

Instructions for use

Histolog[®] Scanner v2

Histolog[®] Scanner v2 **REF** 003

Histolog[®] Dish **REF** 004





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The Histolog[®] Scanner and the Histolog[®] Dish are patent protected products.

See www.samantree.com/ip for more information on intellectual property.

1. Revision history

Version	Date	Change description
1.0	2018-01-28	Initial Version.
1.1	2018-04-23	Update for release of software application version 3.0.0. Changes requested by IEC 61010-1, IEC 61010-2-101 safety tests.
1.2	2018-05-29	Changes requested by IEC 60825-161010-1, IEC 61010-2-101 and IEC 608251-1 safety tests.
1.3	2018-07-05	Add information on the environmental pollution degree, required by IEC 61010-1:2010 + AMD1:2016 §5.4.2. Add recommended material for specimen staining. Add additional approved cleaning agents.
1.4	2019-05-17	Update with new product catalog codes. Add a patent protection statement. Update for release of software application version 3.1.0. Update for release of Histolog Dip product.
1.5	2019-06-21	Removed §11. Improve image quality for print. Add description of symbol for “quantity in package”.
1.6	2020-08-31	Update SamanTree Medical’s address.
1.7	2020-11-16	Update list of compatible cleaning agents. Change contact information. Update patent protection statement with latest issued patents.
1.8	2021-09-15	Update for European Directive EU 2015/863.
1.9	2022-01-13	Update SamanTree Medical’s address. Update copyright and patent protection statements.
1.10	2022-02-10	Update information for safety in line with risk analysis.
1.11	2022-05-26	Restructure the document and move the detailed instructions of Histolog® Scanner Software Application to a separate, dedicated document. Reformulate the intended purpose. Update content of §6, §7, §8, §9, §14. Other changes to get in conformity with Regulation (EU) 2017/746 (“IVDR”) and with the Medical Devices Regulations 2002 (UK).
1.12	2023-12-20	Update §5 and §16 for Edition 3.0 of IEC 61326-1 and 61326-2-6.
1.13	2024-03-19	Update CISPR 11 class in §16.3. Correct wavelength tolerance in §5.3.
1.14	2024-10-28	Update §7.1, §7.2.3, §8.1.1, §8.2.2, §12.1 and §15 in relation to ethernet connection. Correct fuse specification in §15.
1.15	2025-02-04	Update §14.3 for new means to export logs.

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3. Description of symbols

	Batch Code		Temperature limit
	Catalog Number		Atmospheric Pressure Limitation
	Serial Number		Humidity Limitation
	In vitro diagnostic 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-ionizing radiation		Quantity in package
	Authorized EC Representative		Importer
	Unique Device Identification		

	Class 1 laser product, as per IEC 60825-1:2014-05.
	Follow the local regulations for separate collection of Electrical and Electronic Equipment.
	CE marking of conformity with Directive 98/79/EC and Regulation (EU) 2017/746.
	UKCA marking of conformity with the Medical Devices Regulations 2002 (UK).
	- When followed by “WARNING” this symbol means “Warning! Failure to observe could result in injury or death.” - 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.” - When found on equipment, this symbol means: “Attention: consult accompanying instructions for use”.
	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

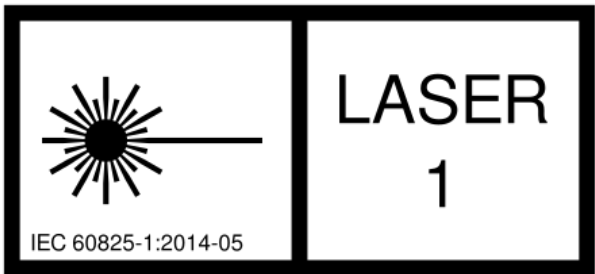
CAUTION

- 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. 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.

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:	200 mW (CW)
Beam divergence:	< 0.7 mrad

6. Intended purpose

6.1. Intended use

The Histolog[®] Scanner is a confocal microscopy device intended for imaging the surface of excised human tissue specimens to visualize morphological microstructures.

