

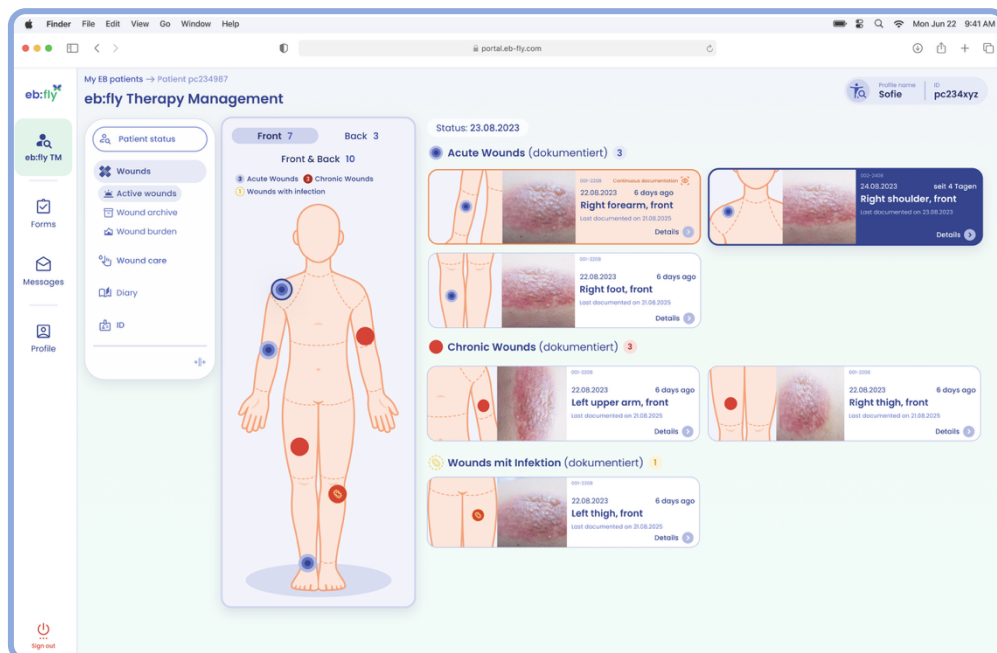
# INSTRUCTIONS FOR USE

eb:fly web portal healthcare professionals

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## The digital application for the self-determined management of your EB





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# 1 General provisions

## 1.1 Information about the instructions for use

This document contains the instructions for use for the eb:fly software with web-based portal for healthcare professionals (HCP) and mobile applications (apps). The instructions for use describe the medical device in terms of its intended use, area of application and functions.

Please read the instructions for use carefully. They represent the support for the proper use of eb:fly in the context of epidermolysis bullosa.

If you are a healthcare professional and have any questions about these instructions for use, please contact our healthcare professional support at [services@eb-fly.com](mailto:services@eb-fly.com).

For further information, please visit our website [www.eb-fly.com](http://www.eb-fly.com) or contact our HCP support at [services@eb-fly.com](mailto:services@eb-fly.com).

## 1.2 Intended use

eb:fly is an app with the purpose of supporting the care delivery for patients with epidermolysis bullosa (EB). The eb:fly app allows patients (or their relatives) to record wound images, perform wound area measurements, document wound care delivery and dressing changes, and record data on everyday life with EB, all with the character of a self-documentation; the data collected may be transferred to the HCP portal in encrypted form. This data can be accessed in the HCP portal by physicians who have been granted access by the patient or their relatives in the app. Following regular data entries, patients and their relatives obtain a better understanding and assessment of their EB disease and wound care actions using status overviews and progress flow charts, thus increasing their own care management competence. Patients can use reminder functionalities in the app to support their care routines such as dressing changes. In addition, useful information on EB is available in the app.

The data collected can be used by patients for self-reflection and better self-assessment and treatment adherence with regards to their EB disease.

The HCP portal allows physicians to access and review the data shared by their connected patients. Data insights may be used to facilitate HCP-patient consultations.

## 1.3 Functionality

eb:fly is based on EB medical findings and insights from people living with EB. Users of the app receive practical support with various options for self-documentation, information on the clinical presentation and everyday management of EB, as well as the option to transfer the collected data to physicians.

