## **General description**

Information listed below serves to identify the health software itself as well as its editor.

## **Health software identification**

Editor name: Laboratoires Urgo

Trade name: Healico

Software version: 6.0.0

## **Editor identification**

Editor name: Laboratoires Urgo

E-mail: contact@healico.uk

Address: 42 Rue de Longvic, 21300 Chenôve

Phone contact: 01 85 65 24 24

Website: https://www.urgo-group.fr/

## Specific skills, trainings and knowledge required for users

Users need to be healthcare professionals to use the application.

No specific training needed to use the app.

## Instruction for use

## Intended use

Healico is intended to assist the user in managing patient and wound data (including pictures) and to provide a tool to track wound progress. The software also allows users to share this data between users and to discuss wounds and patients in a care team.

## Health software description

- Healico connects the patient's care team through a secure chat and keeps them up-to-date on the wound evolution (by sharing wound information and pictures at any time.
- Healico brings together all the wound information in a comprehensive view shared amongst the care team
- Healico helps you easily collect and organise wound information in one place

Health data is stored in a certified health data provider and for data stored on your device it's encrypted (AES-256)

You need an iOS or Android device to use Healico (iOS 12 or later, Android 7 or later).

## Installation and start up

- **Download Healico from the App Store or Google Play Store.** Go to the App Store or Google Play Store on your smartphone and search for 'Healico'. Download the app and open it to start the registration process.
- **Complete the registration process.** When registering, you must connect with your Google or Apple ID or provide your email address and accept the Terms & conditions of use. If you use your email, you must create a password. Then you must provide your first and last name.
- **Give permission to receive push notifications.** This allows you to receive updates about the wound of your patients, especially messages coming from your colleagues or other care team members.
- Verify your professional status. To ensure the safety of patients, Healico is reserved for healthcare professionals and to fully use the app, you need to validate your healthcare professional status. You can do so by sending to the Healico team, through the application, a picture of a proof that you are a healthcare professional (professional card, certification, diploma) and one picture justifying your identity (ID card, passport, driving license). The validation is done in 24 working hours (except during holiday period when the validation may tak longer). You receive a notification when your account is validated.

## **Operating Instructions**

#### Create a patient file

- Click on the Add your first patient button from the homepage or on the + button > Add a patient
- Enter the last name, first name and date of birth of the patient. If a patient with the same information has already been created by another

healthcare professional, you can request to join their care team. *(subject to patient's consent)* 

- Share the patient file with your colleagues, by synchronising your contact list with the app, clicking on the name of the recipient to send an invitation link by text message or email so that they can access the patient file and thus share all the information about the patient with them and be able to communicate with them via the integrated messaging system. (Subject to patient's consent).
- **Request patient consent.** For the security of your patient's data, you must get their consent to save, view and share data related to their health when creating and / or sharing the patient record in Healico.

#### Create a wound

- **Press the Add a wound button** in the patient file or the + button > Create a wound or the + button next to the patient's name on the homepage.
- **Complete the wound creation flow** by indicating the location, type, aetiology and how long the wound has been open.

#### Update and edit a wound

Here is the type of data you can save on a wound from the + button:

- **Photo** from the camera or gallery
- Assessment
- Treatment
- Message

When the wound is healed, you can close the wound in the patient file > patient menu > Close a wound

You can edit photos, assessment, treatment and message by pressing the edit button after clicking on a post in the patient file.

When you upload a photo taken before today's date, Healico automatically classifies it on the data taken. In some cases, beyond our control, the uploaded photos no longer have date data and will therefore be uploaded on today's date.

#### Share wound data with another healthcare professional

From the home page > Patient file, you can share the patient file with another verified healthcare professional, automatically sharing data (photos, assessments, treatments, messages) with them. Click on the Add a new member button at the top right of patient file and synchronize your contact list with the app, click on the name of the recipient to send an invitation link by text message or email. You must get the consent of your patients to share data related to their health.

## **Measuring wounds with MEASURE**

MEASURE is a feature whose technology is provided by the company imito AG. MEASURE helps you measure your patients wounds with a photo.