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

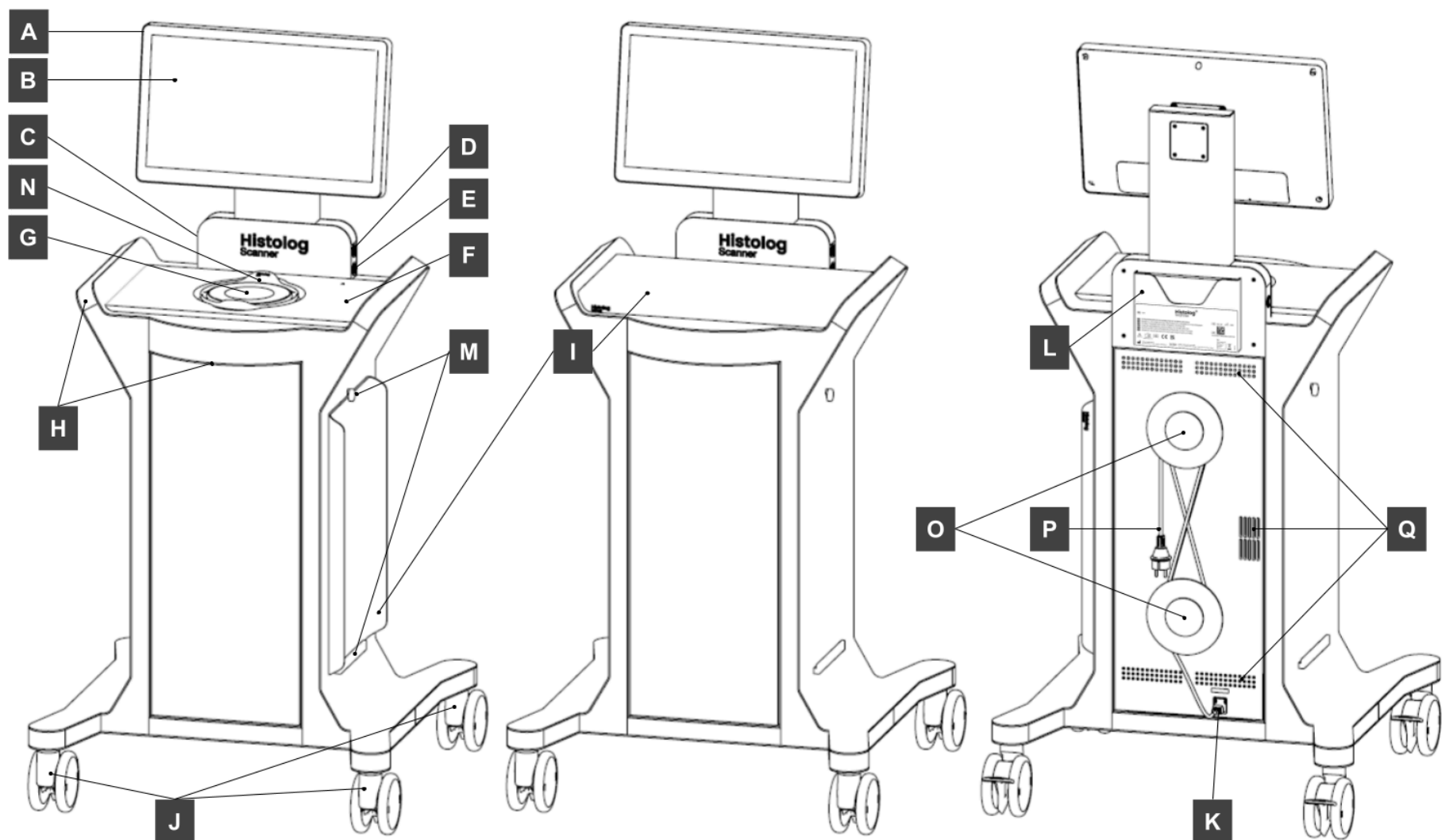
- The Histolog[®] Dish, a single-use protection preventing direct contact of the tissue specimen with the Histolog[®] Scanner during imaging.
- The Histolog[®] Dip fluorescent histological stain.

The Histolog[®] Scanner and its accessory devices are intended to be used *in vitro* for the examination of specimens. They are *in-vitro diagnostic* medical devices.

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

7. Product information

7.1. Overview



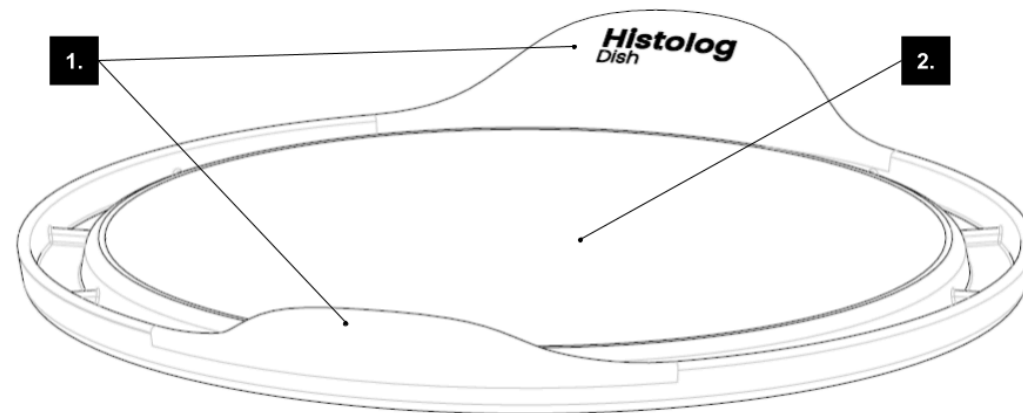
The Histolog® Scanner consists of the following components:

- [A] Touchscreen monitor
- [B] Histolog® Scanner Software Application
- [C] ON/OFF power switch
- [D] USB port
- [E] Ethernet port
- [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

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

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. It is recommended to use a 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.

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

Use a shielded Cat6 ethernet cable to connect the Histolog[®] Scanner to a network socket.