Access to eb:fly is possible at any time and from any location.

The HCP Portal is intended exclusively for use by healthcare professionals. The HCP portal is accessible with credentials provided by the manufacturer di:medi concept or via third-party services providing professional group controls, e.g. DocCheck.

As a German manufacturer, our Software is subject to the General Data Protection Regulation (GDPR). We provide eb:fly in accordance with applicable data protection requirements.

## 1.4 Area of application

eb:fly is intended for the self-documentation of care delivery data and disease data of children and adults diagnosed with epidermolysis bullosa (EB), or by their relatives.

ICD-10: Q81 Epidermolysis bullosa (Q81.0 - Q81.9)

## 1.5 Contraindications: When should eb:fly not be used?



There are no known contraindications. eb:fly is not suitable for indications other than EB and is not intended for such purpose.

## 1.6 Warnings and notes

Self-documentation of care delivery data and disease data with eb:fly does not replace regular visits to and check-ups by the attending physicians. eb:fly is intended exclusively for supporting self-documentation in EB by patients or their relatives. Reminder functions in the app are set by the patients themselves and do not constitute care delivery instructions or treatment advice. Reminders or notifications are only received in eb:fly if the user has provided consent. The settings can be revoked at any time.

Existing medication and/or treatment actions should not be taken or changed without consultation of the attending physician. In any case, the attending physician should be contacted if the patient's health condition or perception of the disease worsens acutely, or if the desired improvement does not show over a longer period of time (several days/weeks).

The results/ progress flow charts are intended to support further development of care delivery routines and care management competence. The data should only be interpreted by a physician. Under no circumstances should the data be used by patients or their relatives for any self-diagnosis or self-therapy.

If the use of eb:fly tends to have a negative impact on care delivery routines, the attending physician should be consulted before patients or relatives continue to use eb:fly.

The extent to which eb:fly can meaningfully support patient care delivery around EB depends on whether self-documentation is being made regularly, and as truthfully and accurate as possible.

## 1.7 Frequency of use

Insights from care delivery and experience with the EB disease indicate that eb:fly should be used ideally from several times a week to several times a day, each time for at least 5-15 minutes.

## 1.8 Side effects

There are no known side effects.

## 1.9 Interactions

There are no known interactions.

## 1.10 Conditions for use and installation

eb:fly can be used as an app on mobile devices such as smartphones or tablets. eb:fly is currently compatible with operating systems from Android 10 and from iOS 12.0, the apps are offered exclusively via the Apple Store and the Google Play Store.

The HCP portal can be used with a web browser, e.g. Google Chrome, Microsoft Edge, or Apple Safari. The HCP portal is available at [www.portal.eb-fly.com](http://www.portal.eb-fly.com). No specific software or application knowledge is required.

To be able to use eb:fly to its full extent, users must continuously update the software, e.g. operating systems or browser software of the respective end device. With older software or software that is not customarily used, users may only be able to use the service to a limited extent or not at all. Make sure that your end devices are protected by up-to-date antivirus software and firewalls or secure connections (VPN). Check your devices regularly for malware.

The use of the eb:fly HCP portal requires an existing internet connection.

Once installed, patients can use eb:fly without entering any personally identifying data. For identification purposes, the software assigns a unique identity code (ID) once, which can be found in the "Profile" section of the app; the ID also enables identification for individual connection and data transfer with attending physicians. Physicians can connect to an unlimited number of eb:fly users (IDs) via the HCP portal.

The HCP portal is only accessible for medical professionals (physicians) and can be used with access credentials issued by di:medi concept as the manufacturer of eb:fly (for information visit [www.eb-fly.com](http://www.eb-fly.com)) or with DocCheck access.

eb:fly currently can only be used by patients and relatives with a single ID on one device at a time; simultaneous use on different devices is not possible. The HCP portal can be used by an unlimited number of physician users at the same time.

## 2 Operating manual eb:fly HCP portal

Physicians are considered as healthcare professionals and eb:fly is a self-explanatory product. It is therefore not necessary to read the instructions for use, but it is recommended. Physicians can access the data of patients who are connected with them in the eb:fly HCP portal.

