# Instructions for use

# Histolog® Scanner

**v2**


Histolog® Scanner v2 REF 003

Histolog® Dish REF 004

Histolog®
Scanner

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# 1. Revision history

| Version | Date | Change description |
|---|---|---|
| 1.0 | 2024-10-15 | Initial version |
| 1.1 | 2025-02-04 | Update §14.3 for new means to export logs. |

# 2. Table of contents

# 3. Description of symbols

| | | | |
|---|---|---|---|
| LOT | Batch Code | | Temperature limit |
| REF | Catalog Number | | Atmospheric Pressure Limitation |
| SN | Serial Number | | Humidity Limitation |
| MD | Medical Device | | Fragile; handle with care |
| | Manufacturer | | This way up |
| | Manufacturing date | | Keep dry |
| | Consult instructions for use | | Do not reuse |
| | Standby or power indicator | | Use-by (expiry) date |
| | Orientation mark | NON STERILE | Non-sterile |
| | Non-ionizing radiation | | Quantity in package |
| Rx only | Prescription only | | Importer |
| UDI | Unique Device Identification | | |

| | |
|---|---|
| LASER 1 | Class 1 laser product, as per IEC 60825-1:2014-05. |
| | Follow the local regulations for separate collection of Electrical and Electronic Equipment. |
| | ● When followed by “**WARNING**” this symbol means “Warning! Failure to observe could result in injury or death.”<br>● When followed by “**CAUTION**”, this symbol means “Caution! Failure to observe could result in damaged equipment, forfeited time or effort, or the need to abort use of the device.”<br>● When found on equipment, this symbol means: “Attention: consult accompanying instructions for use”. |
| **NOTE** | A NOTE sign draws attention to useful information regarding a function or procedure. |

# 4. Introduction

These instructions for use describe the set-up, use and maintenance of SamanTree Medical's Histolog® Scanner device, including its Histolog® Dish accessory.

These instructions for use contain important information for the safe use of the device.

- Read these instructions for use before setting up and using the device the first time.
- Keep the instructions for use accessible for future reference.

Refer to the Histolog® Dip instructions for use for information on the Histolog® Dip fluorescent histological stain.

Refer to the Histolog® Scanner Software Application instructions for use for detailed instructions on how to operate the Histolog® Scanner Software Application.

# 5. Safety instructions

Use only for the purpose described in these instructions for use. Do not use the device if it is not working properly, or if it has suffered any damage. Misuse can cause electrocution, burns, fire and other hazards.

Prior to first use, the Histolog® Scanner device is to be put in service by SamanTree Medical authorized service personnel.

The components located in the inner cavity of the device are not intended to be manipulated by the user. The interior of the Histolog® Scanner may be serviced only by SamanTree Medical authorized service personnel.

Report any serious incident related to the Histolog® Scanner and its accessory devices to SamanTree Medical SA and to your national competent authority.

## 5.1. Warnings

**⚠WARNING**

- The Histolog® Scanner and its accessory devices are intended to be used in vitro for the examination of specimens. They are not intended for use on patients.
- The Histolog® Scanner and the Histolog® Dish are non sterile devices. For use in an intraoperative setting, the Histolog® Scanner and its accessory products shall be located outside the sterile surgical area.
- When handling potentially infectious tissue specimens, avoid skin contact by wearing gloves or other protective equipment.
- This device is not compatible with magnetic resonance (MR) or explosive environments.
- Handles [H] are not provided for lifting the device, but exclusively have a function for pushing/pulling.
- The Histolog® Scanner imaging window [G] is fragile. Avoid impact with foreign objects. Do not load with mass above 1 kg.
- Do not operate the Histolog® Scanner in case of damage to the imaging window [G].
- The protective earthing connection of the Histolog® Scanner is performed through the power cord [P] connection. If this cable is damaged, the device must not be connected to the mains power.
- Only use a power cord [P] having adequate ratings for the Histolog® Scanner.
- Comply with the product safety instructions described in the Histolog® Dip instructions for use.
- Cleaning when the device is connected to the mains power may be hazardous to the operator and/or destructive to the device.

## 5.2. Cautions

**⚠CAUTION**

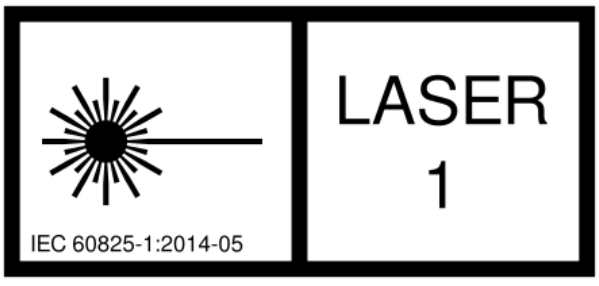
- Only use compatible accessories and parts supplied by SamanTree Medical or by an authorized distributor.
- Do not re-use a Histolog® Dish. A new Histolog® Dish shall be used for every new surgical procedure.
- Do not use a Histolog® Dish, if it is damaged or if its optical interface is visibly dirty.
- If the information about the tissue specimen orientation is critical, the tissue specimen should be marked for orientation before starting the imaging procedure with the Histolog® Scanner.
- Do not apply tissue marking dyes on the tissue specimen before imaging it with the Histolog® Scanner. Tissue marking dyes prevent proper imaging with the Histolog® Scanner.
- Do not use disinfecting products that contain glycolic acid. These disinfecting products may damage the Histolog® Scanner.
- The Histolog® Scanner is intended for use in the electromagnetic environment specified in §16.2 & §16.3.
- The Histolog® Scanner is designed for use in a professional healthcare facility environment. It is likely to perform incorrectly if used in a home healthcare environment.
- 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.”

- 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 Histolog Scanner, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- If it is suspected that performance is affected by electromagnetic interference, correct operation may be restored by increasing the distance between the equipment and the source of the interference.
- Do not use this device in proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional radio frequency (RF) sources), as these can interfere with proper operation.
- Do not use this device in proximity of active HF surgical equipment, as these can interfere with proper operation.

## 5.3. Laser safety

The Histolog® Scanner is a Class 1 laser product, as per IEC 60825-1:2014-05.

Laser radiation in the visible wavelength range is emitted from the imaging window [G] during imaging.




The Histolog® Scanner embeds a Class IIIB laser component with the following characteristics: Wavelength: 488±4 nm
Max output power: 200mW (CW) Beam divergence: < 0.7 mrad

# 6. Intended purpose

## 6.1. Indications for Use

The Histolog® Scanner is a confocal laser system intended to allow imaging of the internal microstructure of tissues including, but not limited to, the identification of cells, vessels and their organization or architecture.

