

Healthcare Practitioner Manual

DEARhealth v2.3



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1. Introduction

What is DEARhealth?

DEARhealth is a software platform that uses care path technology and recommendations to support the healthcare provider in making decisions in the treatment of patients. In the DEARhealth platform, the care of patients with chronic disease is arranged in a smart care pathway.

A care pathway represents the description of successive steps, decision moments and criteria in the care process for a patient group with a specific care need. In short, a care pathway is an overview of who will receive, which care, and when.



How does DEARhealth work?

Based on your patient's medical data as known to you and the results of questionnaires completed by the patient in their DEARhealth app, DEARhealth's care pathway technology provides recommendations. This can lead to adjustments in the care pathway to avoid certain risks. Examples of these risks include worsening of disease specific symptoms or hospitalization.



2. Access to the DEARhealth platform

DEARhealth via the EMR

You can reach the DEARhealth platform via your EMR¹. This functionality is called Single Sign-On or SSO. You log in to your EMR as usual and search for your patient in the way you are used to. If you use the SSO to open the DEARhealth platform, you will get redirected immediately and you don't have to login separately. DEARhealth will open the profile page of the patient that was selected in the EMR. You don't have to search separately for this patient on the DEARhealth platform. It is therefore not possible to switch patients within the DEARhealth platform. You must close the open patient and select a new patient in the EMR, then reopen the DEARhealth platform again via the SSO. The SSO can be used embedded in the EMR or in an external browser, depending on the EMR and EMR version in use.

DEARhealth standalone

In addition, you can also log in directly to the DEARhealth platform via https://practitioner-portal.dearhealth.eu/

1. The opening screen will appear as follows:



2. Enter your email address as known by DEARhealth and then click on login.

 $^{^{1}}$ Not every hospital has chosen to implement this functionality. Be sure that the browser provided by your EMR vendor does meet the required supported browsers. The function of the SSO can be different per EMR and version of the EMR.



3. You will receive a similar email to the one below with a DEAR verification code at your email address. The verification code is valid for 10 minutes. If this time expires before you use the code, start again from step 2.

Please use the code to login to the DEARhealth portal:

436207



DeaR health

4. Manually enter the verification code on the healthcare provider portal and click on 'Verify'.



5. You will then receive a second verification code via SMS, enter this code and click on 'Verify'.





6. You are now logged into the portal.

SSO

The SSO opened in an external browser and DEARhealth stand-alone have an automatic timeout and will be logged out after x minutes of inactivity (configurable per provider). Via the SSO a message will be shown after automatic time-out to notify that DEARhealth is closed because of patient privacy reasons. Stand-alone, you will be re-directed to the provider choice window. If the SSO is opened embedded in the EMR, it has not time-out and follows the EMR logout.



3. Patient Overview DEARhealth Platform

Patient Overview use

After logging in, you'll be taken to the patient overview page, where you can click through, filter, sort, or search for a specific (new) patient.

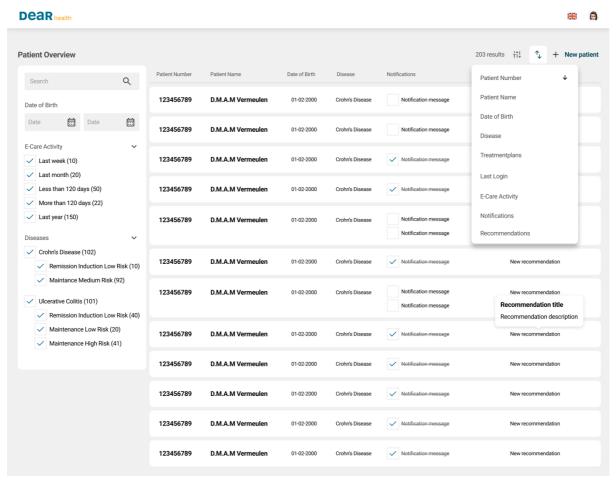


Figure 1 Patient Overview

Top Bar

- By clicking on the DEARhealth logo, you can navigate back to the previous page.
- You can select your preferred language.
- By clicking the user icon on the right, you can log out.