The eb:fly app offers patients and relatives various functions to support daily wound care management and everyday life with EB disease. The self-documentation option allows patients to document and track disease progression, and to share the data collected with their physicians. The direct insights into disease and care delivery obtained in this way can facilitate consultations between physicians and their patients and relatives.

We developed eb:fly together with EB patients and relatives as well as medical experts, and designed the application along the recurring routines of dressing changes to support these. The documentation in the app is divided into two areas that can be used in accordance with personal care routines:

### **Area 1: Wound documentation (wounds, wound care)**

App users can document their personal wound history (e.g. take wound images, perform wound area management, record wound condition) and document wound care delivery (e.g. drug use, dressing changes). The data is organized for each wound as a current status and as historic data series; also, different categories can be evaluated (e.g. acute and chronic wounds). Closed/ healed wounds can be stored in the wound archive.

### **Area 2: Diary**

Users of the app every day can answer a standard set of questions to collect data on quality of life and symptoms with EB. The questions were selected with medical experts and are building on established medical questionnaires for EB.

The questions are organized into a Check-in (prior to or with beginning of dressing changes) and a Check-out (alongside or after dressing changes).

The frequency and scope of documentation (e.g. for which/ how many wounds) can be flexibly selected in eb:fly and coordinated between patients and their physicians.

If physicians are connected to patients in the eb:fly app, the wound documentation data (wounds, wound care) is always made available in the HCP portal, in fully scope as recorded by the patient in the app. For diary data and wound archive data to become available, patients or relatives must grant access for physicians to these data separately in the "Profile" section of the eb:fly app.

## 2.1 Initial application

The web portal is available to physicians at [www.portal.eb-fly.com](http://www.portal.eb-fly.com) and can be used without any software installation on the end device.

The HCP portal is accessible for physicians with the following options:

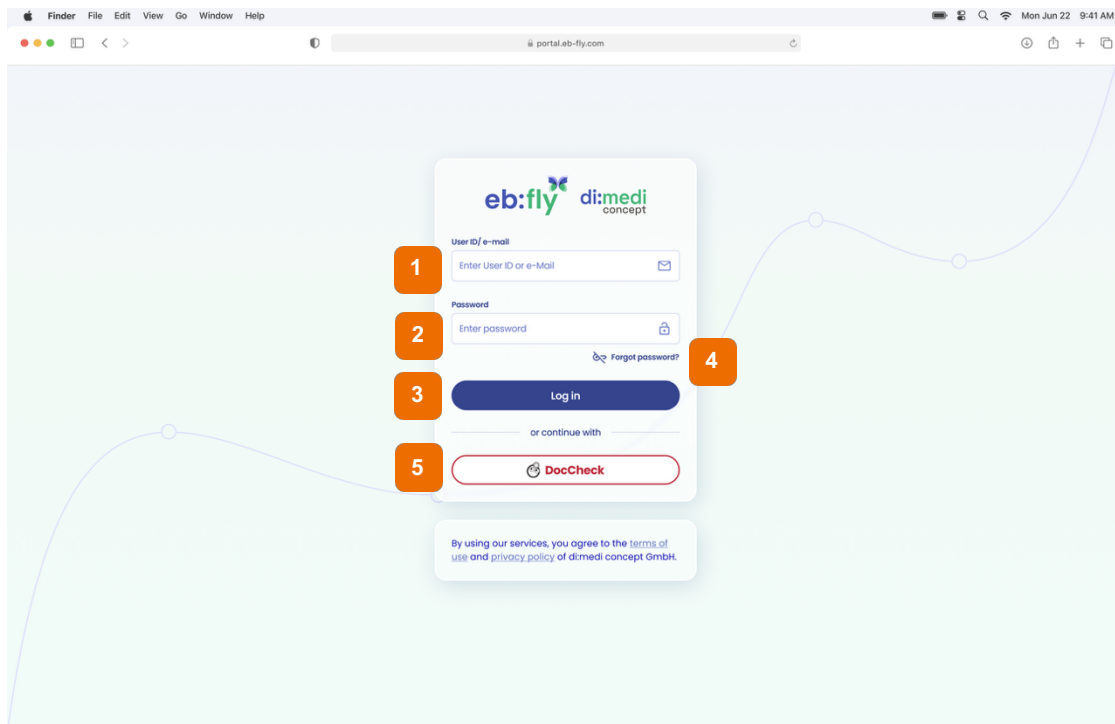
**eb:fly access credentials** (issued by di:medi concept):

Enter your access credentials with user ID or e-mail address (1) and personal password (2), and confirm with the "Log in" button (3).