## 6.2. Intended users

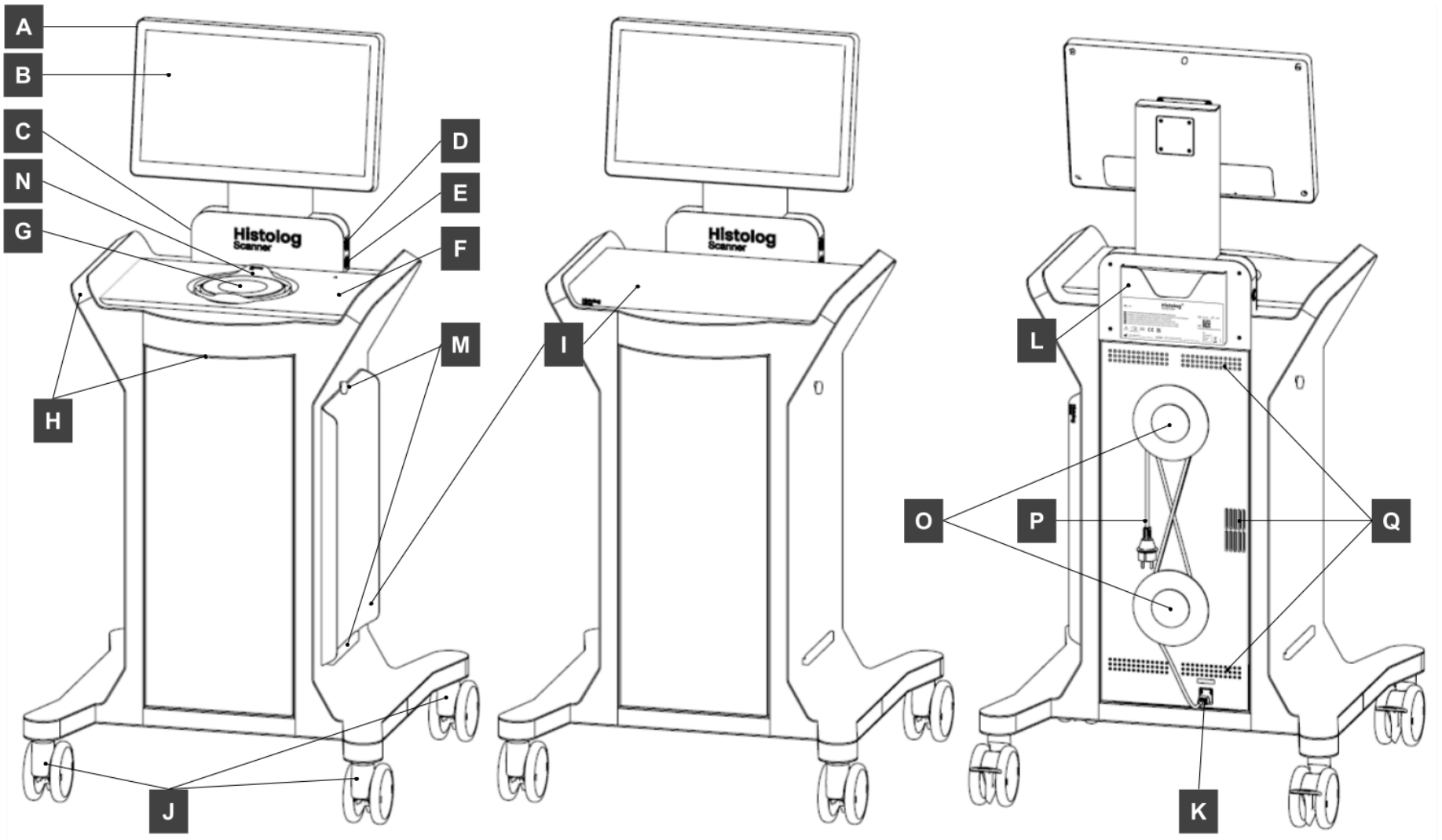
The Histolog® Scanner and its accessory devices are intended to be operated by trained healthcare professionals.

## 6.3. Clinical Utility

The Histolog® Scanner offers an additional source of information to the user by providing rapid, automated visualization of excised tissue microstructure. This information is an adjunct to visual observation of the surface of an excised tissue sample and tissue histopathology assessment.

# 7. Product information

## 7.1. Overview




The Histolog® Scanner consists of the following components:

[A] Touchscreen monitor
[B] Histolog® Scanner Software Application
[C] ON/OFF power switch
[D] USB port
*(for use with USB storage medium only - see §7.2.3 for more details)*
[E] Ethernet port
*(only for maintenance purposes, under guidance of SamanTree Medical authorized service personnel)*
[F] Orientation mark
[G] Imaging window
[H] Handles
[I] Lid
[J] Swivel caster wheels with brakes
[K] Appliance power inlet with fuse compartment
[L] Document holder
[M] Lid storage supports
[N] Histolog® Dish
[O] Cable winder
[P] Power cord
[Q] Ventilation openings

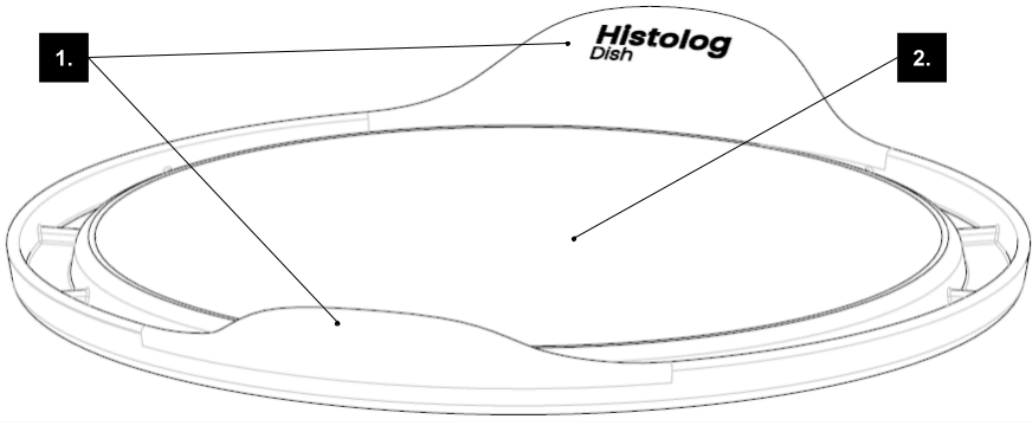
## 7.2. Accessories

The Histolog® Scanner is intended to be used in combination with the following accessory devices:

- The Histolog® Dish, a single-use protection preventing direct contact of the tissue specimen with the Histolog® Scanner during imaging.
- The Histolog® Dip fluorescent histological stain.

### *7.2.1. Histolog® Dish*

The Histolog® Dish is a single-use protection preventing direct contact of the tissue specimen with the Histolog® Scanner during imaging. The Histolog® Dish is provided separately (see §15 for catalog codes).




The Histolog® Dish is placed over the imaging window [G] of the Histolog® Scanner. It is composed of:

1. Two handles protruding from the rigid base for manipulation;
2. An optical interface on which the tissue specimen is placed and through which it is

imaged. It is not intended to be used as a receptacle for transporting or storing tissue

specimens.

The focal plane of the Histolog® Scanner is configured in-factory to lie just above the top surface of the Histolog® Dish optical interface, so that the surface of a specimen in contact with the optical interface is imaged.

### *7.2.2. Histolog® Dip*

The Histolog® Dip is a fluorescent histological stain for imaging tissue specimens with the Histolog® Scanner. The Histolog® Dip is provided separately (see §15 for catalog codes).

### *7.2.3. Other accessories*

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.

USB Storage device

A USB storage device is needed to export images and technical data (see §14.3) from the Histolog® Scanner device. USB storage device is not provided by SamanTree Medical. Use USB 3.0 (or better) storage medium with read/write speeds of at least 300 MB/s and with storage capacity of at least 256 GB. USB storage devices with integrated USB cables and USB extension cables must not be used.

**NOTE** USB storage devices with security lock features (such as PIN protection) are not compatible with the Histolog® Scanner.

Refer to the Histolog® Scanner Software Application instructions for use for detailed instructions on how to export images and for information on supported export formats.

Ethernet cable (for maintenance)

For maintenance purposes, under guidance of SamanTree Medical authorized service personnel, an ethernet cable may be connected to the ethernet port [E] of the Histolog Scanner. Such an ethernet cable should be a shielded Cat6 cable.

## 7.3. Operating principle

The Histolog® Scanner is a digital microscopy scanner for use on excised human tissue. Its operating principle is based on confocal fluorescence imaging modality and uses non-ionizing, low-power optical radiation.

In a conventional wide-field fluorescence microscope, the entire specimen is flooded in light from a light source and the detected fluorescence includes a large part of out-of-focus signal. In contrast, a confocal microscope uses a point illumination conjugated with a pinhole in front of the detector to eliminate out-of-focus signals so that only the fluorescence produced very close to the focal plane in the specimen can be detected. This thin optical sectioning makes the Histolog® Scanner particularly well suited for imaging the superficial cell layer of thick tissue specimens: excised tissue can be immediately imaged, slide-free, without the need for freezing or fixing.

The Histolog® Scanner acquires digital images with high, micrometer-range resolution and enables the visualization of tissue microstructures down to the cellular level.

The Histolog® Scanner is based on a massively parallel signal acquisition and processing technology providing fast digital imaging over large areas.

# 8. Use of the Histolog® Scanner

Prior to first use, the Histolog® Scanner device must be put in service by SamanTree Medical authorized service personnel.

## 8.1. Before use

### *8.1.1. Installing in use location*

1. Move the Histolog® Scanner to the desired location with level ground. ⚠**WARNING** The Histolog® Scanner and the Histolog® Dish are non sterile devices. For use in an intraoperative setting, the Histolog® Scanner and its accessory products shall be located outside the sterile surgical area.

