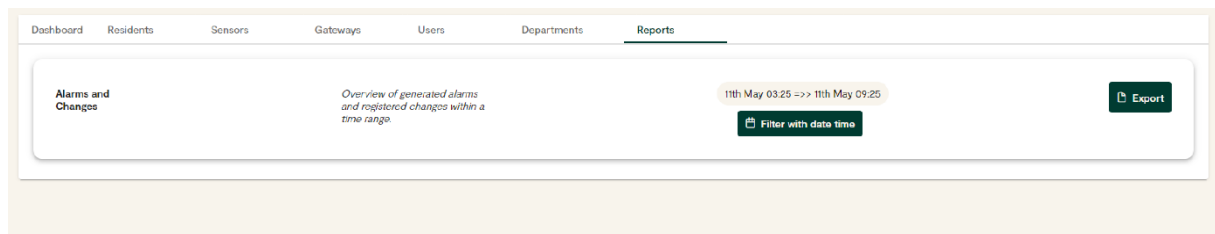
## 5.1 Customer Users screen

**Main purpose:** In the following screen, the user can see information about the users in the organization and what type of user they are (user role).



## 6.1 Customer Reports modal

**Main purpose:** In the following modal the user can get a report of all generated alarms and registered changes that has been made for a selected time range.



# 7 Processing Alarms and Sending Messages

## 7.1 Sensor Device

The DignaCare Sensor Device currently have two types of active sensors:

- Four sensors monitoring temperature and the humidity
- One sensor used to detect movement and provide position data in the format of x, y, z axes.

To communicate wirelessly, the DignaCare unit uses the BLE protocol. It consists of a set of Characteristics, which are grouped in different services which altogether makes up the profile of the device.

The DignaCare Sensor is equipped with four humidity sensors for detection of urine and faeces. The humidity sensors are placed evenly along the circuit board for best detection and a good basis for analyses.

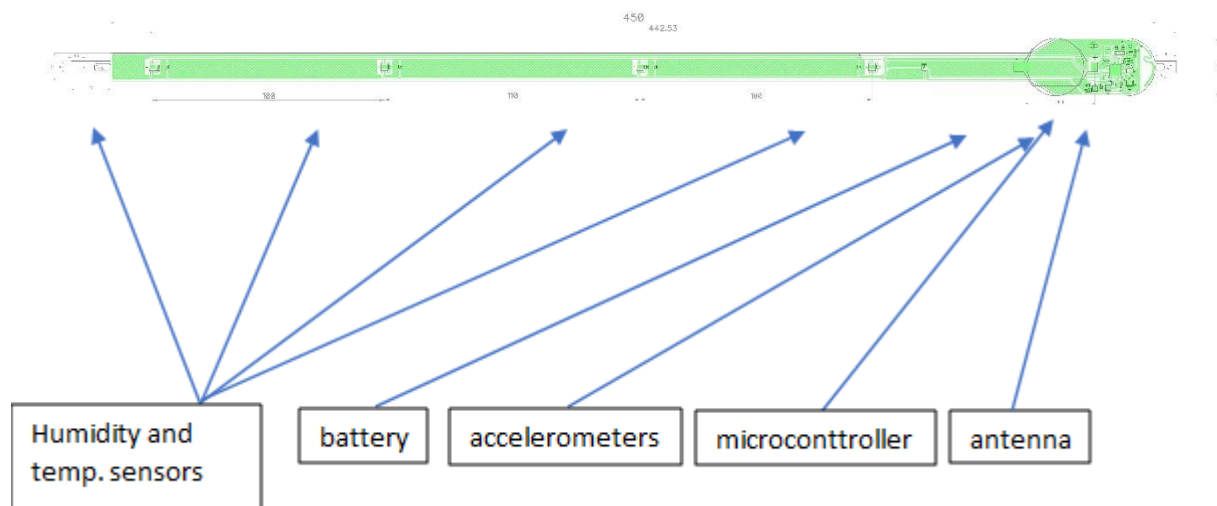
The accelerometers are placed in the front together with the microcontroller. The purpose of the accelerometers is to detect the position of the sensor.

The battery is soldered to the circuit board and is not replaceable.

All electronic components are moulded into a material to protect the electronic components and facilitate correct hygiene measures and cleaning.

## 7.2 Product Description

The Sensor is 460mm long. The front end is wider than the rest and contain the battery, microcontroller, and accelerometers. The humidity sensors are placed along the length of the circuit board and protected by white “membrane” visible to the user on the front side of the sensor.



## 7.3 Software Used in Design of Product

The applications are in Microsoft Azure Cloud Computing Services (Azure).

The different storage services are hosted in a separate security zone from where the web application is running and are maintained with encryption and secure authentication.

The DignaCare Cloud platform ensures encrypted and secure communication over TLS protocols, all the services are hosted in Azure, which functions as different security zones behind firewalls and security borders.

The DignaCare application is divided into separated environments – dev, and production environments. This ensures complete segregation of releases that are still in the respective QA phases and are pending release confirmation.

## 7.4 Third Party Integration

The DignaCare Solution, DignaCare mobile application, integrates toward third parties. The integrations will be achieved through a set of predefined functionalities and API calls. Third party integrations assume that all communication is encrypted and goes over TCP port 443 (HTTPS). SensCom prefers to work with REST APIs and uses JSON as their standard format. SensCom can, however, support multiple formats and modes of communication.

