HS MIOS 5

Standard 14:42:15 28.08.2013

Patient   Recording   Archive

Name, First Name	Sex	Birthday	Pat. No.	Srgy. Date
Bennett, Olivia		23.11.1938	872539	---
Collister, Logan		27.12.1964	375913	---
Connor, David		25.03.1954	934847	---
Franklin, Natalie		02.05.1974	285293	---
Johnson, Sophia		13.08.1964	254396	---
Miller, Ursula		09.02.1965	659875	---
Smith, Daniel		28.07.1946	280316	---
Warren, James		02.10.1937	281548	---

Search

DICOM
Local

Open

q w e r t y u i o p

a s d f g h j k l '

z x c v b n m

/ \ ^

ABC/abc

7 8 9
4 5 6
1 2 3
0 =

New Patient

Exit Program   Settings

Instructions for Use

Microscopical Imaging Operation System

HS MIOS 5
M.COM 2.5
C.MON HD

Look closer. See further.

HS HAAG-STREIT GROUP

Table of Contents

1 Manufacturer's Details and Contact Information

Manufacturer of the surgical microscope system is

Haag-Streit AG
Gartenstadtstrasse 10
3098 Koeniz
Switzerland

European Community Authorised Representative (EC-REP):

Haag-Streit Deutschland GmbH
Rosengarten 10
22880 Wedel
Germany

If you have any questions, please provide your local sales representative the reference and serial numbers for the relevant components. You can obtain these from the respective components' type plates.

You will find the contact details for your local sales representative in the notes pages of these instructions. A current list of local sales representatives worldwide can be found on the Haag-Streit website (https://www.haag-streit.com/haag-streit-group/contact/haag-streit-distributors/distributors).

Illustration 1: Type Plate for MIOS

Item	Name
1	Manufacturer
2	*CE*-Conformity Label
3	Medical Device
4	Degree of Protection by Enclosure (*IP-Code*)
5	*Ref*erence Number
6	Label Identification
7	Serial Number (*SN*)
8	*UDI* Code:
	– (01): Global Trade Item Number (*GTIN*)
	– (11): Date of Manufacture

Item	Name
–	(21): Serial Number (*SN*)
9	QR-Code (*UDI* information)
10	Power Supply Specification
11	Registered Number at Central Drugs Standard Control Organisation (*CDSCO*)
12	Date of Manufacture according to ISO 8601
13	European Community Authorized Representative (*EC-REP*)
14	Product Name

2 Information for Safety

Residual Risks

The equipment from Haag-Streit has been designed and produced according to state of the art standards and best practices at the time of manufacture. However, some residual risks remain and are indicated on the equipment and in the form of safety messages (WARNING, CAUTION, NOTICE) in this document.

Explanation of Warnings

DANGER
Will lead to serious injury or death.

Follow the instructions to avoid a hazard.

WARNING
May lead to serious injury or death.

Follow the instructions to avoid a hazard.

CAUTION
May lead to light or moderately serious injuries.

Follow the instructions to avoid a hazard.

NOTICE
May lead to material damage and / or operating error.

Follow the instructions to avoid a hazard.

2.1 General Warnings

WARNING
Risk of life threatening electrical shock!

Damage to the surgical microscope system may cause live parts to be touched during use.

a) Do not use the surgical microscope system in case of obvious defects i.e. dented casing or power supply lines and sockets with cracked insulation.

b) Call the Haag-Streit Service.

WARNING

Risk of falling parts!

    a) Secure the screws of parts that could potentially fall off with Loctite or use self-locking screws.

WARNING

Risk of personal injury if used improperly!

Follow the instructions for use.

    a) Avoid putting the device under extreme mechanical stress.

    b) Positioning the M.COM immediately next to other devices or in a stack with other devices can result in faulty operation.

    c) If other devices are operated in the immediate vicinity of the M.COM, observe all devices in order to ensure that they are functioning properly.

    d) Never perform service or maintenance work during an operation.

WARNING

Risk of safety failures due to incorrect accessories and spare parts!

The use of other accessories, transformers and lines than those specified (with the exceptions of the transformers and lines which the manufacturer supplies as spare parts for internal components) may increase electromagnetic emissions or reduce the system's immunity to interference.

    a) Only use manufacturer-approved accessories.

    b) Do not exceed the maximum bearing capacity of the floor stand.

    c) Only devices which are defined as being compatible with the M.COM are permissible.

    d) Without additional protective measures, hazardous leakage or touch currents may arise.

    e) An additional multiple-socket outlet or extension cable may not be connected.

    f) Altering, connecting new elements, removing, updating or upgrading the M.COM that is connected to a network/data sharing system may lead to new risks.

    g) All requirements of IEC 60601-1 must be fulfilled at all times.

    h) If the M.COM is modified, then suitable inspections and tests must be conducted to ensure continued safe operation after the modification.

CAUTION

Risk of limited treatment options!

If limitations of the functionality are not detected, the surgical microscope system may not offer all necessary functions during surgery.

    a) Prior to any surgery: ensure that all electrical and mechanical connections are firmly seated and free of defects.

    b) Regularly check the quality of the image from the imaging system.

    c) Do not use the system in case of any obvious defects, error states or functional restrictions. Call the Haag-Streit Service.

CAUTION

Risk of poor treatment!

The Image displayed by system may differ from real situation.

a) Do not make diagnostic decisions solely based on the information displayed by the system.

CAUTION

Risk of limited treatment options!

If defects are not detected, the surgical microscope system may not offer all functions during surgery.

a) Before each use, make sure that all electrical and mechanical connections are firmly seated and free of defects.

b) Regularly check the functionality and quality of the magnified vision.

c) Do not use the system in case of any obvious defects, error states or functional restrictions. Call the Haag-Streit Service.

CAUTION

Risk of possible malfunctions due to electromagnetic fields or interference!

✓ In case of malfunctions of the system, such as blackout of monitor displays or non-functional control elements:

a) Switch the ON/OFF switch off and back on after 2 seconds in order to restart the system.

2.2 Symbols and Warnings

	Follow the instructions Read the instructions for use before operating the device.
Nur für geschultes Personal ! For trained personal only Solo para personas autorizadas ! Uniquement pour du personnel entrîné !	**Qualified personnel** The device may only be operated by trained qualified personnel.
	Pull the power plug Pull the power plug to make sure that the device is currentless. Do this before removing components which are marked with this symbol.

	Disposal
	Observe the disposal information in the instructions for use.

2.2.1 Symbols for connections HS MIOS 5

	Connect a potential equalization conductor as per IEC 60601-1.
in	Connect the mains connection line here. Observe the additional specifications on maximum electrical input power.
out	Connect auxiliary devices here. Observe the additional specifications on maximum electrical input power.

3 Legal Information

The part of the surgical microscope system described in these instructions for use supplements the intended use of the surgical microscope system.

3.1 Intended Use

The Microscope Imaging Operational System (MIOS) is part of a surgical microscope system and is intended for image and video documentation.

The MIOS can be connected to the surgical microscope system with the appropriate attachments.

3.1.1 User Profile

The surgical microscope system is intended to be used only by professionally qualified adult users. The users of the surgical microscope system display the whole variability of anthropometrics, physical strength and biomechanics given worldwide in adult populations. The users might be familiar with different systems of measurement (metric or else). Colours and symbols may be interpreted in differing manner, based on cultural particularities. The users are mentally and physically fit to perform the job.

Only trained personnel familiar with the functions and the controls of this surgical microscope system are permitted to operate and handle the device.

– The user shall be a physician.
– The user shall be medical staff.
– The user shall be a technician.
– The user shall be cleaning personnel.

3.1.2 Relevant User Groups

Physician:

– uses the system during a medical procedure or surgery.

Medical Staff:

– responsible for final set up and post-processing of the system in the operating room.
– preparation of the system for the procedure.
– monitoring of the system during the procedure.

Technician:

– is responsible for the initial safety check up after assembly and maintenance of the system.
– is responsible for service cases.
– provides connection to the hospital's network for the information system (HS MIOS only).

Cleaning Personnel:

– performs cleaning and disinfection of the medical device.
– performs sterilization of approved and dedicated components.

3.1.3 Relevant User Characteristics

Physician:

– completed medical studies.
– has expert knowledge of relevant applications and surgical procedures.
– has knowledge about workflows in the operating room.

– is instructed on the use of the surgical microscope system.

– understands the language of the instructions for use.

Medical Staff:

– completed nursing degree.

– has knowledge about workflows in the operating room.

– has knowledge about workflows of relevant applications and surgeries.

– is instructed on the use of the surgical microscope system.

– understands the language of the instructions for use.

Technician:

– completed technical training.

– completed service training for surgical microscope systems.

– understands the language of the instructions for use, the service manual and installation manual.

Cleaning Personnel:

– instructed on procedures for cleaning and disinfection of the medical devices

– instructed on procedures for sterilization of the dedicated and approved components

– basic knowledge about language and warning labels

– no special skills needed

3.1.4 Conditions of Use

The surgical microscope system is intended:

– for use in hospitals, clinics and physician practices.

– for use within a patient environment.

The surgical microscope system is intended to be installed and used under conditions appropriate to surgical procedures:

– Little vibration.

– Careful handling.

– Aseptic procedure room or operating room.

– Use with sterilizable operating elements; a sterile cover (drape) may be used in addition.

– Use with surgical gloves.

The usage of the surgical microscope system is not limited to certain countries. The distribution is restricted to the dedicated representatives as well as national sister companies which are managed within the Area Sales Management.

The surgical microscope system is designed for an average operating life of ten years. The duration of the usage is depending on the application and surgical procedure and can range from a few minutes to several hours. Therefore, also the amount of applications done with the surgical microscope system can range from one application to several cases per day.

3.2 Constraints

The monitors of the surgical microscope system are exclusively intended to display information, which is directly related to the application. Before use for diagnostic purposes of images or videos on the monitors, the user must subjectively check key parameters, such as color accuracy, gray-level scaling, image size and height to width ratio. The monitors are neither calibrated nor designed for diagnostic purposes. The surgical microscope system is not intended for operations on or near the eye when using a xenon light source.

For some applications the variable line of sight of certain surgical microscope systems is restricted caused by limited movability.
For some applications the variable focus range of certain surgical microscope systems is restricted.

3.3 Important Notes

Obligatory Reporting of Serious Incidents

Any serious incident occurring in relation to the product must be reported to Haag-Streit and the competent authority of the member state in which the user and/or the patient is established.

First Installation and Commissioning

The first installation and commissioning of the medical device must be done in accordance with the instructions in the service manual for the medical device. The first installation and commissioning of the medical device must be performed by the authorized local representative or by Haag-Streit directly.

An installation report, stating the full and error free functionality of the medical device, must be signed by both parties after the medical device has been installed and is commissioned.

Liability for Function and Damage

If the device is modified, repaired or serviced improperly, the warranty of Haag-Streit is void. Only personnel authorized by Haag-Streit may modify, repair or service the device.

Liability for Precaution

The user shall always take precaution appropriate to the application to be able to end the surgical procedure without the surgical microscope system.

Accessories

External accessories from 3rd party manufacturers must only be connected to the system after authorization by Haag-Streit. The interfaces and the combination of systems have to be validated.

Maintenance

The device must only be serviced or repaired following the service manual of the surgical microscope system.

Modifications and maintenance must only be performed by persons explicitly authorized by Haag-Streit. For maintenance only original parts from Haag-Streit as well as approved parts from third-party suppliers have to be installed. After maintenance or technical modifications, the device must be readjusted following the service manual of the surgical microscope system.

In case of technical inquiries, the device name, the reference number (*REF*), and the serial number (*SN*) need to be indicated.

For installation, dismantling and replacement of components, the actual national laws and directions regarding medical products (e.g. traceability, approval of added components, electrical safety) have to be followed. In case of doubt, please contact Haag-Streit.

4 HS MIOS 5

> **NOTICE**
>
> **These instructions for use do apply to the HS MIOS 5 SN ≥ 1000 consisting of the medical-graded PC M.COM 2.5, the C.MON HD display and the software ≥ V2.0.0.**
>
> **As the HS MIOS 5 has been updated, it may occur that illustrations do not correspond to the previous versions.**
>
> **However, the warnings and instructions are still to be followed regardless of the version of the HS MIOS 5 because they are still valid.**

4.1 Combination possibilities

Carrier unit	Component	HS MIOS 5 version
FS 2-25	Adaption FS 2-25	REF 4200044
	M.AED	REF 4000041
	M.DICOM	REF 4000042
	M.WIFI	REF 4000043
	M.AUDIO	REF 4000040

Due to the number of possible combinations there may be deviations from the stated data. For information regarding the compatibility of your surgical microscope system, please contact your local sales representative.