A connection with a bandwidth of ≥ 5 Mbits/s and a latency of ≤ 100 ms is required to support remote connections to/from the Histolog[®] Scanner.

Network-connected computer

To remotely connect to the Histolog[®] Scanner, a specially configured network-connected computer is necessary. Refer to the Histolog[®] Scanner Software Application instructions for use for the required configuration for this network-connected computer.

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 and, optionally, connect the Histolog® Scanner ethernet port [E] to a network socket using an ethernet cable.

⚠ 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](#).

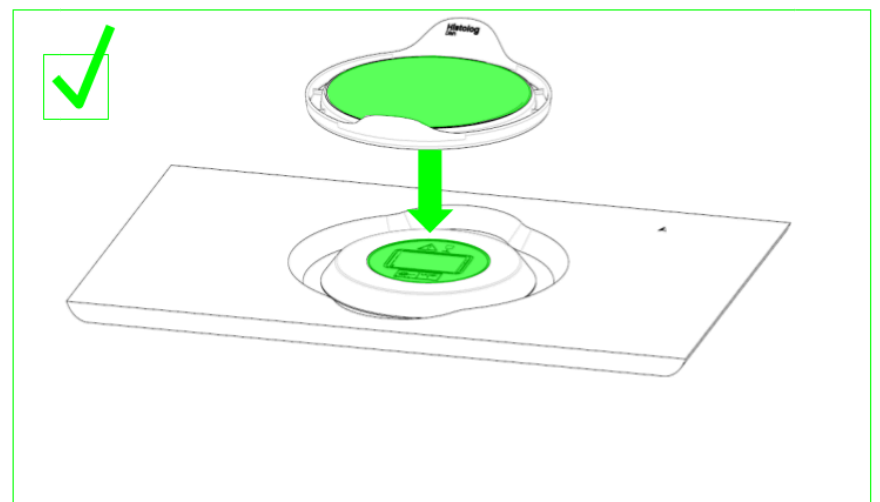
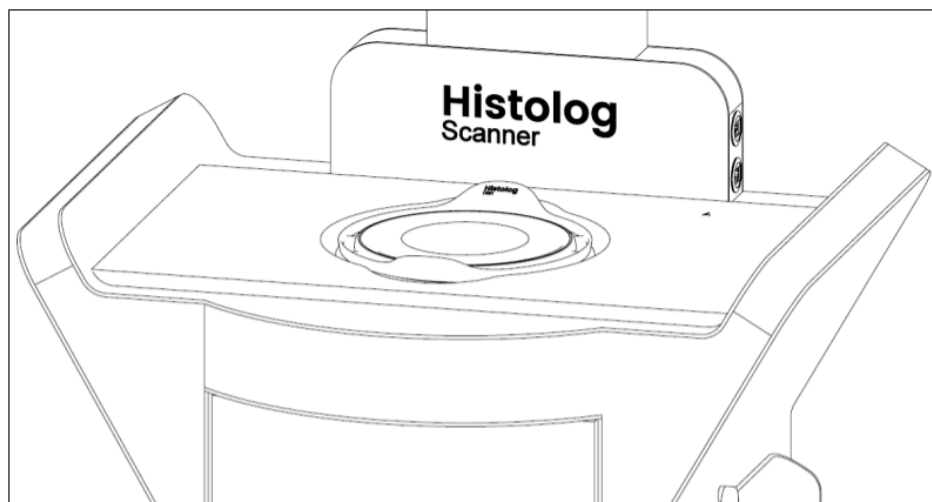
8.1.2. Switching ON

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.