   **NOTE** Leave at least 15 cm of free space around the ventilation openings [Q].

2. When in place, lock the four wheel brakes [J] in downward position to prevent unintended movement of the Histolog® Scanner.
3. Plug the power cord [P] to the mains power outlet.

⚠**WARNING**

- The protective earthing connection of the Histolog® Scanner is performed through the power cord [P] connection. If this cable is damaged, the device must not be connected to the mains power.
- Only use a power cord [P] having adequate ratings for the Histolog® Scanner. Suitable power cord accessories are listed in §15.

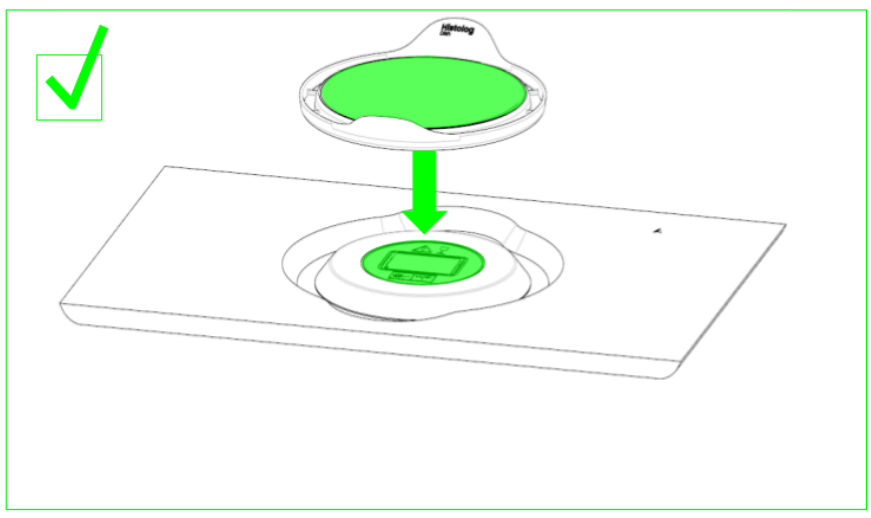
### *8.1.2. Switching ON*

1. Switch ON the power switch [C] and wait for the Histolog® Scanner Software Application to initialize.

   **NOTE** When switched ON, the power switch [C] is pressed and lighted in white.

### *8.1.3. Mounting Histolog® Dish*

1. Remove the Histolog® Scanner lid [I], and store it in its lid storage supports [M].
2. Unpack a Histolog® Dish and mount it over the imaging window [G]. When properly mounted, only the optical interface of the Histolog® Dish is in contact with the Histolog® Scanner.

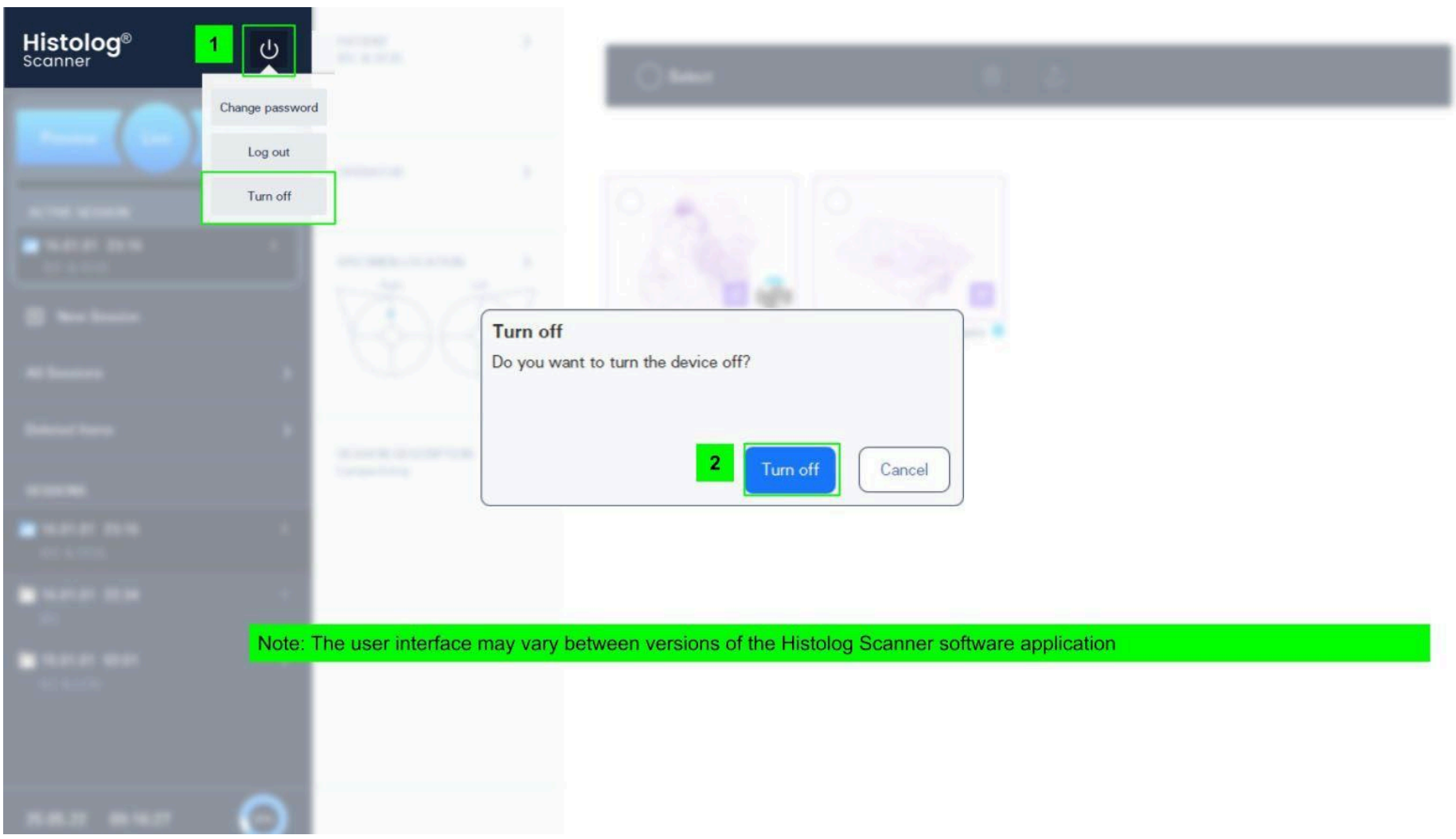



⚠**CAUTION**

- Do not re-use a Histolog® Dish. A new Histolog® Dish shall be used for every new surgical procedure.
- Do not use a Histolog® Dish, if it is damaged or if its optical interface is visibly dirty.

## 8.2. After use

### *8.2.1. Switching OFF*




*Quit the Histolog® Scanner Software Application:*

1. Tap the ⏻ button.

   If User Authentication mode is used in the Histolog® Scanner Software Application, then select the “Turn off” option in the graphical popup control.

2. Confirm the action by tapping “Turn off” to shutdown the device.

   Or tap on “Cancel” if you do not want to shutdown the Histolog® Scanner.

*Power OFF the Histolog® Scanner device:*

3. Wait 15 seconds or until the ‘No Signal’ message is displayed on the monitor, and then switch OFF the power switch [C].

### *8.2.2. Prepare for storage*

1. Dispose of the Histolog® Dish according to §13.1.
2. Unplug the power cord [P] from the mains power outlet and wind it on the cable winder [O].
3. Clean the Histolog® Scanner according to §9.
4. Place the lid [I] back on the Histolog® Scanner to protect the imaging window [G].

## 8.3. Imaging a tissue specimen

⚠**WARNING** When handling potentially infectious tissue specimens, avoid skin contact by wearing gloves or other protective equipment.