4.2 Installation transport and storage

> **NOTICE**
>
> **Request and check an approval from the service technician to ensure that the test after installation or service maintenance was passed.**

> **NOTICE**
>
> **Possibility of interference caused by electromagnetic incompatibility.**
>
> ✓ Medical electrical equipment needs special precautions regarding its electromagnetic compatibility.
> a) Observe the instructions on the electromagnetic compatibility of the device (see appendix).
> b) The installation is performed by a service engineer from your local sales representative.
> c) Follow the instructions regarding transport and storage of your device.

4.3 Overview of the connection panels and other connections

1	Front panel with ON/OFF switch and state indicator LED
2	USB 3.0 connection for storage media
3	DVD / CD burner
4	Connection panel 1
5	Memory card slots for the operating system
6	Connection panel 2
7	Slots for hard disks
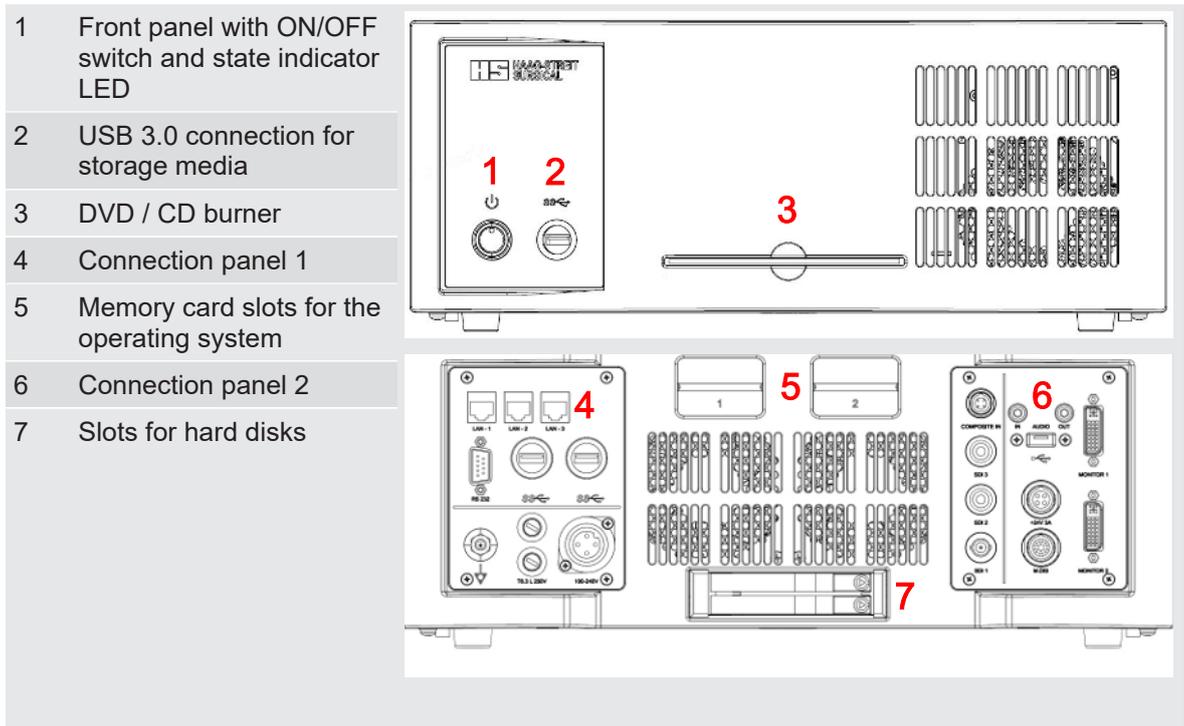
NOTICE

Switch off on unwanted function:

a) When the ON/OFF key is pressed for longer than 3 seconds, then the HS MIOS 5 switches off.

b) All other components of the surgical microscope system will not be switched off.

Connection panel 1

1	LAN-1 for connection to the local area network (e.g. for DICOM communication)
2	LAN connection 2 (Connection to iOCT, GENICAM interface)
3	LAN connection 3 (Connection to ceiling unit CU 3-5x only, for remote control of M.COM)
4	USB 3.0 Connection for a Basler NIR camera for ICG (optional)
5	Mains connection
6	Main fuses
7	Connection possibility of potential equalization line
8	RS 232 connection (Connection to floor stand/ceiling unit)
9	USB 3.0 connection for service purposes
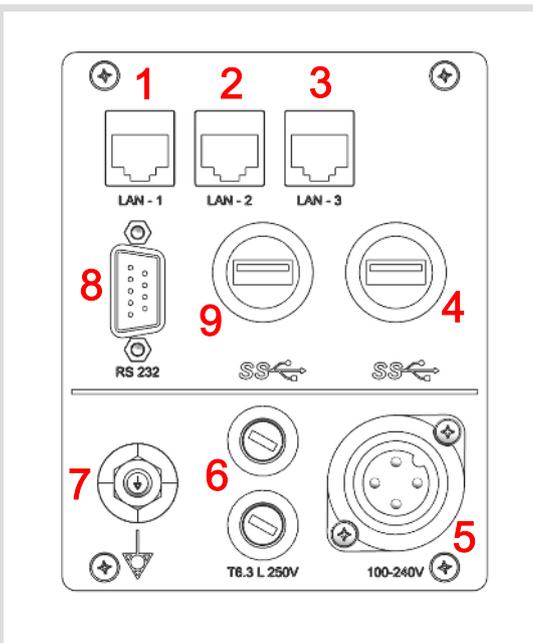
Connection panel 2

10	Composite in Connection for a Sony NIR camera for ICG (optional)
11	Audio input
12	Audio output*
13	DVI-D connection*
14	DVI-D connection to connect to a C.INJECT
15	Connection for a M.DIS
16	SDI 1 HD SDI input to connect a HD video camera
17	SDI 2 HD SDI output of the SDI 1 signal to an optional HD SDI monitor
18	SDI 3 HD SDI input for connecting a second HD video source for the additional module M.REC 2
19	USB 2.0 connection* (Touch function)
20	Power supply 24V/3A*
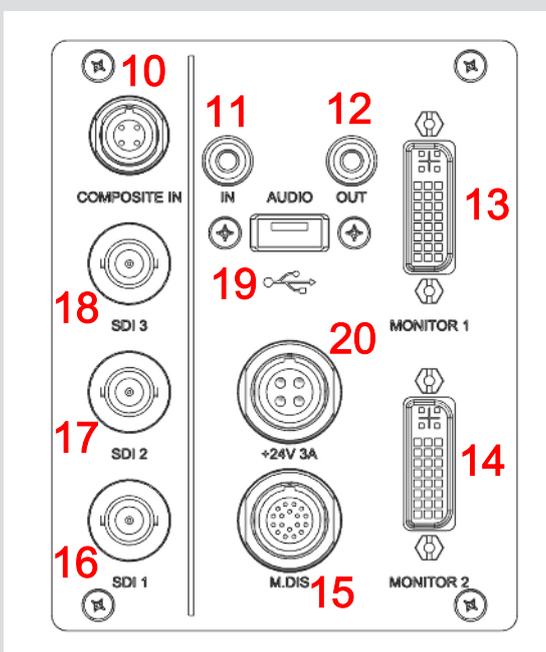
*Connections for C.MON HD monitor

4.4 Operation

4.4.1 Before each operation

Ensure that:

1. the HS MIOS 5 is in operation.
2. the screen does not show an error report.
3. the date displayed on screen is correct.
4. the appropriate patient file is selected.
5. the image of a connected video camera is displayed correct.
6. the HS MIOS 5 touch screen reacts to contact through a sterile drape.
7. all air vent slits of the surgical microscope system are free and the airflow is not blocked by drapes or similar.
8. the surgical microscope system is positioned so that exhaust air flows away from the field of surgery.

4.4.2 Functional test before each operation

Component	Test	Result
Surgical microscope system	Switch on the surgical microscope system. Check that all air vent slits are free and the airflow is not blocked by drapes, for example. Check also that exhaust air from fans do not flow into the operation field.	The surgical microscope system boots and air vent slits are free. Standard times for booting and shutdown are: Boot time: 90 seconds Shutdown time: 11 seconds If not, follow the instructions in chapter "Troubleshooting [▶ 43]" of the respective surgical microscope system.
HS MIOS 5	Check if the HS MIOS 5 Software is booted and displayed on the screen. Check also that the correct patient files are selected. and the date displayed shall be correct.	The HS MIOS 5 is operable, i.e. it can be operated via touch and the camera image is displayed. If not, follow the instructions in chapter "Troubleshooting [▶ 43]".
C.MON HD	Check that the display shows the HS MIOS 5 user interface and is correct in color. It reacts to contact through a sterile drape.	The display functions without problems and shows images properly. If not, follow the instructions in chapter "Troubleshooting [▶ 43]".
C.MOR HD/HD[3]	Check that the camera images correspond to the images in the ocular and on the monitor Check also that the image erection is correct and not inverted.	The camera(s) function without problems and shows video images. If not, follow the instructions in chapter "Troubleshooting [▶ 43]".

Component	Test	Result
Surgical microscope system	Shut down the HS MIOS 5 Software and switch off the M.COM 2.5. Then switch off the surgical microscope system.	The M.COM / HS MIOS 5 shut down without problems. If not, follow the instructions in chapter "Troubleshooting [▶ 43]".

4.4.3 Workflow

The HS MIOS 5 supports the hospital internal workflow by following a three-step process:

– Open the Patient menu to select or create a patient.

    – Personal and hospital related patient data such as name, age, diagnosis and patient number can be entered. New image and video material is automatically assigned to the selected patient. Optionally, patient data can be retrieved from existing data within the hospital network in accordance with the DICOM standard.

– Menu Recording - image and video material are recorded

    – Operations are documented.

– Menu Archive - views of image and video data are archived

    – Captured image and video files can be viewed and posted for archiving to external media. Optionally, the data can be transmitted according to the DICOM standard to the hospital network.

4.4.4 Important information for handling patient records

⚠ **CAUTION**

Risk that the patient may be in danger due to incorrect assignment of patient records!

✓ The HS MIOS 5 connects recorded data such as images and videos with patient records.

a) In order to guarantee the proper assignment of data to a patient, it is not possible to change patient data after exiting the recording menu.

b) Furthermore, it is not possible to change from the menu `Archive` to the menu `Record`.

In order to accomplish a faultless patient allocation, please follow the instructions:

1. Check that all patient data were entered correctly before leaving the menu `Patient`. Amendments are not possible afterwards.

2. Select the correct patient record before beginning the surgery and before you start the recording menu.

When changing from the menu `Record` to the menu `Archive`, the system asks whether the recorded material should be assigned to a patient or not.
Subsequent allocation is not possible.

4.4.5 Important Buttons

Exit program

Shut down the HS MIOS 5.
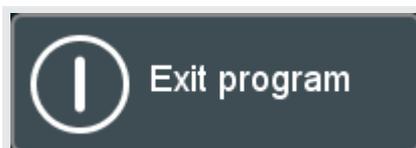
Icon	Description
Exit program	End the session and return to the login page.
Settings	Go to Settings to change system and user settings.
(Patient icon)	Enter Menu Patient to select or create a patient.
(Recording icon)	Enter Menu Recording for live view from connected camera with the option to select recorded images and videos for replay.
(Archive icon)	Enter Menu Archive to view patient data, images and video records with the option to save to external media.
◀	Return to previous menu.
💾	Save and activate the changes.
(Reset icon)	Reset all settings to their default values.
📂	Open a selected image or video in order to view it or open a selected record to display the content.
(Copy icon)	Copy the selected data to a selected location.
🗑	Delete selected data.
▶	Start playback of a video.
■	Stop replay or recording of a video.
● HD Rec	Start a recording.
📷	Save current camera view as an image.
(Full screen icon)	Activate full screen mode.
(Exit full screen icon)	Deactivate full screen mode.

4.4.6 Basic functions

Login

This is the HS MIOS 5 user view:
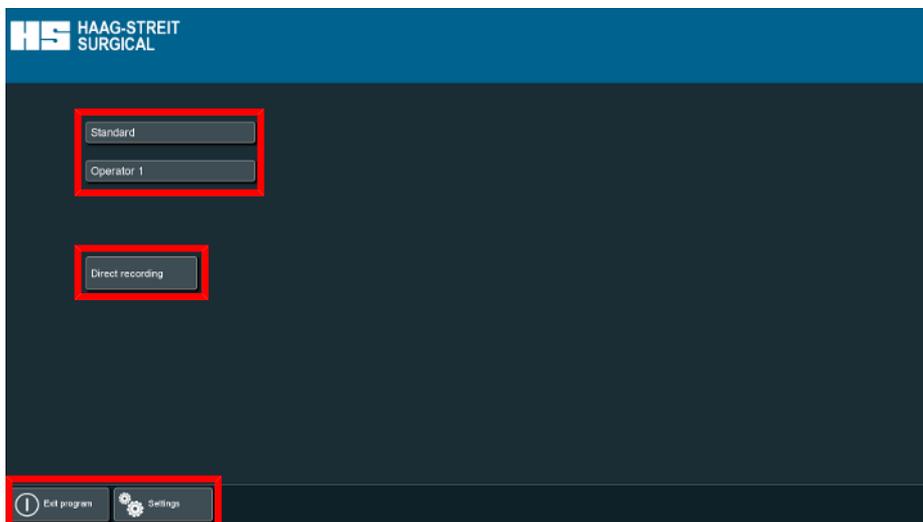
Illustration 2: HS MIOS 5 MIOS user view

1. Select a user to access the menu `Patient`:
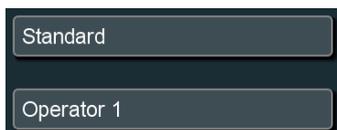
Illustration 3: HS MIOS 5 login user selection

Or go directly to the menu `Recording` without selecting a patient (activate the function in submenu `General` of menu `Settings`).