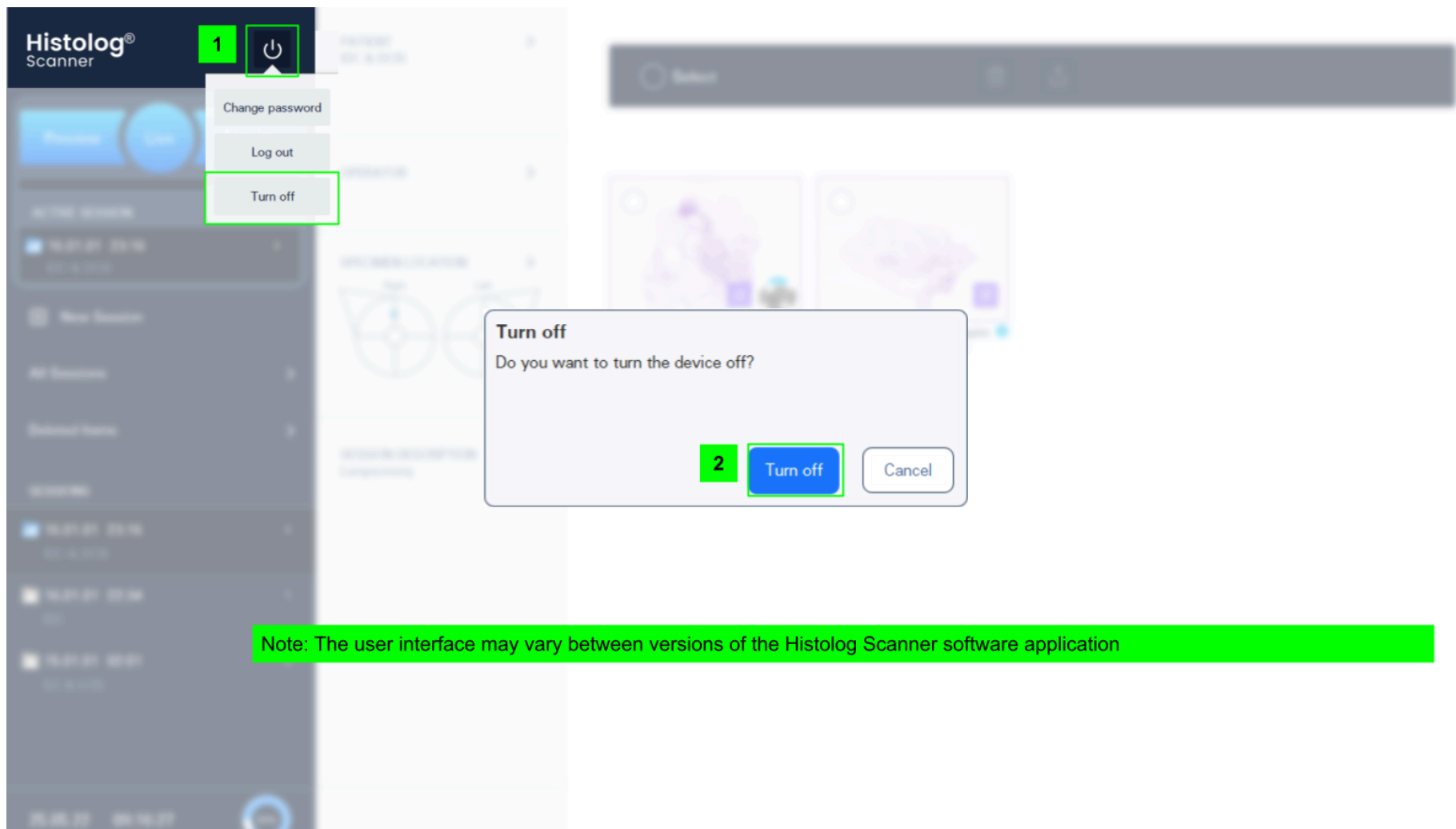


⚠ CAUTION

- 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]. If the Histolog[®] Scanner is connected to a network socket using an ethernet cable, unplug the ethernet cable from the ethernet port [E].
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

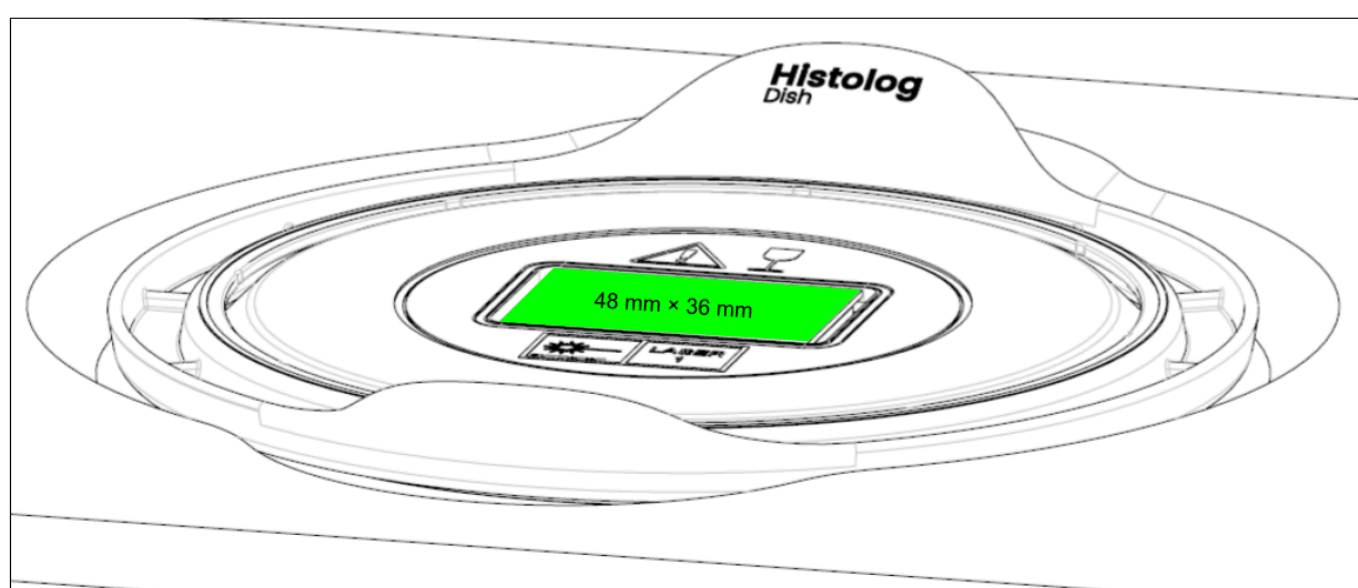
- If the information about the tissue specimen orientation is critical, the tissue specimen should be marked for orientation before starting the imaging procedure with the Histolog[®] Scanner.
- Do not apply tissue marking dyes on the tissue specimen before imaging it with the Histolog[®] Scanner. Tissue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

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 - Didecyltrimethylammonium 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.