⚠**CAUTION**

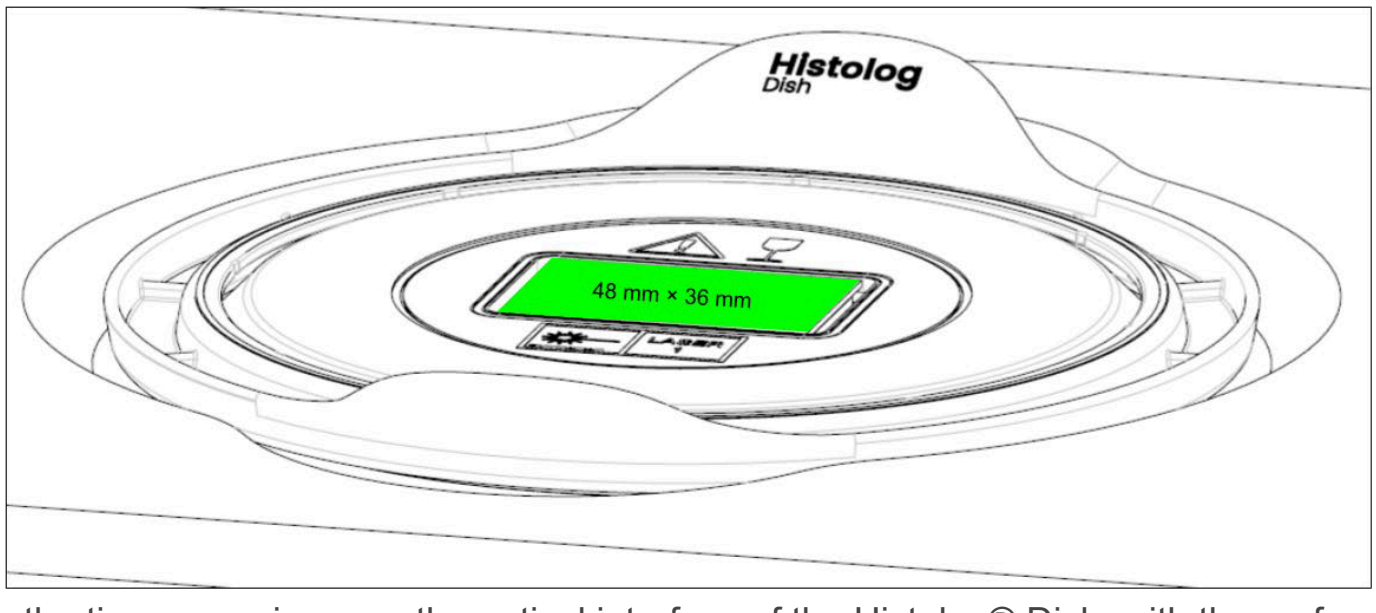
- If the information about the tissue specimen orientation is critical, the tissue specimen should be marked for orientation before starting the imaging procedure with the Histolog® Scanner.
- Do not apply tissue marking dyes on the tissue specimen before imaging it with the Histolog® Scanner. Tissue marking dyes prevent proper imaging with the Histolog® Scanner.

### *8.3.1. Staining the tissue specimen*

Stain the tissue specimen with the Histolog® Dip fluorescent histological stain. Refer to the Histolog® Dip instructions for use for tissue specimen staining procedures.

⚠**WARNING** Comply with the product safety instructions described in the Histolog® Dip instructions for use.

### *8.3.2. Positioning the tissue specimen*




1. Place the tissue specimen on the optical interface of the Histolog® Dish, with the surface of interest pointing downwards.

   **NOTE** Specimen size should not exceed that of the Histolog® Dish (see §16.1). Furthermore, the tissue specimen should be positioned in a way to only contact the optical interface of the Histolog® Dish, but never its rigid base or handles.

2. Make sure that the area of interest of the tissue specimen surface is positioned over the image area and that it is in contact with the optical interface of the Histolog® Dish to guarantee its complete imaging.

3. When the stained tissue specimen is properly positioned for imaging, refer to the instructions for use of the Histolog® Scanner Software Application to perform the imaging and other associated procedures.

   **NOTE** Image quality is negatively impacted by:

   - excess of fluid (especially blood) on the tissue specimen,
   - any treatment (such as cauterization) that alters the tissue specimen surface,
   - any residues or stains on the optical interface of the Histolog® Dish or on the tissue specimen surface,
   - motion of the tissue specimen during image acquisition.

# 9. Cleaning

**⚠WARNING**

- Cleaning when the device is connected to the mains power may be hazardous to the operator and/or destructive to the device.

Thoroughly clean the Histolog® Scanner device after each use with the recommended cleaning agents. After cleaning the Histolog® Scanner device, visually inspect it to ensure it is clean. If there is any visible soiling remaining, repeat the cleaning until the Histolog® Scanner is visually clean.

The device may be cleaned with conventional alcohol-based disinfecting agents for medical devices. Read and follow the instructions supplied with the cleaning product.

Make sure that the disinfecting agent does not enter into the device's inner cavity. The following products are compatible with the Histolog® Scanner:

| Active compound | Tested with |
|---|---|
| Alcohol | Ethanol, 71% |
| | Propanol, 50% |
| Quaternary ammonia compounds | DDAC - Didecyldimethylammonium chloride - (CAS 7173-51-5), 0.075% |
| | Benzalkonium Chloride - benzyl-C12-16-alkyldimethyl, chlorides (CAS 68424-85-1), 0.095% |

**⚠CAUTION**

- Do not use disinfecting products that contain glycolic acid. These disinfecting products may damage the Histolog® Scanner.

**NOTE**

- Take care not to scratch the surface of the touchscreen monitor [A] or imaging window [G]. Avoid contact with hard or abrasive materials.
- The Histolog® Scanner device must be dry before subsequent use.

# 10.Moving

Before moving the Histolog® Scanner, please ensure that:

1. The power cord [P] is disconnected from the mains outlet and secured on the cable winder [O].
2. The brakes of all four of the caster wheels [J] are released (in upwards

position). Use only the handles [H], and not other parts of the device, for

pushing/pulling.

Move the device no faster than walking speed. Move the device over a flat surface. Avoid surfaces and obstacles that could hamper the normal rolling of the wheels [J]. Beware of physical collisions of the device with possible obstacles during the moving.

⚠**WARNING** Handles [H] are not provided for lifting the device, but exclusively have a function for pushing/pulling.

# 11.Storage

After use of the device, follow the instructions of §8.2. The device can then be moved to the storage area. When in place, lock the four wheel brakes [J] in downward position to prevent unintended movement of the Histolog® Scanner.

See §16.1 for specified environmental storage conditions.

# 12.Maintenance

SamanTree Medical recommends an annual maintenance for every Histolog® Scanner device. Such an annual maintenance may be performed only by SamanTree Medical authorized service personnel.

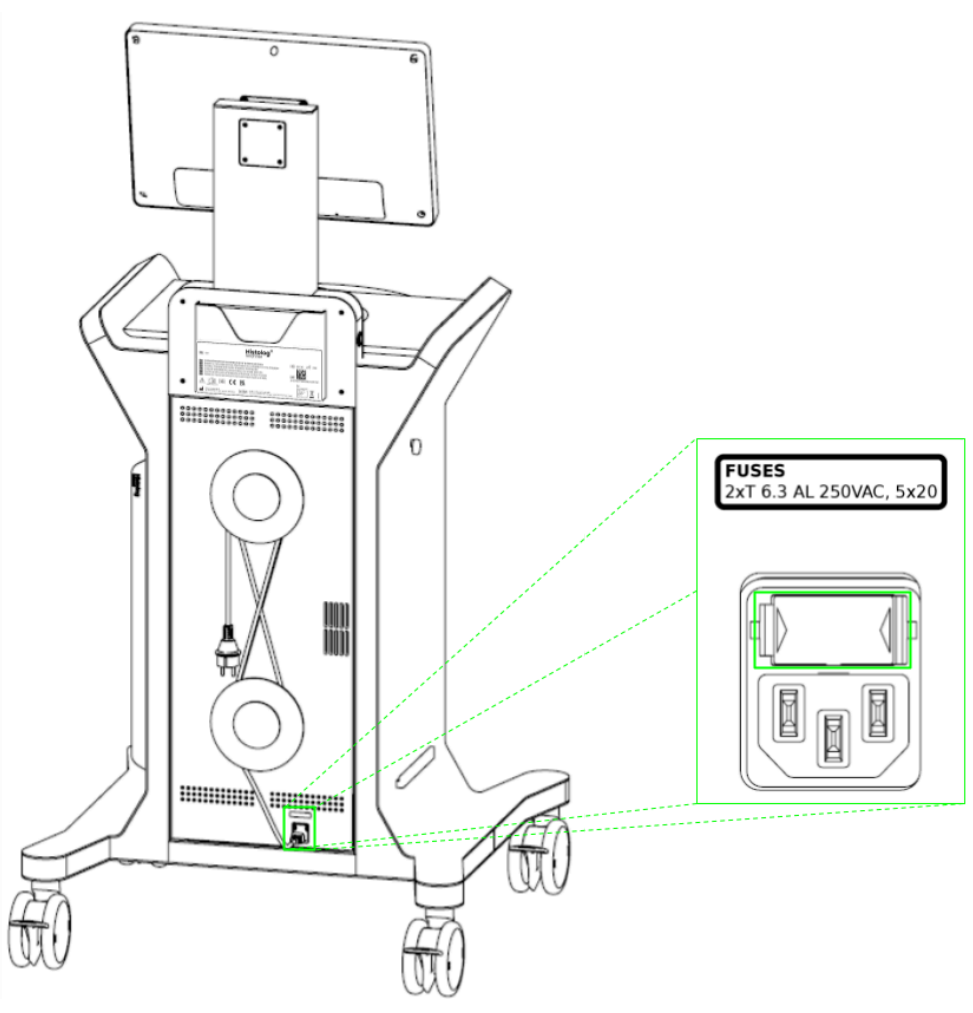
The components located in the inner cavity of the device are not intended to be manipulated by the user. The interior of the Histolog® Scanner may be serviced only by SamanTree Medical authorized service personnel.