You can use MEASURE's two modes:

- Calibi marker mode: you first need to order Calibi markers. See in the section "Ordering Calibi markers" below for the markers ordering instructions
- Manual mode: An object with a size you know: a ruler or dressing for example

Before using MEASURE, make sure you have at your disposal either a Calibi marker or a ruler, dressing, or objectif with a size you know.

#### **Ordering Calibi markers**

- 1. On the homepage, click on the " HEASURE Automatic measure" card, and launch the tutorial.
- 2. On the "Use a Calibi marker" step, click on "I don't have a calibi marker"
- 3. On the appearing white screen, select **"Receive markers** ⊠"
- 4. A web page opens with a form indicating you can order Calibi markers: fill the form with your address information to and receive them in a "sticker" format directly at your home or practice.

You can also order them from Healico's settings:

- 1. Click on the "Settings" card
- 2. On the "MEASURE" section, select "Receive markers ⊠"
- 3. A web page opens with a form indicating you can order Calibi markers: fill the form with your address information to and receive them in a "sticker" format directly at your home or practice.

#### **Printing Calibi markers**

- 1. On the homepage, click on the "State MEASURE Automatic measure" card, and launch the tutorial.
- 2. On the "Use a Calibi marker" step, click on "I don't have a calibi marker"
- 3. On the appearing white screen, select **"Print markers** 🖃 "
- 4. A PDF opens with Calibi markers to print: you can then print them directly in a "paper" format.

You can also print them from Healico's settings:

- 1. Click on the "Settings" card
- 2. On the "MEASURE" section, select "Print markers 🖃 "

Reference : DAR-USR-01	User Manual Healico	Version 5

3. A PDF opens with Calibi markers to print: you can then print them directly in a "paper" format.

#### Testing MEASURE from the homepage

On the homepage, you can test MEASURE without associating the measure to a patient.

- On the homepage, click on the " MEASURE Automatic measure" card, and launch the tutorial.
- To pass the tutorial screens, you can swipe or click right to access the next screen or left to go back to a previous screen of the tutorial.
- On the last tutorial screen indicating you how to associate a measure to a patient file, click on "Test MEASURE"
- Follow the instructions listed on sections "Using MEASURE with a Calibi marker" and "Using MEASURE's manual mode" depending on the mode you want to use
- Once you are done, you can either test MEASURE again, or click on "Done" and go back to the homepage.

Once you are at your patient's home and wish to proceed with a measurement and assessment of their wound, you can use MEASURE to measure your patient's wound.

#### Using MEASURE with a Calibi marker

To use MEASURE with the Calibi marker, make sure you have Calibi markers at your disposal. If that is not the case, you can order them directly in the app. To see how to order Calibi markers, please refer to the "Ordering Calibi markers" section above.

To measure your patient's wound with MEASURE, please follow the instructions below:

- Click on the + button next to your patient file or in your patient file and select " Measure with MEASURE"
- 2. Put a Calibi marker next to the wound you want to measure
- 3. Select the wound you want to measure or create a new one
- 4. Position your phone so that the Calibi marker appears on the screen
- 5. Take the photo once the Calibi marker is detected by the app (circled in green)
- 6. Circle the outline of the wound with your finger:
  - Adjust the outline by moving the green dots on the shape that you drew
  - 2. If you want to remove the circle and start over, click on the cross next to A1
- 7. Click on "Validate" on the top right corner of the screen to validate the wound edge detection

Reference : DAR-USR-01	User Manual Healico	Version 5

- 8. You have now automatically the area, length and width of the wound. You can enter manually the depth by scrolling down the screen and click on "Tap to Add Depth".
- 9. Click on "Continue" to save the measurements in your patient file
- 10. Click on "Validate the measurement" to definitely save your measurement in Healico.
- 11. You can find the measure on the post details and the PDF with a" MEASURE" tag displayed.

#### Using MEASURE's Manual mode

You can use MEASURE even if you don't have Calibi markers, using the manual mode with an object with a size you know, for example a ruler or a dressing.

