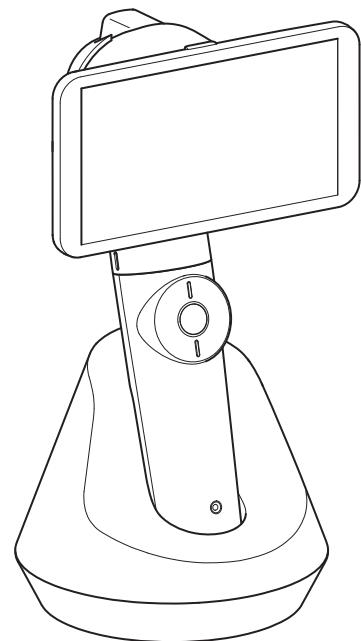


# Barco Demetra



## User Guide

BDEM-01

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1

Welcome!

## 1.1 Use specification

### Indications for Use

The Barco Digital Dermatoscope is a non-invasive skin analysis system, which acquires multispectral and white light dermoscopic images and clinical photographs of the skin. These can be stored, retrieved, displayed and reviewed by trained medical practitioners.

### Intended usage environment

The device is intended to be used in a normal working environment of medical practitioners examining skin conditions. A number of considerations should be taken into account:

- It should be avoided to operate the device with wet hands, in order to prevent dropping the device.
- The touch display of the device can be operated wearing gloves. The following types of gloves were tested to work with the touch display and scroll touchpad:
  - Hartmann Peha-Soft Nitrile Powderfree
  - Hartmann Peha-Soft Vinyl Powderfree
  - Hartmann Peha-Soft Latex Powderfree
- The Demetra solution requires a wifi connection.

### Intended patient population

The device is intended to be used on all patients who consult with a physician or other healthcare professional regarding a certain skin condition, including, but not limited to, melanoma and non-melanoma skin cancers or lesions suspicious for skin cancer, inflammatory skin conditions, skin infections, etc.

### Medical conditions to be diagnosed, treated and/or monitored

Skin conditions, including, but not limited to, melanoma and non-melanoma skin cancers or lesions suspicious for skin cancer, inflammatory skin conditions, skin infections, etc.

### Intended part of the body or type of tissue applied to or interacted with

The device can be used on the following body parts:

- Skin
- Nails
- Hair

The device should not be used:

- For lesions in the eyes. The device should not be pointed towards the eyes. It is recommended that patients close their eyes during examination near their eyes.
- In contact with breached or compromised skin surfaces. In case of small breached or compromised lesions, it is recommended to install the non-contact cone on the Demetra Scope to perform non-contact dermoscopy. In case of large breached or compromised lesions, the non-contact cone should not be used.

### Contra-Indications

The device is not a Computer Aided Diagnosis (CAD) device. The additional information that the device provides is intended as an aid for the trained medical practitioner when reviewing, analyzing and diagnosing skin images. The final clinical decision is with the trained medical practitioner.

### Intended users

The intended users for the Demetra solution are trained medical practitioners, whether they are active in a private practice, hospital or clinic.

### Operating principle

The Demetra solution consists of a hardware device and a stand-alone software application.

The hardware device is a portable, battery powered medical device for acquiring, processing and visualizing images of the skin. The device acquires multispectral optical dermoscopic images in a contact mode (device in contact with the skin). In addition the device can also acquire a clinical close-up image, when it is held at up to 10 to 15 cm from the skin, and a clinical overview image when it is held at approximately 35 to 55 cm from the skin.

The device embedded software can perform image processing, image analysis and image visualization. The device also uploads images to cloud storage.

The stand-alone software application is cloud software with a related web application. This cloud software can also perform image processing, image analysis and image visualization. The cloud software can also generate one or more reports and feedback certain outputs of the image analysis back to the device.

## 1.2 About the Demetra solution

### General

The Demetra solution is a platform for skin examination and analysis. It consists of the following main parts:

1. Demetra Scope for capturing images and optimizing the imaging and documentation workflow.
2. Wireless and secure transfer of images and metadata from the device memory to the cloud, via wifi, for image processing and storage in the cloud.
3. Secure Demetra Web Application for complete patient record and image library management and workflow tools.

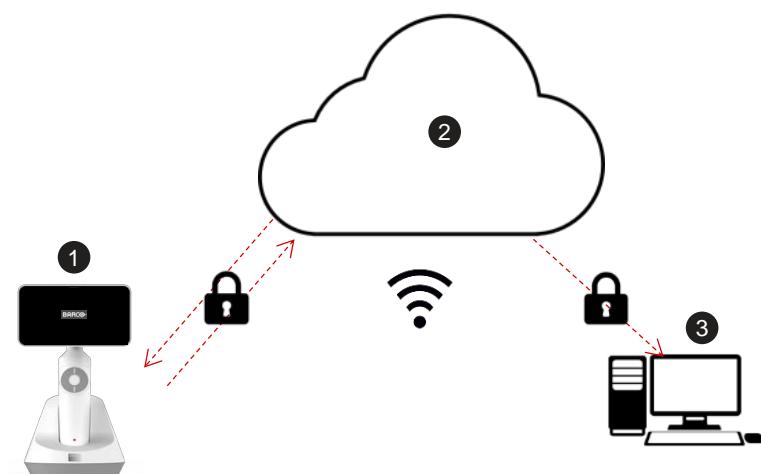


Image 1-1

### Features

- Battery capacity of 3 – 6 hours continuous operation
- Rechargeable and replaceable grip / battery pack
- Demetra Web Application for viewing captured images or photographs
- Primary camera for multispectral dermoscopic images and clinical close-up photographs
- Secondary camera for clinical overview and close-up photographs
- Polarized and non-polarized illumination
- Touch screen with full HD resolution
- Autofocus

## 1.3 What's in the box

### Overview

- Demetra Scope head
- Rechargeable grip / battery pack
- Battery charging station
- Non-contact cone
- Adapter and plugs
- Quick Start Guide

- User Guide



Keep your original packaging. It is the ideal protection during transport of the Demetra Scope and is required to be used in case of service/return.

## 1.4 Demetra Scope

### Overview

The Demetra Scope is a handheld, wireless medical device. Purpose-built for dermoscopic and clinical imaging as well as dermoscopic image analysis, the Demetra Scope offers the most detailed images, an easy-clean design and smart mechanics.

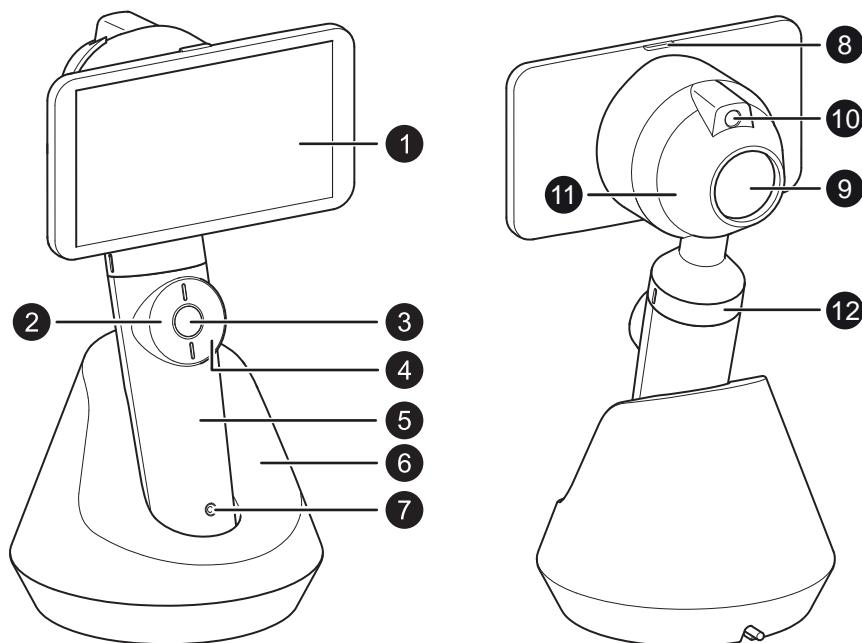


Image 1-2

1. Touch display
2. Left scroll touchpad
3. Main button
4. Right scroll touchpad
5. Rechargeable grip / battery pack
6. Battery charging station
7. LED indicator
  - Off: Default behavior/charged battery (>20%)
  - Steady orange: Battery low (<20%)
  - Slow blinking green: Battery charging (when placed in battery charging station)
  - Steady green: Battery fully charged (when placed in battery charging station)
8. On/Off button
9. Head with primary camera for dermoscopic imaging and clinical close-up photographs (up to 5–10 cm from the skin)
10. Secondary camera for clinical overview photographs and clinical close-up photographs (more than 10 cm from the skin)
11. Non-contact cone
12. Locking ring



The power supply is specified as a part of the Demetra Scope. Use only the delivered power supply for charging your device.

## 1.5 Demetra Web Application

### Overview

The Demetra Web Application is an on-line application which allows the user to view, manage and analyze all patient information and images/photographs captured with the Demetra Scope. The Demetra Web Application offers a lot of functionalities (see “Operation with the Demetra Web Application”, page 27 for more information).

Welcome!

# Installation and configuration

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## 2.1 Setup of Demetra Web Application

### 2.1.1 Minimum system requirements

#### Operating system

Demetra Web Application is supported on the following operating systems:

- Microsoft Windows 7
- Microsoft Windows 8
- Microsoft Windows 8.1
- Microsoft Windows 10



For compatibility and security reasons, please make sure to have the latest updates of your operating system installed at all times.

#### Web browser

Demetra Web Application should be connected to the internet at all times. The following web browsers are supported:

- Google Chrome (version 63 or higher)
- Mozilla Firefox (version 57 or higher)
- Microsoft Edge
- Microsoft Internet Explorer (version 11 or higher)



Please make sure to have the latest updates of your web browser installed and to have an up-to-date virus scanner running at all times.

#### Display resolution

For adequate viewing experience, we recommend to use a display with a minimum resolution of 1920 x 1080 pixels. The displays from Barco's clinical range are an excellent match when using Demetra Web Application.

### 2.1.2 Activation

#### User authentication

When you purchased a Demetra subscription, you will receive a registration link by e-mail. Click this link to register as admin.

As admin it is possible to create / assign new users (see "Configuration (admin)", page 13). When a new user has been added, he will also receive a registration link by e-mail. Click this link to register as user.



Sign in with your username and password

Username

Password

[Forgot your password?](#)

[Sign in](#)

Image 2-1

The web browser will open and a sign-in window will be shown. Fill in your email address as username and the temporary password you received in the registration email. Click *Sign in*.



Image 2-2

A new window opens to set your password. Click *Send* to confirm.