2. If a login with user name and password is activated, you will be asked to enter these with the onscreen keyboard.
3. Touch a text field to display a keyboard:

Illustration 4: HS MIOS 5 onscreen keyboard

4. Press the eject button, which is located on the onscreen keyboard, indicated to eject loaded CDs /DVDs:

Illustration 5: HS MIOS 5 eject button

Menu Patient

Access the menu `Patient` after you have logged in and selected a user.
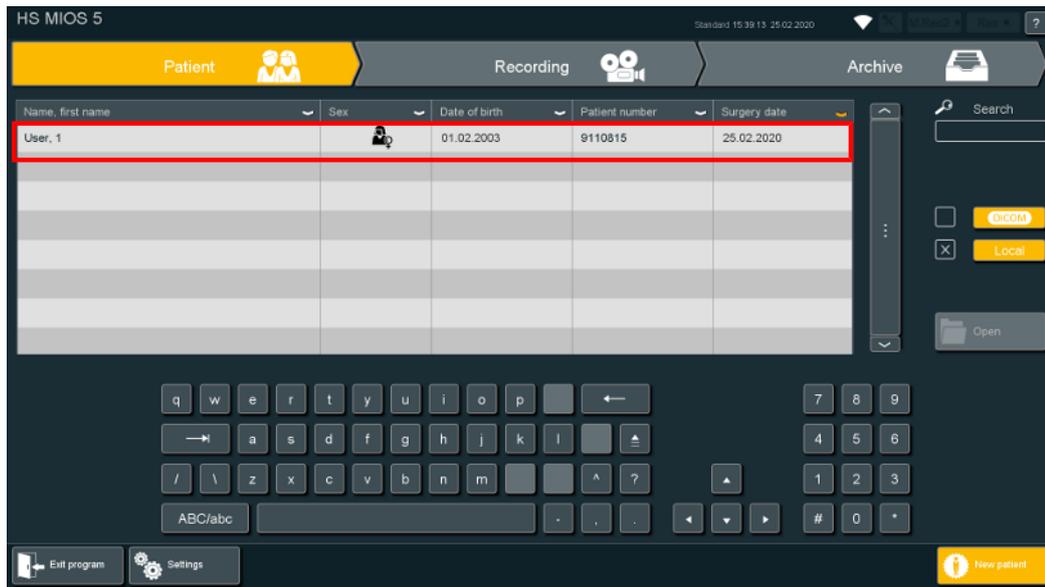
Illustration 6: HS MIOS 5 patient administration overview

Press the corresponding sections to adjust settings / access options:

 Return to the previous menu.

 Save and activate the changes made. After the patient data set is saved, this cannot be changed.

 Open a selected image / video in order to view it or open a selected record to display the content.

 Play the selected video.

Menu Patient

Display of existing patient records.

Select a patient to add more images and videos:
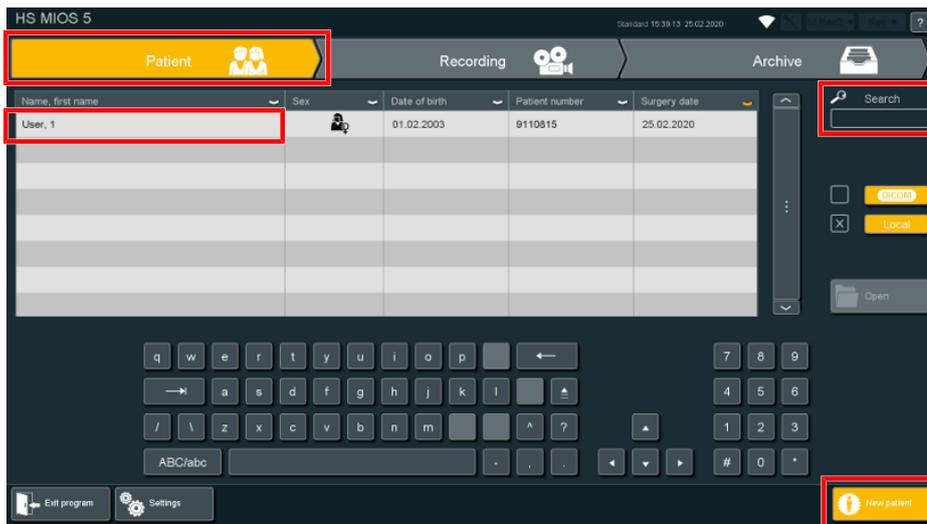
Illustration 7: HS MIOS 5 patient administration

Search

Search for a patient by entering the name or date of birth or patient number:
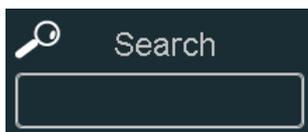
Illustration 8: HS MIOS 5 patient search window

Patient Detail View

Shows all details of a specific patient:
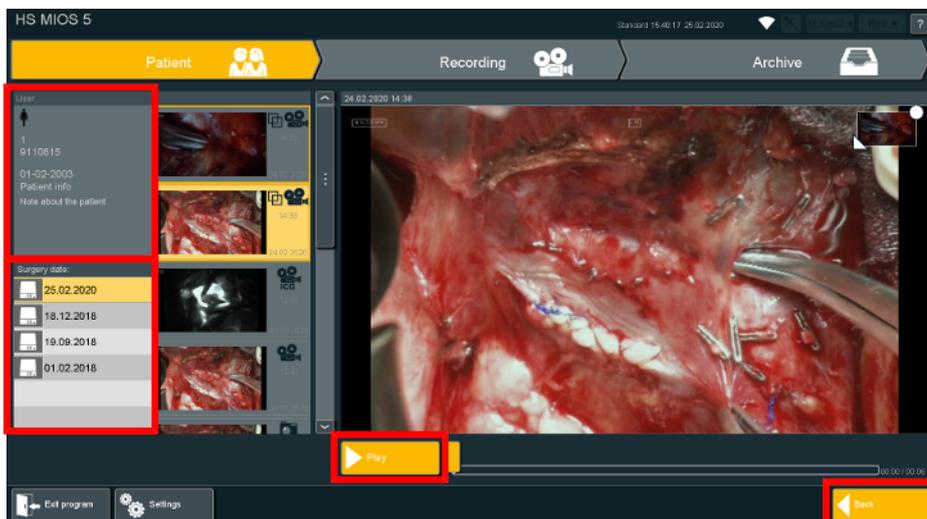
Illustration 9: HS MIOS 5 patient related video overview

User

Display of the patient's personal data:

Illustration 10: HS MIOS 5 detailed patient overview

Surgery date

List of the individual operation data with the respective images and videos:
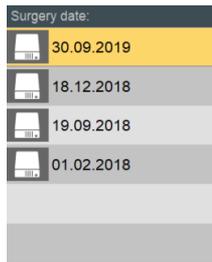
Illustration 11: HS MIOS 5 details surgery date

Select pictures/videos to display/play:
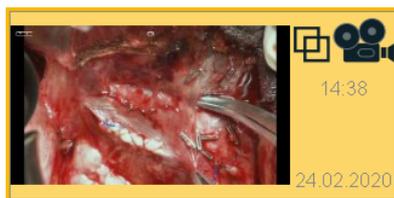
Illustration 12: HS MIOS 5 selected patient video

New patient

Create a data set for a new patient:
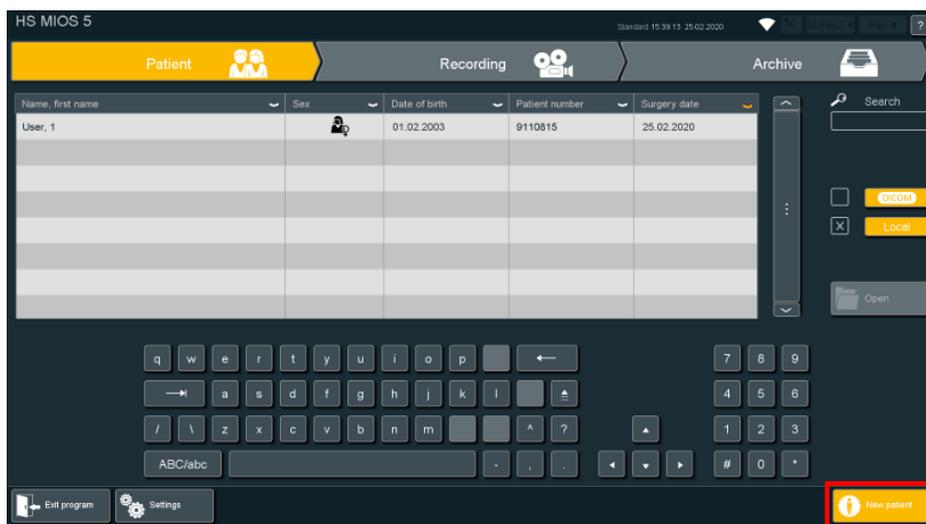
Illustration 13: HS MIOS patient administration new patient

Illustration 14: HS MIOS 5 new patient screen

	Go to the next entry field.
	Save and activate the changes made. After the patient data set is saved, this cannot be changed.
Name, first name*	Touch an entry field to activate it. The first letter of a name is automatically capitalized.
Date of birth*	Enter the date of birth for each patient.
Patient no.	Enter the patient number here.
Gender*	Activate the respective gender.
Notes	Enter any additional information related to the patient in this field. The note can be 70 characters long.

*Mandatory information

Menu Recording

Access the menu `Recording` after you have logged in and selected a user.

Or press `Direct Recording` on the HS MIOS 5 user view to get to this menu.

Press the corresponding sections to adjust settings / access options:
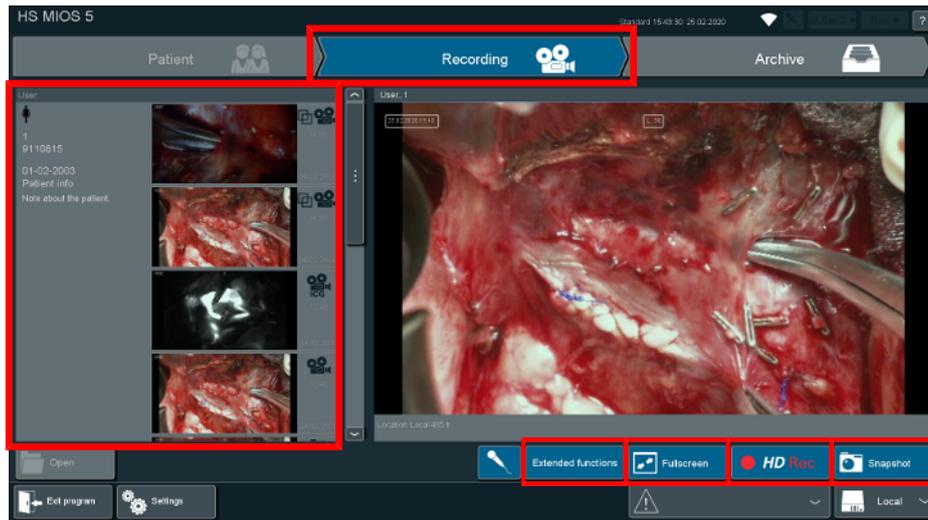
Illustration 15: HS MIOS 5 recording overview

Back	Return to the previous menu.
Open	Open a selected image / video in order to view it or open a selected record to display the content.
Play	Start the playback of the video.
Pause	Stop the playback / the recording of the video.
● **HD** Rec	Start a recording.
Snapshot	Save the current camera view as an image.
Fullscreen	Activate full screen mode.
Fullscreen	Deactivate full screen mode.
Extended functions	Start further functions such as M.REC2 or M.TORIC.

If a patient record is not selected from the menu `Patient` before recording, then the system uses a default patient for recoding. When the recording is left to the archive the system asks the user if he likes to allocate or create a patient. Subsequent allocation is no longer possible.

