



# User Manual

Wound Viewer

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## 1 - Warnings, precautions and notes

The Wound Viewer is a medical device for capturing, storing and analyzing images of skin ulcers.

The device does not require the use of other equipment, medicines or medications to perform its functions. The use of the device does not pose any risk to the user or the patient, therefore no protection of any kind (gloves, glasses, masks, etc.). The device is compatible with the use of medical latex protective gloves.

The correct use of the device does not involve direct contact with the patient, for this reason the device is to be considered as a Class I (CE) device: Non-invasive Medical Device (MD), for temporary use according to 93/42 CE Regulation.

It is recommended that Wound Viewer has to be used exclusively by professional, specialized or properly trained healthcare personnel.

Under no circumstances should the Wound Viewer be disassembled, tampered with or otherwise modified, except by the manufacturer's authorized personnel. Any product violation could make it unusable or defective.

Keep your device away from thermal or magnetic sources; Do not soak in water or other liquids; don't approach open flames; avoid bumps.

## 2 - Description of the Wound Viewer device

### 2.1 – Package Contents

The Wound Viewer package contains the following components:

1. N. 1 Wound Viewer device
2. N. 1 Wire USB - USB-C,
3. N. 1 AC power adapter
4. N.1 User manual.

### 2.2 - Wound Viewer Device Components

The components of the Wound Viewer device are identified and described in relation to Figure 1, 2, and 3.

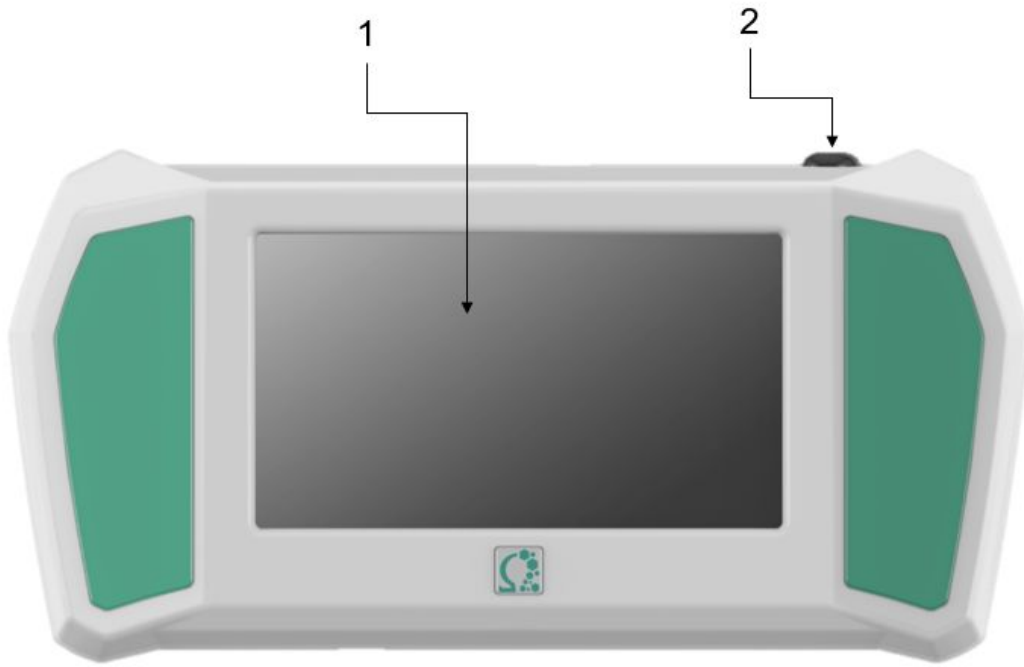


Figure 1: WoundViewer front view

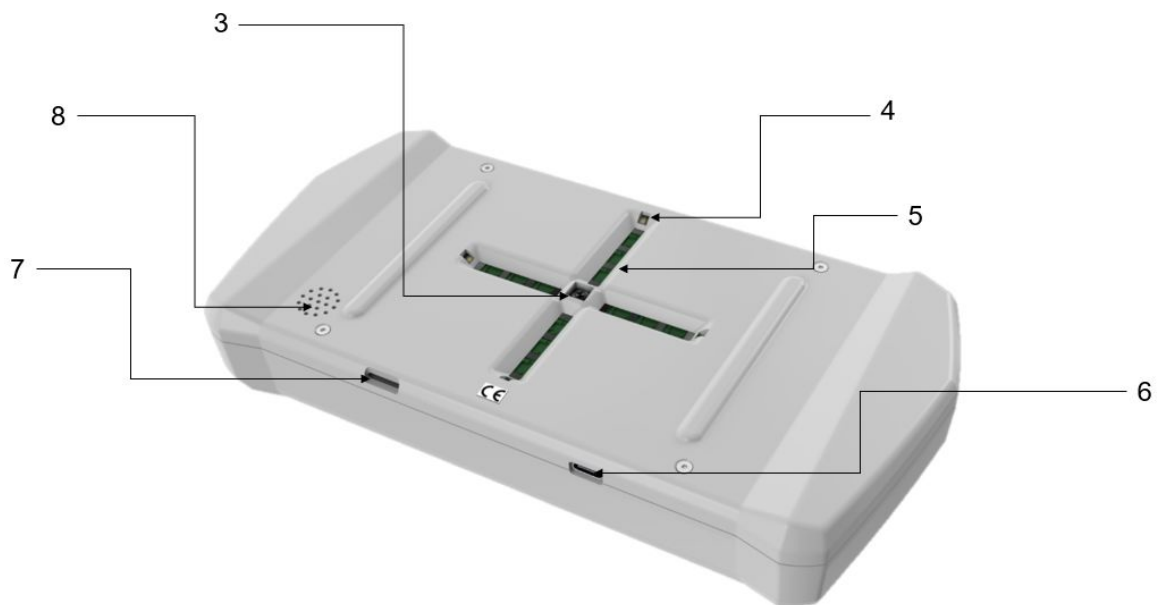


Figure 2: WoundViewer rear-bottom view

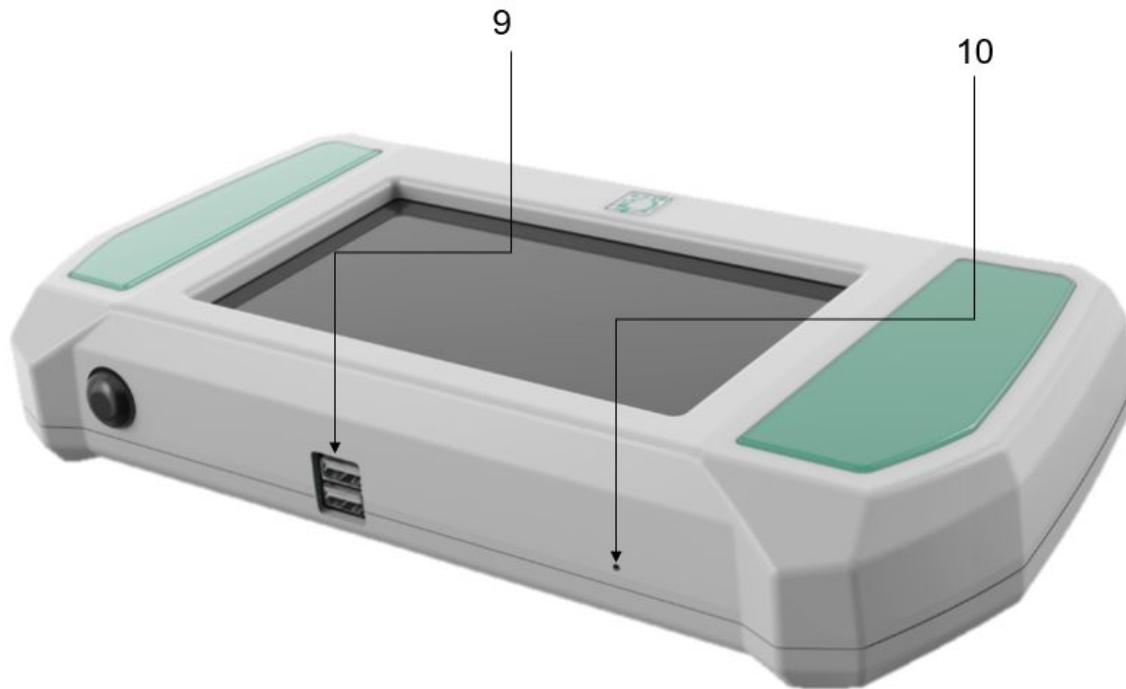


Figure 3: Wound Viewer front-top view

ID	Component Name	Quantity
1	7" LCD touch screen	1
2	On/off/standby button	1
3	5 Mpx camera	1
4	White LEDs	4
5	Distance TOF sensors	16
6	USB-C input for charging	1
7	Micro-SIM housing	1
8	Speaker	1
9	USB Ports	2
10	Microphone	1

### 2.3 - General technical information

The following table shows the general technical data for the successful installation and use of the Wound Viewer device.

<b>Feature</b>	<b>Specification</b>	<b>Other notes</b>
Supply voltage	5 V in power, 3.1 V battery	
Power consumption	15 W	Maximum value of consumption
Class DM	Classe I	CEI EN 93/42
Electric class	Internal supply, type: BF	Following CEI EN 60601-1
Net weight	1 kg	
Overall dimensions	253 x 149 x 50 [mm]	
Noise emissione	None	
IVD device	No	
Active implantable device	No	
Need for ventilation or air conditioning	No	
Stock temperature conditions	-25 - +55 [°C]	
Operating temperature conditions	+5 - +40 [°C]	
Generation of vibration	No	
Explosive atmospheres	Non-generating and non-inter-agent with explosive atmospheres	
Emissions or treatment of chemicals	No	

## 2.4 - Wound Viewer software composition

The Wound Viewer software package allows the user to access the different features of the system, such as the management of the collected data, the control of the utilities and the operation of the device. Wound Viewer software comes in two versions: a mobile version (installed directly on the device) and a desktop version (accessible from any other external mobile device). Clinical data on patients, wounds and visits are synchronized between the two versions.

The Desktop version of Wound Viewer software is available at the following URL:  
<http://wound2019.s3-website-eu-west-1.amazonaws.com/login/login>

The Desktop version is compatible with the following browsers:

1. Google Chrome,
2. Mozilla Firefox,
3. Microsoft Internet Explorer (starting with version 11).

The list of features accessible in the two versions is described in the following table.