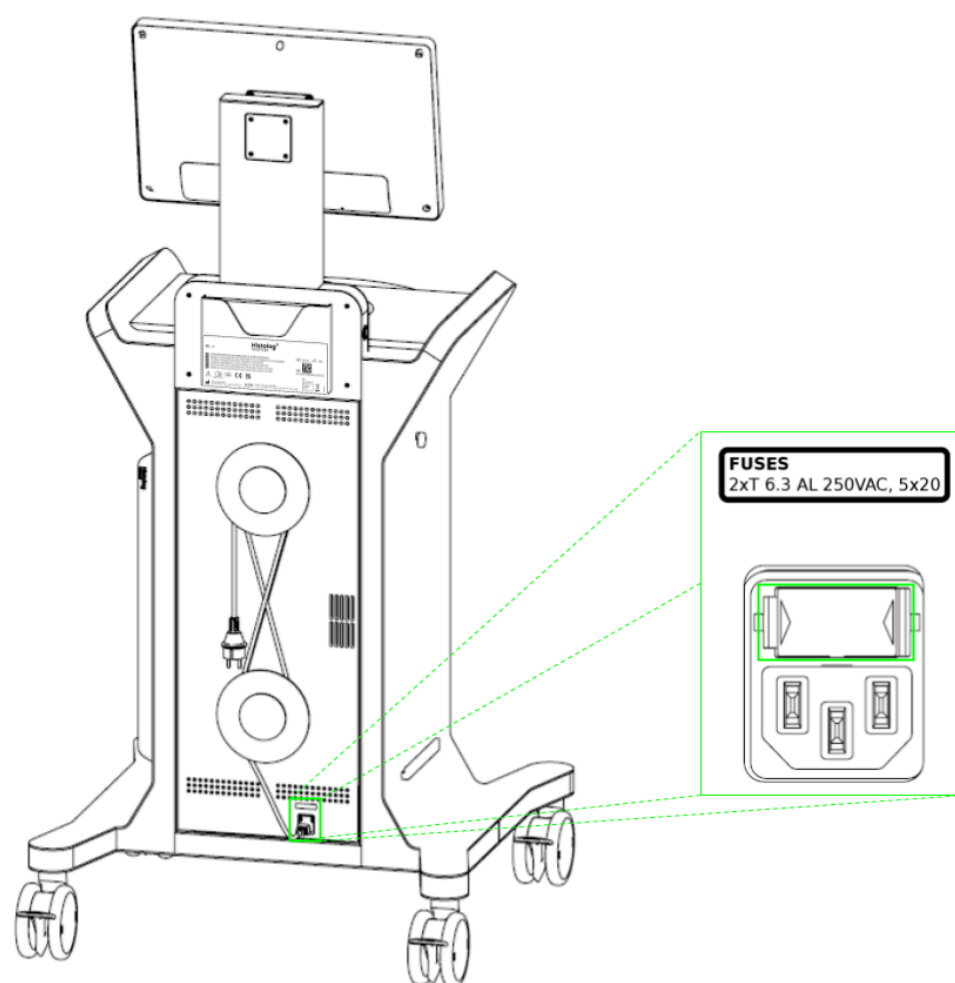
12.1. Software updates

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

Security updates, such as those from the operating system, may be installed by the device administrator, in accordance with the Histolog[®] Scanner OS Service Manual. For connected devices, SamanTree Medical recommends installing such security updates on a periodic basis.