User

Display of existing images and videos:

Illustration 16: HS MIOS 5 details patient information

Error and warning messages

Display of the surgical microscope systems' error and warning messages:

Illustration 17: Error and warning display

Recording media

Select the desired storage location where the recorded media will be saved:

Illustration 18: HS MIOS 5 storage selection

Recording

Indicator lights red while recording a video:

Illustration 19: HS MIOS 5 Recording indicator

Menu Archive

Access the menu `Archive` after you have logged in and selected a user.

Press the corresponding sections to adjust settings / access options:
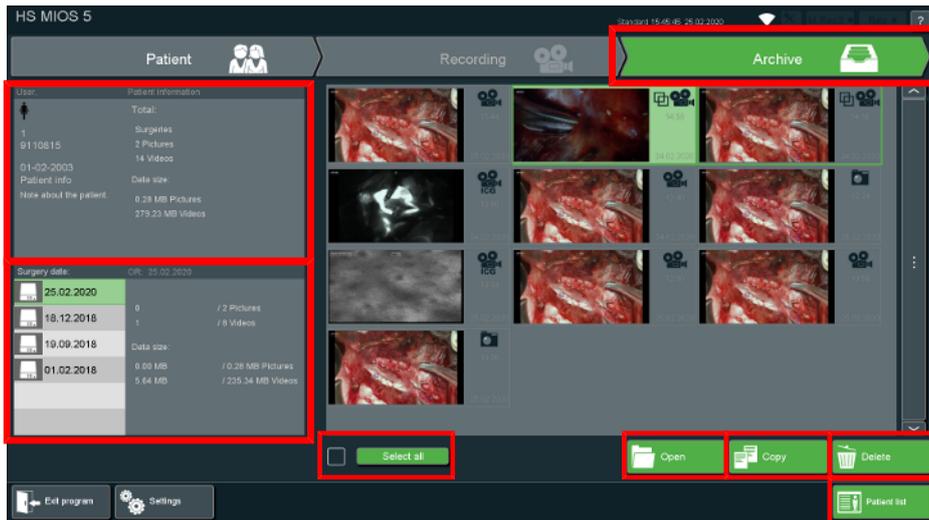
Illustration 20: HS MIOS 5 overview archive
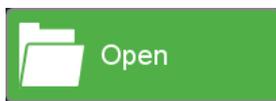
Open	Open a selected image / video in order to view it or open a selected record to display the content.
Copy	Copy the selected data to a selected location.
Delete	Delete selected files.
Play	Start the playback of the video.
Pause	Stop the playback / the recording of the video.
Snapshot	Save the current camera view as an image.
Fullscreen	Activate full screen mode.
Fullscreen	Deactivate full screen mode.
Select all	Selects all files in the current view.

Patient information

Overview of the amount of existing images and videos/amount of data:

Illustration 21: HS MIOS 5 archive patient information

Surgery date

List of the individual data with the respective images and videos:

Illustration 22: HS MIOS 5 archive surgery dates list

Select patients

Open the list of available patients:

This opens the patient list table:

Illustration 23: HS MIOS 5 patient list table

If you have selected the option `Select all` in the archive overview, you select all patient data sets of this table.

Search

Search for a patient by entering the name or date of birth:
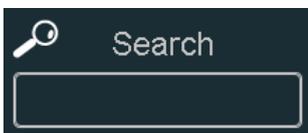
Illustration 24: HS MIOS 5 archive screen search

Display of existing patient records

Select one patient record or more patient records to open, copy, or delete it or them:

Illustration 25: HS MIOS 5 patient list table

Media

Select the desired storage location where the recorded media will be exported / archived:

Illustration 26: HS MIOS 5 selection copy to

4.4.7 Settings

Access the menu `Settings` by pressing the button `Settings` on the HS MIOS 5 user view:
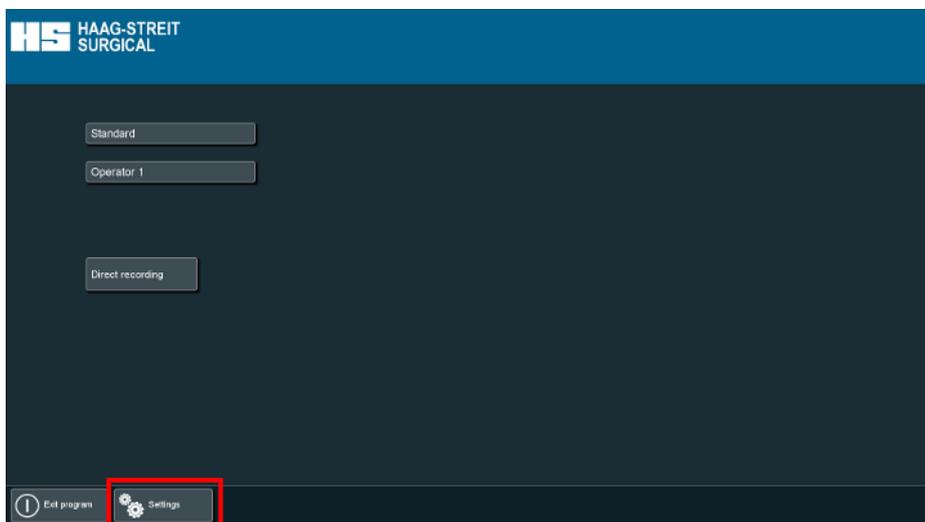
Illustration 27: HS MIOS 5 user view button settings

Or in these menus (`Patient`, `Recording`, `Archive`):
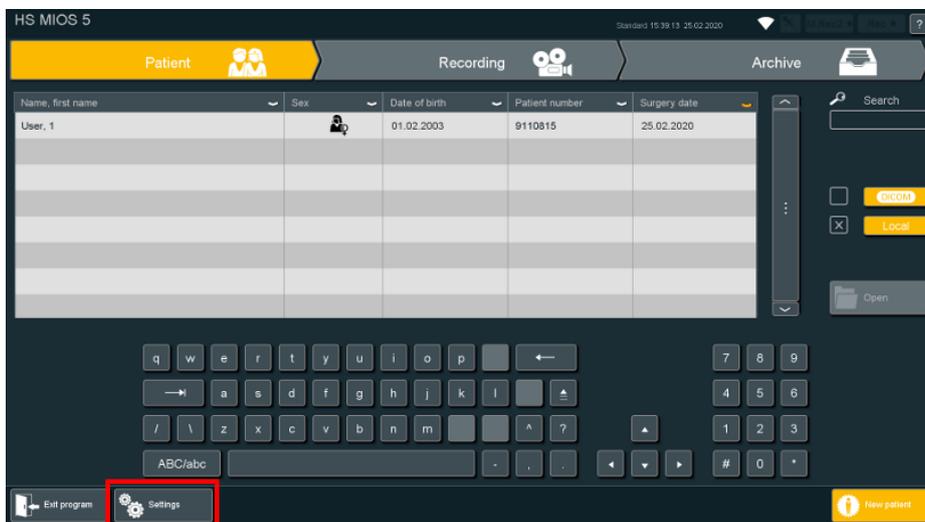
Illustration 28: HS MIOS 5 patient screen button settings

Press the corresponding sections to adjust settings / access options:

General

In this menu, select / activate basic settings related to the HS MIOS 5 system:
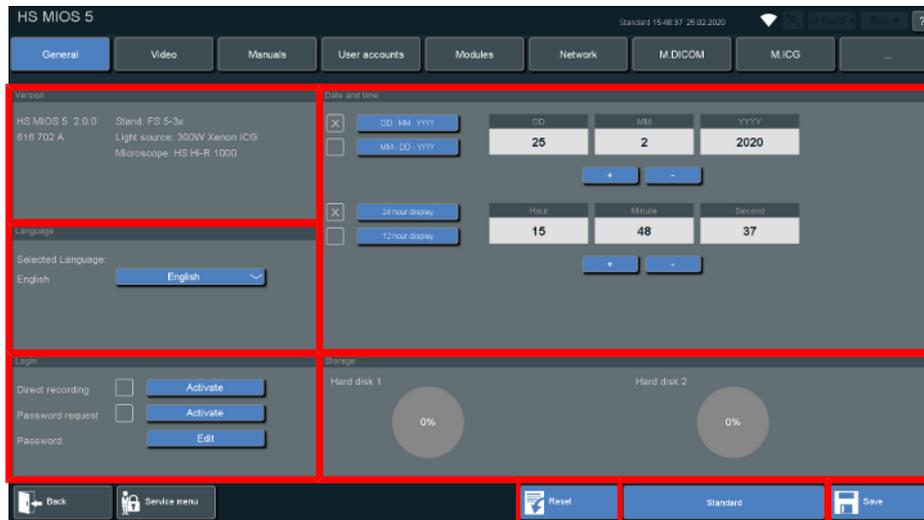
Illustration 29: HS MIOS 5 menu settings overview

Version	Information about the surgical microscope system.
Language	Select the desired language.
Login:	
Direct recording	Deactivate/Activate the direct recording function.
Password Request	Deactivate/Activate the password on login.
Password	Change the password. The password is the same for all users.
Date and Time	Select the desired date and time.
Storage	Displays the current capacities of the two hard disk drives.
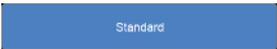
Standard	Select an existing user account in order to load user-specific settings.
Back	Return to the previous menu.
Save	Save and activate the changes made.
Reset	Reset the displayed settings to their default values.
Delete	Delete selected files.
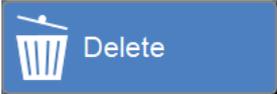
Video

In this menu, select / activate settings related to images and video recording:
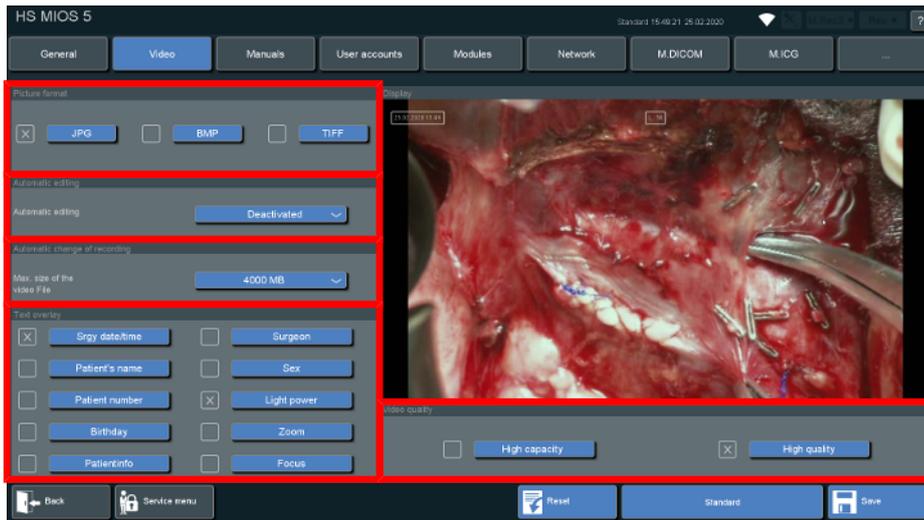
Illustration 30: HS MIOS 5 menu settings video screen

Picture format	Select the desired picture format.
Automatic editing	If a snapshot is taken during live-view. a video sequence will be saved, too. Select the duration of the videos before and after the snapshots.
	This function is available only when the module M.AED has been activated.
Automatic change of recording	Select the maximum size of the video file. If this amount of data is exceeded, a new file is created automatically. The recording is not interrupted.
Text overlay	Choose the information to be laid over pictures and videos.
Video quality	Select the required compression rate/bit rate of the video recording:

- – High capacity: an average of 4 Mbit/s
- – High quality: an average of 8 Mbit/s

Manuals

In this menu, select the instructions for use of your surgical microscope system that you want to read:
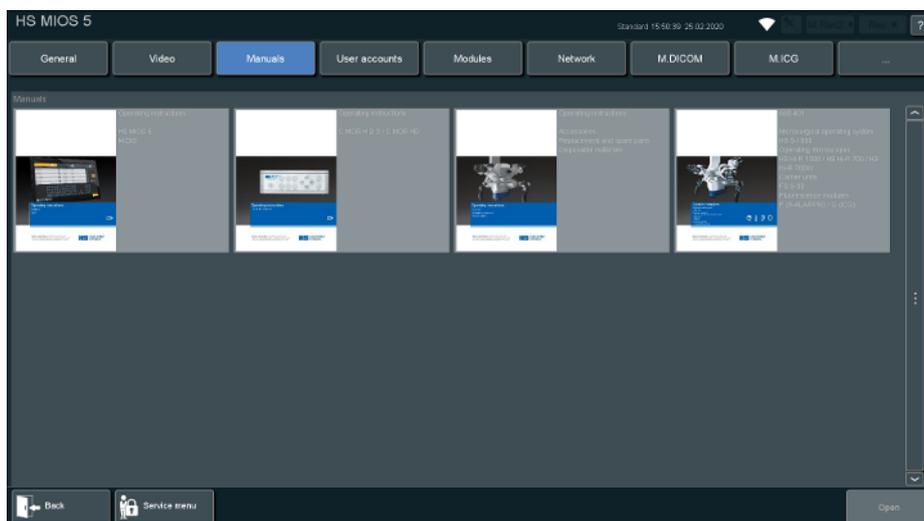
Illustration 31: HS MIOS 5 menu settings manuals