You are then guided to the Demetra welcome screen. As an admin user, refer to "Configuration (admin)", page 13 to start the configuration. As a regular user, refer to "Configuration (user)", page 15.

## 2.1.3 Configuration (admin)

### Language and color scheme

1. After user authentication as admin (see "Activation", page 12), click *Start configuration* on the Demetra welcome screen.
2. Select the desired Language and Color scheme and click *Next* to confirm.

### Permission model and security policies

1. Decide whether patient records will be shared among users in your organization or whether they will be uniquely assigned to a specific user. Note that it is not possible to change this selection afterwards. Click *Next* to confirm.
2. Select the desired security setting:
  - Device authentication: Determine which authentication methods (PIN or no authentication) are allowed to log in on the Demetra Scope. Depending on the allowed authentication method(s), each user can set his personal authentication method (see "Configuration (user)", page 15).
3. Click *Next* to confirm.
4. An overview of the selected settings is shown. Tick the checkbox *I have read the Barco privacy policy* and click *Accept* to confirm.



Click *Barco privacy policy* to open and read the Barco privacy policy.



These settings are now general for each user. To change the settings per user, see 'Users and licenses' under "Configuration (admin)", page 13.

### Users and licenses

There are two types of users: admin users and regular users. By default, admin users have administration privileges only, without access to patient records. By default, regular users have access to patient records, without administration privileges. Both roles can also be combined (see below).

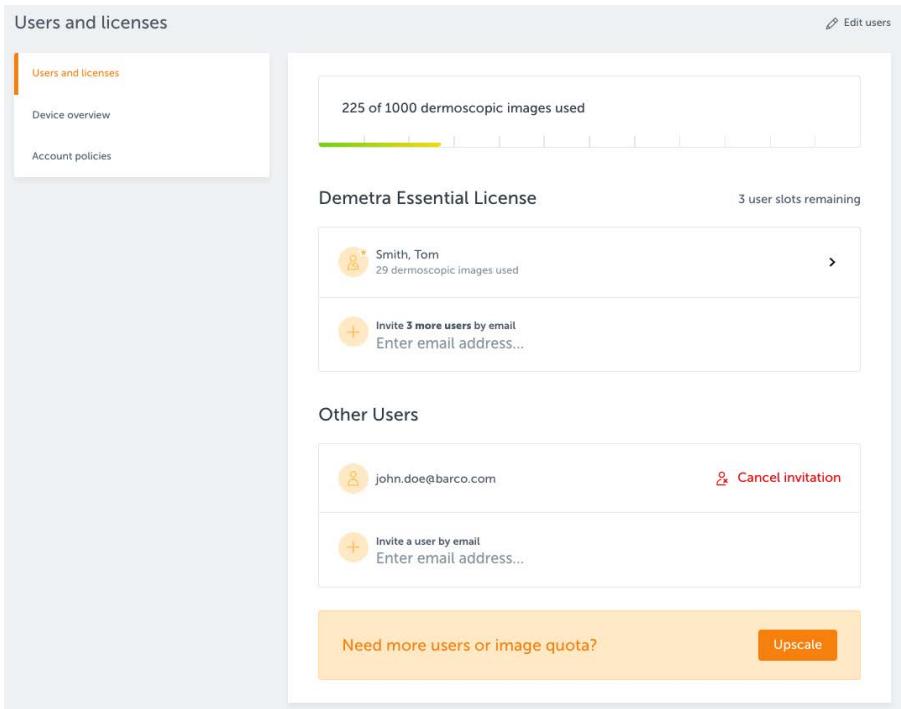


Image 2-3

This screen allows the admin to:

- Add users/admin. Enter their email address in a free user slot. The new users will then receive a registration link by email.
- (Re)assign users to licenses. Select *Edit users* at the top of the page. Drag users to other subscription levels, as long as there is a free user slot available, or to the *Other Users* group. Click *Save changes* to confirm.
- Delete users/admin. Select *Edit users* at the top of the page. Click *Delete* next to the user name. Click *Save changes* to confirm.
- Change the settings per individual user. Select the specific user and change the settings as desired. Click *Save changes* to confirm.

Admin users are by default shown in the group *Other Users*. In order for an admin user to get access to patient records, he needs to be moved to a free user slot under a certain subscription level. A regular user can be assigned administration privileges by clicking on the user name, ticking the checkbox *Admin privileges enabled* and clicking *Save changes*.



These settings can be changed later on (only when logged in as admin) by clicking on the name of the admin (in the Demetra Web Application) and selecting *Admin settings*. Then select the tab *Users and licenses*.

## Device overview

This screen shows the different Demetra Scopes that are linked to the customer account (organization). Click on the specific Demetra Scope to view the device information.

Through this screen it is also possible to add (link) a specific Demetra Scope to this customer account.

### To add (link) a Demetra Scope

1. Select the tab *Device overview*.
2. Perform the configuration of the Demetra Scope (see “Configuration”, page 19) to link a device to the customer account.



These settings can be changed later on (only when logged in as admin) by clicking on the name of the admin (in the Demetra Web Application) and selecting *Admin settings*. Then select the tab *Device overview*.

## Account policies



Those were already set during the previous steps of the configuration (permission model and security policies). Through this screen it is possible to change these settings (except the permission model).



These settings (except the permission model) can also be changed later on (only when logged in as admin) by clicking on the name of the admin (in the Demetra Web Application) and selecting *Admin settings*. Then select the tab *Account policies*.

1. Select the tab *Account policies*.
2. Select the desired security settings and click *Save changes* to confirm. The following security setting can be changed:
  - Device authentication: Determine which authentication methods (PIN or no authentication) are allowed to log in on the Demetra Scope. Depending on the allowed authentication method(s), each user can set his personal authentication method (see “Configuration (user)”, page 15).

## 2.1.4 Configuration (user)

### Settings



Adapt the settings according to your personal preferences in order to have optimal working conditions with the Demetra solution.

1. After user authentication (see “Activation”, page 12) click *Start configuration* on the Demetra welcome screen.
2. In the personal information screen, fill in your first name, last name and telephone number and click *Next* to confirm.
3. Adapt the settings as desired and click *Next* to confirm. The following setting can be adapted:
  - Device authentication: Click *Change device authentication* to configure your device authentication. Depending on the security policies set by the admin (see “Configuration (admin)”, page 13), it is possible to either set your PIN code or choose for no authentication needed to log in on the Demetra Scope. Click *Next* to confirm.
4. Carefully read the safety warnings and recommendations related to the usage of the Demetra Scope. Tick the checkbox *I have read and understand the safety warnings and recommendations* and click *Next* to confirm.
5. An overview of the selected settings is shown. Tick the checkbox *I have read the Barco privacy policy* and click *Accept* to confirm. You are now all set as a user and are able to operate the Demetra Scope.



Click *Barco privacy policy* to open and read the Barco privacy policy.



These settings can be changed later on, see the chapter ‘User’ under “Settings”, page 15.

## 2.1.5 Settings

### Admin

When logged in as admin, click your name at the top of the screen in the Demetra Web Application and select *Admin settings*. Select the appropriate tab and edit the settings as desired. See the chapters ‘Users and licenses’, ‘Device overview’ and ‘Account policies’ under “Configuration (admin)”, page 13 for more details.

### User

When logged in as user, click your name at the top of the screen in the Demetra Web Application and select *Settings*. Edit the settings as desired and click *Save changes* to confirm.

## 2.2 Installation of Demetra Scope

### 2.2.1 Installation of the grip / battery pack

#### Procedure

1. Place the Demetra Scope head on a flat, stable surface.

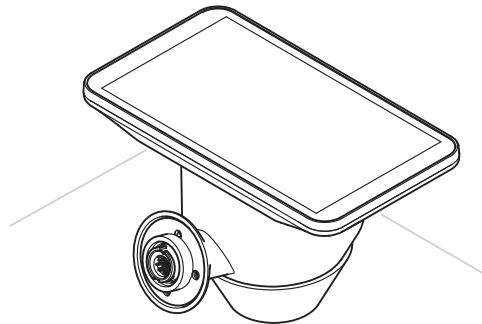


Image 2-4

2. Ensure that the locking ring of the grip is in open position (i.e. the locking ring should be turned to the left).

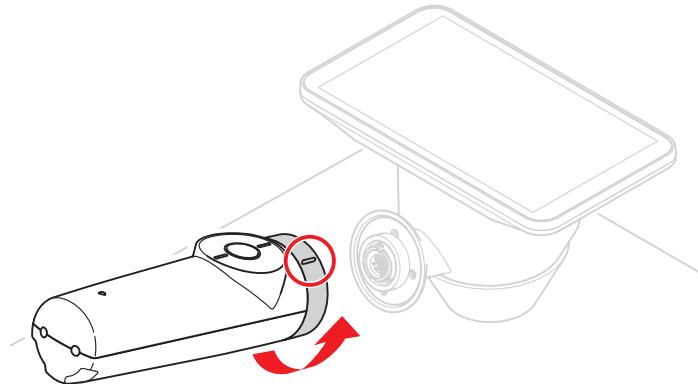


Image 2-5

3. Install the grip on the Demetra Scope head.

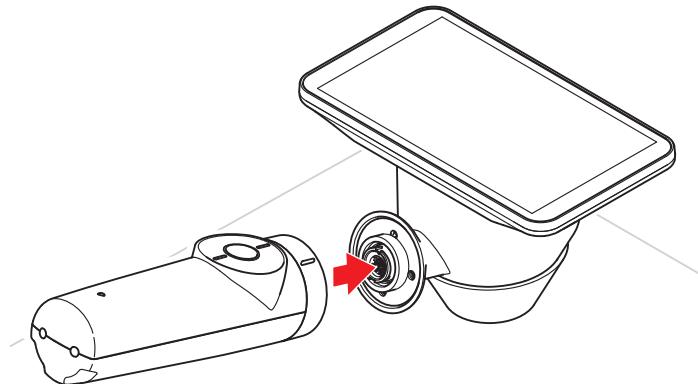


Image 2-6

4. Whilst holding the grip, turn the locking ring of the grip to the right (direction of the locking symbol) until it clicks into the locked position.