<b>Functionality</b>	<b>Mobile</b>	<b>Desktop</b>
Authentication and login	Yes	Yes
Display patients' list	Yes	Yes
Display patients' profiles	Yes	Yes
Edit/Create patients' profiles	Yes	Yes
Display of the profile of an ulcer	Yes	Yes
Edit/Create profile of a ulcer	Yes	Yes
Display of the statistics of a given ulcer	Yes	Yes
Creation and execution of a new visit	Yes	No
Edit old visits	Yes	Yes
Creation of a PDF report of a visit	Yes	Yes
Creation of users' profile	No	Yes
Edit of users' profile	Yes	Yes
Display of users' profile	Yes	Yes
Recovery of access credentials	Yes	Yes
Database management (dashboard)	No	Yes
Edit alert thresholds	Yes	Yes
Message service	Yes	Yes



### 3 - Users

Access to the use of the Wound Viewer device and the Wound Viewer software package is reserved for users authorized by the owner of the device to process patient data and to view their medical records. Operators of the device are divided into three categories of users, each with different privileges. All three different operators have access to Wound Viewer software in both versions (Mobile and Desktop).

1. **Coordinator:** this type of user will have access to all data produced and owned by the institution. It will have access to all the features of the system. The data accessible to them will be visible to them only through the Wound Viewer software. This category of users can create new operator accounts (for both Professional Healthcare Operatore and Auxiliary Operators, described immediately below). In conclusion, the Coordinator is to be considered the contact person and the data manager with respect to the institution he or she is working for.
2. **Professional Healthcare Operator:** this type of user will have access to patients' data, ulcers and visits related to her/his healthcare institution through the Wound Viewer software. Her/His user account can only be created and/or deleted by the Coordinator. She/He will have access to the functions necessary for patient management and visits (creating new patients, ulcers, visits and editing of related data). Unlike the Auxiliary Operator (described below), the Professional Healthcare Operator will have the opportunity to confirm the treatment applied to the patient and to confirm the clinical status of the wound (this user will be authorized to indicate whether and how the wound has to be treated or if it is to be considered healed).
3. **Auxiliary Operator:** as the Professional Healthcare Operator, the Auxiliary Operator has the same access to the data and functionality of Wound Viewer with the only exception that this user will not have the authorization to confirm the type of treatment for the given patient and the clinical state of the wound.

The following table provides the details of the privileges of the various users.

Funcionalities/ User	Coordinator	Professional Healthcare Operator	Auxiliary Operator
Login and authentication	Yes	Yes	Yes
Display patients' list	Yes	Yes	Yes
Display patients' profiles	Yes	Yes	Yes
Edit/Create patients' profiles	Yes	Yes	Yes
Display of the profile	Yes	Yes	Yes

of a ulcer			
Edit/Create profile of a ulcer	Yes	Yes	Yes (except for the clinical state of the ulcer)
Display of the statistics of a given ulcer	Yes	Yes	Yes
Creation and execution of a new visit	Yes	Yes	Yes
Edit old visits	Yes	Yes	Yes (except for the confirmation of the therapy)
Creation of a PDF report of a visit	Yes	Yes	Yes
Creation of users' profiles	Yes	No	No
Edit of users' profiles	Yes	Yes (only her/his own, at personal and authentication level)	Yes (only her/his own, at personal and authentication level)
Display of users' profile	Yes	Yes (only her/his own)	Yes (only her/his own)
Recovery of access credentials	Yes	Yes	Yes
Database management (dashboard)	Yes	Yes	Yes
Edit alert thresholds	Yes	No	No
Message service	Yes	Yes	Yes

#### 4 - Pre-use instructions for the Wound Viewer device

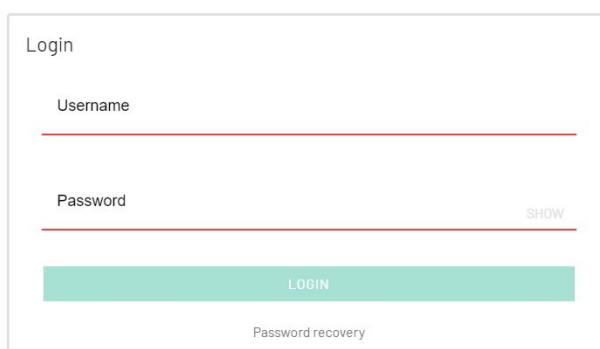
Before use, make sure that the battery is charged, that the camera lens is clean and scratch-free, that each of the LEDs is not obscured, and that there are no obstructions on the distance sensors.

The Wound Viewer software on the device, in any case, will signal that a given operation cannot be completed if one of the components is not working properly or if there are technical issues with the device.

## 5 – Switching on, off, standby and charging the Wound Viewer device

### 5.1 – Switching the device on

The device is turned on by pressing and holding the power button (ID 2, Figure 1) for a time of 2 seconds. Once the device is turned on, the operator has to select the Wound Viewer icon on the desktop. Once the application is started the user will see the login screen (Figure 4).



The image shows a login screen with the following elements:

- Title: Login
- Username input field
- Password input field with a 'SHOW' button to its right
- A large green button labeled 'LOGIN'
- A link for 'Password recovery' at the bottom

Figure 4: Login screen

### 5.2 – Switching the device off

The device is turned off by pressing and holding the shutdown button (ID 2, Figure 1) for more than 2 seconds. The turning off of the device leads to user logout and she/he will need to log in again to access Wound Viewer features.

### 5.3 - Standby

The device goes into standby mode when one of the following conditions occurs:

1. The device is inactive for more than 5 minutes,
2. The standby button (ID 2, Figure 1) is pressed for less than 2 seconds.

To exit the standby mode, press the standby button for less than 2 seconds. If the device has been left in standby mode for more than five minutes, the device will enter in deep-sleep mode. In this case, the recovery of the device might take approximately one second more.

## 5.4 - Reset

It is possible to shut down the device in case of malfunction. To carry out this operation it is necessary to hold down the Reset button (ID 2, Figure 1) for at least 10 seconds. In this case the device will turn off and you can turn it on again as described in section 5.1 of this document.

## 5.4 - Charging the device

When the device is turned on, you can check its charge status at any time by reading the charging icon at the top left of the screen (Figure 5-A). If the device is in need of being charged, the Wound Viewer must be connected to the electrical power supply (220 V, 50 Hz) through a wall plug.

To connect the device to the power supply, the following steps must be followed:

1. Connect the USB - USB-C cable to the appropriate power plug on the USB side,
2. Connect the USB - USB-C cable, on the USB-C side, with the device via the USB-C slot (ID 6, Figure 2),
3. Connect the power plug to an available power outlet.

Once the device is charging, the battery status icon will change as shown in Figure 5-B.



Figure 5: Icons representing the battery charge status (A), and the connection of the device to the power supply (B).

## 6 - Network connection

### 6.1 - Network connection through Wi-Fi

You can connect your Wound Viewer device to the Internet via Wi-Fi. In order to establish the connection, you must access the system settings panel by swiping your finger from beyond the top edge of the screen towards the centre of the screen. This will make the drop-down menu appear as shown in Figure 6.

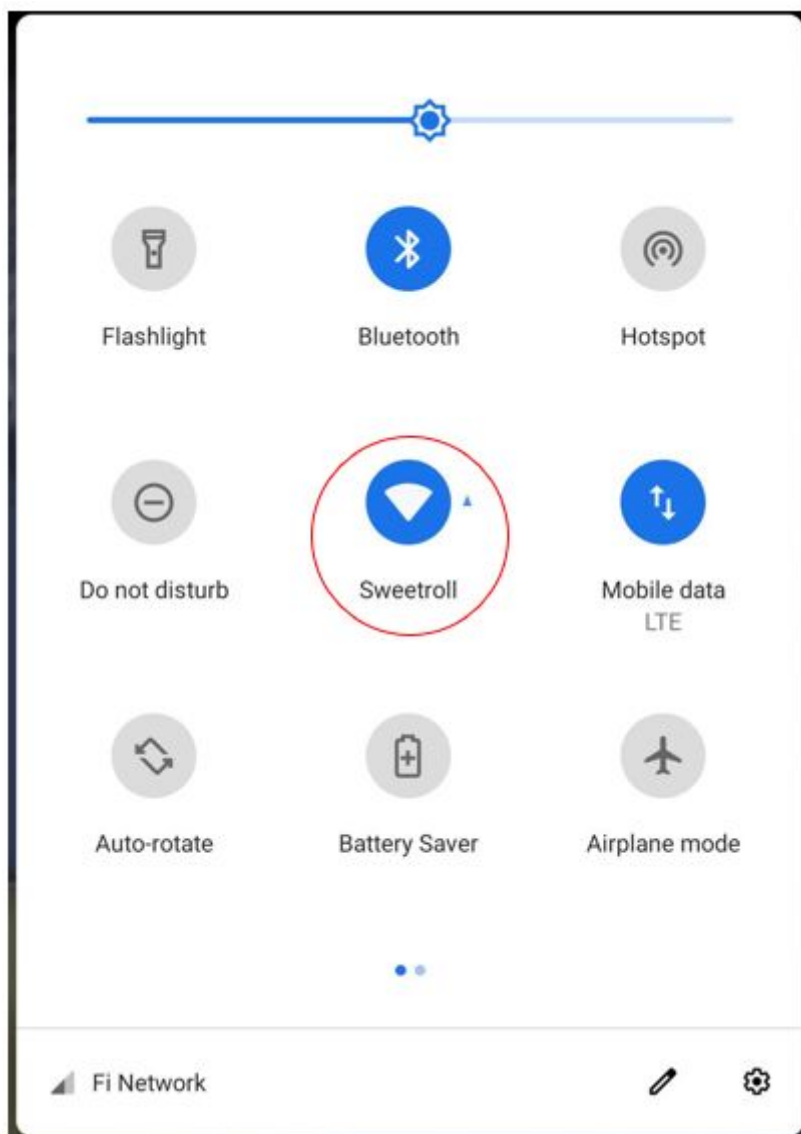


Figure 6: System settings curtain with Wi-Fi network icon highlighted

Selecting from the drop-down menu the Wif-Fi network icon (circled in red in Figure 6), the list of available networks will be displayed. Selecting the network, the operator will be asked

to enter the password to access it (if necessary) or the connection will be made directly in case the network has already been used before.

## 6.2 - Mobile network connection

It is possible to connect the device to the mobile network by inserting a micro-SIM in the appropriate slot (ID 7, Figure 3). Once the SIM is inserted, it is necessary to set the APN. To do this, you must access the system settings drop-down menu by swiping your finger from beyond the top edge of the screen towards the centre of the system. When it appears you need to select the settings icon (circled in red in Figure 7). Once the icon is selected, you must select Mobile Networks->Access Point Names->+. Following this path, the APN setup screen appears and must be compiled according to the SIM card operator settings (available on the respective websites).