User accounts

In this menu, create new users or delete existing users:
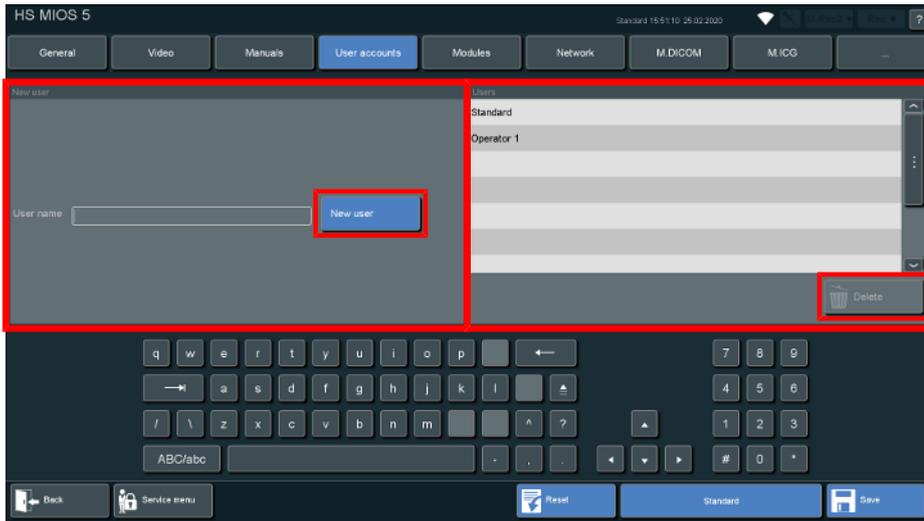
Illustration 32: HS MIOS 5 menu settings user accounts
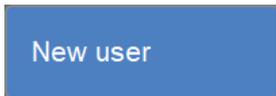
Create a new user account.
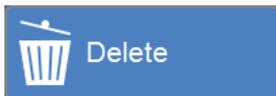
Delete existing user accounts.

Modules

In this menu, the available software upgrades are displayed:
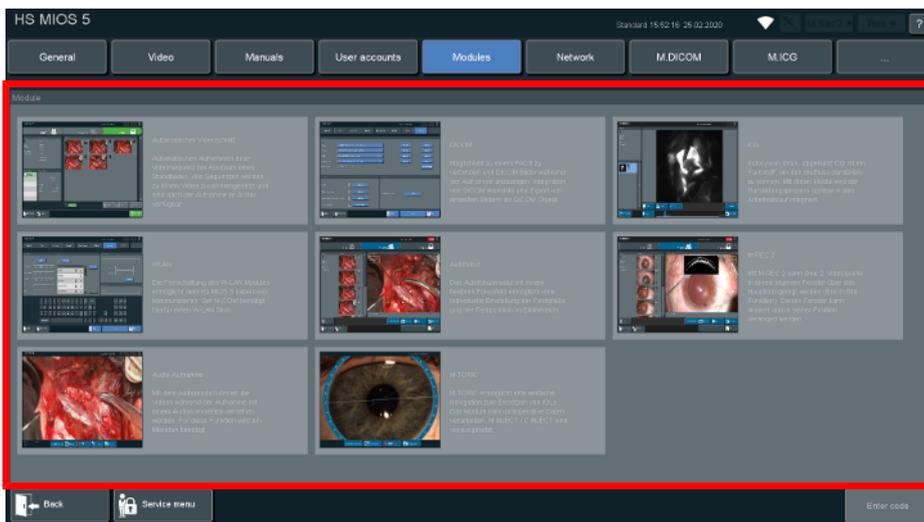
Illustration 33: HS MIOS 5 menu settings modules

– Activate additional modules by entering the key code. It can be obtained from your local sales representative. Please see section Upgrades - activation of additional modules [▷ 31] on how to activate additional modules.

Network

⚠️

CAUTION

Risk of uncontrolled system behaviour due to IT networks!

Application of IEC 80001 required.

In this menu, connect the HS MIOS 5 with a network either via LAN oder WIFI, if M.WIFI is activated:
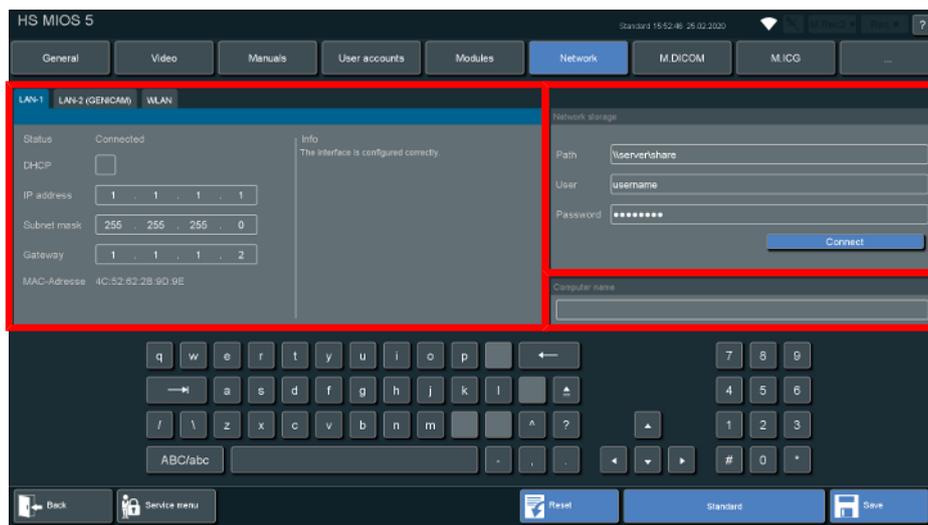
Illustration 34: HS MIOS 5 menu settings network

LAN-1	Configure the LAN interface to connect the HS MIOS 5 system to your secured network. User name and password are mandatory for this connection.
	Set the IP address and gateway for the HS MIOS 5.
WLAN	Select and configure the WLAN to connect the HS MIOS 5 to your system. This function is available only when the M.WIFI module has been activated. See additional module WI-FI".
Network storage	Configure a desired network drive.
Computer name	Enter a computer name for the HS MIOS 5.

Upgrades - activation of additional modules

⚠️

NOTICE

Please note that all additional modules described in the following sections need to be purchased from Haag-Streit before installation.

1. Start up the HS MIOS 5 Software.
2. Enter menu `Settings`.
3. To activate a module, press `Modules`, then select the desired module and press `Enter Code`:
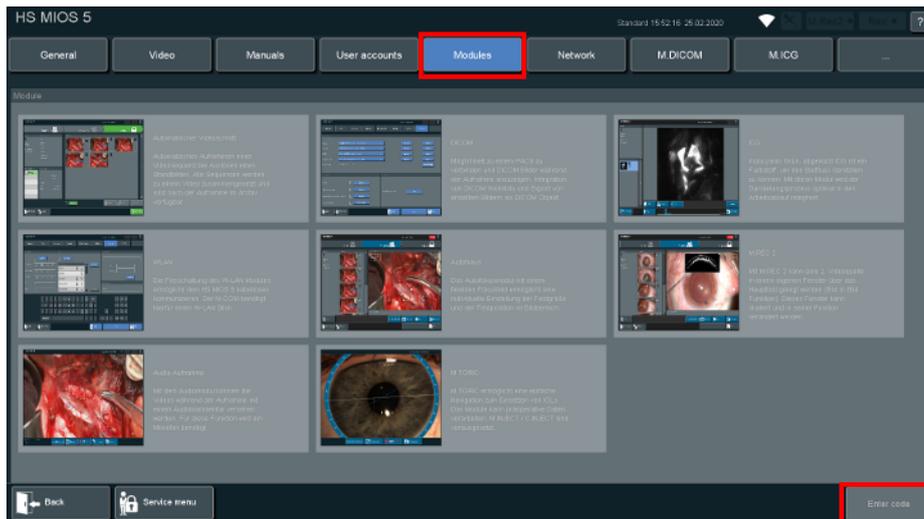
Illustration 35: HS MIOS 5 settings modules overview

4. The menu `Module Activation` displays an ID serial and installation code and a module code is requested:
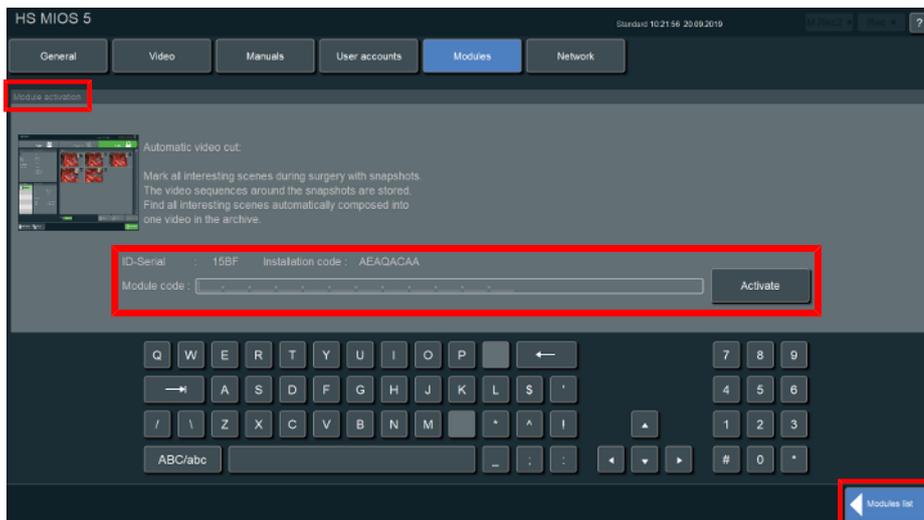
Illustration 36: HS MIOS 5 modules activation

5. Press `Modules list` to go back to the overview of the available modules in case you want to activate a different module.

6. Contact Haag-Streit Service and forward the following information:

   – Which module is to be activated

   – ID serial

   – Installation code

Haag-Streit Service then provides a registration code.

7. Type in the registration code in the area `Module Code` and press `Activate`.

   ⇨ The module is now activated and the view changes to the screen `Settings` of the module.

The following modules are available for purchase:

M.AED

M.WIFI

M.DICOM

M.AUDIO

For module M.AUDIO, an external microphone needs to be connected for the audio recording.

4.4.8 Additional module M.AED

General

The additional module M.AED creates a video once a snapshot is taken. A video sequence is stored within a period of time which is marked by variable points in time before and after the snapshot. After leaving the menu `Record`, all saved video sequences are edited together into a single video.

Press the corresponding sections to adjust settings / access options:

Menu Settings
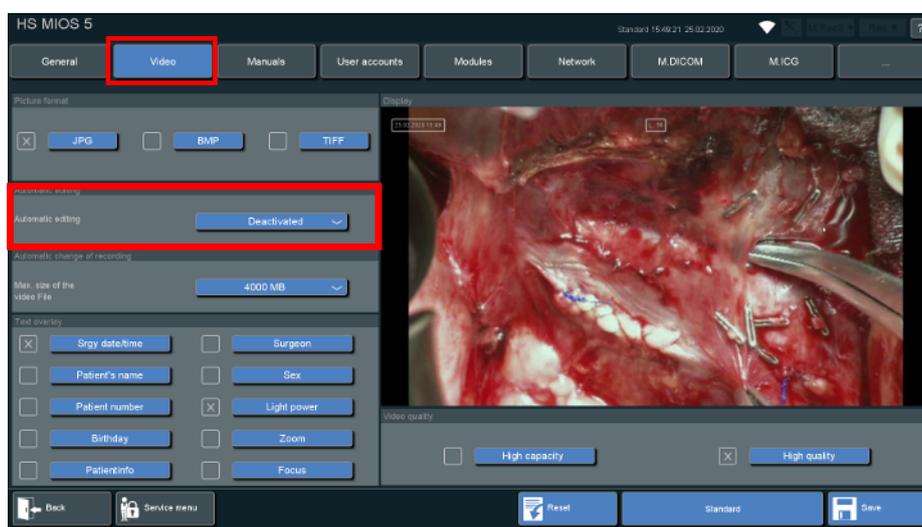
Illustration 37: HS MIOS 5 additional module M.AED

Automatic editing   Automatic editing: Set the desired duration or disable the function.
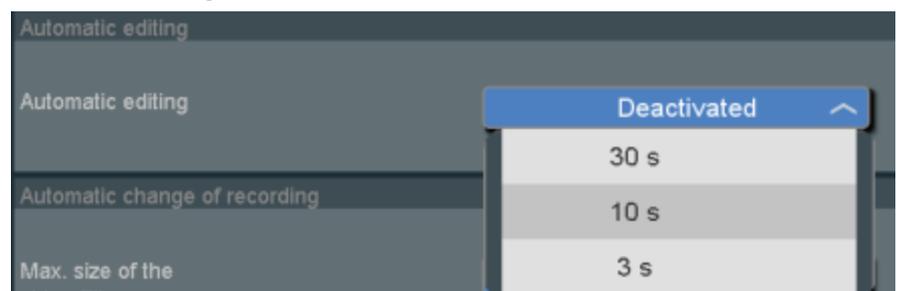
4.4.9 Additional module M.WIFI

General

The additional module M.WIFI allows the HS MIOS 5 to connect via a Wireless LAN to a computer network.