**Caution:** Only turn the locking ring of the grip, not the entire grip itself.

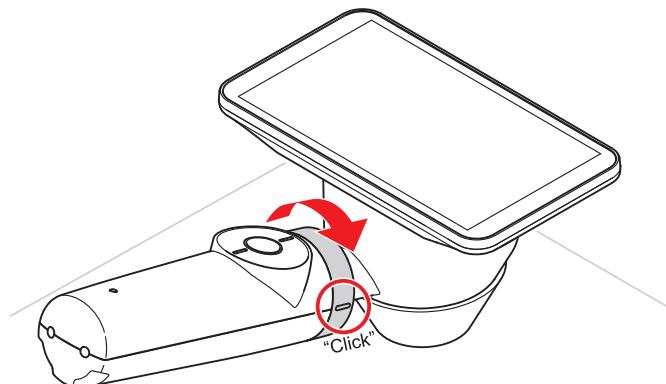


Image 2-7

## 2.2.2 Removal of the grip / battery pack

### Procedure

1. Place the complete Demetra Scope on a flat, stable surface.

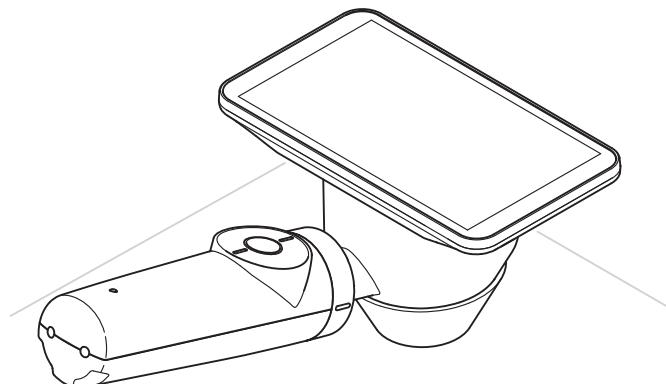


Image 2-8

2. Whilst holding the grip, turn the locking ring to the left (direction of the unlocking symbol) until the grip unlocks.

**Caution:** Only turn the locking ring of the grip, not the entire grip itself.

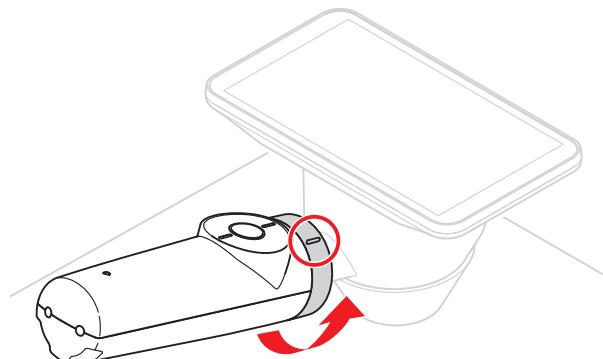


Image 2-9

3. Remove the grip from the Demetra Scope head.

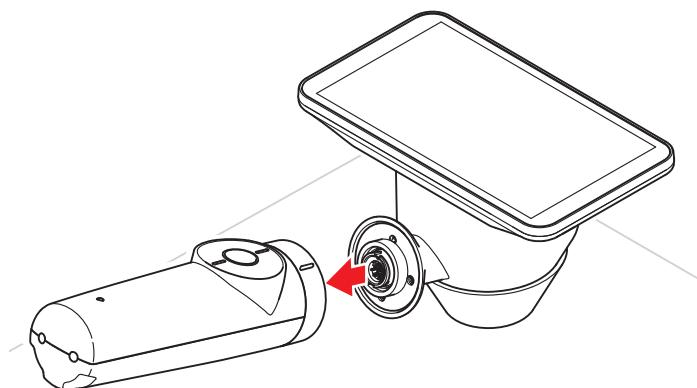


Image 2-10



It may be needed to firmly pull the grip to separate it from the Demetra Scope head.

## 2.2.3 Installation of the non-contact cone

### Non-contact cone

When capturing dermoscopic images with the Demetra Scope in non-contact mode, the non-contact cone can be installed on the Demetra Scope head. This protects the contact glass in the head of the Demetra Scope from any contamination due to possible skin infections (lesion).

Install the non-contact cone on the head of the Demetra Scope. The notch in the non-contact cone must be fitted on the secondary camera. The non-contact cone is held in place safely through a magnetic attachment.

## 2.2.4 Charging the Demetra Scope

### Procedure

1. Connect the adapter to the battery charging station. Route the adapter cable through the notch at the bottom of the battery charging station to put the charging station in a stable position.
2. Place the adapter plug for your country (USA, EU or UK) into the adapter such that the plug fits into the foreseen slots. Slide the plug downwards until it clicks.
3. Plug the adapter into the socket.
4. Place the complete Demetra Scope (with grip installed) or the separate grip in the battery charging station. Make sure that the notches at the bottom of the grip are properly installed on the protrusions of the battery charging station. The complete Demetra Scope (with grip installed) or the separate grip is held in place safely in the battery charging station through a magnetic attachment.
5. The LED on the grip is slowly blinking green during charging. As soon as the LED is steady green, charging is complete.



Complete charging time (from empty battery to fully charged battery) is approximately 3 hours.



For use only with the delivered adapter: model ATM012T-W051V, Adapter Technology Co., Ltd.



The Demetra Scope head also includes a battery. To charge the full battery capacity, install the complete Demetra Scope (with grip installed) in the battery charging station.



Install the battery charging station on a flat, stable surface near an easily accessible socket. Make sure the adapter cable is routed towards the socket in a safe way to avoid damage to the cable and/or charging station.

## 2.3 Setup of Demetra Scope

### 2.3.1 Configuration

#### Procedure



A good Wifi connection is required for sufficient performance of your Demetra Scope.



The Demetra Scope battery must be fully charged before initial setup. Charge for a minimum of 2 hours before initial use.



First perform the configuration (as admin) procedure of the Demetra Web Application (see "Configuration (admin)", page 13).

1. Press the On/Off button to turn on the Demetra Scope. The welcome screen will be shown.
2. Check to make sure that the grip is attached to the head of the device and the locking ring is fully closed, then proceed to the next step.
3. Follow the instructions on the display screen to link your device to your customer account (organization).
4. Scan the QR code shown in the Demetra Web Application with the Demetra Scope.
5. When the QR code was scanned successfully, the Demetra Scope needs to be connected to a Wifi network.
6. Once the Wifi connection is established, the Demetra Scope is linked to the customer account and the device is ready for use.

### 2.3.2 Status bar

#### Overview

The status bar at the top right corner of the Demetra Scope display can be swiped down to:

- Log out the current user
- Access the Settings menu (including legal information)
- View the remaining battery level
- Access the network settings
- View the cloud synchronization status
- View patient information and/or select a(nother) patient

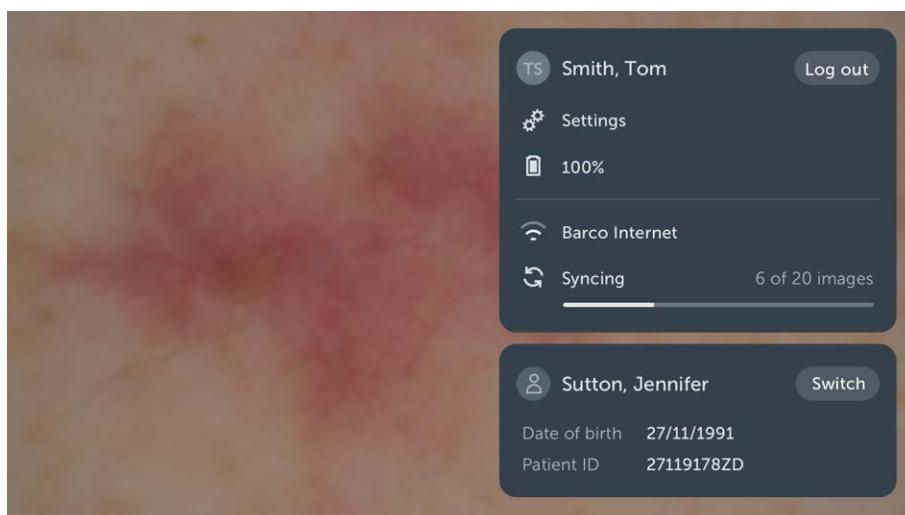


Image 2-11

## 2.4 When the Demetra subscription is terminated

### Instructions

1. When your subscription is terminated, the Demetra Scope must be returned to Barco using your original packaging (see “Repacking instructions”, page 37).
2. There is a possibility to download your patient data from the Demetra solution after terminating your subscription. If you wish to do so, contact the Barco Helpdesk within 60 days after the end date of your subscription.
3. When returning the Demetra Scope to Barco, a factory reset will be performed, erasing all data from the device.

# Operation with the Demetra Scope

3

## 3.1 Start the Demetra Scope

### Log in



When logging in as user, first perform the configuration (user) procedure (see “Configuration (user)”, page 15).

1. Press the On/Off button to turn on the Demetra Scope.
2. Select the desired user. Depending on the authentication method (PIN code or no authentication) set in the user configuration (see “Configuration (user)”, page 15), enter the set PIN code (if needed) to log in on the Demetra Scope.

## 3.2 Basic workflow

### Overview

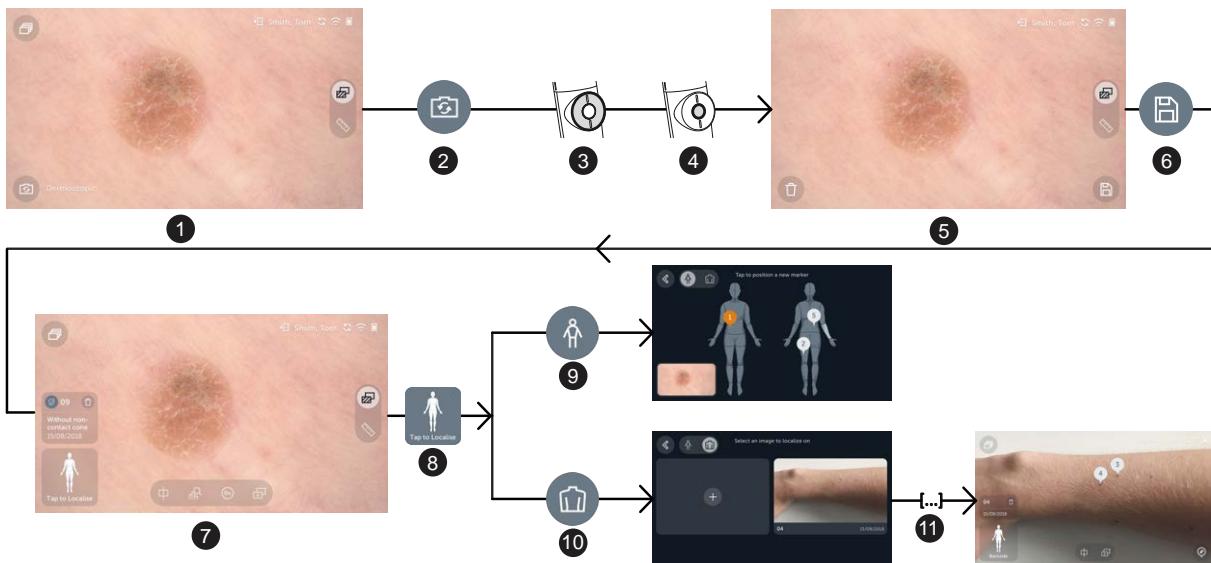


Image 3-1

1. Press the On/Off button on top of the Demetra Scope head. The live video preview screen will be shown.
2. Tap the image mode icon on the display screen and select the desired image mode. The following image modes are available:
  - Dermoscopic mode
  - Close-up mode
  - Overview mode
3. Zoom in/out on the displayed area as desired by scrolling the left touchpad upwards/downwards. Manually adjust the focus of the primary camera by scrolling the right touchpad on the grip of the Demetra Scope. Return to autofocus by tapping the AF icon that appears on the right hand side of the display as soon as the right touchpad on the grip is touched. Manual focus adjustment is only available when dermoscopic mode is selected.
4. Capture an image by pressing the main button on the grip of the Demetra Scope.
5. When an image is captured, the image review screen will be shown. In this screen, the user can perform several actions.
6. Tap the Save icon in the image review screen to save the captured image to the image gallery.
7. When the captured image is saved, the image detail screen will be shown. See “Image detail screen”, page 24) for an overview of the available functionalities.
8. Tap the Localize icon in the image detail screen to link the captured image taken in dermoscopic mode or close-up mode to a location marked on an overview photograph or on a dummy mannequin.
9. Tap the mannequin icon to localize the captured image on a dummy mannequin.