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

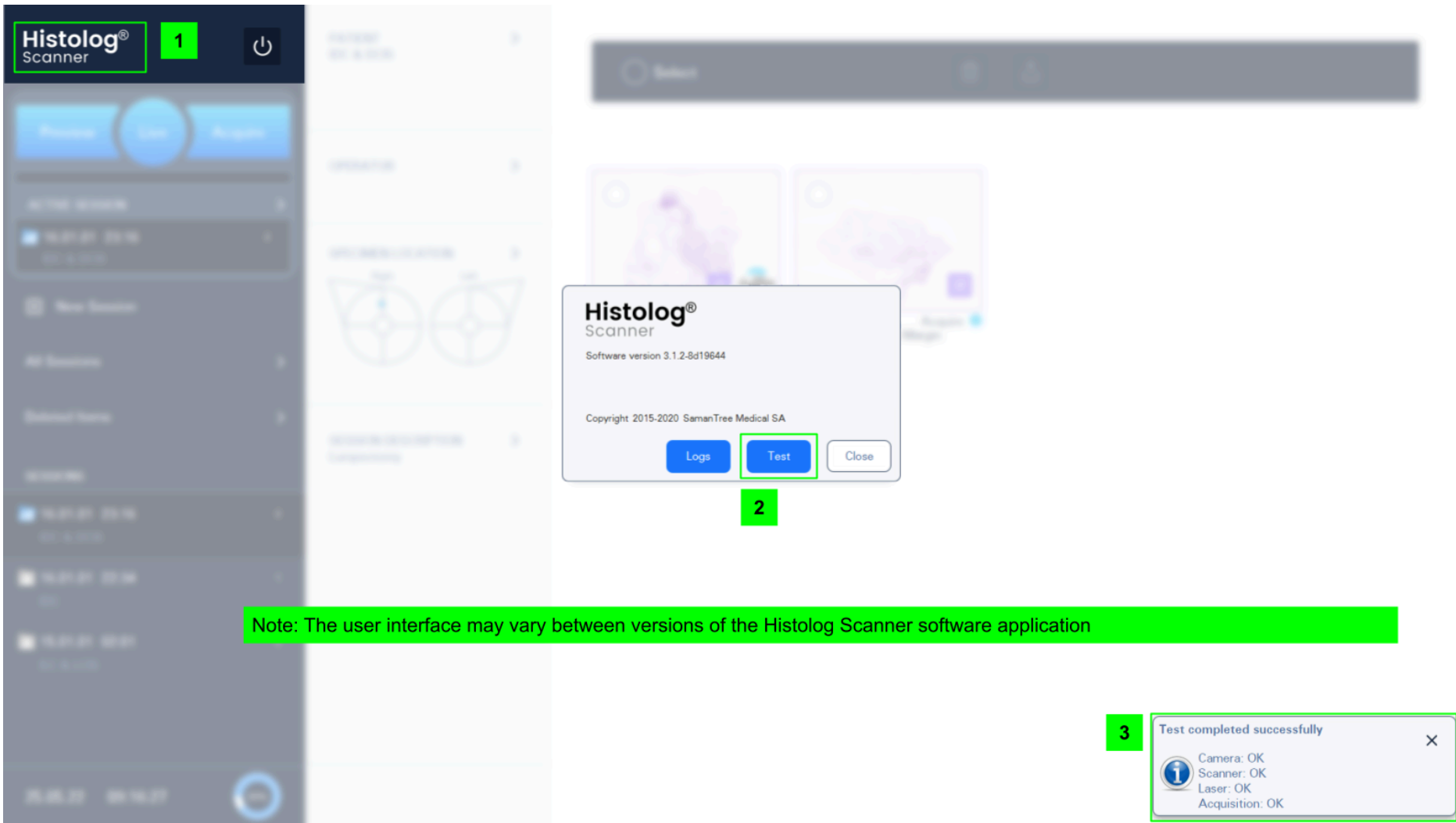
Dispose of the Histolog[®] Dip in accordance with the information contained in its instructions for use.

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. 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. Press and hold the "Touch Disabled" button for 3 seconds to disable the touch function. Clean the front surface of the touchscreen monitor [A] and let it dry completely. 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), 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).
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. If the issue 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).
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), 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).
Device cannot acquire images	Disk is full	Permanently delete images from the Gallery (as per Histolog [®] Scanner Software Application instructions for use) Relaunch the acquisition.
	Device has entered in an unreactive state	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).

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]. Reconnect USB storage device in USB port [D]. If the issue 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)
	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. 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. Remove the Histolog [®] Dish from the Histolog [®] Scanner. 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. 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.

Logs contain technical information for troubleshooting and may be requested by SamanTree Medical authorized service personnel within the frame of technical support. Logs 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)].

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.