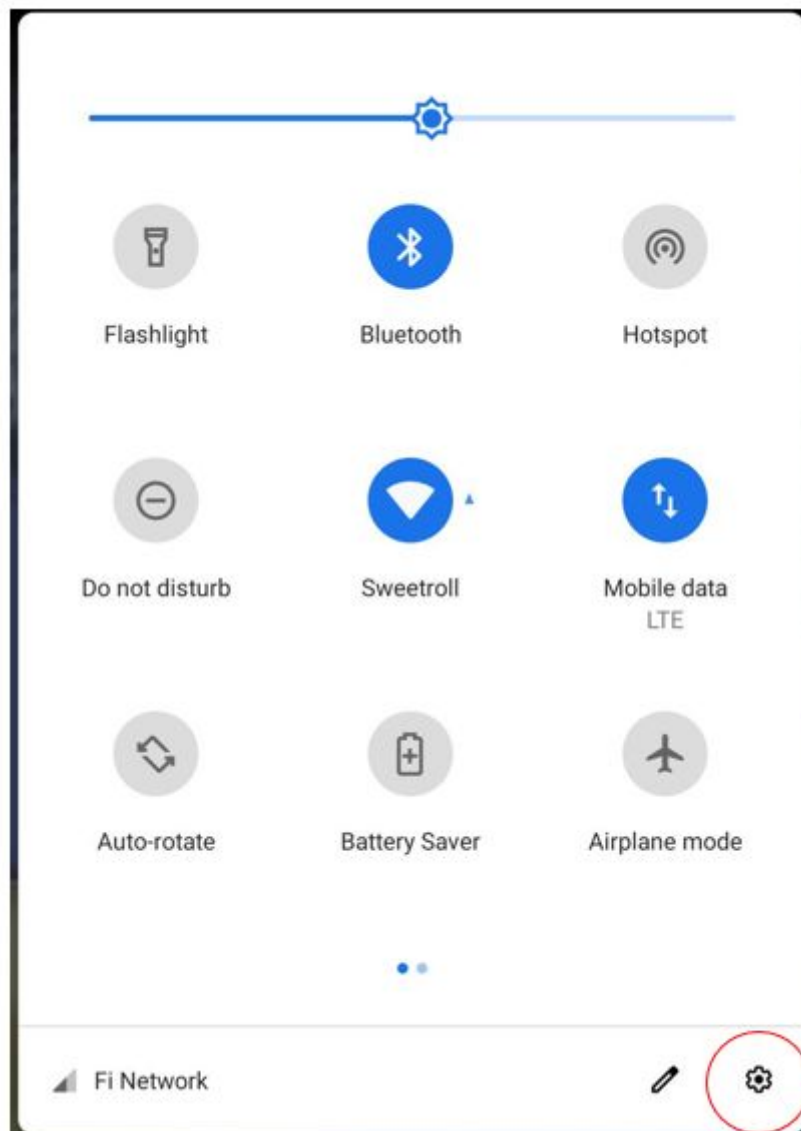


Figure 7: System settings curtain with settings icon highlighted

## 7 - Login, receiving and retrieving credentials

### 7.1 Retrieving credentials

All types of operators receive their credentials via email. In the case of the first user, who is the coordinator for the given institute, these are generated by OmniDermal Biomedics and sent via email to the referred person. For the rest of the operators, their credentials are generated by a Coordinator through the system (the method is described later in this document).

In case of loss of the credentials, the operator in the login screen (Figure 4) selects the password recovery icon. In that case, if the user is still active on the system, they will receive an email with a new temporary password to enter. This can still be changed later as described in the appropriate section.

### 7.2 Login

In order to login, in any case, you must first check that the device is connected to the network as described in Chapter 6 of this document. If the device is connected, in the login screen (Figure 4), the operator must enter the username and password credentials for the device. Once entered, you must select the Login button on the same screen. If the credentials have been entered correctly the user will see the system homepage (Figure 8), otherwise an error message will be displayed and the user will be asked to re-enter the credentials.

## 8 - Homepage e synchronization

### 8.1 - Homepage

Figure 8 shows the homepage of the Wound Viewer software. This page will be displayed every time the operator logs in. The following table describes the various sections of the screen.

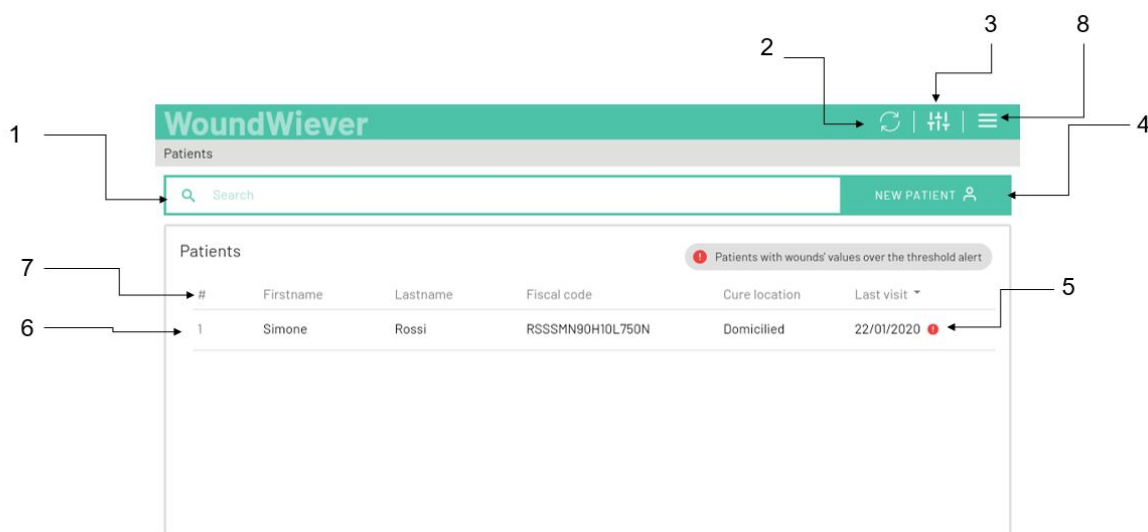


Figure 8: Homepage

ID	Descrizione
1	Patient search bar
2	Synchronization icon
3	Setting icon
4	New patient icon
5	Alert
6	Patient list (worklist)
7	Sorting categories
8	User menu

## 8.2 - Synchronization

The list of patients, and all related data (personal and clinical data, data regarding their wounds and visits) can be synchronized and can be viewed and consulted on all Wound Viewer software platforms (Mobile and Desktop) at any time. When a user logs in to the system, an automatic synchronization will be performed. The rest of the synchronizations have to be performed manually, making sure that the device is connected to the network.

The following steps are required to perform manual synchronization.



1. If you are using the Mobile version of Wound Viewer software (accessing the system through the Wound Viewer device), you must verify that Wound Viewer is connected to the Internet (Chapter 6).
2. On the homepage select the synchronization icon (ID 2, Figure 8): the user will visualize the synchronization screen (Figure 9).

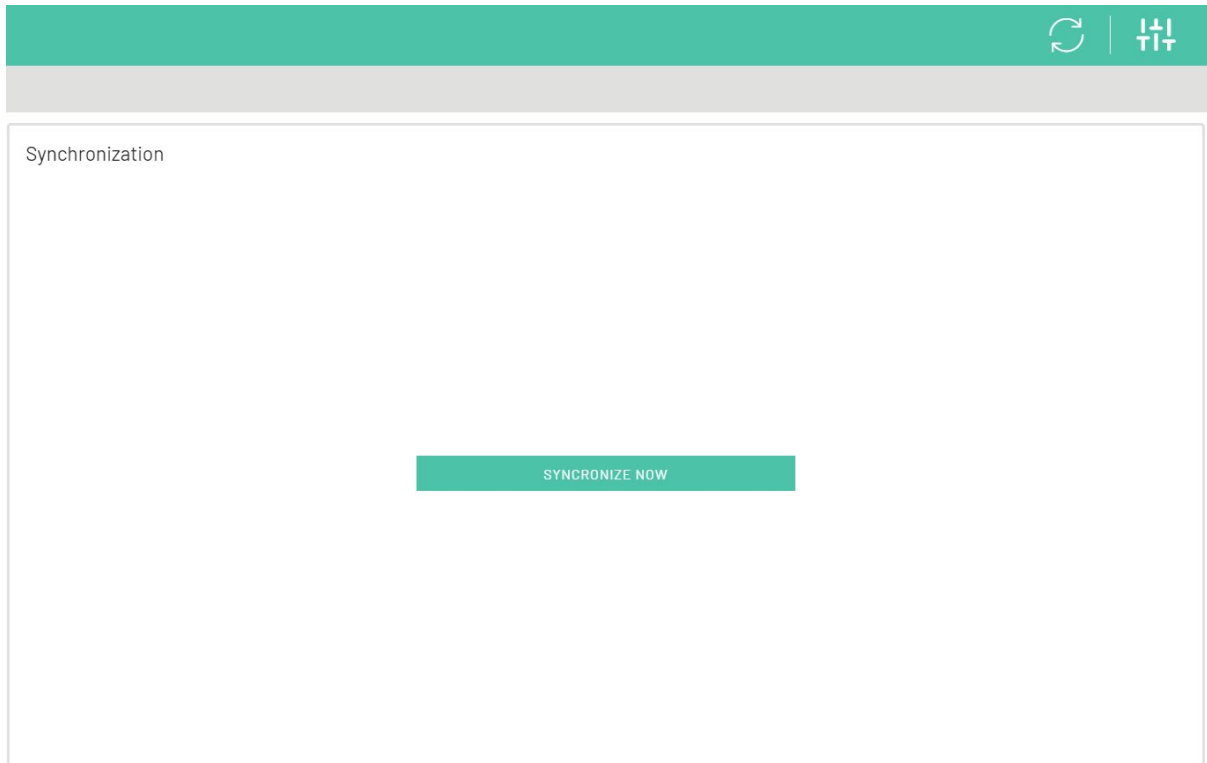


Figure 9: Synchronization screen.

3. Select the "Synchronize Now" icon on the synchronization screen.
4. After a short period of loading (depending on the stability and power of the network signal) the following success message will be displayed (Figure 10)

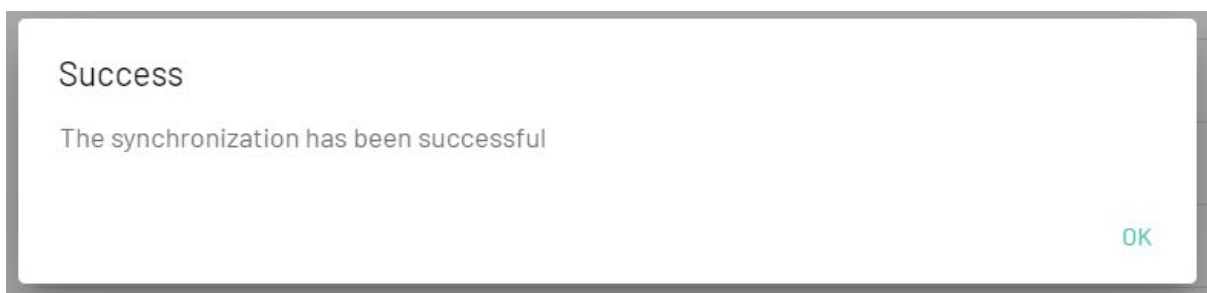


Figure 10: Successful synchronization message.