10. Tap the overview icon to localize the captured image on an overview photograph.
11. Select the desired overview photograph on which you want to localize the captured image. This can be an existing overview photograph, or a new overview photograph can be captured.



Shortly press the On/Off button on top of the head to put the device in standby mode. Keep the On/Off button pressed to open a menu which allows you to safely restart or shut down the Demetra Scope.

## 3.3 Live video preview

### Overview



Press the main button on the grip of the Demetra Scope to return to the live video preview from any other screen.



Image 3-2

1. Battery status indicator
2. Wifi connection indicator
3. Cloud connection indicator
4. Patient name
5. Switch patient: Tap to switch patient
6. Image gallery of the selected patient
7. Image mode: Tap the icon to select the desired image mode
  - When close-up mode is selected, tap the 'switch camera' icon on the display screen to either use the primary camera (up to 5–10 cm from the skin) or secondary camera (more than 10 cm from the skin).
  - Depending on the selected image mode, additional illumination is turned on or off automatically. This additional illumination is turned on when the device is operating in dermoscopic mode or in close-up mode with the primary camera. In the other image modes, this additional illumination is turned off.
8. Polarized/non-polarized illumination
9. Add/remove digital scale

## 3.4 Image detail screen

### Overview

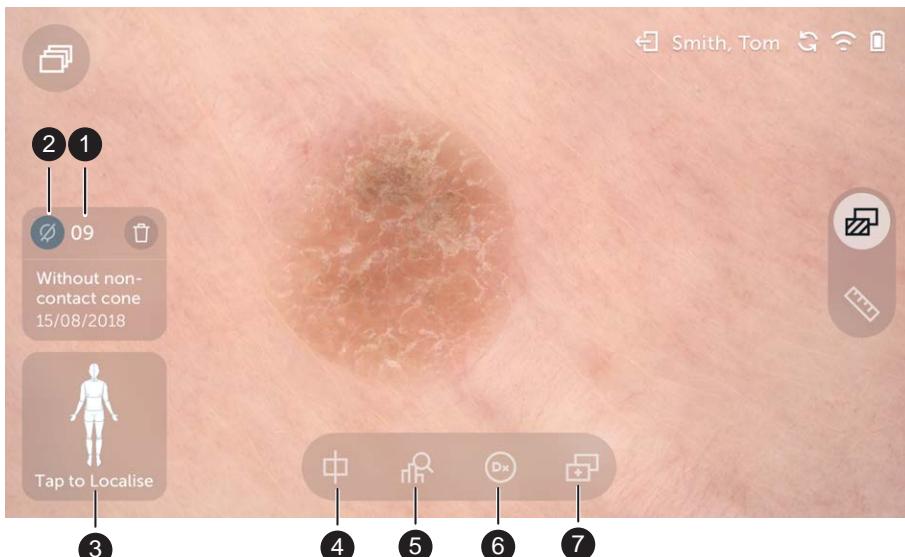


Image 3-3

1. Automatically assigned image number
2. Lesion number: Links the image to a location on an overview photograph or on a dummy mannequin
3. Localize: Allows to localize a dermoscopic or close-up image on an overview photograph or on a dummy mannequin
4. Compare the selected image to any other image (previous image of the same lesion and of the same image type by default (if available)
5. Analyze: Future functionality
6. Diagnose: Add diagnosis and/or management strategy
7. Add follow-up image of the same lesion (in the same image mode)

## 3.5 Localize (on clinical overview)

### Overview

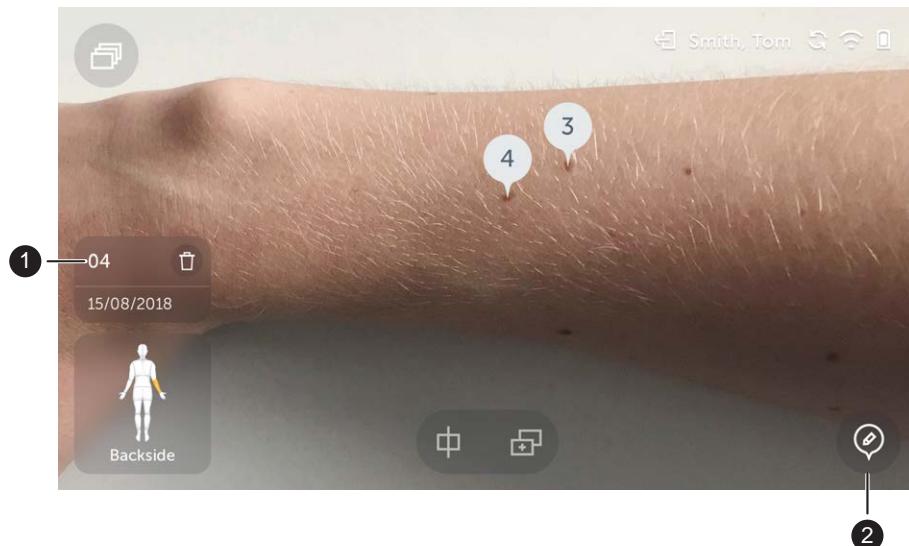


Image 3-4

1. Automatically assigned image number
2. Add a new lesion marker and/or edit existing lesion marker(s) on the clinical overview photograph (and attach a dermoscopic or close-up image to those markers in the next steps)

## 3.6 Diagnose

### Overview

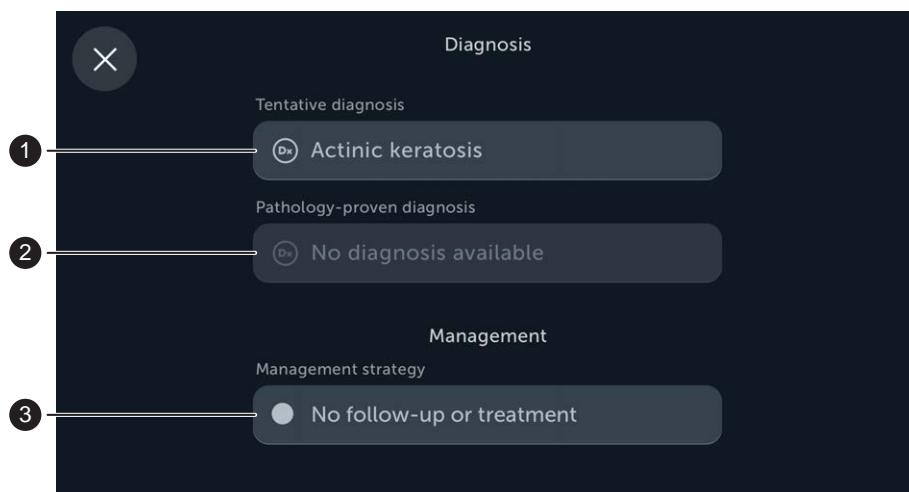


Image 3-5

1. On the Demetra Scope it is possible to select a tentative diagnosis from the predefined list.
2. It is not possible to select a pathology-proven diagnosis. This function is only available through the Demetra Web Application. Once selected via the Demetra Web Application, the pathology-proven diagnosis will be shown on the Demetra Scope as well.
3. Also a management strategy can be selected from the predefined list. Each management strategy is represented by a specific color:
  - No follow-up or treatment: Grey
  - Follow-up: Yellow
  - Treatment: Orange

## Operation with the Demetra Scope

- Excision or biopsy: Red
- Treatment, excision, biopsy finished: Blue

Once a management strategy is selected for a specific lesion, the marker of this lesion on the dummy mannequin or on a clinical overview photograph is displayed in the color of the management strategy. When no management strategy is selected, lesion markers are displayed in grey.

# Operation with the Demetra Web Application

4

## 4.1 Open the Demetra Web Application

### Log in

1. Open the web browser on your workstation.
2. Browse to <https://demetra.barco.com>
3. The Login screen will be shown. Fill in your e-mail address and password (set through user authentication, see "Activation", page 12) and click *Sign in*.  
When logging in for the first time, the configuration start screen will be shown which will guide you through the configuration procedure, see "Configuration (admin)", page 13 when logged in as admin or "Configuration (user)", page 15 when logged in as user.



Image 4-1



When you forgot your password or want to change it, click *Forgot your password?*, enter your e-mail address and click *Reset password*. You will receive a reset link by e-mail, click this link to set a new password.

## 4.2 Main menu

### Overview

The Main menu bar on top of the first screen after login contains the Main menu functionalities:

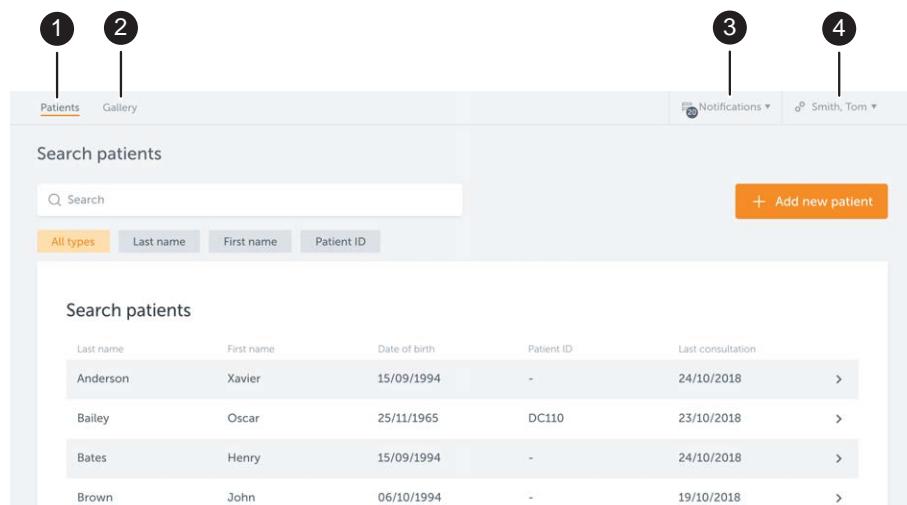


Image 4-2

1. *Patients* tab: Click this tab to add a new patient or select the desired patient and start a new consultation.