If you have forgotten your password, you can request a new password using the "Forgot password" function (4).

**DocCheck access:**

If you already have a DocCheck account, you can click on the "DocCheck" button (5) and access the HCP portal.





## 2.2 Main menu

Following access to the HCP portal, the main menu opens - you find it on the left-hand side of the screen (1). The main menu allows to select the following functional areas:

### EB Therapy Management (EB TM) (2)

In this area, you have access to all data shared by patients connected with you in eb:fly. The list of patients is displayed in the central area.

### Forms (3)

In this area, surveys of patients using eb:fly can be carried out as single questionnaires or based on a defined protocol. This function cannot be used independently by physicians but requires project-related preparation and coordination by di:medi concept.

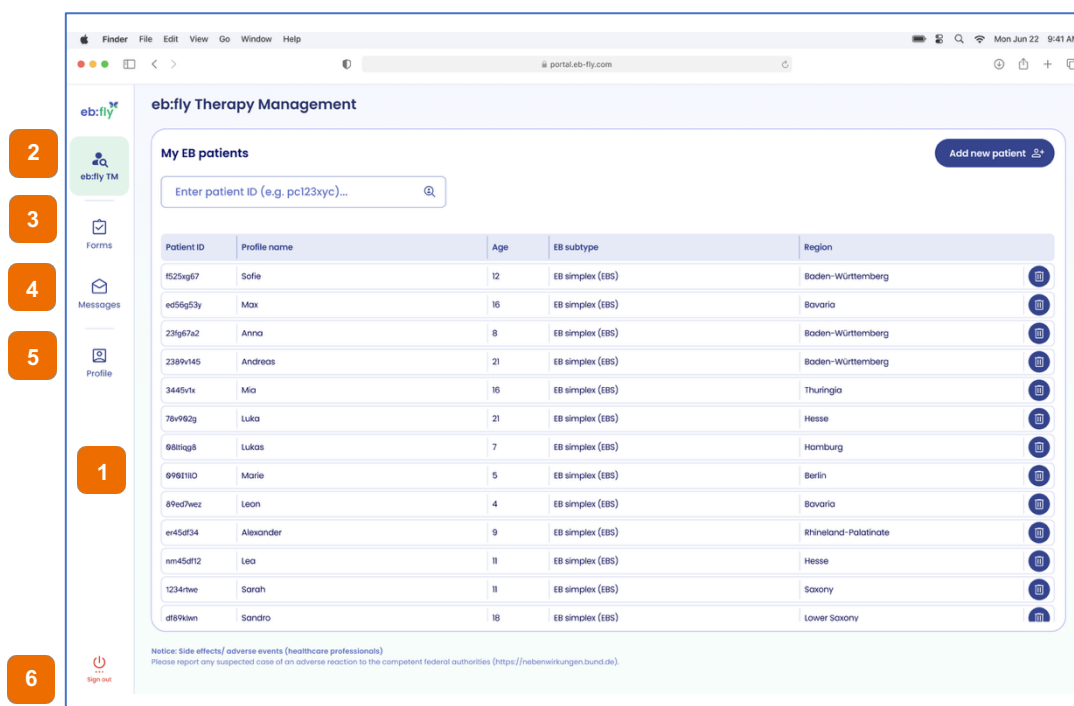
### Notifications (4)

This function allows you to send direct messages to connected patients within eb:fly that are delivered to the app.

### Profile (5)

In your profile, you will find your personal eb:fly user ID. You can add selected information about yourself and your medical institution. This information is displayed to patients connected to you in eb:fly as a confirmation of the connection. You can also give your consent to be found in a list of EB-experienced physicians, available to users in the eb:fly app via the "EB-experienced physicians" function.