Filtering

 Patients can also be **filtered**. Click on Filters in the left-hand menu. An example is shown below:





- In the **search bar** (Search), you can search for patients based on various criteria:
 - o Patient Number.
 - o Patient Name.
 - o Date of Birth.
 - o Disease.
 - o Treatmentplan.
- The **E-Care Activity** column displays patients who have completed their latest E-Care activity within a specific time frame.
- The **Diseases** column indicates which medical conditions are present in the table. It is possible to filter patients by condition and/or scenario.
- Additional filters might be available depending on your system configuration.

Table

- The table consists of the following columns:
 - o Patient Number indicates the unique patient number assigned to the patient.
 - o Patient Name displays the initials and surname of the patient.
 - o Date of Birth displays the patient's date of birth.
 - o **Disease** indicates the patient's medical condition.
 - o **Treatmentplan** indicates the active care plan(s) assigned to the patient.
 - Last Login shows the most recent date the patient used the app.

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- E-Care Activity displays the most recent date an E-Care questionnaire was completed.
- o **Notifications** indicates if there are new notifications. The most recent notification is displayed at the top. Notifications can be handled from the patient overview page by clicking the checkbox.
- o **Recommendations** indicates if new recommendations are available. To view a recommendation, hover the mouse cursor over it. Recommendations can be accepted or rejected by clicking on the patient and processing them on the patient-specific page.

Notifications

- There are 4 types of notifications visible in the "Notifications" column:
 - o Patient has a low score.
 - o Patient's score has worsened compared to the previous measurement (the delta is determined based on the medical condition).
 - o Patient has a low score, but it has not worsened compared to the previous measurement (the delta is determined based on the medical condition).
 - o Patient has submitted a new questionnaire result.
- Notifications can be processed by clicking on the checkbox. After clicking, the notification
 will be crossed out and marked as processed. After some time, the processed notification
 will disappear from the patient overview page.

Sorting

Patients can be sorted in various orders. By default, sorting is based on the notification
 type. Additionally, you can sort by any available column by clicking on the following icon:



- Next, click on the column you wish to sort by. Clicking the same column again will reverse the sorting order (ascending or descending). The sorting direction is indicated by the following icons:
 - o **↓** Descending
- Patients can also be sorted in varius sorting orders:
 - o Patient Number.
 - o Patient Name.
 - o Date of Birth.
 - o Disease.
 - o Treatmentplan.
 - o Last Login.
 - o E-Care Activity.
 - o Notifications.
 - o Recommendations.



Selecting Columns

 Various columns can be added to the table. By clicking on the following icon, you can view all available columns:

- Next, click on the columns you wish to add or remove from the overview. All columns that have been added will display the following icon next to their name:



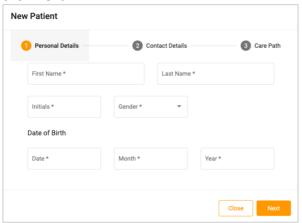
- Columns available for selection are:
 - o Patient Number.
 - o Patient Name.
 - o Date of Birth.
 - o Disease.
 - o Treatmentplan.
 - o Last Login.
 - o E-Care Activity.
 - o Notifications.
 - o Recommendations.

Create new patient account

In the patient overview there is the possibility to create a new patient account. With this account, patients can log in to the DEARhealth mobile app. To create, click on the link:

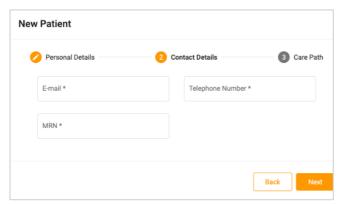


The first screen shows the patient's personal data, after filling in the mandatory required data, click Next.

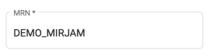


The second screen shows the contact details of the patient, after filling in these mandatory details, click Next.





Note! Please use the country number for the telephone number (e.g +31 for the Netherlands and +1 or US).



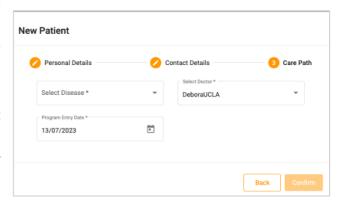
Note! If you want to create a patient to test or demo, use the word 'DEMO' in the MRN field when creating a patient.