2. **Gallery tab:** Click this tab to view all saved images or photographs (of all patients). The following filters are available in this gallery:
  - *Diagnosis:* This filter allows to show all images with a selected diagnosis. If available, the pathology-proven diagnosis is used in this filter. Otherwise the tentative diagnosis is used.
  - *Management:* This filter allows to show all images with a selected management strategy assigned to them.
  - *Image type:* This filter allows to show all images of the selected image type.
3. **Notifications:** Click the “down” icon to see important notifications.
4. **Physician (user) information:** Shows the physician (user) who is logged in on the Demetra Web Application. Click the “down” icon to choose *Settings* or *Sign out*:
  - Click *Settings* to edit the physician (user) information and settings (see “Settings”, page 15).
  - Click *Sign out* to sign out from the Demetra Web Application.



By default, the Patients tab is selected.

## 4.3 Patient detail screen

### Overview

The patient detail screen is shown when a new consultation is started for an existing patient or when a new patient has been created and saved from the *Patients* tab in the main menu.



By default, the *Consultations* tab of the patient detail screen is selected.

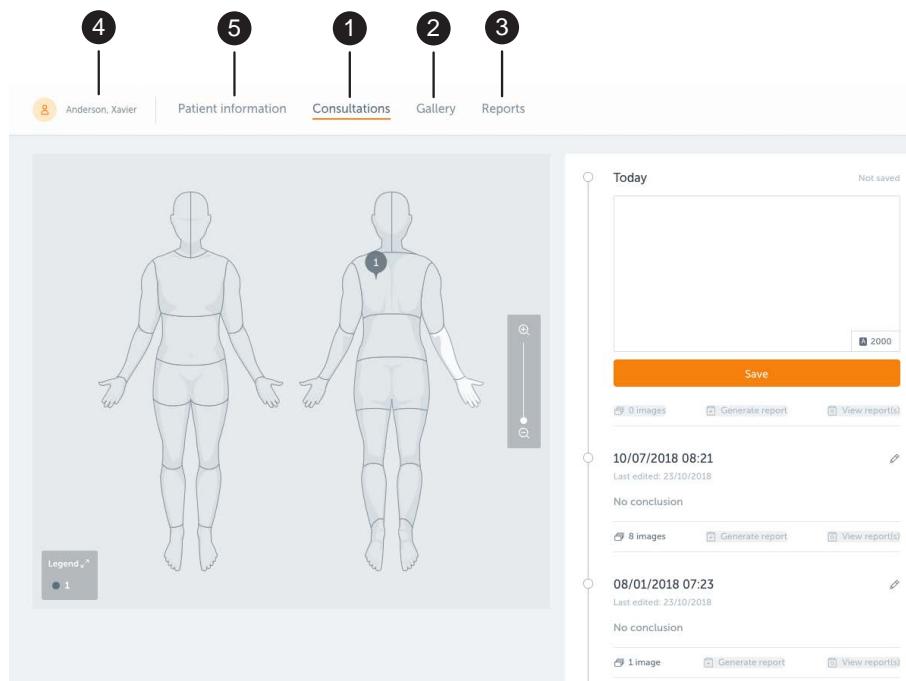


Image 4-3

1. **Consultations tab:** Click this tab to show the Consultations screen of the selected patient (see “Consultations screen”, page 30).
2. **Gallery tab:** Click this tab to view all captured images of the selected patient. The images can be shown in three different views:
  - Mannequin view
  - Hierarchical view
  - Chronological view

The following filters are available:

- *Diagnosis*: This filter allows to show all images with a selected diagnosis. If available, the pathology-proven diagnosis is used in this filter. Otherwise the tentative diagnosis is used.
- *Management*: This filter allows to show all images with a selected management strategy assigned to them.
- *Image type*: This filter allows to show all images of the selected image type.

From these image gallery views, clicking on any image thumbnail opens the image detail screen of this image (see “Image detail screen”, page 30).

3. *Reports tab*: Click this tab to view the Reports of the selected patient or generate a new report.
4. *Patient name*: Shows the selected patient.
5. *Patient information*: Click this button to consult and/or edit the information of the selected patient.

## 4.4 Consultations screen

### Overview

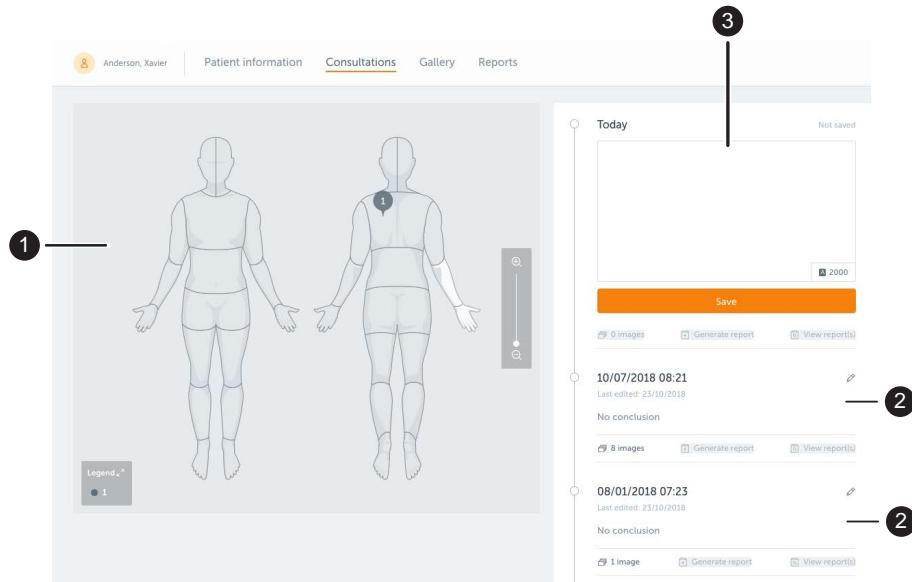


Image 4-4

1. *Dummy mannequin*: Shows the location of the captured images, provided they were localized on the dummy mannequin, from all consultations (previous and current). Click on a lesion marker or highlighted body part to view the images/photographs that are linked to that respective marker (for dermoscopic images or close-up photographs) or body part (for overview photographs).
2. *Consultation history*: Shows the previous consultations of the selected patient in chronological order. For each previous consultation it is possible to:
  - *Edit the consultation summary*
  - *View the images captured during the consultation*
  - *View the saved report(s) (if any)*
  - *Generate a new report*: A standard report of the consultation can be created (see “Reports”, page 33).
3. *Current consultation*: Allows the user to add a summary of the current consultation of the selected patient. A report can be generated (see “Reports”, page 33). Images/photographs captured during the current consultation are shown below the dummy mannequin.

## 4.5 Image detail screen

### About the image detail screen

The image detail screen is shown when a captured image is selected (by clicking on the thumbnail of the captured image). This is possible from different locations in the Demetra Web Application (such as the

different image gallery modes and the images of the current consultation (shown below the dummy mannequin in the *Consultations* screen)).

## Image information

The following information is shown in the image detail screen:

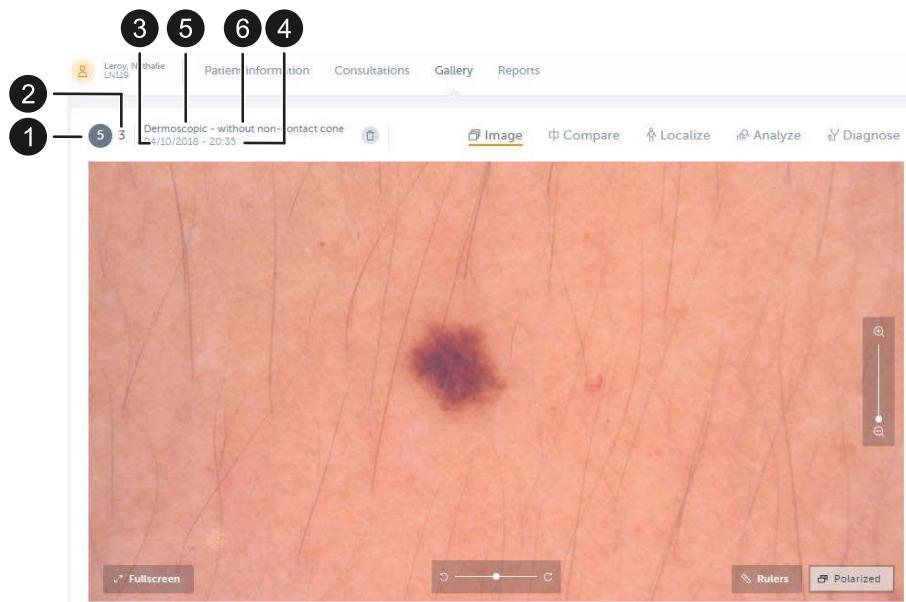


Image 4-5

1. Lesion number: Links the image to a location on a clinical overview image or dummy mannequin
2. Automatically assigned image number
3. Date when the image was captured
4. Time when the image was captured
5. Image mode in which the image was captured:
  - *Dermoscopic* mode
  - *Close-up* mode
  - *Overview* mode
6. Image captured with or without the non-contact cone installed

## Image detail screen functionalities

The following functionalities are available through the image detail screen:

## Operation with the Demetra Web Application

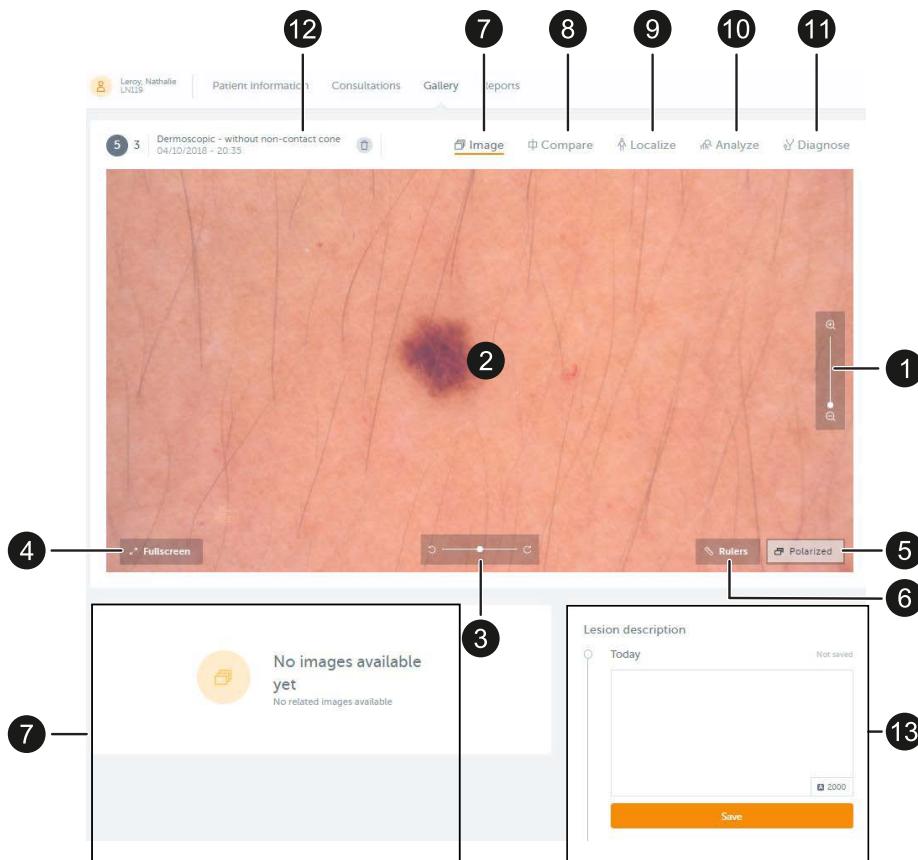


Image 4-6

1. Zoom in/out
2. Pan the image by keeping the left mouse button pressed and move the mouse pointer in the desired direction
3. Rotate image
4. Show image on full screen
5. Show polarized/non-polarized image
6. Add/remove digital scale
7. View all images linked to the selected image e.g. previous images of the same lesion or body part, or linked images of the other image types
8. Compare the selected image to any other image (previous image of the same lesion and of the same image type by default, if available)
9. *Localize*: When a dermoscopic or close-up image is selected, this function allows the user to localize this image on a clinical overview photograph or on a dummy mannequin
10. *Analyze*: Future functionality
11. *Diagnose* (see "Diagnose", page 33 for more information)
12. Delete the selected image
13. Add a new lesion description or edit an existing lesion description. A lesion description is always linked to a lesion and never to an individual image. By consequence the lesion description will be the same for all images of the same lesion.

## 4.6 Diagnose

### Overview

The screenshot shows the 'Diagnose' tab of the Demetra Web Application. At the top, there are tabs for 'Patient information', 'Consultations', 'Gallery', and 'Reports'. The 'Diagnose' tab is active. On the left, there is a clinical photograph of a skin lesion. To the right of the image are several input fields:

- Tentative diagnosis:** A dropdown menu with the placeholder 'Select a diagnosis'. A callout '1' points to this field.
- Pathology-proven diagnosis:** A dropdown menu with the placeholder 'Select a diagnosis'. A callout '2' points to this field.
- Pathology report:** A text input field with a placeholder 'Add a report' and a '+' button. A callout '2' points to this field.
- Management strategy:** A dropdown menu with the selected option 'No follow-up or treatment' (represented by a grey circle). A callout '3' points to this field.
- Lesion description:** A text area with a placeholder 'Optional' and a word count indicator '2000'. A callout '2' points to this field.

Below the main area, there is a section for 'Other images of the same lesion' showing a smaller image of the same lesion with a callout '1' and a summary table with a callout '2'.

Image 4-7

1. On the Demetra Web Application it is possible to select a *tentative diagnosis* from the predefined list or add your own diagnosis by selecting *Other* and specifying your diagnosis in the available text field.
2. It is also possible to select a *pathology-proven diagnosis* in the same way as a tentative diagnosis. A pathology report can be added.
3. Also a *management strategy* can be selected from the predefined list. Each management strategy is represented by a specific color:
  - *No follow-up or treatment*: Grey
  - *Follow-up*: Yellow
  - *Treatment*: Orange
  - *Excision or biopsy*: Red
  - *Treatment, excision, biopsy finished*: Blue

Once a management strategy is selected for a specific lesion, the marker of this lesion on the dummy mannequin or on a clinical overview photograph is displayed in the color of the management strategy. When no management strategy is selected, lesion markers are displayed in grey.

## 4.7 Reports

### Generate a report

The 'Reports' tab in the patient menu allows to generate a standard report for a selected consultation date. This report includes the following information:

- Report information (physician, consultation date, report creation date, imaging device used)
- Consultation summary
- Patient information (to the extent this information is completed in the 'Patient information' tab)
- Dummy mannequin with lesion markers
- All images of the selected consultation with related information (localization, description, diagnosis, management strategy)



# 5

## Troubleshooting

## 5.1 Troubleshooting instructions



Please check the Demetra knowledge base on [www.barco.com/support](http://www.barco.com/support) for the most recent troubleshooting information.

### No live video preview

Fully recharge the battery and check again. If the condition persists, your Demetra Scope may require servicing.

### LED fails

The LEDs used in your Demetra Scope are designed to last over 100,000 hours. If any of the LEDs fail, your Demetra Scope requires servicing.

### LED indicator error codes

In case the LED indicator in the grip of the device shows other behavior than during normal operation, please contact the Barco helpdesk. Normal operation of this LED indicator includes the following:

- Off: Default behavior/charged battery (>20%)
- Steady orange: Battery low (<20%)
- Slow blinking green: Battery charging (when placed in battery charging station)
- Steady green: Battery fully charged (when placed in battery charging station)

### The device doesn't charge

Check the power cable connection

- Has the adapter cable been plugged in correctly into the battery charging station?
- Has the country adapter plug been attached properly?



Use only the power supply included in the Demetra box, or a spare part provided by Barco, for charging your device.

### Service procedures

- First line support should be obtained from a Barco Authorized Reseller, if applicable.
- Second line support under DemetraCare is made available by Barco during regional business hours as specified on [www.barco.com/support](http://www.barco.com/support). Refer to [www.barco.com/support/knowledge-base/KB5034](http://www.barco.com/support/knowledge-base/KB5034) for more details on how to create a myBarco account and service ticket.
- Customers are encouraged to contact the helpdesk via the e-portal and to use available on-call services for critical and time sensitive issues only. Logging service tickets through the e-portal is recommended good practice to ensure that support requests are properly routed and escalated.
- Customer's requests shall be made by a dedicated professional who may be an employee or a service provider of Customer; who should be knowledgeable about the Application and the operating environment; who shall not be replaced without written notice to Barco (the "Customer Contact").
- A service ticket:
  - Can be opened by the Customer Contact only
  - Should include at least the following information:
    - information on the nature, causes, and impact of the issue, in as much detail as possible
    - log files, configuration files, screen images, and other information required for issue troubleshooting and analysis
    - remote login or VPN access to Customer's systems, where required (and where permitted by Customer security policies), or, as an alternative, direct access to Customer's systems while in contact with Barco
    - any other information reasonably requested by Barco to timely respond to questions and requests
  - The Customer Contact shall confirm to Barco whether Barco's support has resolved Customer's issue
  - Barco may close a service ticket on written notice to Customer in the absence of Customer's confirmation or when the issue, in Barco's reasonable opinion is resolved.

# Repacking instructions

6

## 6.1 Repacking overview

### Overview

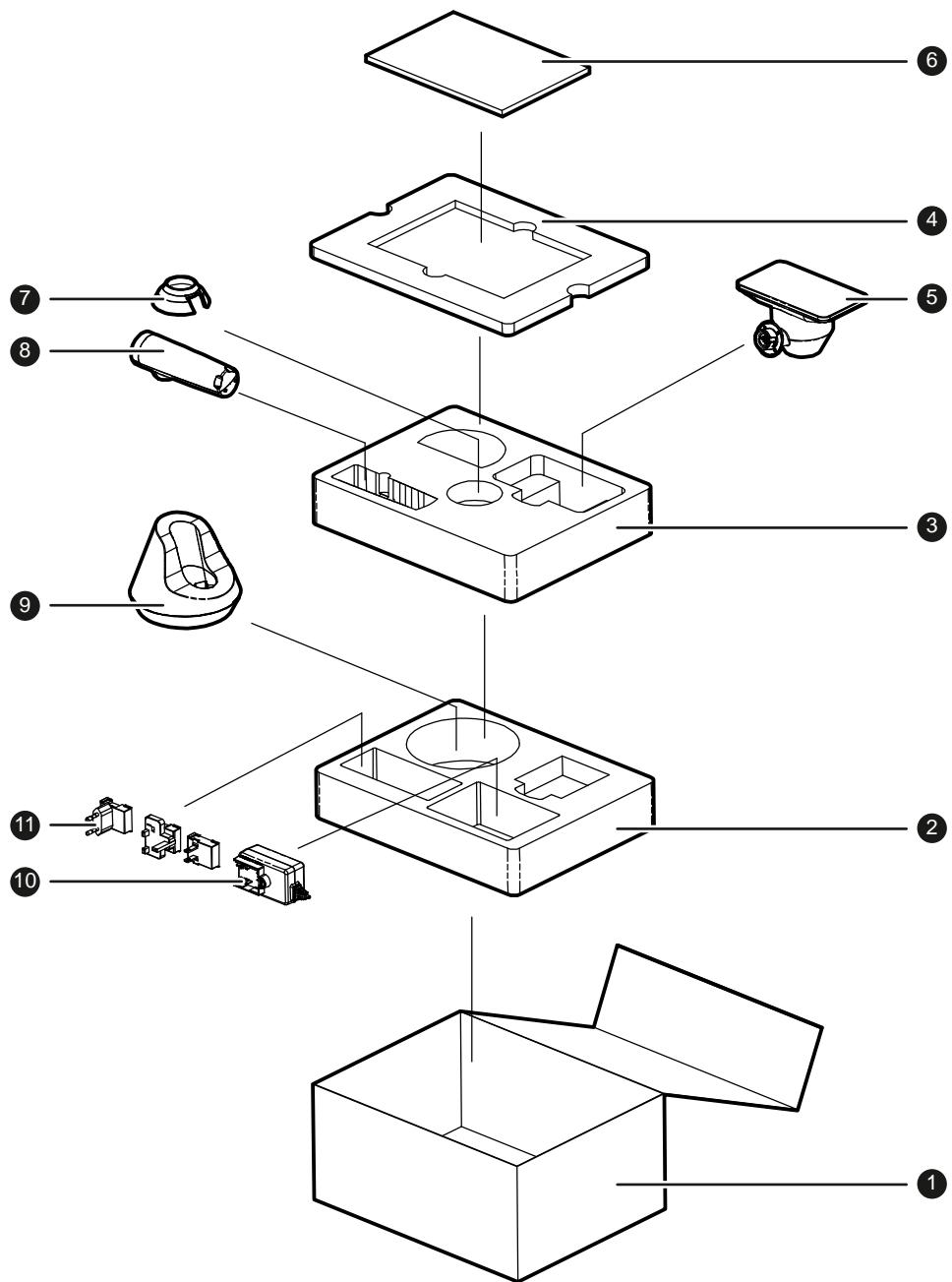


Image 6-1

1. Box
2. Bottom buffer
3. Middle buffer
4. Top buffer
5. Demetra Scope head
6. User documentation
7. Non-contact cone
8. Rechargeable grip / battery pack
9. Battery charging station

- 10. Adapter
- 11. Plugs



# Cleaning and disinfection

7

## 7.1 Instructions

### To disinfect the contact glass and biocompatible plastic of the Demetra Scope

The exterior and contact glass of your Demetra Scope may be cleaned and disinfected by wiping it with a recognized product for disinfection. Read and follow all label instructions on the disinfection product. Disinfection is required at least before every new patient examination, and after touching breached or compromised skin surfaces with the device. Do not use abrasive material on any part of the equipment or immerse the device in liquid. Do not autoclave.