## 9 - Patient management

### 9.1 - Selecting, organizing and sorting of the patient list

The homepage shows the patient list of the system (ID 6, Figure 8). The list can be reordered according to the patient's first name, surname, fiscal code or the date of the last examination. To reorder according to one of the listed parameters, select the desired parameter from the sorting category bar (ID 7, Figure 8).

It is possible to perform a patient search through search bar above the patient list (ID 1, Figure 8). The search can be performed by First Name, Last Name or Fiscal Code. Selecting the bar will display the cursor to enter the data. When characters are entered into the bar, the list below will update to show only profiles that match the search. The greater the number of characters entered, the finer the search result will be.

To select a patient in order to view the profile, simply select the desired name from the patient list (ID 6, Figure 8). Once the patient has been selected, his profile tab described in paragraph 9.2 will be displayed.

**Important:.** If the patient list is not exhaustive, it is advisable to synchronize as described in section 8.2.

### 9.2 - Patient profile

The patient profile screen is shown in Figure 11, the table below describes the various elements that compose it. This screen appears when a patient profile is selected from the patient list on the homepage (ID 6, Figure 8).

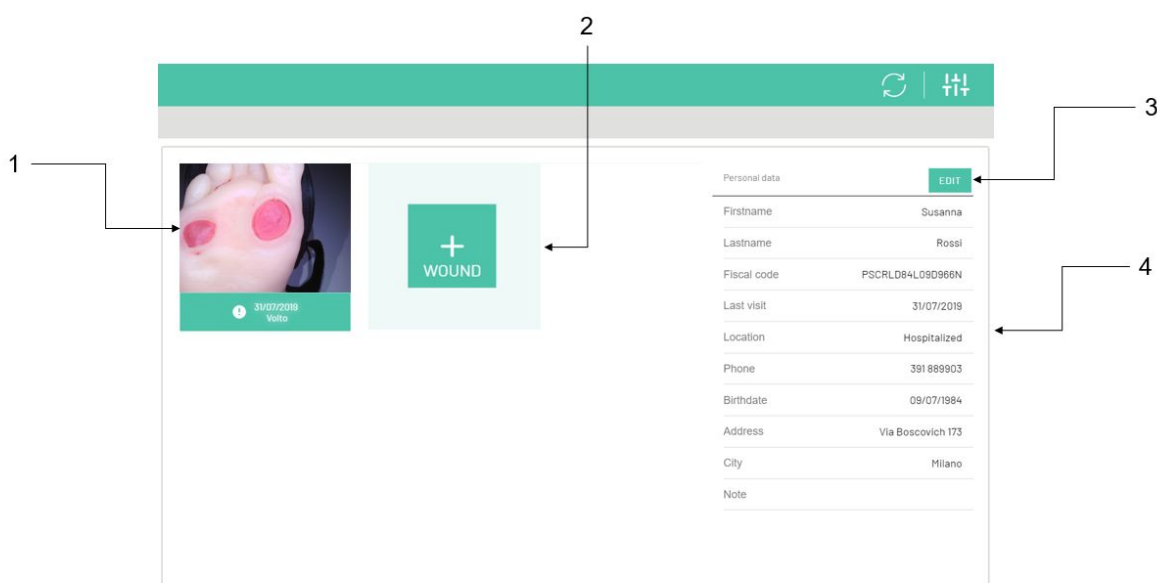


Figure 11: Patient profile page.

ID	Description
1	Tiles of ulcers afflicting the patient with photos of the last visit, date of last visit, body part and alert symbol (if present).
2	New wound icon
3	Patient data edit icon
4	Patient data list

### 9.3 - Adding/editing/deleting a patient profile

The screen shown in Figure 12 shows a patient data entry form. You can access this tab in two different ways depending on the action you want to perform.

1. Add a new patient to the patient list and create a patient profile by selecting the add new patient icon (ID 4, Figure 8),
2. Edit existing patient data: Select the patient data edit icon (ID 3, Figure 11).

Figure 12: Patient data entry form

If the patient is a new entry in the database, the tabs in the form will be empty. If the patient already exists in the database and the intent is to edit his data, then the fields will be pre-filled with the pre-existing data. To enter new data in the form you must select the desired field, at which point the drop-down list (if the field has a choice between several

options), or a cursor will appear to enter the text. Once you have completed the form, you must select the Save icon at the bottom of the same page.

**Important:** Data cannot be saved if the following two conditions are not met:

1. At least the fields Name, Surname and Fiscal Code have not been filled in,
2. A fiscal code of at least 16 characters has not been entered.

You can also delete a patient profile from the same screen. The deletion is done by selecting the Delete icon next to the Save icon.

**Important:** Once a patient's profile is deleted, all data about their injuries and visits will be lost.

## 10 - Wound management

### 10.1 - Wound profile

The ulcer profile section is visible to the operator when the operator selects one of the existing wounds from the patient profile (ID 1, Figure 11). The ulcer profile screen is shown below (Figure 13) and the table below its components are described.

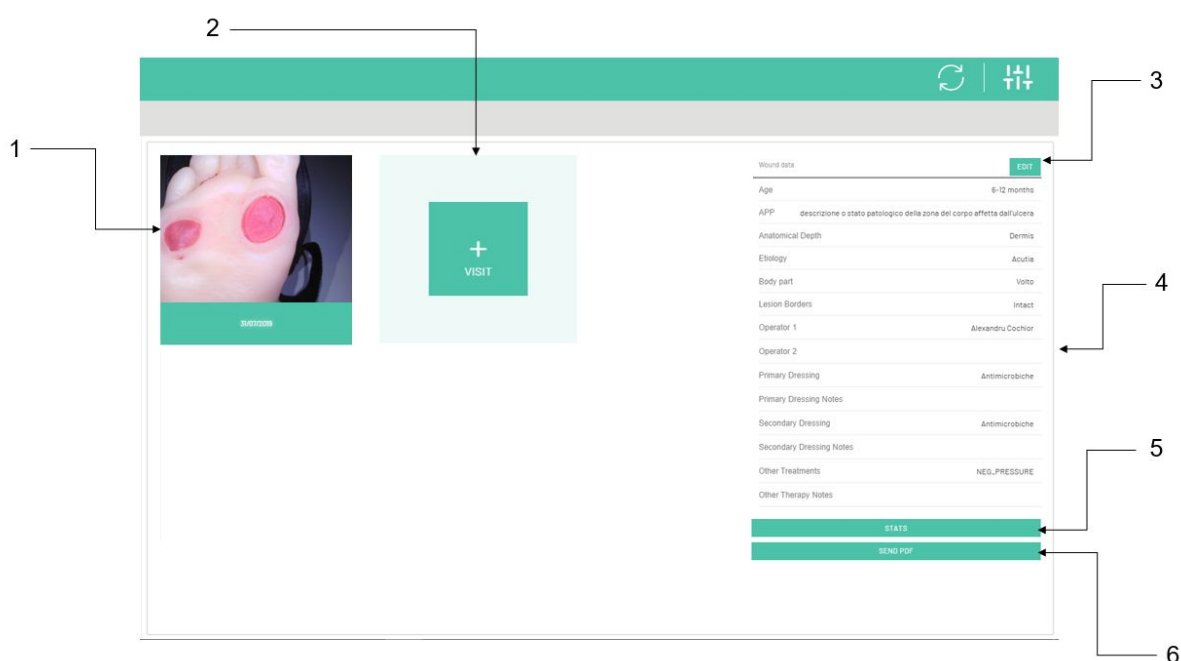


Figure 13: Wound profile.

ID	Description
1	Tiles of the visits made to the ulcer accompanied by photos and

	date.
2	Add a new visit icon.
3	Ulcer data editing icon.
4	List of ulcer data.
5	Ulcer Statistics Icon.
6	Icon for creating a PDF wound report.

## 10.2 - Adding/editing/deleting a wound profile

As in the case of the patient profile, the user has the ability to add a new wound to the patient's medical history or modify the attributes of an existing wound.

1. Add New Wound: Select the Add Wound icon from the patient profile screen (ID 2, Figure 11).
2. Changing the attributes of an existing wound: Select the ulcer edit icon from the patient's profile screen (ID 3, Figure 13).

In the case of a new ulcer, once the Add Wound icon is selected (ID 2, Figure 11), the operator will see the ulcer data entry form as shown in Figure 14.

The screenshot shows a mobile application interface for entering wound data. At the top, there is a teal header bar with a refresh icon and a list icon. Below the header, the form is titled 'Wound data'. It consists of several rows of input fields:

- Etiology \*** (dropdown menu)
- Age \*** (dropdown menu)
- Clinic status \*** (dropdown menu)
- Anatomical Depth \*** (dropdown menu)
- Pathological Proximal Anamnesys** (text input field)
- Healed** (toggle switch, currently off)
- Healing date** (text input field)
- Lesion Borders \*** (dropdown menu)
- Body part \*** (dropdown menu)
- Proven \*** (radio buttons for **SURE** and **ALLEGED**)

At the bottom of the form, there are two buttons: a red **DELETE** button and a teal **SAVE** button.

Figure 14: Ulcer data entry form

If the wound is a new entry in the database, the form will be empty. If the wound already exists in the database and you want to make a change to its data, then the fields will be pre-filled with the pre-existing data that can be changed. In order to enter the required information in the form you must select the desired field, at which point the drop-down list will appear (if the field provides a choice between several options), or a cursor to enter the text. Once you have completed the form, you must select the Save icon at the bottom of the same page.

In case the user wants to delete a wound profile, it is necessary to select the Delete icon at the bottom of the ulcer insertion tab page, as shown in Figure 14.

**Important:** The data cannot be saved if the following fields have not been filled in:

1. Etiology,
2. Age of the ulcer,
3. Clinical status,
4. Anatomical depth,
5. Peri-wound,
6. Body part,
7. Proof of aetiology.

**Important:** Once a profile of a wound is deleted, all data related to the wound and of the visits performed on that wound will be lost.

### 10.3 - Performing a new visit

To perform a new visit on a given wound, the operator must select the icon to perform a new examination (ID 2, Figure 13). Once the icon is selected, the camera control screen will be activated to perform a new examination as shown in Figure 15 (components of the screen in the following table).