The last screen shows the patient's care pathway data. The logged-in healthcare provider is automatically selected as the assigned provider. With confirmation, the patient account is

created. For the insured care in the Netherlands: After creating the patient in DEARhealth, you can activate the telemonitoring code in your EMR.



Note! The patient has not yet received an invitation e-mail currently, this only happens after activating a care pathway.



4. Patient specific

After selecting a patient on the overview, the dashboard of that one specific patient opens. The dashboard consists of the following components:

- 1. "D": by clicking on the symbol of DEARhealth, you will return to the patient overview. Initials: shows name of logged-in provider and offers the possibility of active logout. There is also the possibility to change the language settings.
- 2. **Patient data header:** name, patient number, date of birth, gender, and disease.
- 3. **Delete:** option to delete the patient account.
- 4. **Profile tab:** Profile tab contains the patient information and the option to edit it.
- 5. **DEAR-Recommender:** generating recommendations for the most appropriate care path for this patient based on clinical patient characteristics.
- 6. Treatment plan: manual activation of available scenarios and medication add-ons.
- 7. **Care pathway:** current active care pathway activities.

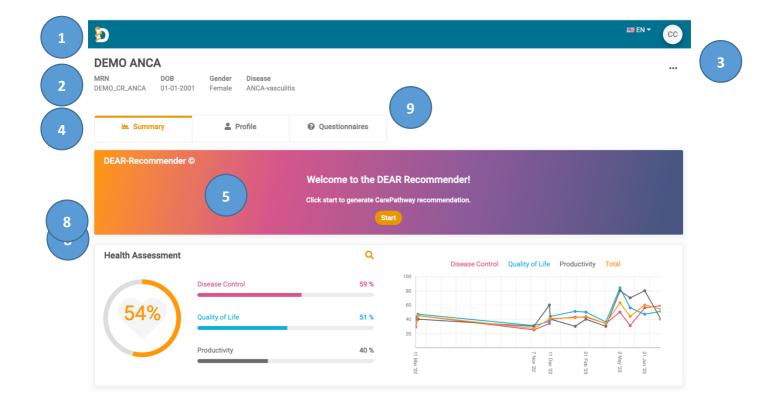


- 8. **Health score:** current score about the well-being of the patient in the context of his/her clinical situation. **Graph:** visual representation of scores of completed questionnaires and the health score.
- 9. **Questionnaires tab:** Questionnaires tab provides an overview of the patient's completed questionnaires.
- 10. **Score questionnaires other than the Health Score:** visual representation of scores of completed questionnaires other than health score (in this example, the LVAS of Anca Vasculitis).
- 11. **Send messages**: Ability to send messages to the patient in question.

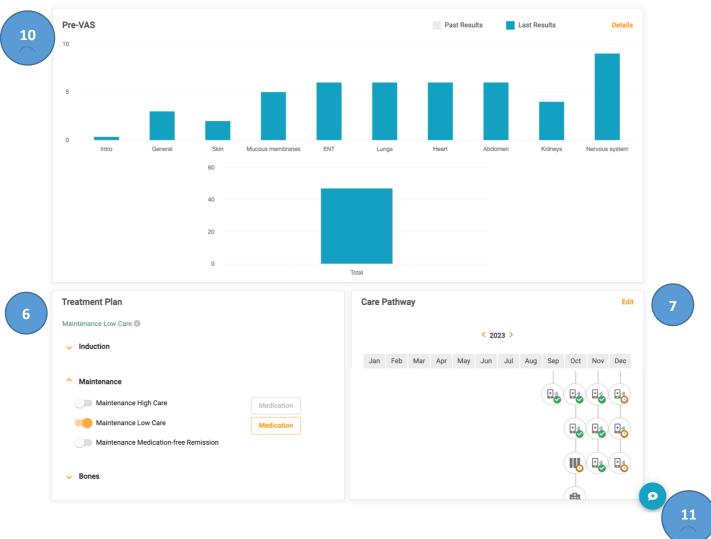
There are two ways to activate a care pathway:

- 1. Via **Recommender**: Accept recommended scenario (5)
- 2. Via Treatment Plan: select a scenario yourself (6)

After activation, the patient receives an email and instructions on how to download the DEARhealth app. The patient must accept the terms of use in the DEARhealth app before the app can be used.