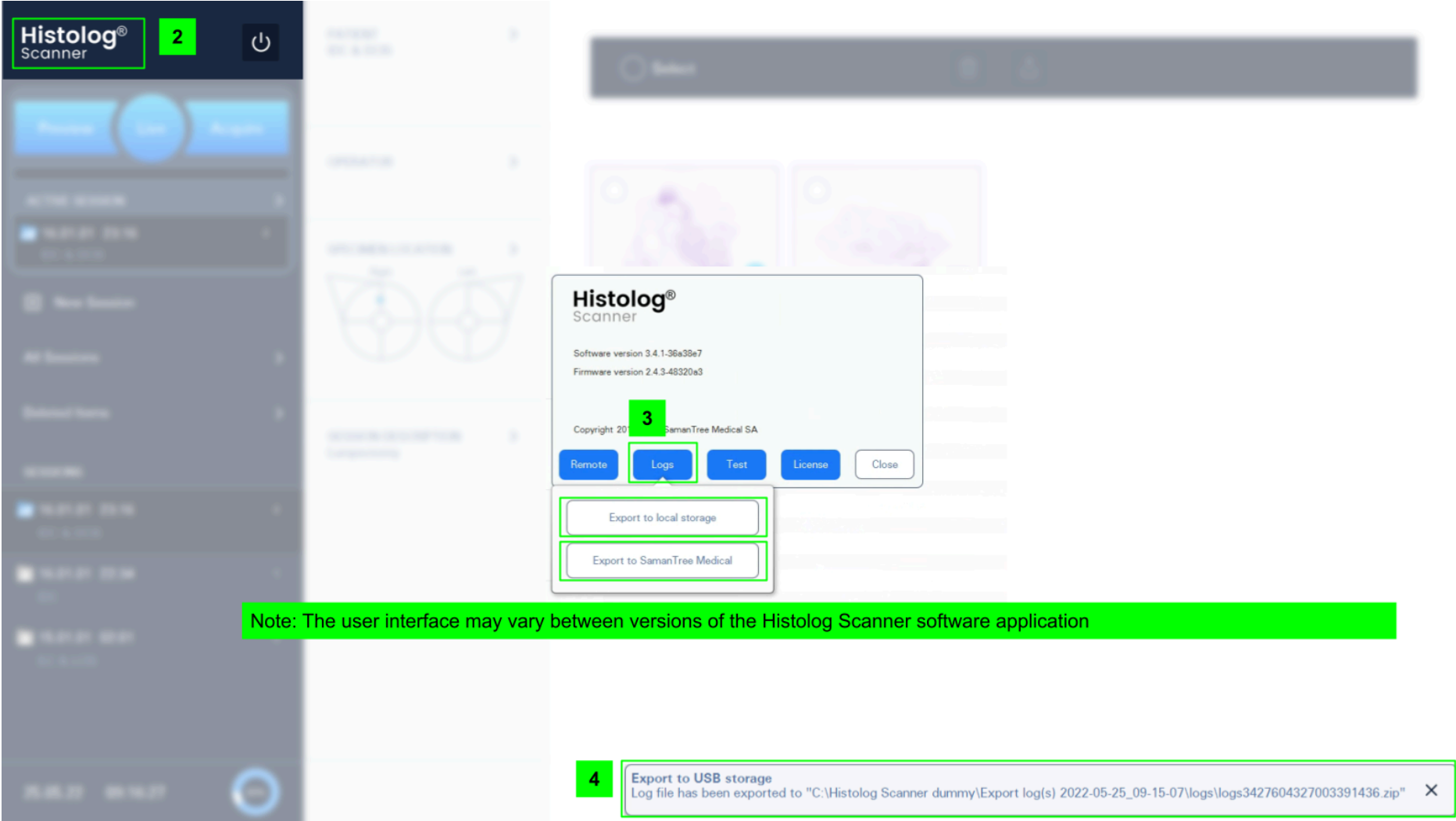
2. Tap the Histolog® Scanner button in the upper left corner of the user interface.
3. Tap the “Logs” button in the message window and then tap the “Export to local storage” button to export the logs.
4. A message window to the bottom right corner of the screen indicates that the logs have been successfully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



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 (T 6.3A L 250VAC, 5x20mm, slow-blow, low breaking capacity)
PN446	Power Cord – Swiss plug
PN458	Power Cord – Euro plug
PN482	Power Cord – United Kingdom plug
PN460	Power Cord – North America plug

Documentation

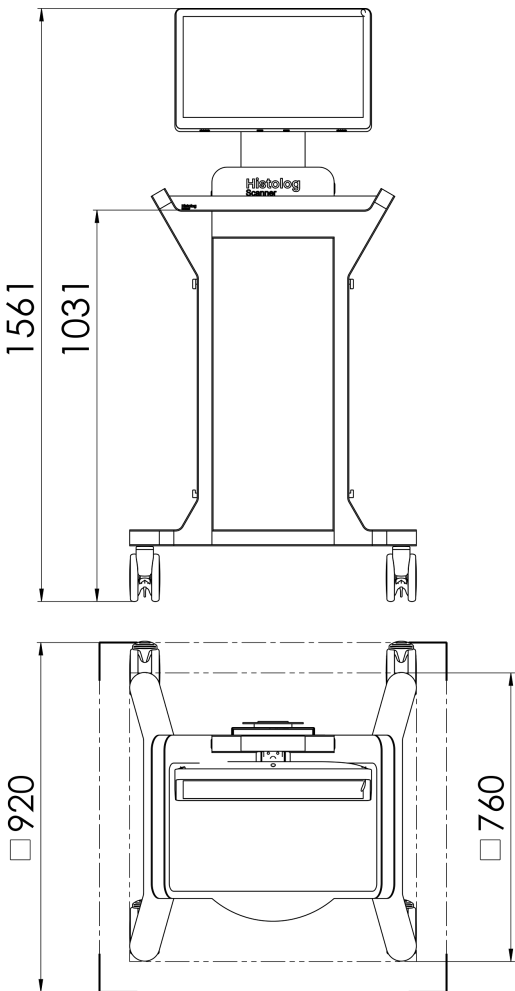
Document #	Description
1223	Histolog® Scanner and Histolog® Dish – instructions for use
1423	Histolog® Dip – instructions for use
1823	Histolog® Scanner OS Service Manual
2023	Histolog® Scanner Software Application – instructions for use