## 12.1. Update of Histolog® Scanner Software Application

Update of Histolog® Scanner Software Application may be installed only by SamanTree Medical authorized service personnel.

## 12.2. Fuse replacement

Fuses are located in a compartment above the appliance power inlet [K] located at the back of the device.




To replace fuses:

1. With the device switched off, disconnect the power cord [P] from the appliance power inlet [K].
2. Using a flat screwdriver, open the fuse drawer on the back of the device.
3. Replace the blown fuses with new ones meeting the specifications of §16.1.
4. Close the fuse drawer.
5. Reconnect the power cord [P] to the appliance power inlet [K].

# 13.Disposal

## 13.1. Histolog® Dish

Dispose of the Histolog® Dish according to local procedure for handling biomedical waste.

## 13.2. Histolog® Scanner

Follow the local regulations for separate collection of electrical and electronic equipment.

## 13.3. Histolog® Dip

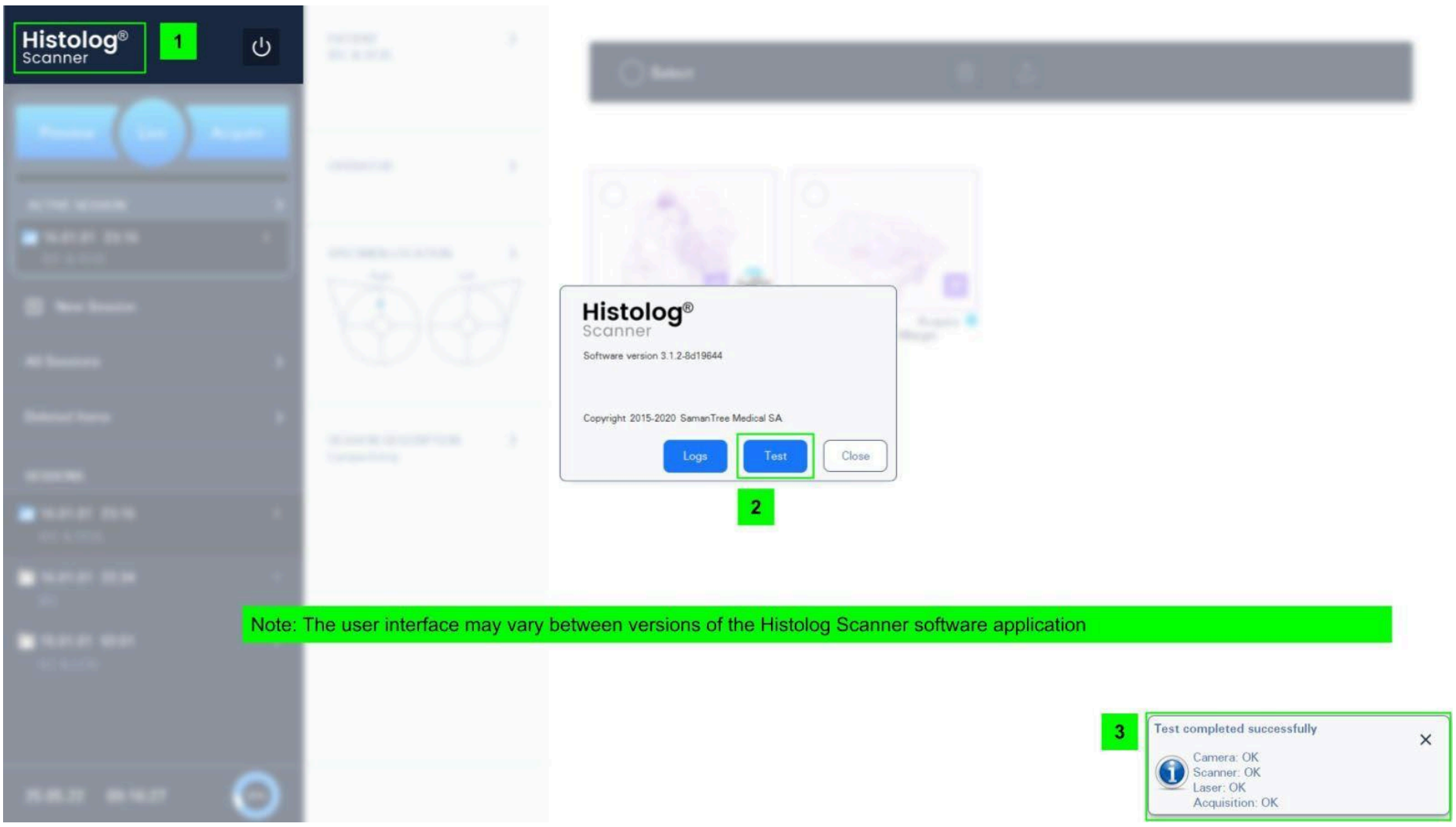
Dispose of the Histolog® Dip in accordance with the information contained in its instructions for use.

# 14.Troubleshooting

This section contains important troubleshooting instructions for the Histolog® Scanner device. Additional troubleshooting instructions specifically related to the Histolog® Scanner Software Application may be found in the Histolog® Scanner Software Application instructions for use.

## 14.1. Test procedure

The Histolog® Scanner offers means to test that its different core components are functioning properly. The test procedure may serve to verify that the Histolog® Scanner is performing as intended. It is suggested to execute this test procedure in case of doubt about the proper operation of the Histolog® Scanner device.




To run the test procedure:

1. Tap the Histolog® Scanner button in the upper left corner of the user interface.
2. Tap the “Test” button in the message window to start the test procedure. The test procedure normally takes less than a minute to complete.
3. Once the test procedure is completed, the status of the different components is displayed in a message window to the bottom right corner of the screen:

   ‘OK’ means that the component is functioning properly. Even if all components are functioning properly, some issues may still be experienced. Refer to §14.2 for troubleshooting instructions.

   ‘FAIL’ accompanied by a message means that the component is **not** functioning properly. If any one of the components returns a ‘FAIL’ status:

   I. Wait 1 minute and try the test again.
   II. If the failure persists, switch OFF the device (as per instructions of §8.2.1), unplug the power cord [P] from the mains power outlet, wait 10 seconds, plug the power cord [P] to the mains power outlet, switch ON the device (as per instructions of §8.1.2) and try the test again.
   III. If the failure persists, stop using the device, note the displayed message and contact SamanTree Medical authorized service personnel for technical support (contact information may be found on page 2).