Delete patient account (3)

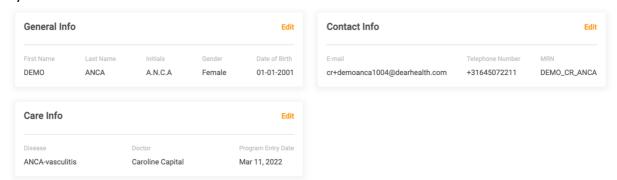
At the patient dashboard in question there is the possibility to delete the patient account by clicking on the three dots.

After selecting "**Delete**", a confirmation question will be asked, after which the patient will be removed from the system and no longer have the option to log in to the mobile app. (The patient's history will remain available anonymous for clinical research).

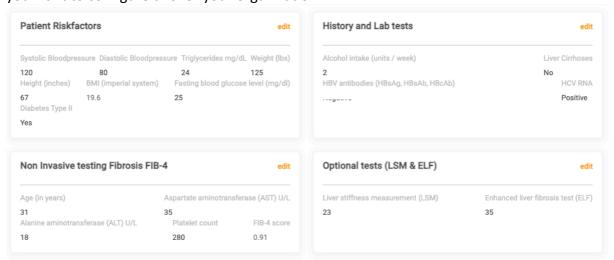


Change patient account (4)

Via the profile tab, you can access the patient's personal data. Here it is possible to change data with the "Edit" option, for example, the telephone number or the e-mail address used by the patient. By changing the email address, the patient receives a new invitation email to log into the mobile app. If there is an EMR integration, the field "last name" will always be synced from the EMR.



Depending on the configuration for your organization and disease of the patient, a second tab is available with specific treatment related questions. Please contact Customer Success if you want to configure this for your organization.



Recommender (5)

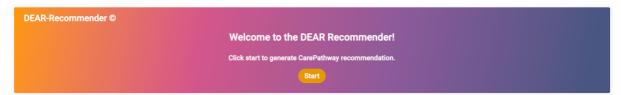
DEARhealth offers a so-called **Recommender** to generate recommendations to provide the most appropriate treatment for the patient. The recommender will generate recommendations on events that happen in the system, for example a Health Assessment Questionnaire that is answered by a patient or a recommender questionnaire that you fill out as a practitioner.

You can find the DEAR-Recommender at the top of the DEARhealth dashboard.

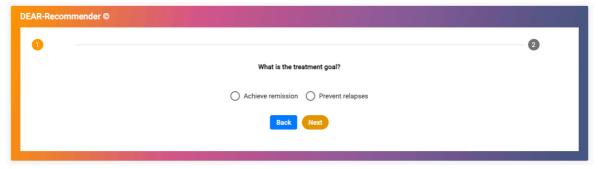
Recommender Questionnaire

To manually start the recommender to get an initial scenario recommendation (not available for every disease or provider), click "Start".

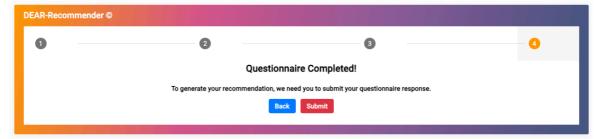




Several patient specific questions need to be completed, such as patient characteristics, that are considered when generating a recommendation. Complete these questions; you can change questions by using "Back" and "Next" if necessary:



After completing the last question, you can save and submit all your answers by clicking "Submit," subsequently a recommendation will be generated:



Recommender based on events happening in DEARhealth

There are several events that can trigger recommendations:

- Recommendations based on answers in the questionnaires that the patient fills out in the mobile app
- Recommendations because of a scenario or addon activation
- Recommendations based on the profile (including the treatment related information) of a patient)

These recommendations are not configured by default for your organization and disease, but are part of the Medical Data Model developed together with you. If you would like to use these recommendations, please contact the Customer Success team.

Recommendations will be displayed on top of the dashboard.