Press the corresponding sections to adjust settings / access options:

Menu Settings
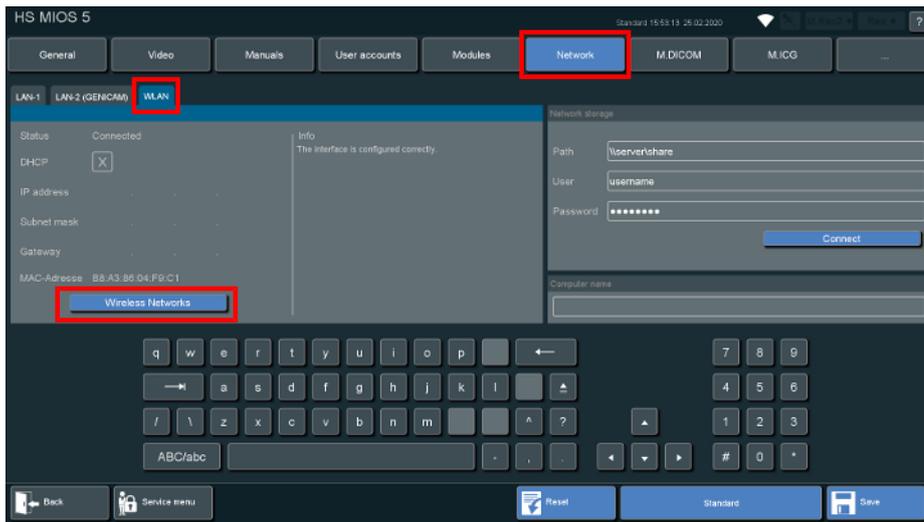
Illustration 38: HS MIOS 5 additional module M.WIFI

Menu Wireless Networks

    Enable/Access the wireless network function.

The following screen is displayed:
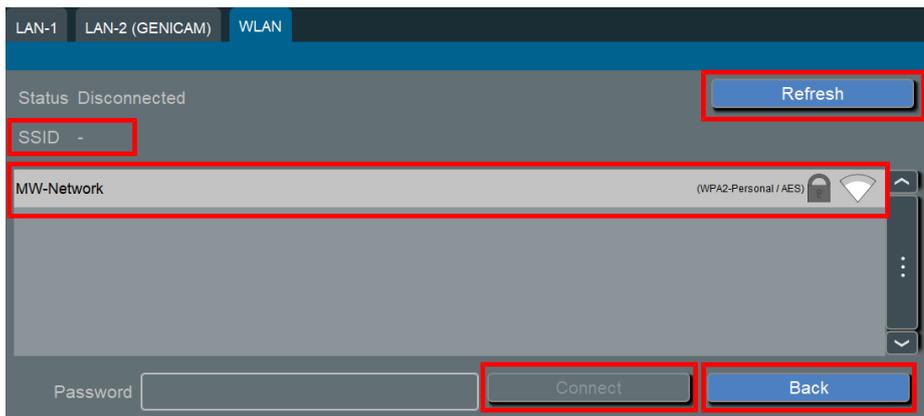
Illustration 39: HS MIOS 5 M.WIFI WLAN disconnected

SSID	Name of the connected network
Refresh	Refreshes the list of available networks.
Password	Password required to access the desired network.
Connect	Connects to the desired network.
Back	Use to go back to the WLAN tab.

How to connect to a network:

1. Select the desired network.
2. Enter the password.
3. Press `Connect`.

The following screen is displayed:
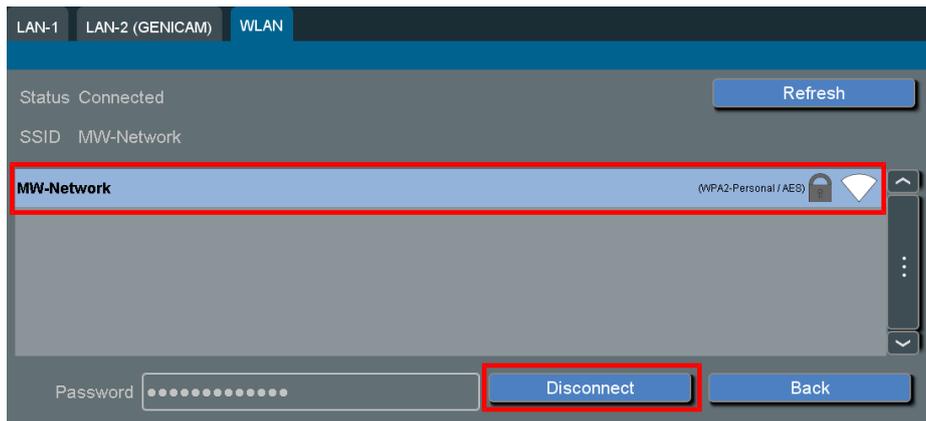
Illustration 40: HS MIOS 5 M.WIFI WLAN connected

| SSD | The connected WLAN is highlighted in blue. |
| Disconnect | Disconnects the network. |

4.4.10 Additional module M.DICOM

General

The additional module M.DICOM provides an interface to the hospital network. Data can be synchronized between the hospital network and the HS MIOS 5 via DICOM standard.

⚠ **CAUTION**

Risk of uncontrolled system behaviour due to IT networks!

Application of IEC 80001 required.

⚠ **NOTICE**

To be able to use the DICOM functionality with the HS MIOS 5 you have to configure the *AE name and AE port in the settings among other things.

*Application Entity

Press the corresponding sections to adjust settings / access options:

Menu Patient
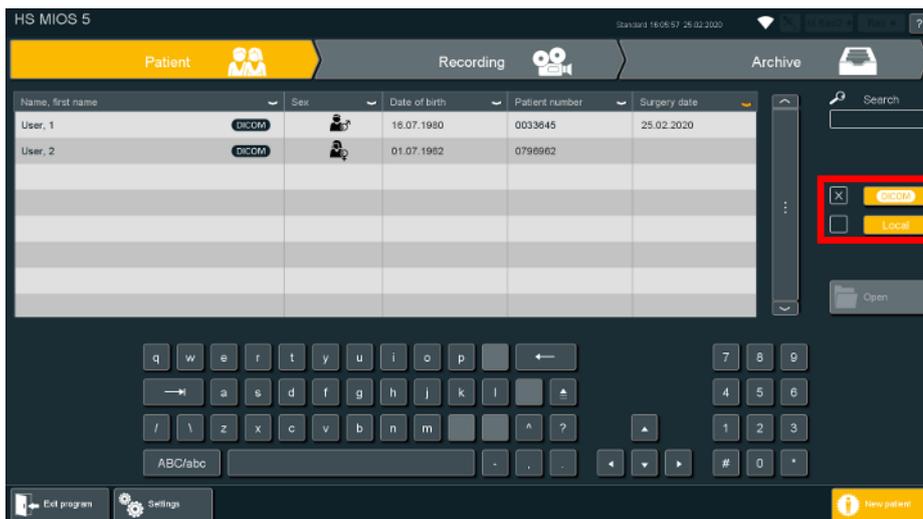
Illustration 41: HS MIOS 5 menu patient for M.DICOM

Patient records may be downloaded locally or via the DICOM interface. Therefore use the button

to download all DICOM patients from the connected Worklist server. The data sets from the DICOM worklist are marked with

in the list view. The configuration of the different DICOM Servers is described in menu `Settings` -> `DICOM server configuration` in the following section.

Local patients, which are stored on the HS MIOS 5 without DICOM context, can be deactivated with the button

for a more focused overview. DICOM Patients can be pre-filtered which is explained in detail in menu `Settings` -> `Worklist filter` in the following section.

Menu Archive
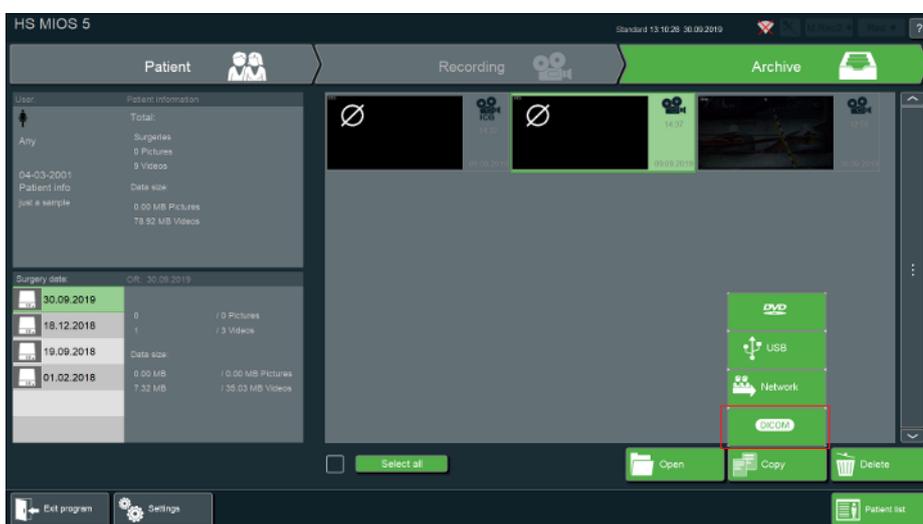
Copy data over the DICOM interface to the hospital network.

Menu Settings
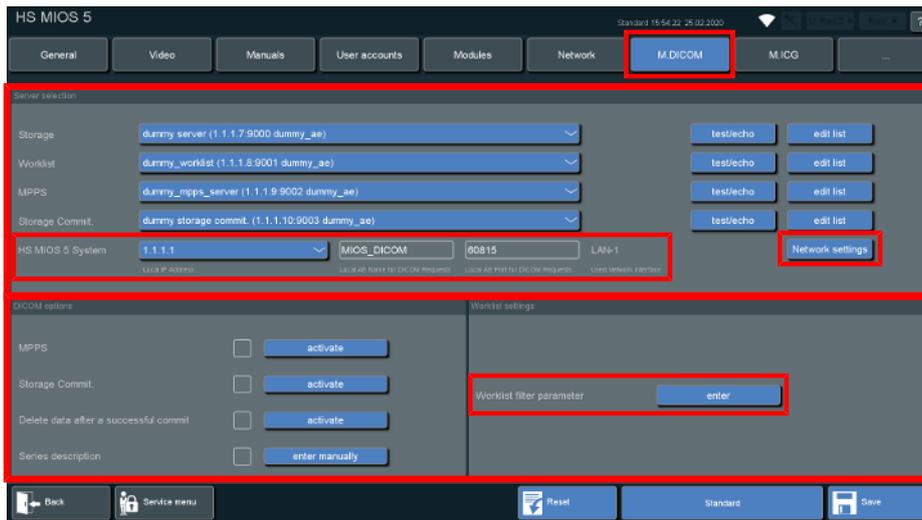
Server selection	Select one of the configured preset servers. (The server configuration is explained in the following section **DICOM server configuration.**
	test/echo — Test the connection to the appropriate server.
	edit list — Set the IP address, AE title and port for the required server for synchronizing data over DICOM standard. (The server configuration is explained in the following section **DICOM server configuration**.
DICOM options	Enable the desired DICOM services. Detailed information can be found in the **DICOM statement of HS MIOS 5 (REF 4200049)**.
HS MIOS 5 System	**Local IP address** (drop-down menu)

Displays the IP address of the selected network interface, LAN-1 or WLAN (which is an optional purchase module described in chapter M.WIFI). You can change the interface you want to use via the drop-down menu. Configure the network interfaces on the tab `Network`.

Local AE name for DICOM Requests (textbox)

The local Application Entity name for identification of the HS MIOS 5. Also used to expect/receive queries / replies.

Local AE port for DICOM Requests (textbox)

The local Application Entity port on which the HS MIOS 5 DICOM expects/receives queries / replies.

⚠️ **NOTICE**

Ports in the range between 0 and 65535 are allowed. However, we recommend to use the port in the range between 1024 and 49151 and to coordinate this with the administrator of the network.