**Important:** Performing a visit is a feature found only in the mobile version of Wound Viewer software.

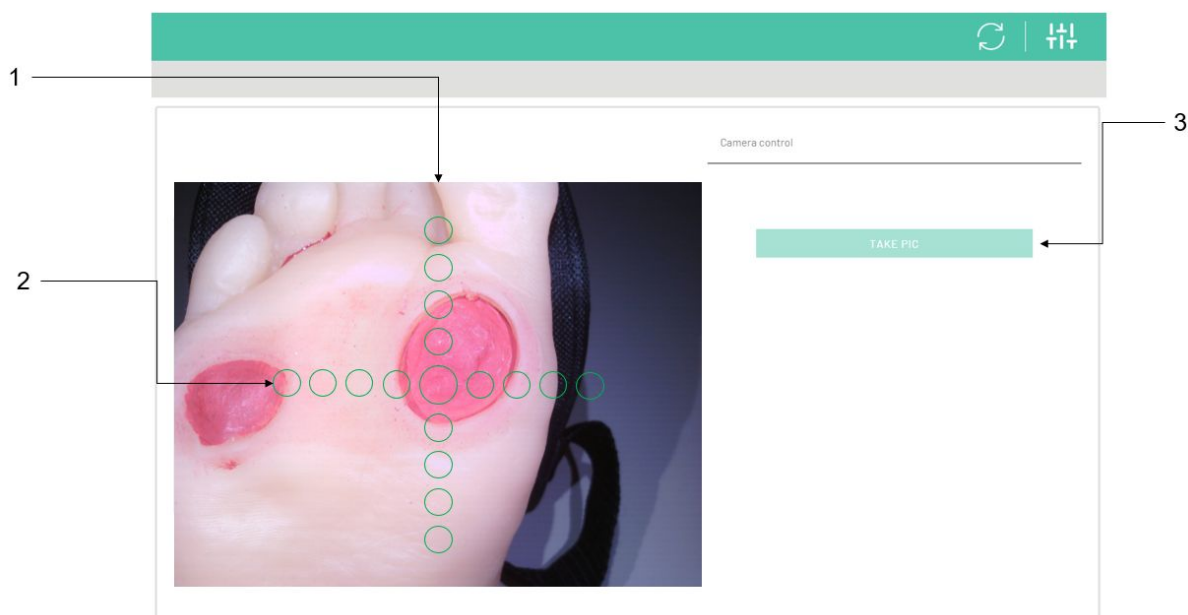


Figure 15: Camera control screen

ID	Description
1	Camera Streaming Screen: This frame shows what is being framed by the camera in real time
2	Pointer for correct targeting of the device
3	Take picture icon

**Important** When the camera streaming is active, before taking the picture, make sure that all 4 white LEDs on the back of the device are lit and working.

**Important:** Make sure that the wound is fully visible and not covered by bandages before the examination. Ensure that the wound is clean and there is no dressing or dressing residue (where possible).

To carry out the visit it is necessary to follow the following steps in order to obtain the best possible quality of the analysis.

1. Through the streaming screen, point the device at the wound so that the wound is fully framed.
2. Position yourself, with the device at a distance between 5 cm and 40 cm from the wound plane, so that the device is as parallel as possible to that plane (as shown in Figure 16).

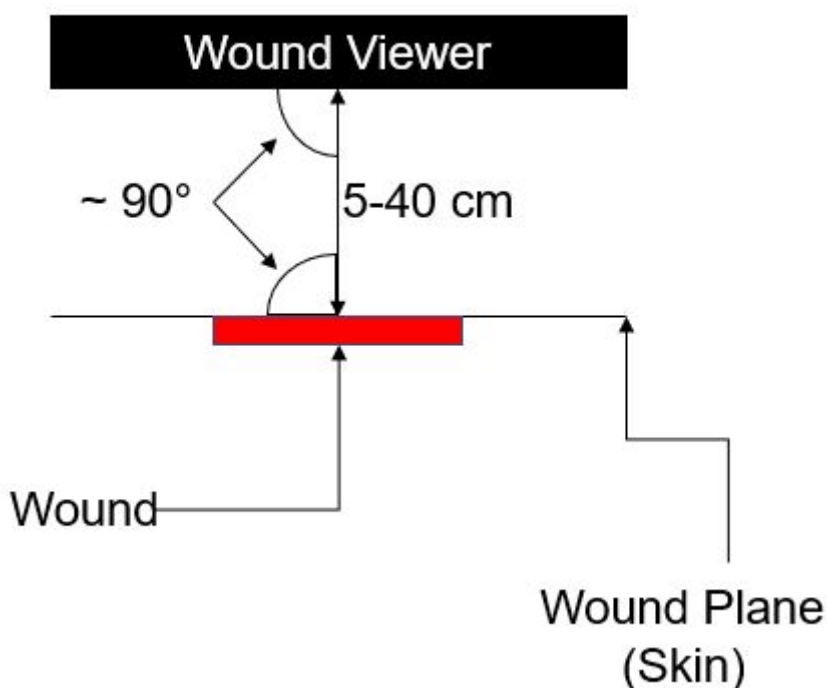
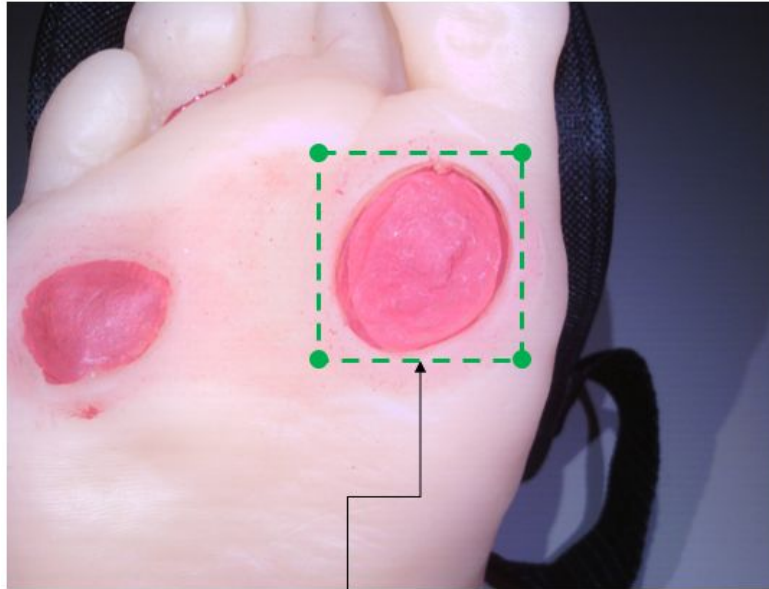


Figure 16: Correct positioning of the Wound Viewer in relation to the wound plane

3. Using the pointer (ID 2, Figure 15), position yourself so that:
  - a. The central dot falls inside the wound and at least one of the other dots on the axes of the cross falls outside the edges of the wound, but still on the wound plane (the positioning shown in Figure 15 is to be considered optimal),
  - b. One of the axes of the pointer is parallel to the main axis of the analysed limb (e.g. run along the length of the forearm or leg, where possible).
4. Make sure the image is in focus (the device implements an auto-focus system, within one second after framing the camera will focus the image).
5. If the previous points have been followed you can take the picture by pressing the take picture icon (ID 3, Figure 15).
6. Once the take picture icon is pressed, hold the device in the same position for 2 seconds to collect all the images necessary for analysis.
7. Once the images have been collected, the photo taken with the highest illumination will appear on the device screen. To proceed it is necessary for the operator to confirm by means of the appropriate icon. In case the photo taken is not considered satisfactory, it is possible to discard it and proceed to a new image collection (repetition of points 1 to 5).
8. If the photo is confirmed, the Region of Interest - ROI selection screen will appear (as in Figure 17). The ROI must be selected by moving and changing the size of the highlighted box:
  - a. The box can be positioned by dragging it inside the image while keeping your finger pressed inside the box.
  - b. You can change its size by dragging and moving the points positioned on its corners with your finger.
9. Select the ROI such that:



- a. The entire wound is selected,
- b. The edges of the box should be as close to the edges of the wound as possible,
- c. Avoid inserting parts of the image that depict background objects (e.g. other body areas, objects placed near the wound) into the frame (if possible).
- d. The ROI shown in Figure 17 shows an ideal example of positioning.



ROI

Figure 17: Correct ROI positioning

10. Once the ROI is confirmed through the ROI icon, the Wound Viewer analysis algorithm will bring the user to the peri-wound calculation selection screen (Figure 18). The peri-wound calculation is not mandatory for the visit, but it is an option selectable by the user. If you want to proceed with the calculation you must select the "Calculate Peri-Wound" icon and proceed with what described in point 11, otherwise selecting the "Proceed" command you will get the results of the visit (unless the peri-wound calculation). If you do not want to proceed with the per-wound calculation, proceed to point 12.

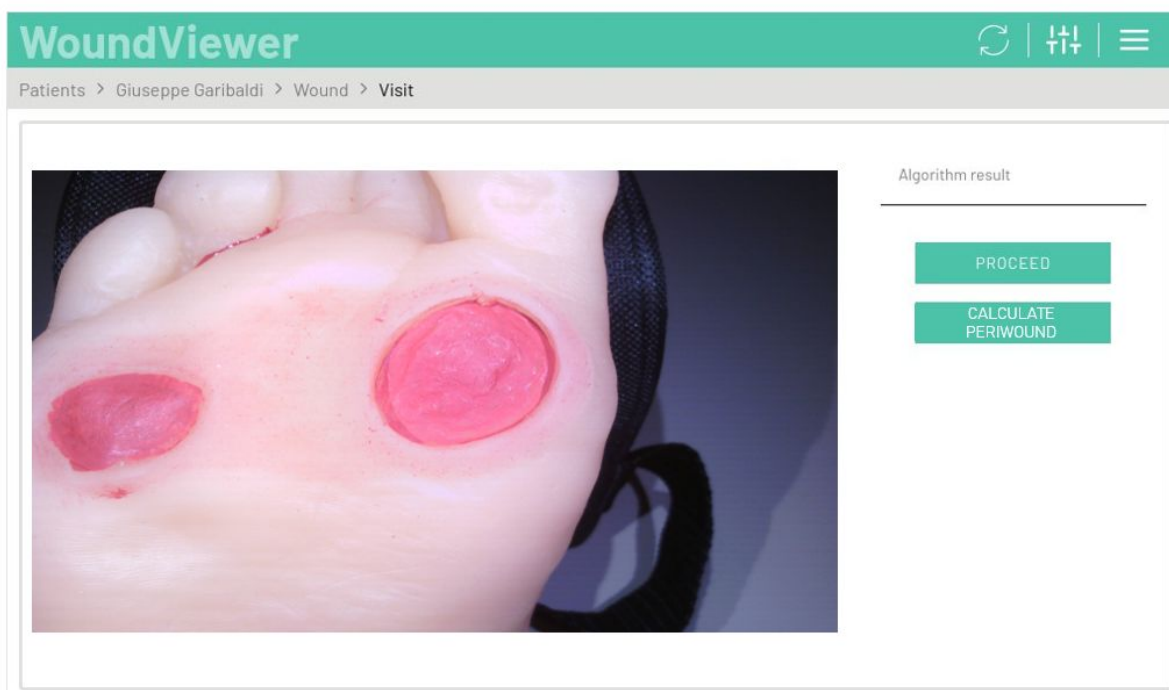


Figure 18: Selecting the peri-wound calculation.