You find the "**Log out**" button (6) at the bottom of the main menu which allows you to log out from and close the HCP Portal.



The functional areas are explained in more detail in the following chapters.

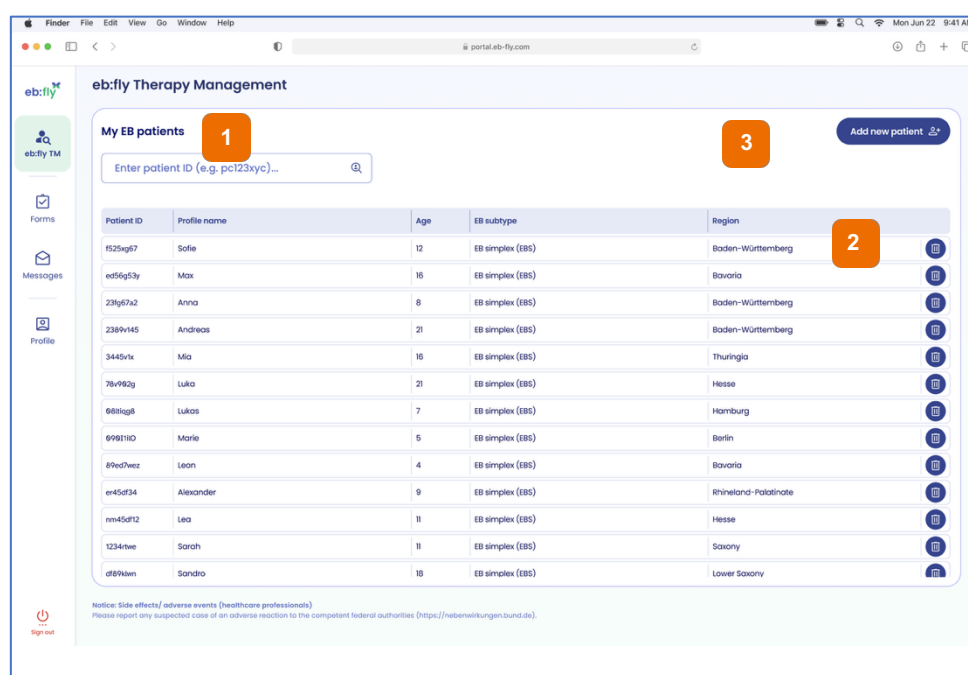
## 2.3 EB Therapy management

The functional area EB Therapy Management (EB TM) includes all data that connected patients self-record in the wound documentation (wounds and wound care). If made accessible by your patient, you also find the diary data here.

The starting point is an overview of all patients connected with you in eb:fly (1). The eb:fly app is used without personally identifying data; the data is made available pseudonymized with the patient's personal ID. Selected information of the patient's user profile is displayed in the overview (e.g. age, form of EB) (2). By selecting a patient in the list (click the individual line), you can access this patient's data (continue in chapter 2.3.2). If needed, you can also search for a specific ID.

Make a note of your connected patients' IDs also outside of eb:fly, e.g. in the patient record of your hospital or practice.

You can use the "Add new patients" button to connect with new patients that have already installed/ are using the eb:fly app (3; continue in chapter 2.3.1).



### 2.3.1 Add new patient

In order to gain access to your patients' data, they must expressly agree to the transfer to the HCP portal and confirm this in the eb:fly app. This requires the individual ID, which is automatically assigned to the patient in the eb:fly app; the ID can be found in the "Profile" section of the patient's app.

To be able to view your patient's data, you must first establish a connection with the patient's eb:fly app. You have two options for this:

**On site at the practice (1):** You generate a QR code. Your patients or their relatives must scan this on site using the eb:fly app.

**Remote/ not on site at the practice (2):** You generate an access code that you provide to the patient or their relatives. They must enter the access code in the eb:fly app. Please note that the access code is set to be valid only for 24 hours for data security reasons.

**Add new patient** ⓘ

**QR code scan (on site)**
1

Generate a QR code an allow your patient to screen it with the eb:fly app, to get access to the patient's data.

**Generate QR code**

**Remote contact to patient**
2

Generate a 6-digit pass key to provide to your patient. Ask your patient to enter the pass key in the eb:fly app, to get access to the patient's data.