The following products can be used for disinfection:

Disinfection products:

- Clinell wipes
- Cleaning agent: Neodisher® MediClean

Disinfection products based on following substances:

- Isopropyl alcohol <70%
- Ethanol based < 90%

### To clean the contact glass of the Demetra Scope

The contact glass should be treated as high quality photographic equipment and should be cleaned with standard cleaning equipment and protected from harmful chemicals.

### To clean the display of the Demetra Scope

Clean the display using a sponge, cleaning cloth or soft tissue, lightly moistened with a recognized cleaning product for medical equipment. Read and follow all label instructions on the cleaning product. In case of doubt about a certain cleaning product, use plain water.

Do not use following products:

- Alcohol/solvents at higher concentration > 5%
- Strong alkalis (lye), strong solvents
- Highly acidic detergents
- Detergents with fluoride
- Detergents with ammonia
- Detergents with abrasives
- Steel wool
- Sponge with abrasives
- Steel blades
- Cloth with steel thread



**CAUTION:** Take care not to damage or scratch the display. Be careful with rings or other jewelry and do not apply excessive pressure on the display.



**CAUTION:** Do not apply or spray liquid directly to the display as excess liquid may cause damage to internal electronics. Instead, apply the liquid to a cleaning cloth.

# Important information

# 8

## General information

This device is for use in professional healthcare facility environments only.

With the installation of the device, use only the delivered external cables and power supply or a spare part provided by the legal manufacturer. Using another can result in a decrease of the immunity level of the device.

## 8.1 Safety information

### General recommendations

Read the safety and operating instructions before operating the device.

Retain safety and operating instructions for future reference.

Adhere to all warnings on the device and in the operating instructions manual.

Follow all instructions for operation and use.

### Electrical Shock, Fire Hazard and Mechanical Hazard



Only in accordance with ANSI/AAMI ES 60601-1 (2005) + AMD (2012) and CAN/CSA-C22.2 No. 60601-1: 14 (Label UL Mark)

To prevent electric shock or fire hazard, do not remove cover.

No serviceable parts inside. Refer servicing to qualified personnel.

Do not expose this apparatus to rain or moisture.

Make sure the electrical contacts of the grip / battery pack and battery charging station are dry and clean to avoid short circuit.

Keep the On/Off button on top of the head pressed to safely shut down the Demetra Scope.

### Modifications to the unit

Do not modify this equipment without authorization of the manufacturer.

### Inspection and maintenance

Inspect the display and contact glass of the Demetra Scope for damage or scratches at regular intervals.

Properly clean and disinfect the Demetra Scope. See "Cleaning and disinfection", page 41 for more details.

### Type of protection (electrical):

The Demetra Scope has an insulation protection class II power supply adapter.

### Power connection

- Power requirements: The equipment must be powered using the delivered adapter and appropriate plug (for your country).
- The adapter must be powered by the AC mains voltage.
- The power supply is specified as a part of the ME equipment or combination is specified as a ME system.
- The equipment should be installed near an easily accessible outlet.
- The equipment is intended for continuous operation.
- Disconnecting the adapter from the building mains outlet is the proper means of isolation from the mains supply.

### Battery and charging

Your Demetra Scope uses a special lithium battery, which can only be purchased from Barco or from an authorized Barco dealer. Do not under any circumstances use another battery other than the one designed for this unit. Doing so could result in damage to the unit.

### Transient over-voltage

If the device is not used for a long time, remove it from the battery charger to avoid damage by transient over-voltage.

To fully disengage the power to the device, please remove it from the battery charger.

## Image review

To have sufficient image quality, a suitable display should be used to review images in the Demetra Web Application (see the part 'Requirements' in the chapter "Activation", page 12 for more details).

## High magnetic environment

- The device shall not be used in the high magnetic environment of an MRI scanner.
- The installer shall assess the magnetic environment before installation or use of the device.

## Water and moisture

Never expose the device to rain or moisture.

Never use the device near water - e.g. near a bathtub, washbasin, swimming pool, kitchen sink, laundry tub or in a wet basement.

## Eye safety

Hold your Demetra Scope so that the LEDs are aimed in the direction of the lesion to be examined.

Do not look directly into the bright LED light. It is recommended that patients close their eyes during examinations.

The Demetra Scope is not intended to be used for lesions in the eyes.

Do not stare at operating lamp. May be harmful to the eyes. Product tested against IEC62471.

## Glass temperature

The temperature of the contact glass can reach 46.5 °C.

Please verify the temperature of the contact glass and the condition of the patient before using contact mode. Limit the contact duration to less than 1 minute, or use non-contact mode instead.

## Breached or compromised surface

Avoid contact between the Demetra Scope and breached or compromised surfaces, even when the non-contact cone is installed.

In case of large breached or compromised lesions, do not use the non-contact cone. Make sure to keep appropriate distance between the Demetra Scope head and the lesion.

## Risk patients

As the Demetra Scope contains several magnets (for the attachment of the non-contact cone and for the installation in the battery charging station), pay attention when examining specific risk patients (e.g. patients with a pacemaker, ...).

## Malfunctions

Contact the Barco helpdesk under the following conditions:

- If the power cord or plug is damaged or frayed.
- If liquid has been spilled into the equipment.
- If the equipment has been exposed to rain or water.
- If the equipment does not operate normally when the operating instructions are followed. Adjust only those controls that are covered by the operating instructions since improper adjustment of other controls may result in damage and will often require extensive work by a qualified technician to restore the equipment to normal operation.
- If the equipment has been dropped or has been damaged.
- If the equipment exhibits a distinct change in performance, indicating a need for service.

## Technical data

For detailed information, see "Technical specifications", page 56.

## National Scandinavian Deviations for CL. 1.7.2

Finland: "Laite on liitettävä suojaamadoituskoskettimilla varustettuun pistorasiaan"

Norway: "Apparatet må tilkoples jordet stikkontakt"

Sweden: "Apparaten skall anslutas till jordat uttag"

## 8.2 Environmental information

### Disposal Information

Waste Electrical and Electronic Equipment



This symbol on the product indicates that, under the European Directive 2012/19/EU governing waste from electrical and electronic equipment, this product must not be disposed of with other municipal waste. Please dispose of your waste equipment by handing it over to a designated collection point for the recycling of waste electrical and electronic equipment. To prevent possible harm to the environment or human health from uncontrolled waste disposal, please separate these items from other types of waste and recycle them responsibly to promote the sustainable reuse of material resources.

For more information about recycling of this product, please contact your local city office or your municipal waste disposal service.

For details, please visit the Barco website at: <http://www.barco.com/AboutBarco/weee>

## 8.3 Regulatory compliance information



Regulatory e-labeling information can be found on the Demetra Scope (Mains screen > click Wifi logo > click Settings).

### 8.3.1 EU statement

#### RF information

Hereby, Barco NV declares that this device is in compliance with the Directive 2014/53/EU. The full text of the EU declaration of conformity is available at: <https://www.barco.com/support/Demetra/docs>

	AT	BE	BG	HR	CY	CZ	DK
	EE	FI	FR	DE	EL	HU	IE
	IT	LV	LT	LU	MT	NL	PL
	PT	RO	SK	SI	ES	SE	UK

The device is restricted to indoor use only when operating in the 5150 to 5350 MHz frequency range.

WiFi maximum EIRP power:

- 2.4 GHz band: 20 dBm
- 5 GHz band: 20 dBm

### 8.3.2 FCC statement

#### FCC ID

This device is registered under FCC ID 'SXE-BDEM01'.

## FCC class B

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This device has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This device generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this device does cause harmful interference to radio or television reception, which can be determined by turning the device off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the device and receiver.
- Connect the device into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

**FCC responsible:** Barco Inc., 3059 Premiere Parkway Suite 400, 30097 Duluth GA, United States, Tel: +1 678 475 8000

## Radiation exposure statement

The product complies with the FCC portable RF exposure limit set forth for an uncontrolled environment and are safe for intended operation as described in this manual. The further RF exposure reduction can be achieved if the product can be kept as far as possible from the user body or set the device to lower output power if such function is available.

These requirements set a SAR limit of 1.6 W/kg averaged over one gram of tissue. The highest SAR value reported under this standard during product certification for use when properly worn on the body is 0.820 W/kg.

## 8.3.3 Industry Canada statement - Avis d'industrie Canada

### IC

This device is registered under IC '9393B-BDEM01'.

Cet appareil est enregistré sous IC '9393B-BDEM01'.

### ICES - NMB

This Class B digital apparatus complies with Canadian ICES-003.

Cet appareil numérique de la classe B est conforme à la norme NMB-003 du Canada.

### ISED

This device complies with ISED license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d' ISED applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

## Permitted frequency ranges - Gamme de fréquences autorisée

Operations in the 5.25-5.35 GHz band are restricted to indoor usage only.

Les opérations dans la bande de 5.25-5.35 GHz sont limités à un usage intérieur seulement.

Operation in the band 5150-5250 MHz is only for indoor use to reduce the potential for harmful interference to co-channel mobile satellite systems.

## Important information

La bande 5 150-5 250 MHz est réservés uniquement pour une utilisation à l'intérieur afin de réduire les risques de brouillage préjudiciable aux systèmes de satellites mobiles utilisant les mêmes canaux.