11. Once the calculation is requested, after a short calculation time, the peri-wound identified by the algorithm will be proposed (Figure 19). In this screen the user will have the possibility to modify the calculated contour by moving the cardinal points of the contour on the screen. Each time one of the points is moved, it will change automatically. Once the contour is found to be satisfactory, by selecting the "Elaborate Contour" command the user will be taken to the result screen, described in point 12.

**Important:** The contour calculated in this interface does not reflect the contour of the wound, but of the peri-wound.

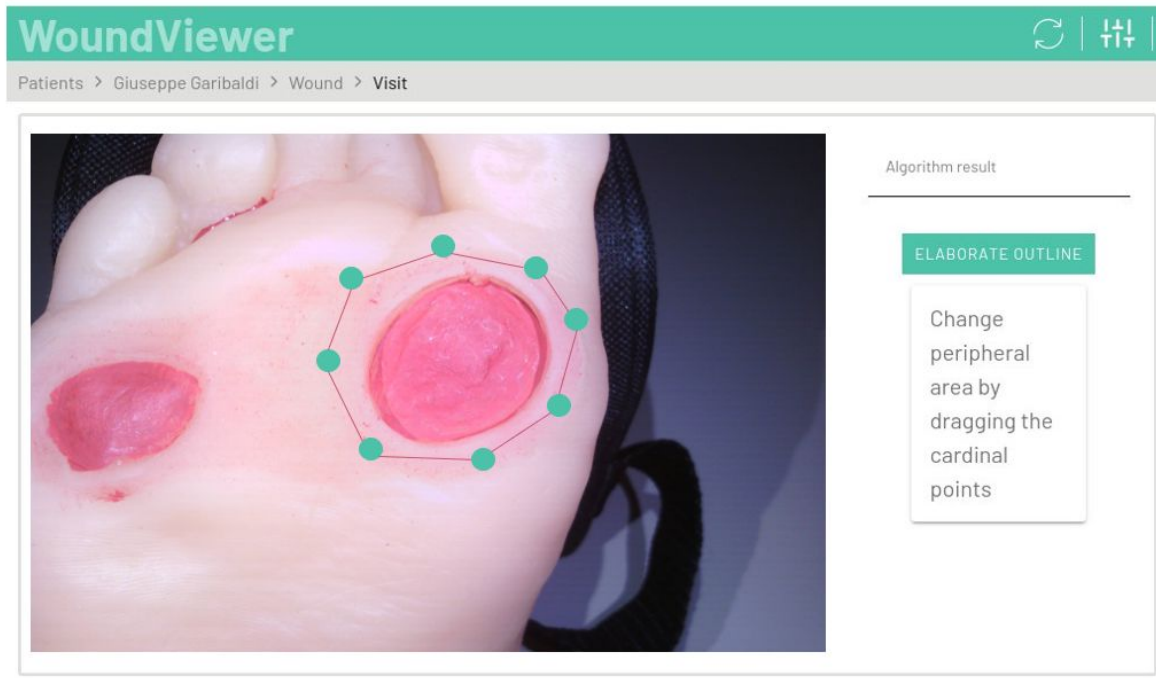


Figure 19: Outline representation of the peri-wound contour with the cardinal points, whose positions can be modified by the user.

12. Once the inputs have been confirmed, Wound Viewer will produce the result of the visit which will be visible in the result screen (Figure 20) where the parameters returned by the analysis will be displayed:
  - a. Wound area in  $\text{cm}^2$ ,
  - b. Wound depth in mm,
  - c. Wound volume in  $\text{cm}^3$ ,
  - d. Peri-wound area (if calculated) in  $\text{cm}^2$ ;
  - e. Percentage of Red, Yellow, Black and White,
  - f. Granulation classification according to the Wound Bed Preparation (WBP) scale (ref: Falanga, Vincent, Liliana J. Saap, and Alexander Ozonoff. "Wound bed score and its correlation with healing of chronic wounds." *Dermatologic therapy* 19.6 (2006): 383-390).

Visit date

Area [cm <sup>2</sup> ]*	Depth [cm]*	Volume [cm <sup>3</sup> ]*
3,5	1,5	3

Yellow %*	Red %*	Black %*	White %*
0	100	0	0

Infection degree (K&H)\*

1 2 3 4 5 6 7 8 9 10 11

Pain\*

1 2 3 4 5 6 7 8 9 10

Dressing

Primary Dressing\* None

Primary Dressing Notes

Secondary Dressing\* None

Secondary Dressing Notes

Secondary Dressing\* None

Secondary Dressing Notes

Other Treatments\*

Other Therapy Notes

Operators and details

Visit date\* 01/08/2019 Location

Operator 1\* Alexandru Cochior

Approved\*  Approval date

Operator 2\*

Approved\*  Approval date

Operator 2\*

Classification

WBP Score\* A B C D Exudate\* 1 2 3

**DELETE** **SAVE**

Figure 20: Visit result

**Important:** All parameters returned by the algorithm can be modified and corrected in case there is a clinical need by the operator.

11. All other parameters on the screen must be entered manually by the operator:
  - a. Degree of infection according to the Cutting and Harding scale through the selection of the criteria established for its determination (ref: Cutting, K. F., and K. G. Harding. "Criteria for identifying wound infection." Journal of Wound Care 3.4 (1994): 198-201),
  - b. Degree of exudate compared to the WBP scale,
  - c. Degree of pain perceived by the patient (on a scale of 1 to 10),
  - d. Primary dressing and description,
  - e. Secondary dressing and description,
  - f. Instrumental therapy and description,
  - g. Confirmation of the dressing.

**Important:** In case the practitioner has a Professional Healthcare Professional profile or a Coordinator then the dressings if inserted will be automatically confirmed. In case he is an Auxiliary Operator then these can only be confirmed at a later date by another type of operator and these will remain only as suggested.

12. Once the parameters entered are considered correct, you can save the system visit using the icon provided. At this point the new examination will be visible in the analyzed ulcer profile (Figure 13).
13. If any of the parameters exceed the thresholds set in the system or there is a clear worsening of the wound condition, an alert will be marked on the patient and the wound. This alert will remain active until the parameters are clinically improved with subsequent visits. For more information on thresholds and their setting, refer to section 11.2 of this document. Patients who have an active alert are displayed with the alert symbol on the homepage (ID 5, Figure 8).

## 10.4 - Editing a visit

Selecting the single visit tile (ID 1, Figure 13) allows you to access the single visit outcome screen (similar to the screen shown in Figure 20). The operator can correct the results of the examination and the results obtained at any time. In the case of a Coordinator or Professional Healthcare Professional, they will be able to confirm the dressings applied.

If you want to delete an already performed examination you need to access the desired examination result (ID 1, Figure 13) and select the Delete icon at the bottom of the same screen as shown in Figure 17. It is also possible to perform the operation on an examination that you are currently performing using the same procedure. In this case you will be returned to the screen shown in Figure 15.

**Important:** Once a visit is deleted, the visit data is lost.

## 10.5 - Ulcer Statistics, PDF Reports and Messaging Service

By selecting the appropriate icon (ID 5, Figure 13) you can access the ulcer statistics screen. The screen displays a photo of your last visit and a summary of the data collected. In addition, the screen contains graphs showing the time trend of the following parameters regarding the visits performed:

1. Wound area in  $\text{cm}^2$ ,
2. Wound depth in mm,
3. Wound volume in  $\text{cm}^3$ ,
4. Pain perceived by the patient (on a scale of 1 to 10),
5. Degree of infection according to the Cutting and Harding scale,
6. WBP classification,
7. Appearance of wound tissue (granulation in percent red, black, white and yellow).

Moreover, two additional functions can be performed from the same page:

1. Generate a PDF report: Selecting the "PDF Report" icon generates an overall patient and wound report that includes all the information that is entered on the same statistics page, in PDF format. The generated report is sent immediately (if the device is connected to the internet) to the operator's e-mail address (same as the Username). If the device is not connected, the report cannot be generated. In order to generate the report and send it, a synchronization must be performed first.
2. Send a message: you can send a message to other users in relation to a visit made. The message can be read by all users who have access to the patient data. This service is described in detail in paragraph 10.6 of this manual.

## 10.6 - Messaging service between users

As described in the previous paragraph, operators are given the possibility to write and send messages to other operators (who have access to the same data).

### 10.6.1 - Access to the messaging service

You can access the messaging service in three different ways. Each one leads to the same screen and will refer to the visit on which you want to send a message.

1. From the User Menu (ID 8, Figure 8): by selecting the User Menu you will be able to access the messages by selecting the "Last Messages" option from the dropdown that appears on the right side of the screen,
2. Select a specific visit from the Ulcer Profile screen (ID 1, Figure 13),
3. Selecting the "Go to Chat" icon from the Ulcer Statistics screen (described in paragraph 10.5 of this manual).

By performing any one of the three actions the user will be directed to the Visiting Results screen (described in paragraph 10.4). In the section below the photo of the visit (as shown in Figure 21) is displayed the space dedicated to writing, sending and reading messages.

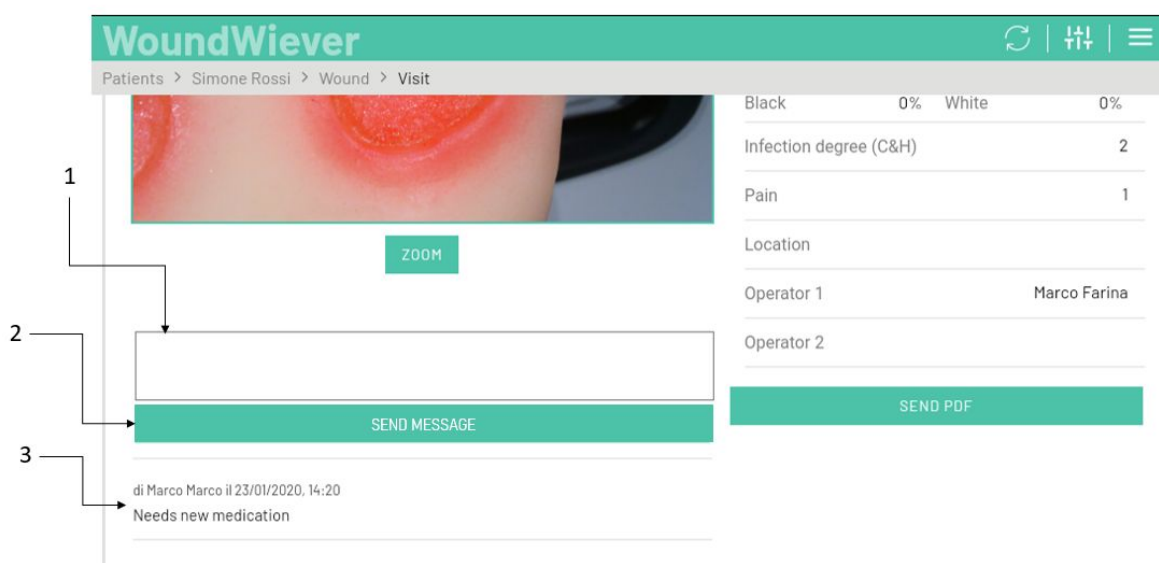


Figure 21: Messaging section.