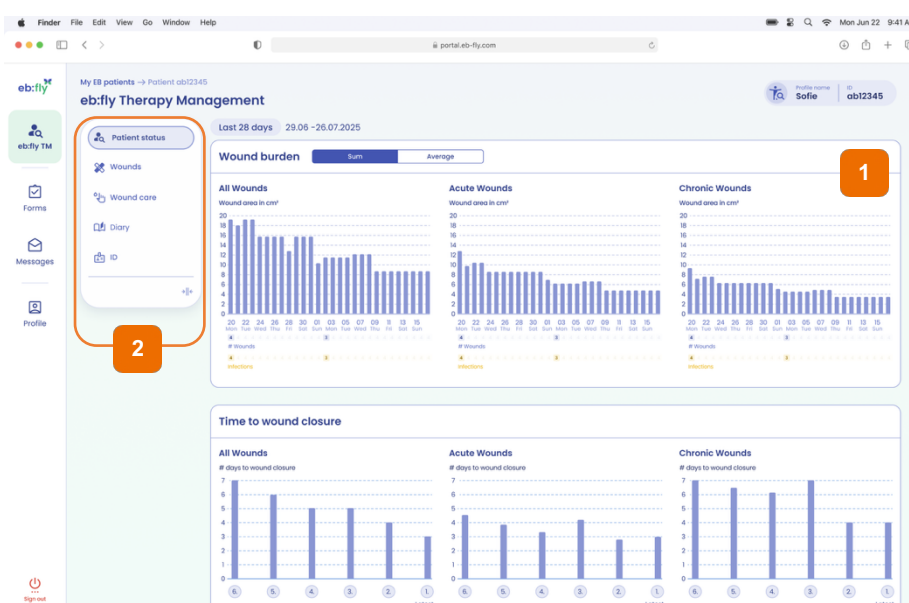
**Access key**

As soon as the connection is confirmed and you know the ID of your connected patient, you can access their data recorded in eb:fly.

## 2.3.2 Patient status

**The patient status** provides you with an overview of the current data/ time progress flows (last 28 days) of the individual patient (1). The status shows selected data: Wound burden, time to wound closure, and wound care delivery. If made accessible by your patient, you will also see data from the diary. Clicking the respective diagram provides an enlarged view; moving the mouse over a bar in the diagram shows the underlying values.

In the **patient menu** (2), you can access the data recorded for the various categories of wound documentation: Wounds, Wound care delivery and Diary (if made accessible). The individual areas are detailed below:



### 2.3.3 Wounds

The Wounds section provides data and diagrams on the wounds documented by your connected patients. Click on the menu items to access further data categories: the **"Active wounds"** section shows acute and chronic (wound age >14 days) wounds that are in current wound documentation, closed/ healed wounds are accessible in the **"Wound archive"** (this area requires individual access granted by your patient). The wound area measurements are displayed in **"Wound burden"**, similar to the information provided in the "Patient status".

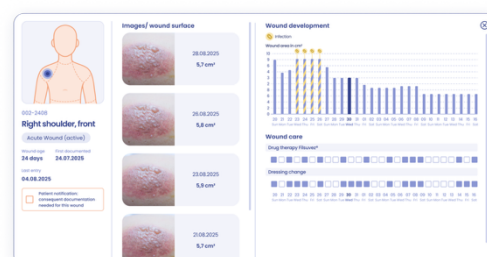
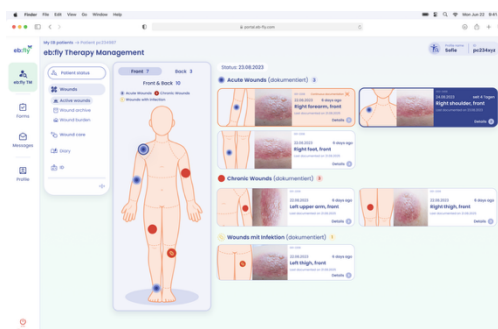
#### Active wounds

Active acute and chronic wounds are shown here, displayed as body view (choose "Front" or "Back") and as list view.