To use MEASURE's manual mode, follow the instructions below:

- Click on the + button next to your patient file or in your patient file and select " Measure with MEASURE"
- 2. Put an object of known size (ex: a ruler or a dressing) next to the wound you want to measure
- 3. Click on "Manual mode" by scrolling your finger to the left
- 4. Position your phone so that the object of known size (ex: a ruler or a dressing) appears on the screen
- 5. Take the photo of the wound with the object of known size
- 6. Position the 2 green pointers on an object of a size you know, and tap the green pen to indicate the size of that object. (ex: one graduation on a ruler or the length of a dressing)
- 7. Tap the green button with the pen to adjust the value and units of the distance
- 8. Click on Continue
- 9. Circle the outline of the wound with your finger:
- 10. Adjust the outline by moving the green dots on the shape that you drew
- 11. If you want to remove the circle and start over, click on the cross next to A1
- 12. Click on "Validate" on the top right corner of the screen to validate the wound edge detection
- 13. You have now automatically the area, length and width of the wound. You can enter manually the depth by scrolling down the screen and click on "Tap to Add Depth"
- 14. Click on Continue to save the measurements in your patient file
- 15. Click on Validate to save definitely your measurements in Healico
- 16. You can find the measure on the post details and the PDF with a "**MEASURE**" tag displayed.

You can access a video tutorial of MEASURE's manual mode from the same screen.

To see the video tutorial, click <u>here</u>

#### Communicate with the care team through messaging

From the home page > Patient file, you can communicate with the patient care team by commenting posts in the patient file. They'll be automatically notified of your comment and will be able to answer you in real time. To comment, go in a patient file from the homepage then clikc on Comment at the bottom of a post.

#### Export your data in a PDF

From the homepae > Patient file, click on "..." at the top right of a post then click on Exporte in PDF and click on Open the PDF to download the PDF with your data (photo, assessment, treatment, and/or messages).

#### Edit and delete a patient file

From the home page > Patient file > Patient menu, you can:

- Add/Edit patient's administrative information;
- Add/Edit patient's health information;
- Visualise the list of wounds of the patient;
- Close a wound;
- **Leave a file.** By leaving a patient's file, you will no longer be able to view any information related to that patient in Healico.
- **Delete patient file.** This action is irreversible and at the request of the patient.

#### Access to the training guide

From the homepage, click on the button with a book at the top right and you have access to articles and guidelines helping you treating patients with wounds and understanding wound healing.

#### Access to the help and support

From the homepage, cog whell near your first name, you can then:

- Contact us
- Access to the legal documents
- Watch or rewatch a short introduction about Healico
- Disconnect
- Delete your account

## **Quit the application**

<i>Reference : DAR-USR-01</i>	User Manual Healico	Version 5

To close the app on iOS: on an iPhone X or later, or an iPad with iOS 13 or later, or iPadOS, from the Home screen, swipe up from the bottom of the screen. On an iPhone 8 or earlier, click the Home button to go back on the home screen.

To close the app on Android: click on the Home button or on the virtual Home button at the middle of the navigation bar.

## Messages

#### Success

- Your account has been deleted: when you ask for your account deletion
- Your request has been received: when you ask for you data export
- **B** Good news! Your profile has been successfully approved: when your healthcare professional status has been validated
- All good! "Your patient's name" has been deleted: The patient's file has been deleted
- Your pictures are saved: your pictures have been added to the patient's file
- Your assessment is saved: the assessment has been added to the patient's file
- Your treatment is saved: the treatment is added to the patient's file
- You message is saved: the message is added to the patient's file
- Your patient is registered in Healico! All I need is their consent to start saving their health data: confirmation that the patient has been created, but inform you that you are not able to access it until you get their consent.
- The wound is closed: the wound has been closed
- You are no longer part of this patient's file. You'll be missed!: You have left the patient's file.
- All good! Patient's data has been deleted!: The patient has been deleted
- Your refusal has been taken into account. Your caregiver does not have access to your file: You were adding new people to the care team, but the patient refused. The invitations are now deleted
- Email address copied in clipboard: The text has been copiped to the clipboard
- Error: patient not found: the patient was not found on the database or server.