## 14.2. Troubleshooting

| Issue | Cause | Action(s) to take |
|---|---|---|
| Device does not power up | Power cord [P] is not connected | Verify that the power cord [P] is connected to the Histolog® Scanner appliance power inlet [K] and to the mains power outlet. |
| | ON/OFF power switch [C] is not pressed | Verify that the Histolog® Scanner is switched ON (power switch [C] is pressed and lighted up in white light). |
| | Fuses have blown | If it still doesn't power up, verify that the fuses haven't blown. Fuse replacement instructions are available in §12.2. |
| Nothing is displayed on the screen | Touchscreen monitor [A] is switched OFF | Verify that the touchscreen monitor [A] is switched ON. The monitor's power indicator light, a circular green light located at the right below the active display area, should be illuminated. If not, switch ON the monitor by pressing the illuminated power button located at the right below the active display area, next to the power indicator light. |
| Touchscreen is not responding as expected to touch gestures | Touch function is disabled | A "Touch Disabled" button is backlit in the bottom right corner of the touchscreen monitor [A], close to the power indicator light.<br>Press and hold the "Touch Disabled" button for 3 seconds to enable the touch function. |
| | Stain on the touchscreen disrupts its touch function | Tap on the bottom right corner of the touchscreen monitor [A], close to the power indicator light. Backlit keypads will appear.<br>Press and hold the "Touch Disabled" button for 3 seconds to disable the touch function.<br>Clean the front surface of the touchscreen monitor [A] and let it dry completely.<br>Press and hold the "Touch Disabled" button for 3 seconds to enable the touch function. |
| | Touchscreen has entered in an abnormal state of operation | Switch OFF the device (as per instructions of §8.2.1),<br>Unplug the power cord [P] from the mains power outlet,<br>Wait 10 seconds,<br>Plug the power cord [P] to the mains power outlet,<br>Switch ON the device (as per instructions of §8.1.2). |
| Device cannot be moved | Wheel brakes [J] prevent motion | Verify that all four wheel brakes [J] are released (in upward position). |
| Image acquisition stops before reaching 100% | Device has encountered an error | Relaunch image acquisition.<br>If the issue persists:<br>- Switch OFF the device (as per instructions of §8.2.1),<br>- Unplug the power cord [P] from the mains power outlet,<br>- Wait 10 seconds,<br>- Plug the power cord [P] to the mains power outlet,<br>- Switch ON the device (as per instructions of §8.1.2). |
| Histolog® Scanner Software Application is not responsive | Device has entered in an unreactive state | Switch OFF the device (as per instructions of §8.2.1),<br>Unplug the power cord [P] from the mains power outlet,<br>Wait 10 seconds,<br>Plug the power cord [P] to the mains power outlet,<br>Switch ON the device (as per instructions of §8.1.2). |
| Device cannot acquire images | Disk is full | Permanently delete images from the Gallery (as per Histolog® Scanner Software Application instructions for use)<br>Relaunch the acquisition. |
| | Device has entered in an unreactive state | Switch OFF the device (as per instructions of §8.2.1),<br>Unplug the power cord [P] from the mains power outlet,<br>Wait 10 seconds,<br>Plug the power cord [P] to the mains power outlet,<br>Switch ON the device (as per instructions of §8.1.2). |

| Issue | Cause | Action(s) to take |
|---|---|---|
| Export of images data, reports or logs fails | No USB storage device is connected | Verify that a USB storage device is connected to the USB port [D]. |
| | Issue with USB storage device connection | Remove any USB storage device from the USB port [D].<br>Reconnect USB storage device in USB port [D].<br>If the issue persists,<br>- Switch OFF the device (as per instructions of §8.2.1),<br>- Unplug the power cord [P] from the mains power outlet,<br>- Wait 10 seconds,<br>- Plug the power cord [P] to the mains power outlet,<br>- Switch ON the device (as per instructions of §8.1.2) |
| | USB storage device does not have enough available storage capacity | Verify that the USB storage device has at least 1 GB of available storage capacity. |
| Poor quality of images: low intensity | No/poor staining of tissue specimen | (Re-)stain the tissue specimen according to §8.3.1. |
| | Excess of fluid (especially blood) on the tissue specimen | Gently swab the tissue specimen to remove excess fluid. |
| | Tissue specimen has been stained with tissue marking dyes | Do not use tissue marking dyes on the tissue specimen before imaging with the Histolog® Scanner. |
| Poor quality of images: low intensity, blurred images | Excess of fluid on the tissue specimen | Gently swab the tissue specimen and the optical interface of the Histolog® Dish to remove excess fluid. |
| | Surface of the tissue specimen not fully in contact with the optical interface of the Histolog® Dish | Reposition the tissue specimen to ensure better contact.<br>Use tools and/or weights to help in positioning and improving the contact between the tissue specimen and the Dish. |
| | The optical interface of the Histolog® Dish is not fully in contact with the Histolog® Scanner imaging window [G] | Remove the tissue specimen from the Histolog® Dish.<br>Remove the Histolog® Dish from the Histolog® Scanner.<br>Reposition the Histolog® Dish on the Histolog® Scanner (as per instructions of §8.1.3) and gently wipe the optical interface of the Histolog® Dish to remove air between it and the Histolog® Scanner imaging window [G]. |
| Poor quality of images: blurred images presence of debris, scratches in the images | Histolog® Dish is dirty. | Use a new, clean Histolog® Dish to image your tissue specimen. Do not re-use a Histolog® Dish. |
| Poor quality of images: Image contains sharp discontinuities at regular interval | Tissue specimen has moved during acquisition | Wait for the tissue specimen to stabilize and relaunch image acquisition.<br>If the issue persists, use tools (e.g., forceps) to hold the specimen in the desired position. |

If the issue cannot be resolved with the above instructions, stop using the device. Shut down and prepare for storage as per §8.2. Contact SamanTree Medical service personnel for technical support (contact information may be found on page 2). If an error message is displayed, please note the error code and message, and communicate it to the service personnel.

## 14.3. Export logs

The Histolog® Scanner offers means to export technical data (“logs”) on the use and status of the device to a USB storage device. Logs contain technical information for troubleshooting and may be requested by SamanTree Medical authorized service personnel within the frame of technical support. These Logs are fully anonymized logs and do not contain any protected health information (PHI) [in the meaning of the Health Insurance Portability and Accountability Act of 1996 (HIPAA)], nor any personally identifiable information (PII) [personal data, in the meaning of General Data Protection Regulation (GDPR)]. Logs contain technical information for troubleshooting and may be requested by SamanTree Medical authorized service personnel within the frame of technical support.

To export the logs to a USB storage device:
1. Connect a USB storage device to the USB port [D]

**NOTE** The USB storage device should have at least 1 GB of available storage capacity.

2. Tap the Histolog® Scanner button in the upper left corner of the user interface.
3. Tap the “Logs” button in the message window and then tap the “Export to local storage” button to export the logs to the USB storage device.
4. A message window to the bottom right corner of the screen indicates that the logs have been successfully exported to the USB storage device. You may now remove the USB storage device.

To export logs to a network-connected shared drive (only available for Histolog® Scanner devices connected to the network and a network-connected shared drive configured by the Histolog® Scanner ‘admin’ account user):
1. Connect the Histolog® Scanner ethernet port [E] to a network socket using an ethernet cable.