Click on a single wound to go to the **individual view**. Basic data, image flows, wound area measurements and wound care delivery forms are displayed here. By clicking or navigating the mouse over individual elements, you can enlarge images or see data values.

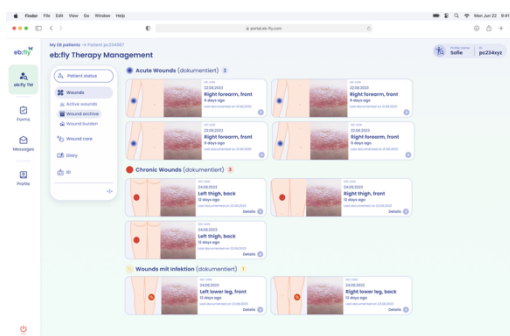
If a wound requires special attention from the physician's point of view: Select the option **"Patient notification: consequent documentation needed for this wound"**. This marker will show to the patient with the individual view of the selected wound in the app. You can also de-select this marker here at any time.

Close the view with the "x" button to return to the list view.



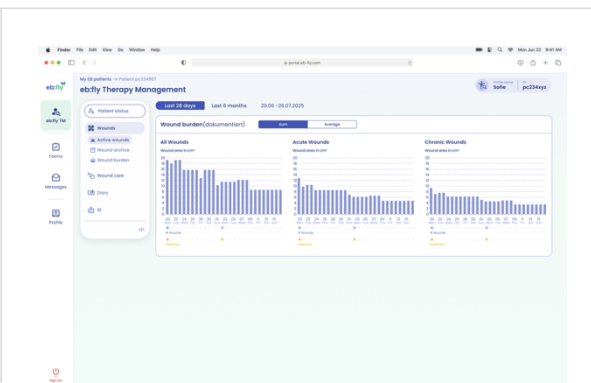
#### Wound archive

Here you will find previously documented wound data for wounds already categorized as "closed" (healed). The prerequisite is the patient's consent for access to this data category.



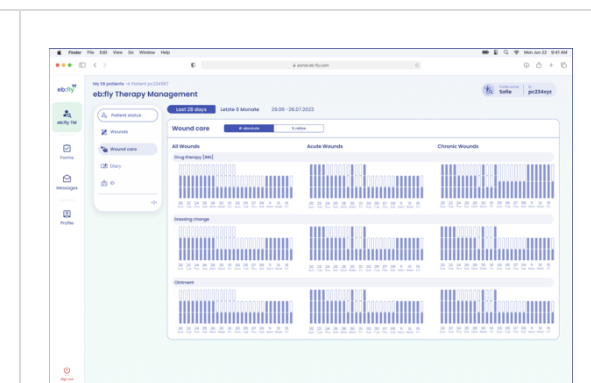
## Wound burden

You will find flow diagrams for wound area progression, in absolute and average values for the documented wounds (# wounds underlying to the data is displayed). Potential infections (documented "Wound conditions") are being highlighted.



## 2.3.4 Wound care

The **wound care** section provides graphical schemes of care delivery forms applied to wounds recorded in eb:fly. Drug therapies, dressing changes, and other forms of wound care provide insights into patient behaviour, e.g. treatment adherence.



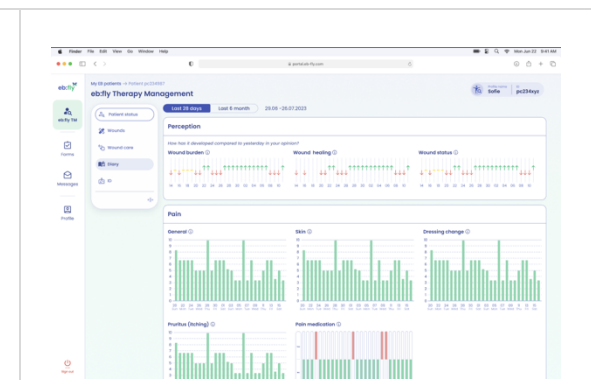
## 2.3.5 Diary

The **Diary** section gives you insights into your patient's quality of life and everyday handling of their EB.

You will find response data from the recurring patient questions on symptoms and perceptions/ behavior, divided into the areas of **general** (e.g. sleep, daily routine, ability to concentrate, motivation, nutrition), **pain**, and **perception** (EB disease trends). You can display the underlying questions asked to the patients using the "information" button ("i").