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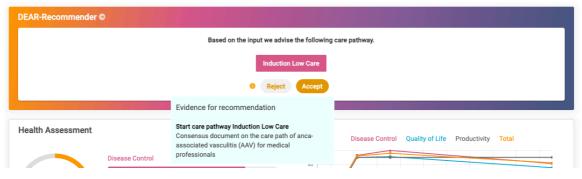
Recommendation types

The recommender generates two types of recommendations:

- 1. Free text recommendations, no action connected, see above.
- 2. Recommendation of one of the standard scenarios of the treatment plan. This scenario will be activated after acceptation of the recommendation.



If you hoover your mouse over the "i", you can find the rationale behind all the recommendations.



You have the choice to "Accept" or "Reject" this recommendation. You as a practitioner must always actively accept or reject. The recommendation will stay active, until you accept or reject the recommendation.

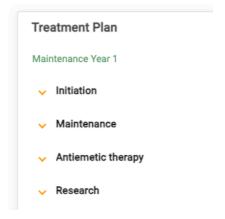
In the case of a scenario recommendation, after "accept", the recommended scenario is activated, and the patient's care pathway is filled with the associated activities. You will see a preview of the proposed scenario before you activate the care pathway permanently, see also 6. In case of "reject" you will be asked to manually select and activate a scenario Care yourself via **Treatment Plan** (see 6).



Treatment plan: manually activate a scenario (6)

If the **Recommender** is not able to generate a recommendation regarding the most suitable care pathway, or you have rejected a recommendation, it is also possible to select and activate one or more scenarios via **Treatment Plan** itself. One of the risk scenarios (maintenance or initiation) can be activated at the same time. Of the other scenarios, it depends on the desired configuration whether several or only one can be activated here at the same time.

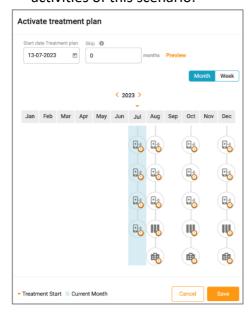
 The various treatment plan groups are closed by default. Open the group to trigger a desired scenario.



2. Click on the gray slider next to the desired scenario: the slider turns orange.

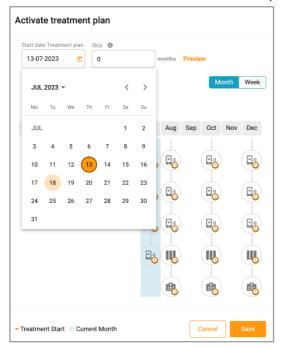


3. You will see a screen with more information, such as a preview of the care pathway activities of this scenario:





4. Choose a date when the scenario should start under "Start date" by clicking on "Choose a date". You will see a calendar, select the desired day:



You can also choose to start the scenario at any point in time by "skipping" several weeks or months of the scenario

Activate treatment plan



5 Then click "Save" to activate the scenario from the selected start date. The care pathway is shown (see Chapter 6). The risk scenario that is active, is shown in green. The 'i' shows the other scenarios that are active (without having to open the groups)

Treatment Plan



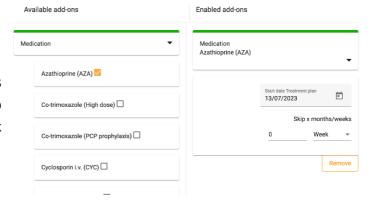


- 6 You can also click the active (orange) slider in **Treatment Plan** to deactivate an active scenario. This clears the care path (see chapter 7), and you can reactivate a scenario.
- 7 You can add "Medication add-ons" to the treatment plan. By clicking the Medication button behind the selected treatment plan, you will find a list of available medication add-ons.



Choose a date when the medication add-on should start.

Activating a medication add-on works similar to activating a treatment plan. To deactivate a medication addon, click Remove.