#### Information

- It seems like you are not connected to internet: when you do not have an internet connection and try to do an action that requires it
- You need to be logged in to access this patient channel: when you try to join a care team via an email invitation without being authenticated

- To benefit from all Healico's features, your professional status must be verified. Do it now?: when your healthcare professional status is not verified yet
- You will shortly receive an email with further instructions: An email has been sent to change the password
- You need to verify your healthcare professional status to share the file: The user needs to verify their professional status to do this operation
- Unable to upload the photo: the file is too large: unable to upload the picture due to its size

#### **Error and warning**

- An unexpected error has occurred... Please, retry: in case of system errorPlease
- provide a valid email: when the format is not correct for an email field

• Your professional status must be verified before joining a care team: when you try to join a care team when your healthcare professional status has not yet been verified

• This link has already been used by another Healico member. Please, request a new one: when you try to join a care team via an email invitation whose link has already been used

• An unexpected error has occurred. Please, retry or contact support: when the invitation link to join a care team does not work for an unknown reason

• You have already added this person: when the user tries to add a member already belonging to the care team

• You are already part of this patient care team: The user tried to create a patient which has a namesake. They tried to join the care team of this namesake, but are already part of it

• **Unable to open this link:** when you try to open a link, but the app was not able to parse this link

• You need to be logged in to access this patient file: when you try to open a link to join a care team but you are not connected. The link will be used next time you are signed in (if you have just been created, the link will be ignored)

• Your account has been suspended: your account has been disabled

• Error while trying to take a picture: unable to capture the photo

• The application can't work if your phone doesn't have a passcode. Secure your phone with a passcode, fingerprint or facial recognition from your phone settings and try again: the app could not find an authentication method (pin code, touch id, face id)

• The wound is closed, you can't do any action on it anymore: the wound is closed and can not be modified

• Your first name should only contain letters, dash or space: the name entered is invalid, probably due to an unauthorized character

• **The name is too long:** the name entered is too long (limit of 50 characters)

• Your surname should only contain letters, dash or space: the name

entered is invalid, probably due to an unauthorized character

• Email is invalid: Email is invalid

• Your email is already in use: you are trying to sign in with your email but have already an account with Apple or Google

• Wrong password: wrong password for your account

• **Unable to upload the photo:** unable to upload the selected picture (unknown error)

• Your patient's first name should only contain letters, dash or space: the name entered is invalid, probably due to an unauthorized character

• Your patient's last name should only contain letters, dash or space: the name entered is invalid, probably due to an unauthorized character

• **The operation could not complete:** the server returned a 400 error : the app is sending a wrong request (error on front side)

• You are not properly authenticated on server: the server returned a 401 error : this request needs the user to be properly authenticated and it is not the case

• You are not authorized to perform this operation: the server returned a 403 error: the user is not allowed to do this operation (for exemple, he is not a hcp and cannot join a care team)

• Operation could not complete. Please check that you use the last version of Healico in the Play Store: the server returned a 404 error: the resource asked doesn't exist (for exemple, the patient / wound has been deleted)

• **No email application found:** Android doesn't find an application on the user phone which is capable to handle a mail intent

• **The server is not responding. Please try again:** the server returned a 500 error: the error is on the server side

• **Network error. Please check your connection:** the request could not be done: the user doesn't have an internet connection or the operation timed out

• I am not able to find the date of this picture. I will take the current date as a replacement: you chose a photo without the EXIF metadata, the app consider it as a photo taken the current day

• Only letters can be entered in this input: the text contains invalid characters

• **Please enter the proper sentence:** you are asked to fill a text to validate an action but have not entered the right text

• I need your permission to access your contacts to be able to share patient file with your colleagues: you refused to give the authorisation to access the contacts

• There was an error when trying to save this consent: the operation could not be done for a reason that has not been caught by another case

• **Please log in!:** the operation could not be done for a reason that has not been caught by another case