Also, recorded patient **weight data** is being displayed here.

Note: Patients must grant access to the diary data in the eb:fly app ("Profile" section).



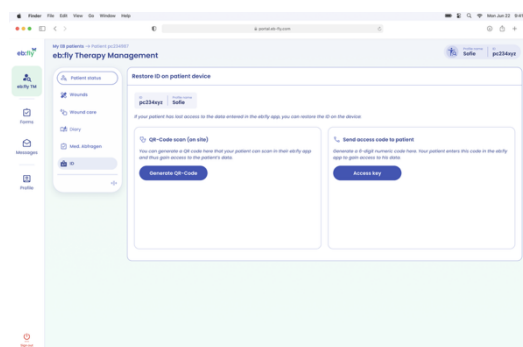
## 2.3.6 Medical forms

When using the forms function (not activated for regular eb:fly usage), questionnaires assigned to individual patients and their status are displayed here (see section 2.4).

## 2.3.7 ID

Here you can **restore your patient's ID** if they no longer have access to their eb:fly app, e.g. because the smartphone/ tablet used for eb:fly was lost.

For restoring the ID, the same two options are available as for connecting with a new patient: "On site"/ QR code and "Not on site" in the practice"/ Access code (see section 2.3.1).



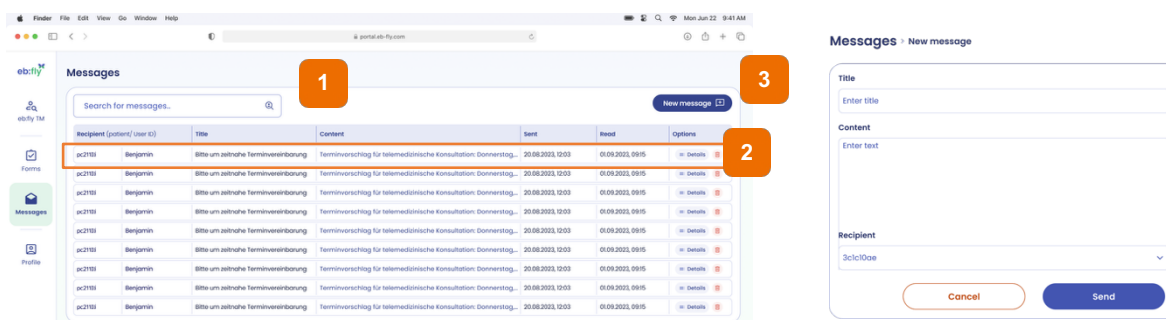
## 2.4 Forms

In this area, surveys with patients connected to eb:fly can be carried out individually or based on a protocol. This function cannot be used independently by physicians but requires project-related preparation and coordination by di:medi concept.

For using the forms function, you will be provided separate instructions for use.

## 2.5 Messages

This function allows you to send direct messages to connected patients within eb:fly, from the HCP portal to the app. The overview (1) shows the messages you have sent and their status. Further information can be displayed using the "Details" button (2). Send messages using the "New message" button (3).



## 2.6 Profile

In your profile, you will find your personal eb:fly user ID. You can add selected information about yourself and your medical institution. The information is displayed to patients connected with you in eb:fly as a confirmation of the mutual connection.

You can change your details using the "Edit" button (1) and "Save" afterwards in the individual parts of your profile ("Personal details", "Account")

You can also give your consent to be found in a list of EB-experienced physicians by users of eb:fly in the app's "EB-experienced physicians" function.

The screenshot shows the eb:fly Profile page in a web browser. The page is divided into three main sections: Personal details, Account, and Mandatory disclosures. The Personal details section includes fields for Title, First name, Last name, Medical specialty, and Experience with EB patients. The Account section includes fields for User ID, E-mail, Current password, and Select language. The Mandatory disclosures section includes links for Instructions for use, Terms of use, Privacy statement, and Imprint. An orange box labeled '1' highlights the 'Edit' button in the Personal details section. Another orange box labeled '2' highlights the 'Show me in EB-experienced HCPs' checkbox.