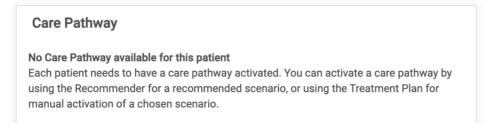
<u>Please note:</u> Questionnaires can be completed by the patient directly via the DEARhealth app at the planned time in their care path, without additional actions. However, it is currently not possible for DEARhealth to automatically convert activities resulting from activating the care path in the DEARhealth platform to orders within the EMR. <u>This means that you have to create orders (such as appointments and lab) in the EMR.</u>



Care pathway: view and edit care pathway (7)

The current care pathway activities that are valid for this patient show up under **Care pathway**. These are the recommended activities associated with the triggered scenario.

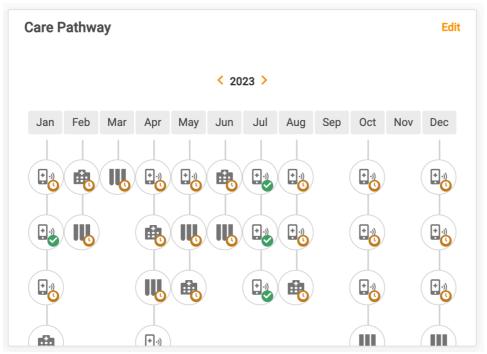
If no care pathway has been activated, you will see the following message (see below):



In case the care pathway shows up empty, use the **Recommender** or **Treatment Plan** to activate one or more scenarios.

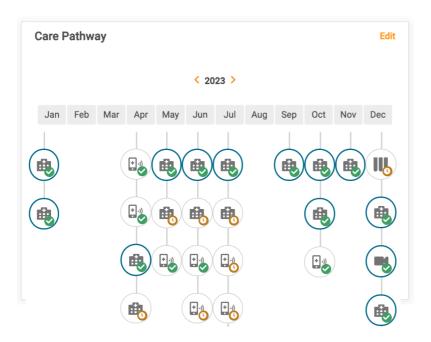
.

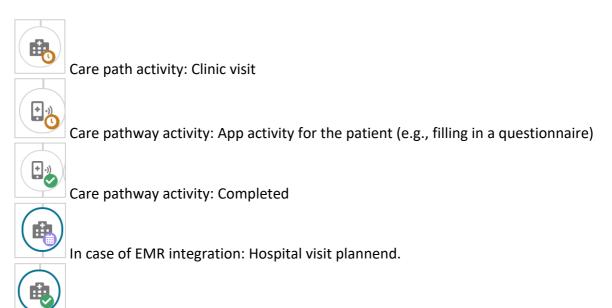
After activating, the care pathway will show up filled with activities. Example without EMR integration:





Example including EMR-integration. Here also the planned appointments booked in the EMR are visible:





In case of EMR integration: Hospital visit completed.



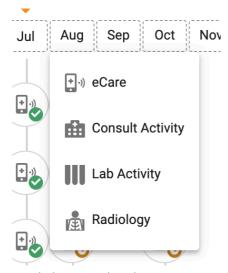
<u>Please Note:</u> If a data integration between your EMR and DEARhealth has been realized, the actual scheduled appointments are shown here. If **no data integration** has been realized, it is not possible to show the actual scheduled appointments. The care path activities therefore do not correspond to the actual scheduled appointments within the EMR. You cannot rely on the dates

shown for certain activities as presented by DEARhealth: these may differ from the scheduled appointment. The appointment information within the EMR therefore remains leading.



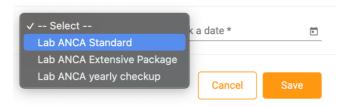
Add activities.

By clicking on the "edit" button, you can adjust activities in the care pathway. By clicking on the box of a specific month, you will see the available activities.



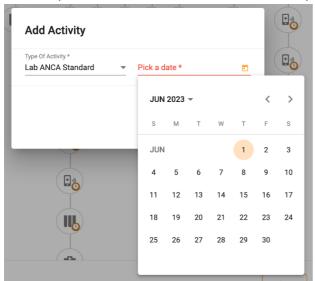
By clicking on the chosen activity (for example Lab activity), you will be presented with a drop-down menu: you can subsequently select a specific activity.

Add Activity





Next step: select the date on which this activity should be scheduled:



The extra activity has been added to the patient's care pathway.