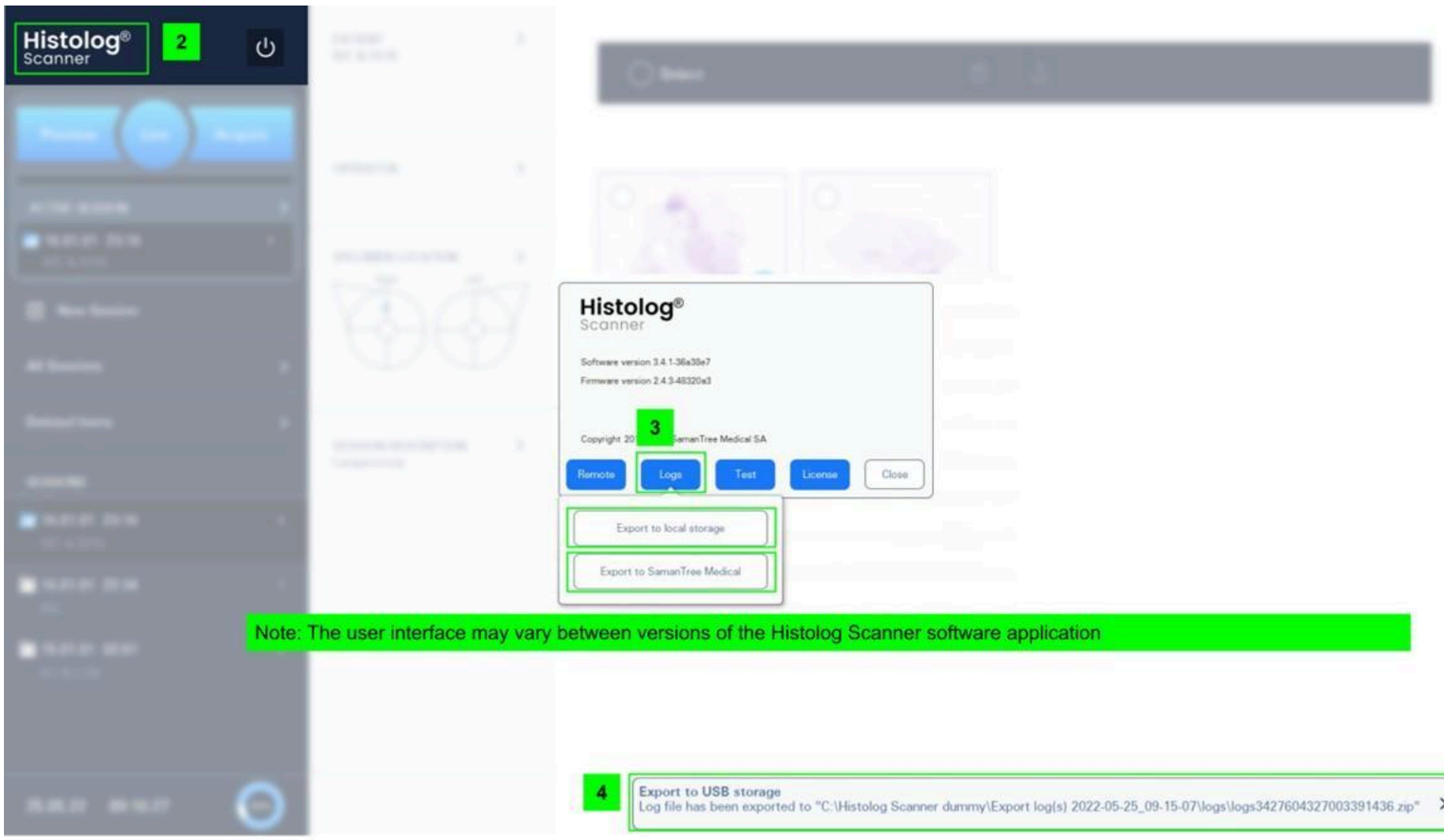
**NOTE** The network must allow the Histolog® Scanner to access a network-connected shared drive that was previously configured by the Histolog® Scanner ‘admin’ account user.

2. Tap the Histolog® Scanner button in the upper left corner of the user interface.
3. Tap the “Logs” button in the message window and then tap the “Export to local storage” button to export the logs.
4. A message window to the bottom right corner of the screen indicates that the logs have been successfully exported to the shared drive. You may now disconnect the device from the network.

To export the logs directly to SamanTree Medical over the internet using secure, encrypted communication (only available for Histolog® Scanner devices connected to the network and with access to internet):
1. Connect the Histolog® Scanner ethernet port [E] to a network socket using an ethernet cable.

**NOTE** The network must allow the Histolog® Scanner to access the internet.

2. Tap the Histolog® Scanner button in the upper left corner of the user interface.
3. Tap the “Logs” button in the message window and then tap the “Export to SamanTree Medical” button to export the logs.
5. A message window to the bottom right corner of the screen indicates that the logs have been successfully exported. You may now disconnect the device from the network.


Histolog®
Scanner
2
Histolog®
Scanner
Software version 3.4.1-36a38e7
Firmware version 2.4.3-48320e3
3
Copyright 20 SamanTree Medical SA
Remote
Logs
Test
License
Close
Export to local storage
Export to SamanTree Medical
Note: The user interface may vary between versions of the Histolog Scanner software application
4
Export to USB storage
Log file has been exported to "C:\Histolog Scanner dummy\Export log(s) 2022-05-25_09-15-07\logs\logs3427604327003391436.zip"

# 15.Product catalog codes

To purchase replacement parts from SamanTree Medical or from an authorized distributor, please use the following product catalog numbers.

**Products**

| Product Catalog Code (REF) | Description |
|---|---|
| 003 | Histolog® Scanner v2 |
| 004 | Histolog® Dish |
| 005 | Histolog® Dip |

**Replacement Parts**

| Part Number | Description |
|---|---|
| PN282 | Fuse for Histolog® Scanner appliance power inlet (T6.3 AL 250VAC 5mm × 20mm) |
| PN446 | Power Cord – Swiss plug |
| PN458 | Power Cord – Euro plug |
| PN482 | Power Cord – United Kingdom plug |
| PN460 | Power Cord – North America plug |

**Documentation**

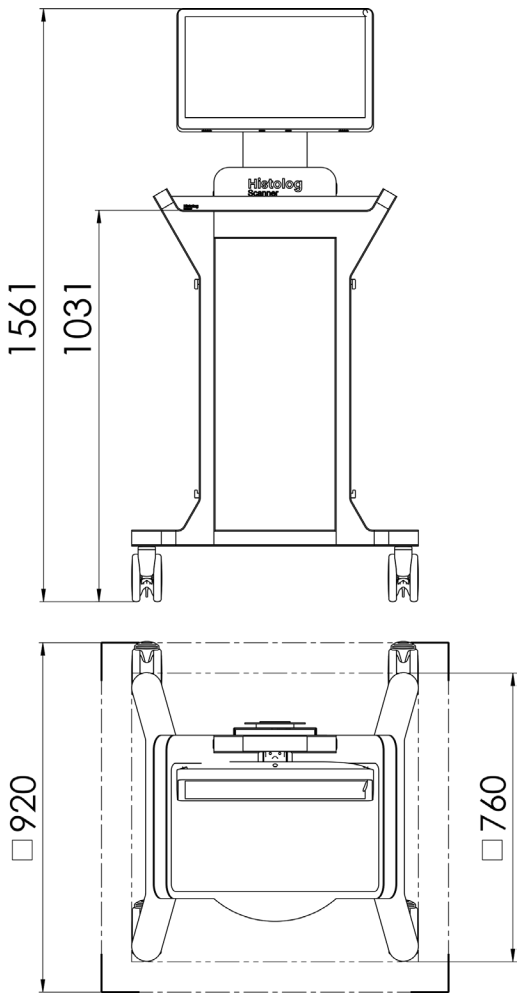
| Instructions for use |
|---|
| Histolog® Scanner and Histolog® Dish – instructions for use (this document) |
| Histolog® Dip – instructions for use |
| Histolog® Scanner Software Application – instructions for use |

⚠**CAUTION** Only use compatible accessories and parts supplied by SamanTree Medical or by an authorized distributor.