## 8 Component Overview

The DignaCare software is developed from the software platform based on the TI CC2540/41 complete System-on-Chip (SoC) solution. The solution combines a 2.4-GHz RF transceiver, microcontroller, up to 256KB of in-system programmable memory, 8KB of RAM, and a full range of peripherals. The controller, host, profiles, and application are implemented on the CC2540/41 as a true single-chip solution.

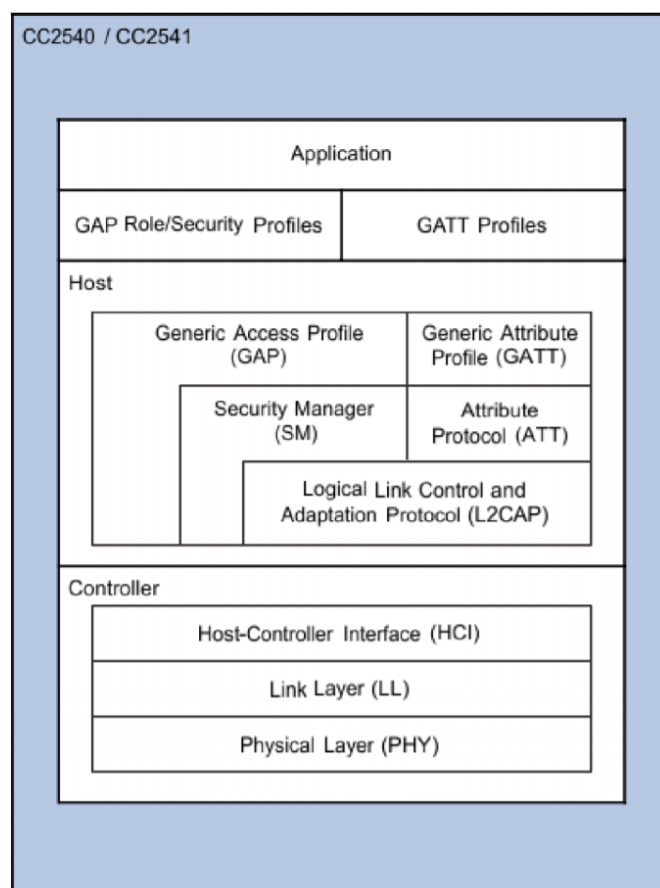


Figure 1

From Figure 1 The host and the controller together make up the BLE (Bluetooth Low Energy) stack, while the DignaCare specific software is contained in the application and the profile definition.



Thus, the software consists of the following 5 major components:

- OSAL – the operative system
- HAL – the Hardware Acceptance Layer
- The BLE Protocol Stack
- Profiles – the BLE profile definition
- Application – the application specific top-layer

OSAL (Operating System Abstraction Layer) and the BLE Stack are components that remains unchanged and can be downloaded from TI along with documentation.

The DignaCare consist of four main parts:

- Battery
- BLE radio
- Microcontroller
- Sensors

The Battery is a standard lithium coin cell battery with CR2530 size. The battery capacity is typically 250mAh.

The BLE radio and the microcontroller is one integrated circuit. CC2540 from Texas instruments is used. The BLE radio antenna is a special designed pcb antenna.

There are four moisture and temperature sensors placed along the unit for best detection according to function. The flexible pcb is also equipped with two 3-axis accelerometers.

## **8.1 Component Relation to Function**

In detail, the DignaCare profile consists of a set of mandatory (M) services that are defined by the Bluetooth Sig Group (3) and a set of services that are related to the functionality of the device (D). More specifically, each type of sensor has its own service including characteristics that is used to configure the sensor and where sensor values can be read.

### **8.1.1 Application**

At the very top layer the application software is located. This code ties together the different components and access these according to the desired functionality of the device. There are mainly two functions of the device. To read and publish temperature and humidity values, in addition to detect and publish micro movement.

To detect movement the DignaCare unit employ an accelerometer that is set up to report any changes in the position of the unit.

### **8.1.2 Payload Definition**

The payload in the advertisement telegram will consist of 26 bytes. The first byte will consist of a status byte including a battery level indication (4 bit), a bit indicating whether a fall has been detected or not and a bit telling if the sensors are enabled or not. The second byte represent a pseudo timestamp used to decide if 2 packets are identical. The last 24 bytes will

consist of a mix of version number and sensor values. We have several sensors producing humidity(H0-H7) and temperature(T0-T7) readings, each represented by two bytes. The 16 bits values are simply read from the sensor and put into the registers.

Components outside of scope of this document includes:

1. Sensor hardware and firmware including:
  - a. BLE protocol
2. Gateway hardware and firmware including:
  - a. Transfer protocol for gateways to external servers
  - b. Sensor communication

## **9 DignaCare App**

The DignaCare Application is a client-side Cross-Platform application leveraged through the Flutter SDK. Flutter is an open-source kit created by Google, and is used to develop applications for Android, iOS, Linux, and the web from a single codebase. The front-end application is written in DART, and it communicates with the backend through a dedicated REST API using HTTPS. The frameworks and SDKs used in the Flutter application includes:

- SDK for connection to Azure
- Firebase for notifications

### **9.1 Cloud Environment**

The backend and related functionality are developed using C# and are realized through the Microservice Architectural Pattern. Microservice Architecture is a variant of service-oriented architecture and decouples the application modules in separate services. The services are typically fine-grained, and the transport and communication protocols between the services are lightweight.

Different business areas and functions are separated into different services that are independent of each-other.