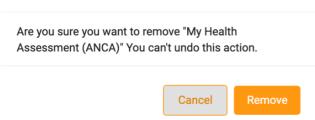
Delete activities

Via "Edit" you can also delete activities. Hovering your mouse over an activity reveals a trash can symbol.



If you click on the trash can symbol, you will receive the following message.

Remove Activity



Click on "delete" and the activity will be removed from the care pathway.



Health score (8)

The most relevant for monitoring the patient's health status is the **Health Score**. This is an overall health score specifically focused on the patient's disease and consisting of disease specific patient-reported outcomes to discriminate among disease states and understand the well-being of the patient.

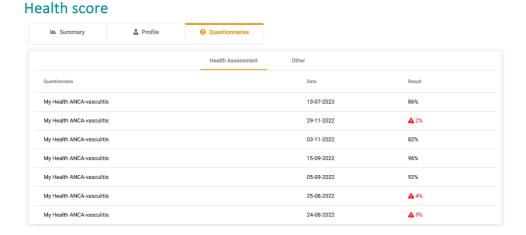
This score is calculated based on input from the questionnaires that the patient completed (either planned according to their care pathway or are added as an additional activity).

The patient's current health score shows up on the patient's dashboard with a visual representation of both the total score and scores for each specific item:



Questionnaires (9)

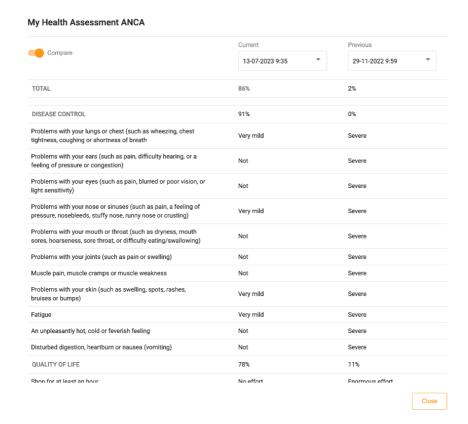
By clicking on the tab "questionnaires ", you will see an overview of the completed questionnaires. There are two types of questionnaires: 1) the questionnaires that generate the health score and 2) Other questionnaires.



You will be able to review the answers and score by clicking on a questionnaire. In addition, you can review and compare questionnaires over time: by turning on the 'compare' slider. In the date field, choose which questionnaires you want to compare.







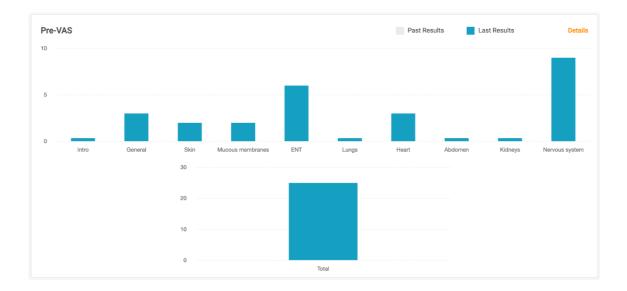
Other questionnaires

For example: questionnaires in preparation for a clinic visit, vitals, etc.



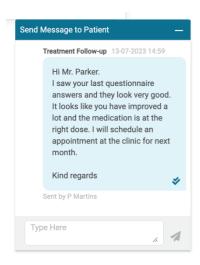
Score of other questionnaires (different from Health Score) (10)

Other questionnaires can also generate a score and a graph on the patient dashboard; depending on what kind of questionnaire it is and how the scoring works. Via the details button, the Questionnaires tab opens on the "Other" tab. The score is calculated based on the questionnaires that the patient completed (either planned according to their care pathway or added as an additional activity).



Send messages (11)

On the patient dashboard there is the option to send messages. To do this, click on the icon at the bottom right: Then a message screen will appear. Here you can send messages to the patient and view the history of messages. You can see who sent the message and if a colleague already has sent a message. The patient has the option to view these messages in the mobile app.





Note! The patient cannot send messages back. The checkmarks are not a read receipt, but only a confirmation that the message has reached the patient properly.



5. Medical Device Regulation DEARhealth

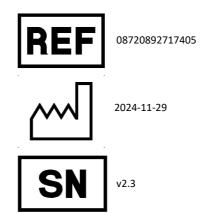


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Instructions for use are supplied in electronic form instead of paper form.