 **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

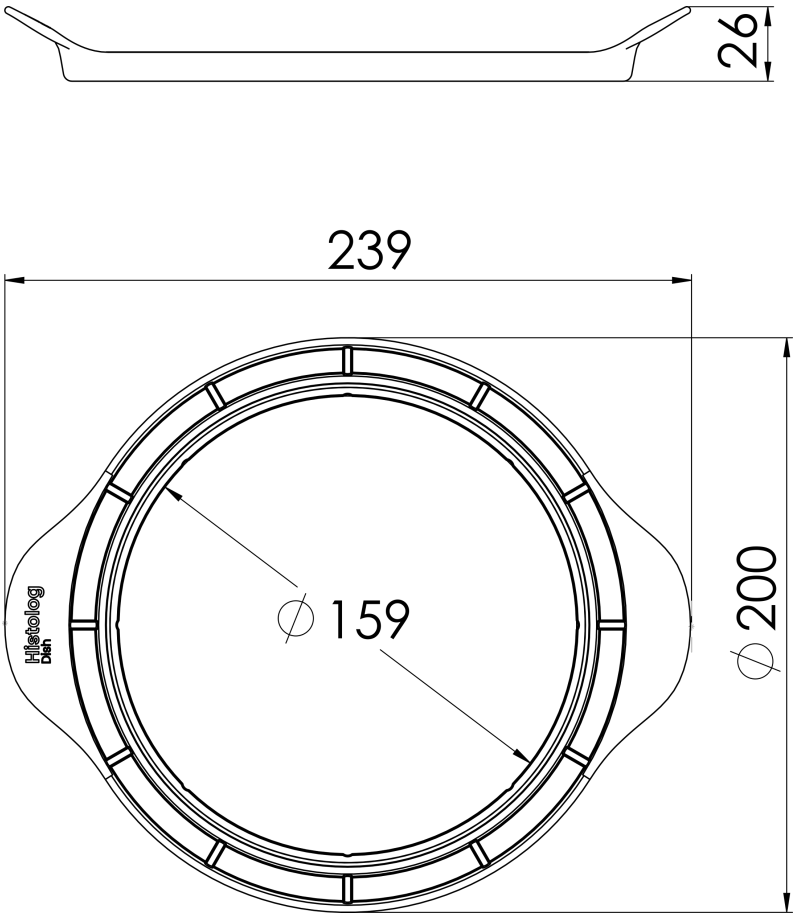
16.1.1. Histolog[®] Scanner



HISTOLOG [®] SCANNER	
Dimensions (W x D x H)	0.76 m x 0.76 m x 1.56 m
Weight	95 kg
Electrical Power Input	100–240 VAC, 50/60 Hz
Maximum Rated Power	305 W
Power Cord Length	5 m
USB port standard	3.0
Ethernet port connector	RJ45
Fuse type	T 6.3A L 250VAC, 5x20mm, slow-blow, low breaking capacity
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 approx. 1 minute for images at resolution of 2 µm per pixel
Operating Conditions	
Area of application	Indoor use only
Pollution degree	2 (as per IEC 61010-1)
Temperature	15–35 °C
Humidity	30–80 % (non-condensing)
Pressure	80–106 kPa
Transport Conditions	
Temperature	0–60 °C
Humidity	10–80 % (non-condensing)
Pressure	70–106 kPa
Storage Conditions	
Temperature	0–60 °C
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
Inner Dimension (Ø)	159 mm
Weight	54 g
Storage temperature conditions	15°C-30°C

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.			
Immunity test	IEC 61326-2-6 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±4 kV contact ±2, ±4, ±8 kV air	±4 kV contact ±2, ±4, ±8 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	±1 kV for power supply lines ±0.5 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV line-to-line (mains cable) ±1 kV line-to-ground (mains cable) ±1 kV common mode † (ethernet port)	±1 kV differential mode ±2 kV common mode ±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 (100% dip in UT) for 1 cycle 0% UT (100% dip in UT) for 0.5 cycle 70% UT (30% dip in UT) for 0.5 s 0% UT (100% dip in UT) for 5 s	0% UT (100% dip in UT) for 1 cycle 0% UT (100% dip in UT) for 0.5 cycle 70% UT (30% dip in UT) for 0.5 s 0% UT (100% dip in UT) For 5 s	Mains power quality should be that of a typical commercial or hospital environment. 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	3 A/m ‡	Complies (does not contain any components susceptible to magnetic fields)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial and/or hospital environment.
† Histolog Scanner devices with a manufacturing date of 2022 or before were not tested for these requirements, since this was not required by the version of IEC 61326-2-6 applicable at that time. ‡ Histolog Scanner devices with a manufacturing date of 2022 or before were not tested for this requirement, since this was not required by the version of IEC 61326-2-6 applicable at that time for devices that did not contain potentially magnetically sensitive equipment. 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 61326-2-6 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	–
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 6 GHz †	3 V/m 80 MHz to 6 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. Minimum separation distance $d = 6 / E \cdot \sqrt{P}$ where <i>d</i> is the minimum separation distance in meters, <i>P</i> is the maximum power in watts, and <i>E</i> is the immunity test level in V/m. Interference may occur in the vicinity of equipment marked with the following symbol: 
† Histolog Scanner devices with a manufacturing date of 2021 or before were tested from 80 MHz to 2.7 GHz in accordance with the version of IEC 61326-2-6 applicable at that time. 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 $d=2 \cdot \sqrt{P}$
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 61326-2-6.

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)	