⚠️ **NOTICE**

The following ports are used by the HS MIOS 5 and cannot be used for the DICOM: 8080.

Used Network Interface *(text)*

The selected network interface (either LAN-1 or WLAN) which is used for the DICOM communication.

Network settings *(button)*

Change to the view `Network`.

Menu DICOM server configuration

For each of the available servers (Storage, Worklist, MPPS and Storage Commitment) it is possible to store up to 10 different servers.

Illustration 42: HS MIOS 5 M.DICOM server configuration

Connection name	A meaningful name that describes the DICOM server.
IP address	The IP address of the DICOM server.
AE	The AE Name of the DICOM server.
Port	The remote Port of the DICOM server.
echo	Test the connection to the appropriate server.
clear	Clears the configuration in the line to remove a server.

Available storage servers:

Illustration 43: HS MIOS 5 M.DICOM available storage servers

Available worklist servers:

Illustration 44: HS MIOS 5 M.DICOM available worklist servers

Available MPPS servers:

Illustration 45: HS MIOS 5 M.DICOM available MPPS servers

Available storage commitment servers:

Illustration 46: HS MIOS 5 M.DICOM available storage commitment servers

Menu Worklist filter parameter

Illustration 47: HS MIOS 5 M.DICOM worklist filter parameter

Filter options	Pre-filter the worklist entity's on the server side by patient name, patient ID, modality and / or AE title to reduce the amount of patient datasets which will be retrieved from the HS MIOS 5.
Date filter	Pre-filter the worklist by date to reduce the amount of patient datasets which will be retrieved from the HS MIOS 5.

4.4.11 Additional module M.AUDIO

General

The additional module M.AUDIO allows recording of video with audio.

An external microphone needs to be connected for the audio recording.

Press the corresponding sections to adjust settings / access options:

Menu Recording
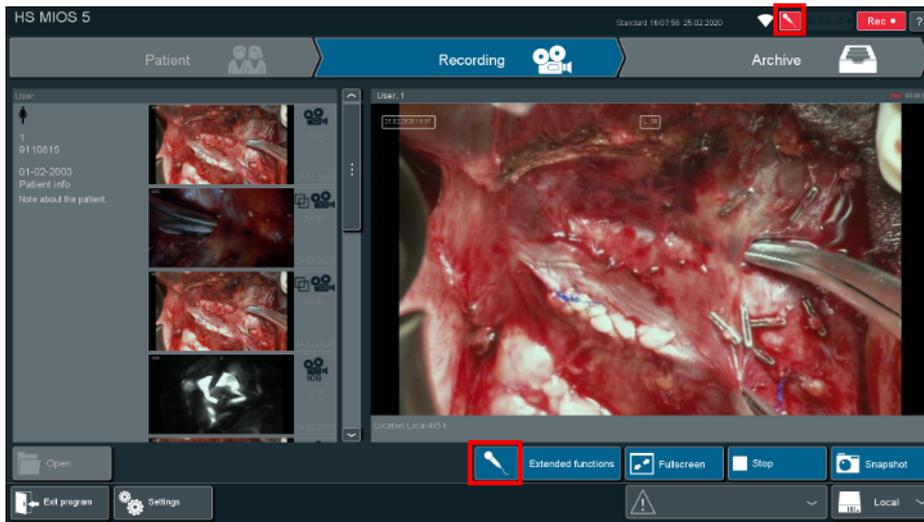
Illustration 48: HS MIOS 5 additional menu M.AUDIO

 The microphone is enabled.

Tap on the key to mute the microphone.

 The microphone is muted.

Tap on the key to enable the microphone.

 Audio recording is active.

Menu Settings
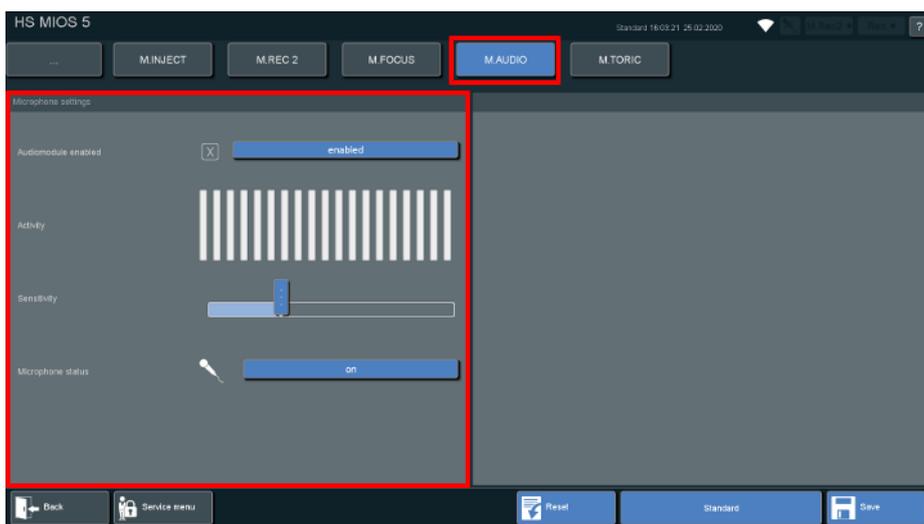
Illustration 49: HS MIOS 5 M.AUDIO settings

Audiomodule enabled/ disabled	Enable/disable M.AUDIO.
Activity	Visual display of the microphone input level.
Sensitivity	Adjust the sensitivity of the microphone.
Microphone status	Mute/unmute the microphone.

Microphone connection at M.COM 2.5
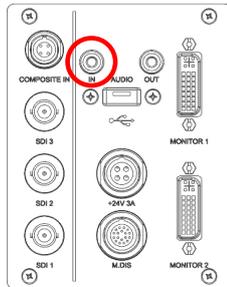
Connect the external microphone to the audio input (IN).

4.5 Service and Troubleshooting

4.5.1 Hard disk exchange

All patient-related data is found on the hard disk(s). You must remove all hard disks before you send the HS MIOS 5 to your local sales representative for servicing or other reasons.

> ⚠ **CAUTION**
>
> **Possibility of internal defects because of a hard disk change during operation!**
>
> Only exchange the hard disk(s) if the HS MIOS 5 is shut down.

1. Unlock the hard disk slot with the key provided. Alternatively, you can use a slotted screw-driver size 3:
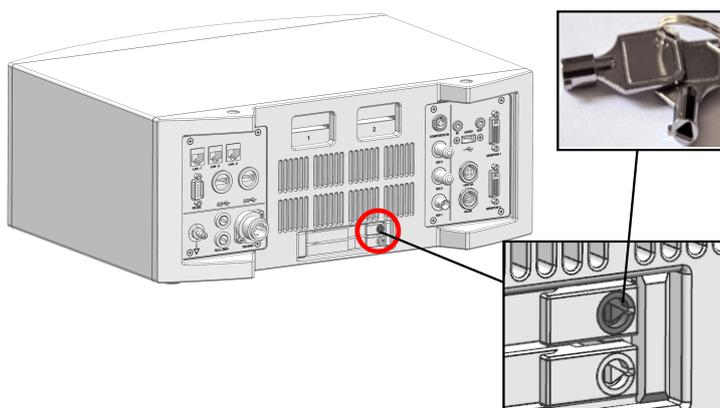
2. Open the slot (1) and exchange the hard disk (2):
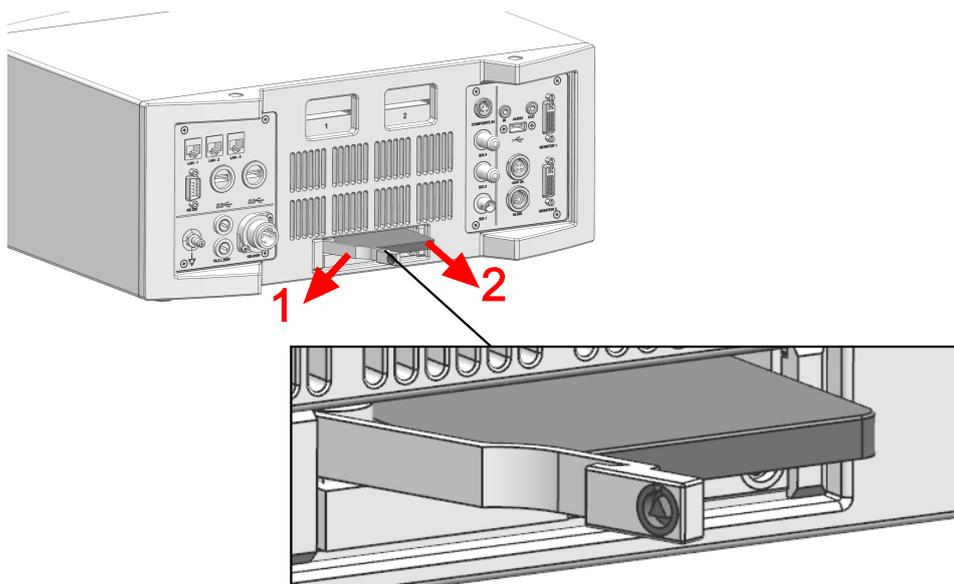
3. Remount the unit in reverse order.

4. Reconnect the HS MIOS 5 to the surgical microscope system.

4.5.2 CF card exchange

⚠	**NOTICE**
	The compact flash (CF) cards contain no patient-related data and are read-only.

If an update of the HS MIOS 5 V2.0 will be necessary in the future, follow the steps below.

⚠	**CAUTION**
	Possibility of internal defects because of a CF card change during operation!
	Only exchange the CF card if the HS MIOS 5 is shut down.

1. Location of CF card(s):
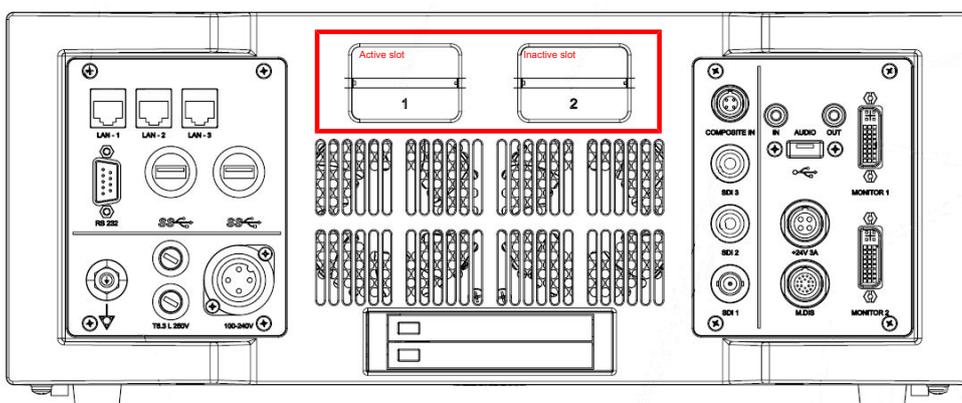
2. Pull the CF cards to remove them:
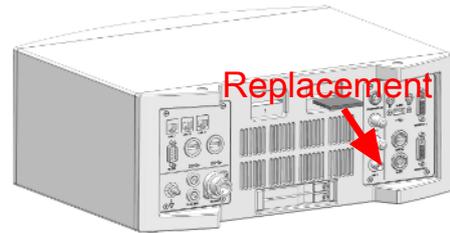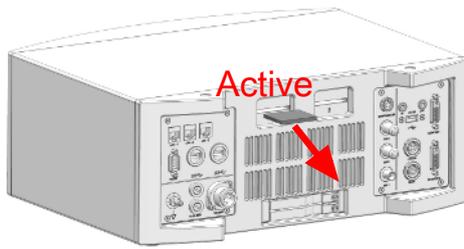
3. Insert a new CF card in the active slot and a new CF card in the replacement slot:
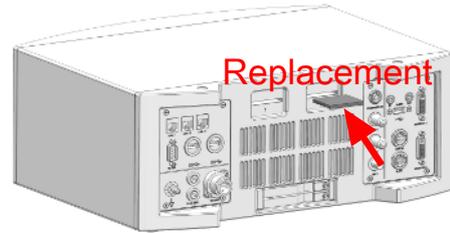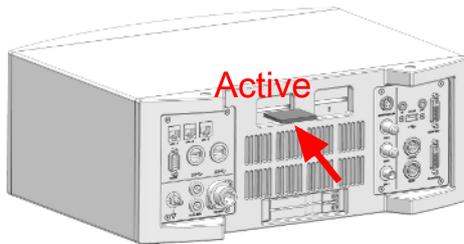
4.5.3 Troubleshooting

> ⚠️ **CAUTION**
>
> **Risk of limited treatment options!**
>
> If defects are not detected, the surgical microscope system may not offer all functions during surgery.
>
> a) Before each use, make sure that all electrical and mechanical connections are firmly seated and free of defects.
>
> b) Regularly check the functionality and quality of the magnified vision.
>
> c) Do not use the system in case of any obvious defects, error states or functional restrictions. Call the Haag-Streit Service.