ID	Description
1	Section dedicated to writing the message
2	Message sending command
3	Stream of the messages sent by users with information about the user who sent the message, date and time

**N.B.** If you wish to access the messaging functionality through the User Menu, this option will allow the user to access the messages already sent in order to provide a reply. If you wish to write a new message on a visit where there are no previous messages, you must access the functionality through the other two options described (i.e. select the visit from your Ulcer Profile or through the "Go to Chat" command from the Statistics screen).

### 10.6.2 - Writing, sending and reading messages

As shown in Figure 18 the messaging service is present on the Visit Outcome screen. By selecting the Message Writing Section (ID1, Figure 21) you can type a message. Once you have typed the message you will be able to send it to other users by selecting the "Send Message" icon (ID 2, Figure 21).

Once the message has been sent, all users who have access to the patient's data, and consequently to the data for the particular examination, will be sent the message. By synchronizing (as described in section 8.2) the device, all other users will be able to see the message left by the colleague. All messages left by users can be viewed in chronological order with the reference to the sending user, the date and time the message was sent.

**Important:** When a message is sent, all users who have an active account will receive the notification email at their inbox that matches their username.

**Important:** It is not possible to send a message about a visit that is not saved.

**Important:** Messages are related to a single visit. A new chat thread is created for each visit.

## 11 - System settings:

Each user has the possibility to access the system settings through the appropriate icon on the homepage (ID 3 , Figure 8). When the icon is selected, the settings screen is accessed (Figure 22).

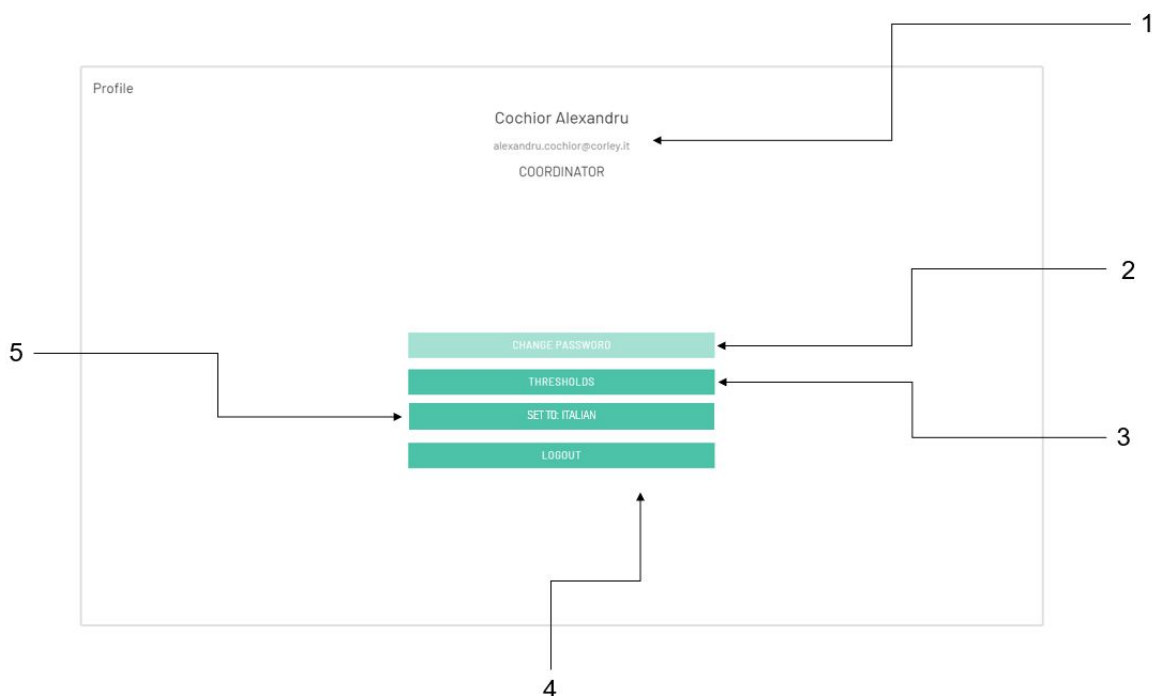


Figure 22: Settings screen

ID	Description
1	User profile and typology
2	Password change icon
3	Alarm threshold setting icon
4	Logout
5	System language change icon

### 11.1 - Changing the password

The operator has the possibility to change his password according to personal criteria. To make the change, the user must select the appropriate icon (ID 2, Figure 22) on the settings screen. The system will make the user to enter the new password and confirm it. Once confirmed, the new password will be automatically saved to the system.

**Important:** After changing the password it is advisable to perform a synchronization as described in section 8.2.



## 11.2 - Displaying and changing alert thresholds

The system has set some clinical thresholds that serve to warn the operator of the worsening condition of the wounds. These alerts are triggered when the parameters worsen between visits. There are two thresholds that are editable (only by a Coordinator operator) and are displayed on the screen shown in Figure 23 (the screen can be accessed by selecting the appropriate icon from the ID 3 settings screen, Figure 22).

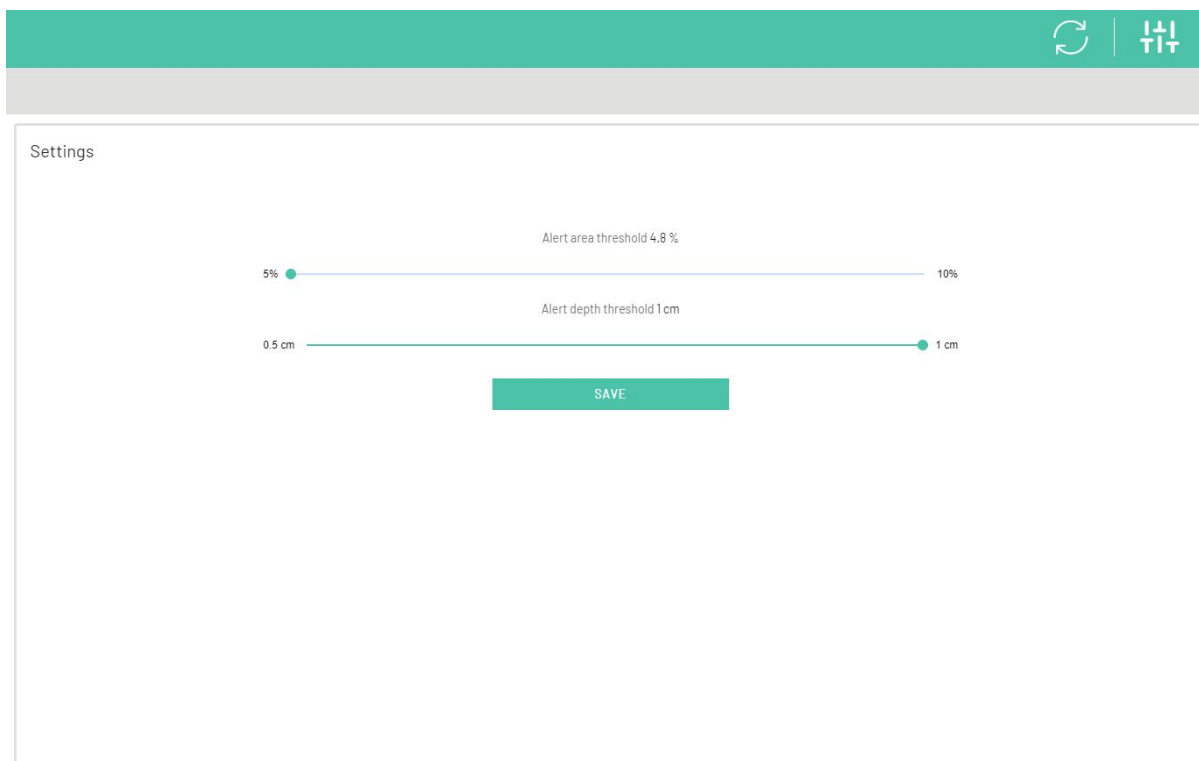


Figure 23: Alarm threshold setting screen

In the screenshot in Figure 23 you can set the alarm thresholds for worsening wound area and wound depth. These can be set according to the following conditions:

1. Area thresholds: in percentage value between 5% and 10%,
2. Thresholds depth: between 0,5 mm and 1 cm.

All other wound parameters will trigger alerts (described in points 10 and 11 of paragraph 10.3) when the parameter worsens.

The new thresholds will be saved by selecting the appropriate saving icon.

**Important:** After changing the thresholds, it is advisable to perform a synchronization as described in section 8.2. The modified thresholds will be activated with the new criteria on all the devices to which the entity belongs.

**Important:** Operators other than those with coordinator credentials can only view the values set for the thresholds, they cannot change them.

### 11.3 - Logout

To log out of the system, select the logout icon on the settings screen (ID 4, Figure 22). When you exit the system, you will be able to log in again from the login screen (Figure 4).

### 11.4 - Language change

It is possible to change the language from the system using the appropriate icon on the Settings screen (ID 5, Figure 22). The currently selectable languages are Italian and English.

## 12 - Features reserved for Coordinators

Users who have Coordinator credentials have access to the following additional features:

1. Dashboard,
2. User management.

These two features are accessible only through the Desktop version of Wound Viewer software. In details, the dedicated menu in the Desktop version is located on the left side of the individual screens (Figure 24).



Dashboard
Users
Patients
Settings
Synchronization
Logout

Figure 24: Dedicated menu for the Desktop version of Wound Viewer software

### 12.1 - Dashboard

The dashboard is the tool for the extensive management of the data collected with the devices for the use of the entities. Through the dashboard it is possible to find any cynical data concerning patients, wounds and visits and connect them to the users who have

collected them. To access the dashboard, select the appropriate icon in the menu dedicated to the Desktop version shown in Figure 24.

Figure 25 shows the diagram of the dashboard. Inside the dashboard there are several tiles that collect data about the entity, patients, visits, wounds and operators. By selecting an icon from the various tiles, the other data will be automatically filtered. For example, if selected a single practitioner, data about the patients they visited, the visits they made and the wounds they treated will be shown.