URL: https://www.dearhealth.com Email: support@dearhealth.com

Paper instructions for use can be requested at no additional costs by contacting us

Using the indicated email address and will be delivered within 7 days.

Intended purpose

The DEARhealth software intends to:

- 1. Support health care practitioners in their decision making, by providing care pathway recommendations based on events such as Patient Reported Outcomes and clinical data.
- 2. Provides monitoring and signal functionalities, allowing health care practitioners to remotely monitor the patients health status, supporting them in the transition from in-person care to hybrid health care.

Current indications for use are: Inflammatory Bowel Disease [Crohn's disease, ulcerative colitis], Renal Disease [ANCA Vasculitis + Systematic Lupus erythematosus], Rheumatoid Artritis, Chronic Heart Failure.

Intended users

The use of DEARhealth is only for patients who have been diagnosed with a chronic disease(s) supported by the DEARhealth platform and for which the healthcare provider has approved the use of the software for the specific patient.

Users are:

- 1. Patients of affiliated hospitals (intended patient population)
- 2. Healthcare providers of affiliated healthcare systems
- 3. Caregivers of connected patients.



Intended patient population

DEARhealth supports in the identification of effects on clinical outcome (e.g., use of medical device improves the rates of improvement on clinical outcome parameters, such as pain). The DEARhealth platform can be configured for any chronic disease.

The following diseases are currently available in DEARhealth:

- Inflammatory bowel disease (Crohn's disease, ulcerative colitis)
- Kidney diseases (ANCA Vasculitis)
- Rheumatoid arthritis
- Chronic heart failure
- Systemic lupus erythematosus

Contra indications

There are certain circumstances in which DEARhealth is contraindicated:

- There is no Internet connection available.
- The user has no computerized device
- The user has impaired visual function.
- The user has no basic knowledge of the use of computers or mobile phones.

Clinical Claims and benefits

DEARhealth claims that by supporting healthcare providers in clinical decision-making, healthcare consumption can be reduced without compromising the quality of treatment for patients or patient engagement.

Implementation and training

To access the DEARhealth software in the production environment, the healthcare provider opens the DEARhealth healthcare portal via a web page or from the EMR.

The integration with the EMR in use in the relevant hospital will be realized in the implementation phase. There are currently no known limitations with existing EMRs to access DEARhealth from the EMR. The limitation for implementing the SSO EMR integration is the embedded web browser of the EMR in use. DEARhealth supports versions of Internet Explorer and Google Chrome that are still in support by their vendor, aka IE11 is not supported because is end of life as from June 2022.

Instructions for use (manuals) and superuser training are offered to the healthcare professionals. During the first phase of implementation, a local DEARhealth team is available remotely or on site to support and train superusers. Our Customer Success Team is trained to support physicians, nurses, study coordinators and administrative staff during patient onboarding. After the initiation phase, users can obtain support and provide feedback via the support desk.



Stop using the DEARhealth platform

DEARhealth has concluded a processing agreement with the hospital.

As soon as the collaboration between DEARhealth and the hospital is terminated, DEARhealth will deliver the data present on the platform, if the hospital requests it, to the hospital and then destroy it. Data without patient identification will be stored for analysis purposes (e.g., Post Market Surveillance)

Questions about the use of the DEARhealth platform

If you want to report problems, you can do so via the DEARhealth support desk. If the patient wants to report user problems with the app, they can also report this via the DEARhealth support desk, but it is also possible that they report it to their own healthcare provider. For some problems, it is occasionally necessary to visit a specific patient in the production environment by the support team of DEARhealth. This is possible in the database and will always be done based on an internal patient ID (de-identified) and therefore not based on the actual name and address details of the patient. The internal patient ID can be seen by a healthcare provider in the URL of the healthcare provider portal and this ID can then be passed on to DEARhealth.

IT Requirements

• Web browser: Internet Explorer, Google Chrome (versions that are supported by the vendor of the browser)





If a serious incident occurs that compromises patient safety due to the use of the DEARhealth platform, you must report this as soon as possible to DEARhealth as a manufacturer and to the relevant competent authority.