# 16.Device specifications/technical information

## 16.1. Technical specifications

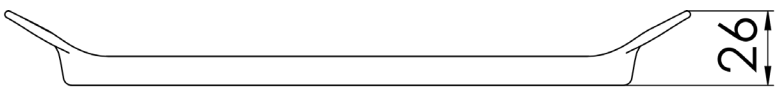
### *16.1.1. Histolog® Scanner*

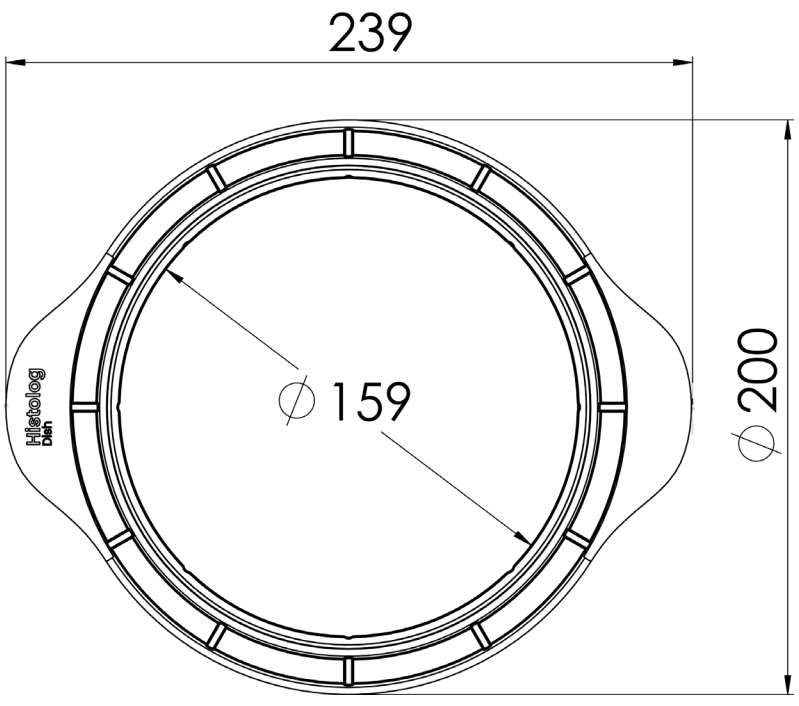



| HISTOLOG® SCANNER | |
|---|---|
| Dimensions (W x D x H) | 0.76 m x 0.76 m x 1.56 m (30” x 30” x 59”) |
| Weight | 95 kg (209 lbs) |
| Electrical Power Input | 120 VAC, 60 Hz |
| Maximum Rated Power | 305 W |
| Power Cord Length | 5 m (197”) |
| USB port standard | 3.0 |
| Ethernet port connector | RJ45 |
| Fuse type | T6.3 AL 250VAC, 5x20mm, slow-blow |
| **Display** | |
| Active screen size (diagonal) | 547 mm (21.5”) |
| Active screen size (W x H) | 476.64 mm x 268.11 mm (18.77” x 10.56”) |
| Resolution | 2 MP (1920 x 1080) |
| Viewing angle (H, V) | 178° |
| Contrast ratio | 3000:1 typical |
| **Fluorescence Settings** | |
| Laser wavelength | 488 ±4 nm |

| | |
|---|---|
| Emission filter | Longpass, cut-on at 500±3 nm |
| **Images** | |
| Image area | 48 mm × 36 mm |
| Time to image | approx. 10 seconds for images at resolution of 10 µm per pixel<br>approx. 1 minute for images at resolution of 2 µm per pixel |
| **Operating Conditions** | |
| Area of application | Indoor use only |
| Pollution degree | 2 |
| Temperature | 15–35 °C (59-95 °F) |
| Humidity | 30–80 % (non-condensing) |
| Pressure | 80–106 kPa |
| **Transport Conditions** | |
| Temperature | 0–60 °C (32-140 °F) |
| Humidity | 10–80 % (non-condensing) |
| Pressure | 70–106 kPa |
| **Storage Conditions** | |
| Temperature | 0–60 °C (32-140 °F) |
| Humidity | 10–80 % (non-condensing) |
| Pressure | 70–106 kPa |

### *16.1.2. Histolog® Dish*




| **HISTOLOG® DISH** | |
|---|---|
| Outer Dimensions (L x W x H) | 239 mm x 200 mm x 26 mm (9 3/8” x 7 7/8” x 1”) |
| Inner Dimension (Ø) | 159 mm (6 ¼ “) |
| Weight | 54 g (2 oz) |
| Storage temperature conditions | 15°C-30°C (59-86 °F) |

## 16.2. Electromagnetic immunity

| Guidance and manufacturer's declaration – Electromagnetic immunity | | | |
|---|---|---|---|
| The Histolog® Scanner is intended for use in the electromagnetic environment specified below. The customer or the user of the Histolog® Scanner should ensure that it is used in such an environment.<br>When the Histolog Scanner is exposed to any of the disturbances below, you might notice one of the following effects:<br>● Screen flickering<br>● Screen blackout during 1-2 seconds<br>● Imaging acquisition interrupted with error<br>None of the listed effects above have an impact on the essential performance or safety of the Histolog Scanner device.There are no unacceptable risks for user, patient or environment to be expected. | | | |
| Immunity test | IEC 60601-1-2<br>test level | Compliance level | Electromagnetic environment – guidance |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±8 kV contact<br><br>±2, ±4, ±8 kV, ±15 kV air | ±8 kV contact<br><br>±2, ±4, ±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<br><br>±1 kV for input/ output lines | ±2 kV for power supply lines<br><br>±1 kV for input/ output lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ±1 kV line-to-line (mains cable)<br><br>±2 kV line-to-ground (mains cable)<br><br>±2 kV common mode (ethernet port) | ±1 kV differential mode<br><br>±2 kV common mode<br><br>±2 kV common mode | 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 IEC61000-4-11 | 0% UT<br>(100% dip in UT)<br>for 1 cycle<br><br>0% UT<br>(100% dip in UT)<br>for 0.5 cycle<br><br>70% UT<br>(30% dip in UT)<br>for 0.5 s<br><br>0% UT<br>(100% dip in UT)<br>for 5 s | 0% UT<br>(100% dip in UT)<br>for 1 cycle<br><br>0% UT<br>(100% dip in UT)<br>for 0.5 cycle<br><br>70% UT<br>(30% dip in UT)<br>for 0.5 s<br><br>0% UT<br>(100% dip in UT)<br>For 5 s | Mains power quality should be that of a typical commercial or hospital environment.<br>If the user of the Histolog® Scanner requires continued operation during power mains interruptions, it is recommended that the Histolog® Scanner be powered from an uninterruptible power supply. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 30 A/m | 30 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial and/or hospital environment. |
| Proximity magnetic fields IEC 61000-4-39 | 30 kHz, 8 A/m CW<br><br>134.2 kHz, 65 A/m pulse modulation 2.1 kHz<br><br>13.56 MHz, 7.5 A/m pulse modulation 50 kHz | 30 kHz, 8 A/m CW<br><br>134.2 kHz, 65 A/m pulse modulation 2.1 kHz<br><br>13.56 MHz, 7.5 A/m pulse modulation 50 kHz | |
| **NOTE** The electromagnetic environment should be evaluated prior to operation of the device. | | | |

| Guidance and manufacturer's declaration – Electromagnetic immunity | | | |
|---|---|---|---|
| The Histolog® Scanner is intended for use in the electromagnetic environment specified below. The customer or the user of the Histolog® Scanner should ensure that it is used in such an environment. | | | |
| Immunity test | IEC 60601-1-2<br>test level | Compliance level | Electromagnetic environment<br>–<br>guidance |
| Conducted RF<br>IEC 61000-4-6 | 3 Vrms<br>150 kHz to 80 MHz<br><br>6 Vrms<br>ISM bands between 150 kHz to 80 MHz | 3 Vrms<br>150 kHz to 80 MHz<br><br>6 Vrms<br>ISM and amateur radio bands between 150 kHz to 80 MHz | – |
| Radiated RF<br>IEC 61000-4-3 | 3 V/m<br>80 MHz to 2.7 GHz | 3 V/m<br>80 MHz to 13 GHz | Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the minimum separation distance calculated from the equation applicable to the frequency of the transmitter.<br><br>Minimum separation distance<br><br>$d = 6 / E \cdot P\sqrt{}$<br><br>where *d* is the minimum separation distance in meters, *P* is the maximum power in watts, and *E* is the immunity test level in V/m.<br><br>Interference may occur in the vicinity of equipment marked with the following symbol:<br>  |
| **NOTE** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | | |

| Recommended separation distances between portable and mobile RF communications equipment and the Histolog® Scanner | |
|---|---|
| The Histolog® Scanner is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer of the user of the Histolog® Scanner can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Histolog® Scanner as recommended below, according to the maximum output power of the communications equipment. | |
| | Separation distance according to frequency of transmitter |
| Rated maximum output power of transmitter W | 80MHz to 6GHz<br>$d=2 \cdot \sqrt{P}$ |
| 0.01 | 0.2 (0.66 ft.) |
| 0.1 | 0.64 (2.08 ft.) |
| 1 | 2.00 (6.56 ft.) |
| 10 | 6.33 (20.75 ft.) |
| 100 | 20.00 (65.62 ft.) |
| For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter in watts (W) according to the transmitter manufacturer. **NOTE** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | |

## 16.3. Electromagnetic compatibility

The Histolog® Scanner complies with the emission and immunity requirements of IEC 60601-1-2.

NOTE The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

| Guidance and manufacturer's declaration – Electromagnetic emissions | | |
|---|---|---|
| The Histolog® Scanner is intended for use in the electromagnetic environment specified below. The customer or the user of the Histolog® Scanner should ensure that it is used in such an environment. | | |
| Emission test | Compliance | Electromagnetic environment – guidance |
| RF emissions CISPR 11 | Group 1, Class A | This equipment is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments. |
| Harmonic emissions IEC 61000-3-2 | Class A | |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | Complies (unlikely to produce voltage fluctuations or flicker) | |