For the frequency 5600-5650 MHz, no operation is permitted.

Pour la fréquence 5600-5650 MHz, aucune opération est autorisée.

### Radiation exposure statement

These requirements set a SAR limit of 1.6 W/kg averaged over one gram of tissue. The highest SAR value reported under this standard during product certification for use when properly worn on the body is 1.148 W/kg.

Ces exigences établissent une limite SAR de 1,6 W/kg en moyenne sur un gramme de tissu. La valeur SAR la plus élevée déclarée selon cette norme lors de la certification du produit à utiliser lorsqu'il est correctement porté sur le corps est de 1.148 W/kg.

### 8.3.4 General information

#### Manufacturing country

The manufacturing country of the product is indicated on the product label ("Made in ...").

#### Importers contact information

To find your local importer, contact one of Barco's regional offices via the contact information provided on our website ([www.barco.com](http://www.barco.com)).

## 8.4 EMC notice

#### General information

This device is for use in professional healthcare facility environments only.

With the installation of the device, use only the delivered external cables and power supply or a spare part provided by the legal manufacturer. Using another can result in a decrease of the immunity level of the device.



**WARNING:** Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.



**WARNING:** Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.



**WARNING:** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Demetra solution, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

#### Electromagnetic emissions

The Demetra solution is intended for use in the electromagnetic environment specified below. The customer or the user of the Demetra solution should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – Guidance
RF emissions CISPR 11	Group 1	The Demetra solution uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Demetra solution is suitable for use in all establishments, including

Emissions test	Compliance	Electromagnetic environment – Guidance
Harmonic emissions IEC 61000-3-2	Class A	domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

This Demetra solution complies with appropriate medical EMC standards on emissions to, and interference from surrounding equipment. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Interference can be determined by turning the equipment off and on.

If this equipment does cause harmful interference to, or suffer from harmful interference of, surrounding equipment, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna or equipment.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced technician for help.

## Electromagnetic immunity

The Demetra solution is intended for use in the electromagnetic environment specified below. The customer or the user of the Demetra solution should assure that it is used in such an environment.

Immunity test	IEC 60601 test levels	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines 100 kHz repetition frequency	± 2 kV for power supply lines ± 1 kV for input/ output lines 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC61000-4-5	Line to line: ± 0.5 kV, ± 1 kV Line to ground: ± 0.5 kV, ± 1 kV, ± 2 kV	Line to line: ± 0.5 kV, ± 1 kV Line to ground: ± 0.5 kV, ± 1 kV, ± 2 kV	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% residual voltage for 0.5 period at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% residual voltage for 1 period at 0° 70% residual voltage for 25 periods at 0° Voltage interruptions: 0% residual voltage for 250 periods at 0°	0% residual voltage for 0.5 period at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% residual voltage for 1 period at 0° 70% residual voltage for 25 periods at 0° Voltage interruptions: 0% residual voltage for 250 periods at 0°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Demetra solution requires continued operation during power mains interruptions, it is recommended that the Demetra solution be powered from an uninterruptible power supply or a battery
Power frequency (50/60 Hz) magnetic field	30 A/m	Not applicable <sup>1</sup>	Power frequency magnetic fields should be

1: Demetra solution doesn't contain susceptible components to magnetic fields

Immunity test	IEC 60601 test levels	Compliance level	Electromagnetic environment – guidance
IEC 61000-4-8			at levels characteristic of a typical location in a typical commercial or hospital environment
Conducted RF IEC 61000-4-6	3 Vrms (6 Vrms in ISM bands) 150 kHz to 80 MHz	3 Vrms (6 Vrms in ISM bands)	-
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	

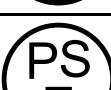
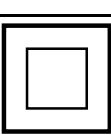
### Immunity to RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380 – 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430 – 470	GMRS 460, FRS 460	FM $\pm$ 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						
1720	1700 – 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1/3/4/25, UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						
2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240	5100 – 5800	W LAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500						
5785						

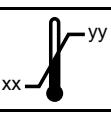
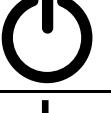
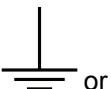
## 8.5 Explanation of symbols

### Symbols on the device

On the device or power supply, you may find the following symbols (nonrestrictive list):

	Indicates compliance with Part 15 of the FCC rules
	Indicates the device is approved according to the UL regulations MEDICAL – GENERAL MEDICAL EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES 60601-1 (2005) + AMD (2012) and CAN/CSA-C22.2 No. 6060-1 (2014)
	Indicates the device is approved according to the UL regulations for Canada and US
	Indicates the device is approved according to the UL regulations for Canada and US
	Indicates the device is approved according to the UL Demko regulations
	Indicates the device is approved according to the CCC regulations
	Indicates the device is approved according to the VCCI regulations
	Indicates the device is approved according to the KC regulations
	Indicates the device is approved according to the BSMI regulations
	Indicates the device is approved according to the PSE regulations
	Indicates the device is approved according to the EAC regulations
	Caution: Federal law (United States of America) restricts this device to sale by or on the order of a licensed healthcare practitioner.
	Indicates the USB connectors on the device
	Indicates the DisplayPort connectors on the device
	Type BF applied part
	Class II equipment

## Important information

	Indicates the legal manufacturer
	Indicates the manufacturing date
	Indicates the temperature limitations <sup>2</sup> for the device to safely operate within specs
	Indicates the device serial number
	Indicates the device part number or catalogue number
	Revision of the part number or catalogue number
	<b>Warning:</b> dangerous voltage
	<b>Caution</b>
	Consult the operating instructions
	Indicates this device must not be thrown in the trash but must be recycled, according to the European WEEE (Waste Electrical and Electronic Equipment) directive
	Indicates Direct Current (DC)
	Indicates Alternating Current (AC)
	Stand-by
	Equipotentiality
	Protective earth (ground)

### Symbols on the box

On the box of the device, you may find the following symbols (nonrestrictive list):

2: Values for xx and yy can be found in the technical specifications paragraph.

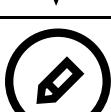
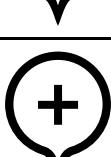
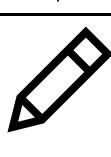
	Indicates a medical device that can be broken or damaged if not handled carefully when being stored.
	Indicates a medical device that needs to be protected from moisture when being stored.
	Indicates the storage direction of the box. The box must be transported, handled and stored in such a way that the arrows always point upwards.
	Indicates the maximum number of boxes to be stacked on each other.
	Indicates that the box should be carried with two persons.
	Indicates that the box should not be cut with a knife, a cutter or any other sharp object.
	Indicates the temperature limits to which the medical device can be safely exposed when being stored.
	Indicates the range of humidity to which the medical device can be safely exposed when being stored.
	Indicates the range of atmospheric pressure to which the medical device can be safely exposed when being stored.

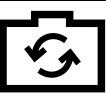
## 8.6 Explanation of icons

### Overview

	Settings		Add/remove digital scale
	Device		Delete image
	Battery status: full		Save image
	Battery status: empty		Compare images

Important information

	Battery issue (contact Barco helpdesk)		Analyze
	Wifi error: offline		Diagnose
	Wifi status: full strength		Add follow-up image
	Wifi status: no Wifi		Image set
	Protected Wifi network		Take new image
	Wifi warning: no internet connection		No localization
	Cloud connection indicator: synchronizing		Edit mode for lesion markers (add/edit/remove)
	Cloud connection indicator: synchronizing error		Add new marker
	Patient		Edit
	Physician (user)		Undo
	Admin user		Rotate clockwise
	Physician-admin user		Rotate counter-clockwise
	Delete physician (user)		Report

	Switch patient		Generate report
	Image gallery		View report
	<ul style="list-style-type: none"> <li>• Mannequin view of image gallery</li> <li>• Localize on mannequin</li> </ul>		Zoom in
	Hierarchical view of image gallery		Zoom out
	Chronological view of image gallery		Pan
	Switch image mode		Notification
	Dermoscopic mode		Warning
	Close-up mode		Image swap (select image)
	<ul style="list-style-type: none"> <li>• Overview mode (to capture an image)</li> <li>• Localize on clinical overview</li> </ul>		Lock rotation
	Switch camera (in close-up mode)		Lock pan
	Overlay		Lock zoom
	Polarized/non-polarized image		Show legal information
	Brightness low		Autofocus
	Brightness full		

## 8.7 Legal disclaimer

### Disclaimer notice

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## 8.8 Technical specifications

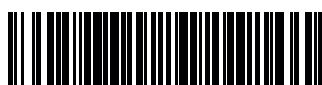
### Overview

Internal camera	3840 (H) x 2160 (V), aspect ratio 16:9
Secondary camera	3264 (H) x 1836 (V), aspect ratio 16:9
Multispectral LEDs for dermoscopic images	<ul style="list-style-type: none"><li>• Amber</li><li>• Deep Red</li><li>• Green</li><li>• Cyan</li><li>• Blue</li><li>• Royal Blue</li><li>• Far Red</li><li>• Red-Orange</li></ul>
White LEDs for live video preview	6500K
Screen technology	AMOLED, 1920 (H) x 1080 (V), aspect ratio 16:9, capacitive touchscreen
Wireless communication	Wi-Fi 802.11 a/b/g/n/ac
Input rating	5V 3A
Battery in grip	Lithium-Cylindrical Battery of capacity 5000mAh (typical)
Battery in head	Lithium battery of capacity 2670mAh (typical)
Housing color	Renol-White

Dimensions scope (head + grip mounted) (H x W x D)	231 x 143 x 78 mm
Dimensions packaged (D x W x H)	347 x 260 x 150 x mm
Net weight scope (head + grip mounted)	<ul style="list-style-type: none"> <li>Without non-contact cone: 528 g</li> <li>With non-contact cone: 552 g</li> </ul>
Net weight packaged (box with all parts included)	2.2 kg
Operating temperature range	0°C to 35°C
Storage temperature	-20 °C to 60 °C
Operating humidity	Maximum 85% non-condensing
Storage humidity	Maximum 95% non-condensing
Operating pressure	70 kPa minimum
Storage pressure	60 to 106 kPa
Certifications	<p>CE (MDD 93/42/EEC; A1:2007/47/EC class I device)</p> <p><b>Safety:</b> CE, ANSI/AAMI ES 60601-1 (2005) + AMD (2012) and CAN/CSA-C22.2 No. 60601-1 (2014)</p> <p><b>EMI:</b> EN 60601-1-2 : 2015, IEC 60601-1-2 ed 4.0, EN55011 : 2009+A :2010, CISPR 11 ed 5.1, IEC 60601-2-57, FCC Part 15, ICES-003/NMB-003 @@@</p> <p><b>RF:</b> Radio Equipment Directive 2014/53/EU</p>



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