• An error happened when deleting the patient, please try again: the operation could not be done for a reason that has not been caught by another case

• No PDF reader application found. Please go to the Play Store and

**install a PDF reader:** can not open the PDF since you have no application to open it

• Please enter a valid date: the date entered is not valid

• **Sorry, but you cannot access this patient:** the operation could not be done for a reason that has not been caught by another case

• Please authorize Healico to access your camera to verify your professional status: you refused to give the authorisation to access the camera

• **Cannot access microphone:** you refused to give the authorisation to access the microphone

• **To add photos of the wound, I need to access your camera:** you refused to give the authorisation to access the camera

• Please verify your healthcare professional status to join the care team: you have not a verified profile and can't join a care team

• To chat and share patients' files with your colleagues, verify now

**your healthcare professional status:** you have not a verified profile and can't join a care team

• It seems like you are not connected to internet: the request could not be done: the user doesn't have an internet connection or the operation timed out

• Your account has been suspended: you could not be signed in (account disabled)

• You must access your settings to allow the app to use the speech recognition: you refused to give the authorisation to access the microphone or something wrong happened during the recognition

• Not implemented yet!: you tried to use a functionality not developed yet

• An error happened when signing out, please try again: you tried to sign out, but it didn't work

• An error happened while trying to delete your account, please try again: you tried to delete their account, but it didn't work

• **Please connect using Google authentication:** you tried to sign in with their email, but it has already been used to sign in with Google

• **Please connect using Apple authentication:** you tried to sign in with their email, but it has already been used to sign in with Apple

• Your password isn't very strong. Please use at least 10 characters with caps, letters, numbers and at least one special character!: the password doesn't not follow the requirements

• Your evaluation is invalid: you try to save an assessment which is considered invalid by the server

• Failed to save the assessment: the operation could not be done for a reason that has not been caught by another case

• **An error has occurred, please try again later:** you were adding new people to the care team, but the patient refused. The invitations could not be deleted

## **Decommissioning and disposal**

<i>Reference : DAR-USR-01</i>	User Manual Healico	Version 5

#### Deletion of your account and its consequences

If you want to permanently delete your account, you can do it yourself from your account settings (accessible by clicking on the icon next to your first name on the opening page). **Deleting your account is an irreversible action** that we cannot reverse even if you do it by accident.

#### To delete your account:

- 1. Open Healico
- 2. Go to Settings > Delete my account
- 3. Type DELETE and press Yes, confirm

#### Once your account is deleted:

- Your personal information will be permanently deleted. Copies of certain items such as logs may remain on our database but are separate from personal identifiers. Please refer to our Privacy Policy for more information
- You will no longer be able to reactivate your account, access it again or recover data, once the deletion request is made. If you want to use Healico again, you will need to create a new account
- Your account will be removed from all care teams
- The data of patients for whom you are the only healthcare professional monitoring them will be automatically deleted twelve months after the deletion of your account. The data of your patients followed by other healthcare professionals will be kept.

#### **Delete Healico**

- On iPhone
  - 1. Touch and hold the app.
  - 2. Tap Remove App.
  - 3. Tap Delete App, then tap Delete to confirm.
- On Android
  - 1. Touch and hold the app.
  - 2. Tap OK to confirm.

## Troubleshooting

In case of issue using the application, please send us an email on <u>contact@healico.uk</u>

## **Technical description**

Healico is a health software composed of two interfaces: An Android and iOS mobile application, each developed using Android and iOS native framework.

Reference : DAR-USR-01	User Manual Healico	Version 5

Although Healico can temporarily store data locally in a database in the user's phone, it is designed to communicate with a server-side application to store securely and process data. This application server is hosted by a certified health data hosting company.

In order to fully function, Healico therefore requires the user to have an internet connection.

# Information to support security goals and capabilities

• Use of Healico necessarily requires an authentication system on your device via password, fingerprint or facial recognition

- Do not create a patient's file without their consent
- Do not share a patient's file without their consent
- Do not share your account with another person

• Use a password with at least 10 characters with caps, letters, numbers and at least one special character

• Do not share your password with another person