> ⚠️ **NOTICE**
>
> **Resettable error reoccurs twice or more**
>
> The error may be due to a systematic fault in the medical device and must be attended by Haag-Streit.
>
> Please contact your local representative or Haag-Streit, stating the product name, type and serial number together with a description of the error and the circumstances under which the error occurs.

Microscope Imaging Operation System (MIOS)

Malfunction	Cause	Troubleshooting
C.MON does not light up.	The HS MIOS 5 is not switched on.	Switch on the HS MIOS 5.

Malfunction	Cause	Troubleshooting
The power LED remains off when the power button is pressed.	The carrier unit is not connected to mains power supply.	Connected the carrier unit is to mains power supply.
	The HS MIOS 5 is not connected to the power supply in the carrier unit.	Connect the HS MIOS 5 to the power supply in the carrier unit.
	One or more fuses in the MIOS are faulty.	Replace faulty fuses.
The power LED is lit, but the HS MIOS 5 does not start.	The CF card is defective.	Replace the CF card.
The HS MIOS 5 displays the wrong date after switching on / off.	The internal computer battery is empty.	Contact your local sales representative.

Error Messages

In case of unexpected incidents an error message will appear on the display.

The error message will inform what caused the error message and contains information to solve the cause of the error message.

4.5.4 Suspicion of computer virus

Computer viruses cannot implement themselves permanently at operating system level of the HS MIOS 5 due to its hardware architecture. If a virus infection of the stored data is suspected, do the following:

1. Switch off the HS MIOS 5 (Important Buttons [▷ 16]) and remove the hard disk(s) (Hard disk exchange).
2. Check the hard disk(s) on viruses in an external system and remove infected data with a proper antivirus program.
3. Re-insert the hard disk(s) or insert new hard disk(s).
4. Re-start the HS MIOS 5.

4.5.5 Sending the HS MIOS 5 for repair

⚠️ **CAUTION**

Data protection and data security!

Should it be necessary to return the HS MIOS 5 to the manufacturer or your local sales representative, then you must protect the privacy of all personal data and remove it from the device (Cyber security [▷ 53]).

1. Turn off the HS MIOS 5 (Important Buttons [▷ 16]) and remove the built-in hard disk(s) (Hard disk exchange [▷ 41]).

5 Technical data

Microscope Imaging Operative System	HS MIOS 5
Identification	
REF	4000039
Environmental conditions, operation	
Operating temperature [°C]	+ 10 – + 40
Operating, relative air humidity [%]	10 – 90
Operating, air pressure [hPa]	795 – 1060
Environmental conditions, storage	
Storage and transport, temperature [°C]	- 20 – + 70
Storage and transport, relative air humidity [%]	10 – 90
Storage and transport, air pressure [hPa]	600 – 1060
Conformity	
Classification	$C\,\epsilon$ Regulation (EU) 2017/745 Class I
Safety	EN 60 601-1 Appliance class I equipment
EMC	EN 60 601-1-2
UMDNS	12-539
GMDN	12539
Degree of protection by enclosure (IP-Code)	IP20
M.COM	
Mechanical data	
Height [mm]	165
Width [mm]	400
Depth [mm]	336
Weight [kg]	9.8
Electrical data	
Possible operating voltages [V ~]	100 ... 240 V ~
Operating voltage tolerance [%]	± 10 V
Possible mains frequencies [Hz]	
Maximum power consumption [VA]	200 VA
Internal battery	3 V, Type CR 2032
Processor	Intel i7

Microscope Imaging Operative System	HS MIOS 5
RAM	2x4GB DDR4-2400
Hard disk	2 x 1000 GB, 2.5"
Optical drive	CD-R/ - RW, DVD ± R/ ± RW/ ± R DL
Boot time	90 seconds
Shutdown time	11 seconds
Connections	
USB	3x USB 3.0 (universal connections) 1x USB 2.0 (C.MON HD)
RS 232	1 x
LAN	3 x
M.DIS connection	1 x
DVI-D Out	2 x
Composite In	1 x
24 V / 3 A supply	1 x
Audio in	1 x, stereo jack, 3.5 mm
Audio out	1 x, stereo jack, 3.5 mm
HD SDI Out	1 x
HD SDI In	3 x
C.MON HD	
Identification	
REF	4000010
Mechanical data	
Height [mm]	326
Width [mm]	537
Depth [mm]	55
Weight [kg]	5
Optical data	
Diagonal screen size ["]	21.5
Resolution	1920 x 1080 p
Colours	16.7 Mio
Light intensity [cd/m2]	300
Contrast	5000:1

6 Cleaning and disinfection

Prepare the M.COM according to the instructions in the appendix.

7 Disposal

Dispose of the surgical microscope system and its components according to national and regional legislation.

Within the European Union, the surgical microscope system and its components are subject to EU-Directive on Waste of Electrical and Electronic Equipment and may not be disposed together with waste from private households.

The manufacturer shall take the surgical microscope system and its components back for proper recycling or disposal. Please contact your local Haag-Streit sales representative.

8 Maintenance

User	
Interval	**Type of test**
Before each use	Before each operation and Functional test before each operation
After expiration of recommended service life	Contact Haag-Streit national representative service Manufacturer's Details and Contact Information
Every 6 months	– Check to make sure that the mounted accessories are fully functional and connected firmly

By Haag-Streit national representative service	
Interval	**Type of test**

Every year
 	
Additionally:
– According to national regulations
– After replacing spare parts
	Safety testing
	– Test electrical safety according to IEC 62353
	– Check information on cyber security. See Cyber security [▶ 53]
	– Check for visible damage to cables, housing parts
	– Check important safety information
	   – Inspect the type plate (REF number and serial number) on the bottom of the device
	   – The instructions for use (REF 668 501 xx) is on hand and accessible

Every 2 years	– Visual inspection and cleaning
	   – Carefully vacuum / clean the inside of the device to remove dust
	   – Check the CPU cooler for damage
	   – Check that the CPU fan runs smoothly and draws in air from above
	   – Check that the fans in the back and front panel run smoothly and draw in air from the inside
	– Check, if hard disk exchange is necessary
	– Check the fuses and replace them if necessary
	– Inspect all visible cables and mechanical connections for damage, e.g. crushing

Every 5 years	– Copy log files from HS MIOS 5 and send to Haag-Streit national representative service including reference numbers and software version of the entire surgical microscope system.

9 Appendix

9.1 Specifications on electromagnetic compatibility

Phenomenon	Test standard	Level
Emissions	CISPR 11	Class A
Harmonic currents	IEC 61000-3-2	Class A, stationary
Voltage fluctuations and flicker	IEC 61000-3-3	
Discharge of static electricity	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
High-frequency electromagnetic fields	IEC 61000-4-3	3 V/m @ 80 MHz ... 2.7 GHz 27 V/m @ 380 MHz ... 390 MHz 28 V/m @ 430 MHz ... 470 MHz 9 V/m @ 704 MHz ... 787 MHz 28 V/m @ 800 MHz ... 960 MHz 28 V/m @ 1.7 GHz ... 1.99 GHz 28 V/m @ 2.4 GHz ... 2.57 GHz 9 V/m @ 5.1 GHz ... 5.8 GHz
Electrical fast transient disturbance/bursts	IEC 61000-4-4	For signal lines: ± 1 kV @ 100 kHz For the supply input: ± 2 kV @ 100 kHz
Surge voltages	IEC 61000-4-5	± 0.5 kV, ± 1 kV line against line for the supply input ± 0.5 kV, ± 1 kV, ± 2 kV line against ground
Conducted disturbances induced by high-frequency fields	IEC 61000-4-6	3 V @ 0.15 MHz ... 80 MHz 6 V @ ISM frequency bands
Magnetic fields with energy-related rated frequencies	IEC 61000-4-8	30 A/m
Voltage drops, voltage interruptions	IEC 61000-4-11	0% BDC; 10 ms (φ = 0; 0.25; 0.5; 0.75; 1; 1.25; 1.5; 1.75 * π) 0% BDC; 20 ms 70% BDC; 0.5 s 0% BDC; 5 s

9.2 Cleaning, disinfection and sterilization

> ⚠️ **CAUTION**
>
> **Risk of falling touchscreen!**
>
> The touch screen of the C.MON HD may become detached during surgery, if aggressive, non-approved cleaning agents or disinfectants are used.
>
> a) Only use approved cleaning agents or disinfectants. Do not use liquids or gas that contain chloride.
>
> b) See following instructions for proper cleaning agents.

> ⚠️ **CAUTION**
>
> **Risk of damage to the M.COM by ingress of liquids!**
>
> a) Make sure that no liquids get inside the M.COM.
>
> b) Do not use any abrasive agents or abrading materials.

Perform the treatment before each use.

The operator must ensure that the preparation is performed within a suitable validated procedure in accordance with the respective national regulations.

The treatment process must at least meet the following requirements:

– Cleaning and disinfectant agents must be approved for the treatment of medical products.

– Steam sterilization in accordance with ISO 17665 and EN 285 standards if applicable.

– Cleaning and disinfecting devices and agents according to ISO 15883 standard.

Refer to the instructions from the manufacturer of the disinfectant regarding resolution and contact time.

Manual cleaning	
Monitors	**Materials required** – Damp cloth with suitable cleaning agent – Dry microfiber cloth **Process** – Clean the surfaces with the damp cloth. Then dry the surface with the microfiber cloth.
External surfaces	**Materials required** – Cotton or microfiber cloth – pH-neutral cleaning agent (pH 6 − 10) which is suitable for aluminum and plastic surfaces. **Process** – Apply the cleaning agent with the cloth. – Wipe off the surfaces of the device. – Make sure that the cleaning agent does not get onto the glass surfaces and into the insides of the housing.

Disinfection

Materials required

- – Disposable gloves
- – Cotton or microfiber cloth, disposable tissues or wipes
- – Alcohol-based surface disinfectant or disinfection agent recommended by national hygiene guidelines in required concentration

Process

- – Use disposable gloves.
- – Soak the cloth with a sufficient amount of the disinfectant.
- – Apply the disinfectant by sweeping with moistened tissue or wipe under slight pressure into one direction.
- – Disinfect all surfaces of covers and all touchable surfaces colored in black such as handles, push-bars, knobs, touchscreens and the rubber O-rings of oculars (where applicable).
- – Avoid spraying the disinfectant onto surfaces.
- – Make sure that the disinfectant does not get into the insides of the housing.
- – Let disinfected surfaces dry out in air.
- – Be aware of contact time and of applied concentration of utilized disinfectant agent.

Sterilization

- – Sterilization is not possible. The M.COM, M.DIS and C.MON HD are not equipped with sterilizable control elements.

9.3 Inspection and testing

As items are cleaned, disinfected or sterilized, they should be inspected:

1. Check all items before and after each treatment for mechanical damage.
2. Replace damaged items.
3. Ensure that no visible residual impurities or contaminations remain on the articles.
4. Ensure that glass surfaces are clean and free of streaks.

9.4 Cyber security

It is assumed that HS MIOS 5 is used within a secured environment. It is assumed that a secured environment includes at a minimum:

1. Firewall or router protections to ensure that only approved external hosts have network access to HS MIOS 5.
2. Firewall or router protections to ensure that HS MIOS 5 only has network access to approved external hosts and services.
3. Any communication with external hosts and services outside the locally secured environment use appropriate secure network channels (e.g. such as a Virtual Private Network (VPN)).

Other network security procedures such as automated intrusion detection may be appropriate in some environments. Additional security features may be established by the local security policy and are beyond the scope of this conformance statement.

Glossary

CDSCO

CDSCO is the abbreviation for "Central Drugs Standard Control Organisation", India's national regulatory authority for drugs and medical devices.

CE

CE is the abbreviation for "Communité Européen", the European Community. The abbreviation is used in a special graphic layout to state that the given product is designed and produced according to the European guidelines for product safety and user protection.

EC-REP

EC-REP is the abbreviation for "European Community Authorized Representative". Medical device manufacturers located outside the EU must designate an authorized representative located in the EU to fulfill the CE requirements for placing medical devices on the EU market.

GTIN

GTIN is the abbreviation for "Global Trade Item Number", a unique and internationally recognized identification for a product with 14 digits.

IP-Code

IP xx, indicates how well a cabinet protects the circuits and switches against ingress of fluids.

REF

REF is the abbreviation of the term "Reference Number". Each product and all spare parts have a unique reference number, by which they can be ordered.

SN

SN is the abbreviation of the term "Serial Number". Every product is given a unique serial number, by which the specific technical data can be retrieved.

UDI

UDI is the abbreviation for "Unique Device Identification". The UDI code enables medical device traceability and prevents product diversion and counterfeiting.

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