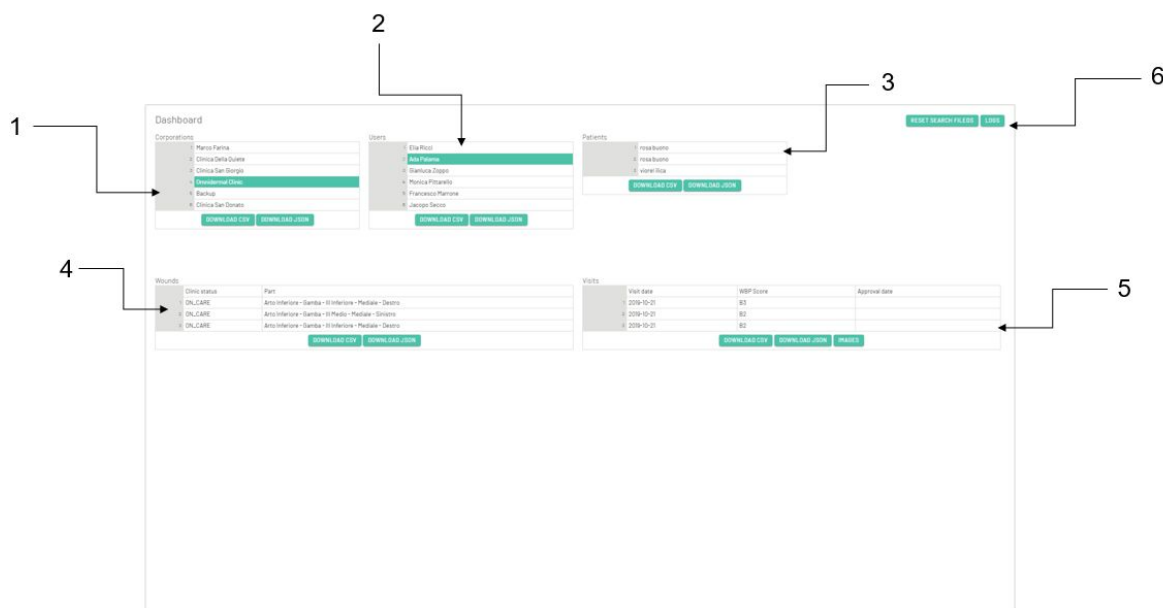


Figure 25: Dashboard

ID	Description
1	Entity tiles
2	User tiles
3	Patient tiles
4	Wound tiles
5	Visit tiles
6	Icons for resetting selections and logs

The dashboard also allows you to download the selected data locally via the appropriate icon. The numeric and text data will be downloaded in a CSV or JSON file on the terminal through which you are accessing the system. The image files of the individual visits will instead be downloaded with a ZIP file. The individual images are automatically named by the system with the code of the visit in which they were taken so that they can be traced back to

the other accessible data. As described in ID 6 in Figure 25, you can reset the selections made in the dashboard and generate log files for maintenance and control purposes on your database.

**Important:** It is the responsibility of the individual entity to keep the data and disclose them in accordance with the law.

## 12.2 - User management

Coordinator users are the only ones who have the necessary privileges to add, modify and delete a user related to an entity. This can be done through the user management screen. Figure 23 shows the user management screen and the table below describes its components.

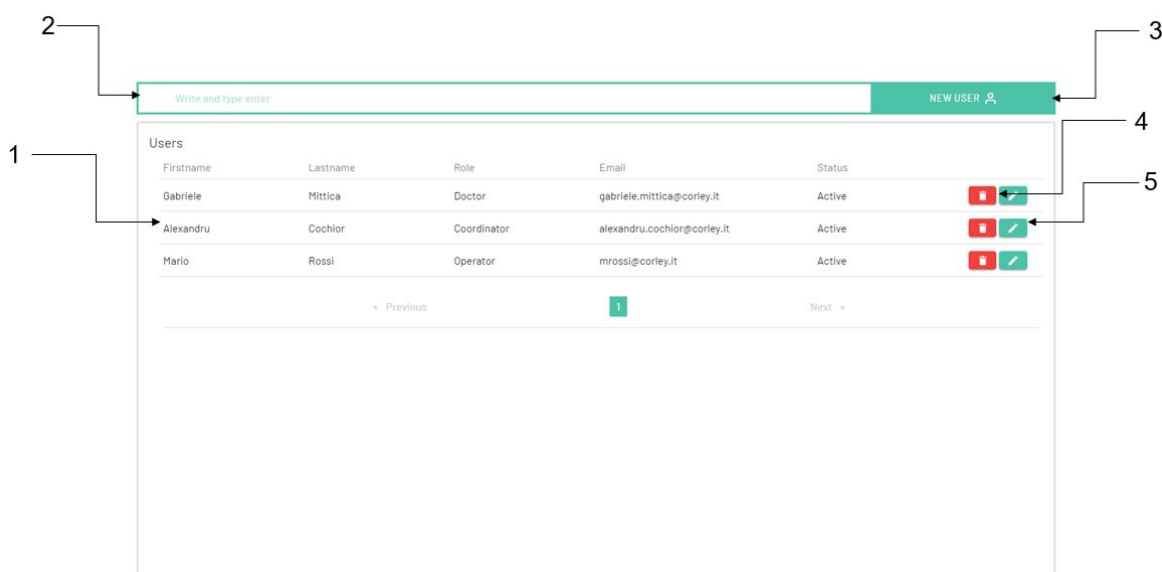


Figure 26: User management screen

ID	Description
1	Operators' list
2	Operator search bar
3	New operator icon
4	Delete operator icon
5	Edit operator icon

By selecting the user search bar (ID 2, Figure 26) it is possible to search for the individual user by typing in the first or last name of the desired user. In this case the list below (ID 1, Figure 23) will be updated according to the search criteria.

### 12.2.1 - Adding/Editing a new user

The Coordinator user has the privileges in his credentials to add a new operator in the structure or to modify his attributes. Depending on the action to be performed, the user must select:

1. The icon to add a new operator (ID 3, Figure 26) in case the user is a new user not registered in the system,
2. Select the operator data edit icon (ID 4, Figure 26) in case the operator is already present in the system. The icon to be selected must refer to the user whose data is to be modified.

In both cases the user data entry form will be displayed (Figure 27). In this screen the operator must fill in all the fields so that the user can be saved correctly in the system. Once the fields have been filled in or modified, the Coordinator operator must select the appropriate save icon.

Figure 27: Operator data entry form

In case the user is new, the form will be empty, in case of data modification the card will be pre-filled with the data of the selected user.

**Important:** In case of creation of a new user, it is necessary that the Coordinator user enters a temporary password for the newly created operator. This password will be automatically communicated by the system to the new user by email.

**Important:** The operators will be created active by default. In case an operator is deactivated he will no longer be able to access the system or use the Wound Viewer device.

**Important:** After the addition or modification of a user it is advisable to perform a synchronization as described in paragraph 8.2.

### 12.2.2 - Deleting an operator

The deletion of an operator is done by selecting the deletion icon referring to the user it is desired to be deleted (ID 5, Figure 23). If an operator is deleted from the system, he will no longer have access and will no longer be able to use a device. Unlike the deactivation of a user, if you want to proceed to restore the user, they should be recreated from scratch.

**Important:** After the addition or modification of a user it is advisable to perform a synchronization as described in paragraph 8.2.

## 13 - Limits and precautions when using the Wound Viewer device

1. You cannot use Wound Viewer to analyze circumferential ulcers (e.g., ulcers that revolve around a limb).
2. The depth measurements of cavity ulcers are referred to the first layer of tissue visible from the distance sensors, verify the correctness of the data.
3. Depth measurements of ulcers that have a length (distance between the furthest points of a wound) greater than 10 cm may not be accurate. A verification of the data obtained is necessary.
4. In the case of analysis of ulcers archipelagos, the operator is free to analyse them as a single wound or as a group of wounds. In the first case it is necessary that these are within a radius of 5 cm from the centre of the archipelago and must also be evaluated in subsequent visits as a single wound.

## 14 - Maintenance

1. It is suggested to keep the device always dry and away from staining substances.
2. Avoid soiling the surface of the camera, LEDs and distance sensors. In case of dust or dirt, you can clean the camera, LEDs and sensors by wiping them with a slightly damp cotton cloth. Do not allow liquids to enter the device housing. Dry immediately after cleaning.
3. Avoid keeping the device near heat sources.
4. In case of malfunction, contact the manufacturer and report the problem. Do not attempt to repair or modify the device without prior indication from the manufacturer's technical personnel. Any attempt to tamper with the device may result in its malfunction.
5. It is possible to clean and disinfect the device and with a cotton cloth damp with ethanol or with a disinfectant solution. Use caution while performing this operation close to the sensors and the camera.

## 15 - Certifications

The Wound Viewer system has been implemented and designed according to the following standards.

1. EN ISO 13485 Medical devices - Quality management systems - Requirements for quality management systems - Requirements for regulatory purposes.
2. EN 60601-1 Medical electrical equipment - Part 1: General requirements for safety.
3. EN 60601-1-11 Medical electrical equipment - General requirements for basic safety and essential performance, side-standards: Requirements for medical electrical equipment and medical electrical systems used in the domestic healthcare environment
4. EN 60601-1-2 Medical electrical equipment - Part 1: General requirements for safety 2: Collateral standard: Electromagnetic compatibility - Requirements and testing
5. EN 62304 Medical device software - Software life cycle processes.
6. EN ISO 14971 Medical devices - Application of risk management to medical devices.
7. 1907/2006 Regulation (EC) of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency.
8. 2011/65/EU Directive of the European Parliament and of the Council of 8 June 2011.
9. 2011 on the restriction of the use of certain hazardous substances (RoHS) in electrical and electronic equipment (recast).
10. EN ISO 14971 Medical devices - Application of risk management to medical devices.
11. EN 62366-1 Medical devices. Application of usability engineering to medical devices.
12. The device is certified and classified as Class I according to EC 93/42.



### 15.1 - Compliance with data management and data protection regulations

The data obtained through the Wound Viewer system are subject to current legislation in terms of data protection and security (GDPR, Regulation (EU) 2016/679). The ownership of the data and the rights related to them are agreed through specific commercial regulations

stipulated between the parties. For this purpose, all data collected through the Wound Viewer system are maintained and managed through the Amazon Web Services platform, partner of Omnidermal Biomedics, which is compliant with current legislation and guarantees to the owners and users of the data all the rights assigned to them.

In particular, in accordance with the regulations in force, those entitled may exercise the following rights:

1. request and obtain information regarding the existence of your personal data, the purposes of processing and access to such data;
2. request and obtain the modification and/or correction of your personal data if you believe that they are inaccurate or incomplete;
3. request and obtain the deletion - and/or limitation of the processing - of your personal data if it is data or information that is not necessary - or no longer necessary - for the above purposes;
4. request and obtain the portability in a structured, commonly used, machine-readable format of personal data that are processed by automated means and request their transfer to another data controller.

## 16 - Producer and contacts

The Wound Viewer device have been developed and distributed by:

### **Omnidermal Biomedics srl**

Galleria Polidoro, 7

43121 Parma

P.I. 02895260343

[info@omnidermal.it](mailto:info@omnidermal.it)

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