DYSIS
Smart Colposcopy

DYSIS Digital Colposcope Instructions for Use

DYSIS Smart Colposcopy

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1. General Information

Thank you for purchasing a DYSIS Digital Colposcope, manufactured by DYSIS Medical Ltd.

These Instructions for Use cover the following devices:

- DYSIS Ultra 2.0 Digital Colposcope (product code DYS403)
- DYSIS Ultra 3.0 Digital Colposcope (product code DYS404)
- DYSIS View Digital Colposcope (product code VIE001)

Please read this guide carefully before using your equipment. DYSIS has been designed to maximize safety and minimize strain for users and patients. However, precautions must be taken to further reduce risk of personal injury or damage to the device.

Be careful to follow the general precautions in this User Guide and note the cautions included. To maintain your DYSIS Digital Colposcope in good working condition, please follow the operation and maintenance procedures described herein.

Refer to the Declaration of Conformity (0250-83339) for a list of the compliance standards and guidelines for the DYSIS Digital Colposcope. DYSIS Medical operates a Quality Management System that has been certified for compliance with the requirements of ISO 13485:2016.

The CE mark on this product indicates it has been tested to and conforms to the provisions noted in the 2017/745 European Medical Device Regulation.

The UKCA mark on this product indicates it has been tested to and conforms to the provisions noted in UK MDR 2002 (The Medical Devices Regulations 2002).

CE 2797

UK CA 0086

USA Patent No 7749162
FDA 510(k) Clearance letter K092433

2. Intended Population

2.1. Intended Population (Users)

The DYSIS Digital Colposcope is a digital imaging system designed to assist clinicians in the *in vivo* evaluation, documentation and follow up of the lower genital tract. The DYSIS Digital Colposcope is intended to be used in hospitals and clinics by users thoroughly trained in the appropriate medical procedures. DYSIS intended operator education/minimum knowledge:

- A physician or a medical professional who is trained in, and qualified to perform, colposcopic procedures
- Language Understanding: English

Permissible Impairments: As applied in regular colposcopic practice.

DYSIS Medical provides training on the setup and use of the device.

2.2. Intended Population (Patients)

The DYSIS Digital Colposcope is intended to be used on patients undergoing a colposcopic examination in hospitals and clinics by healthcare providers who are trained in the relevant medical procedures. The medical conditions to be diagnosed include, but are not limited to, cervical and vaginal pathology and general pathology and conditions of the lower genital tract. Patient selection criteria are according to local practice and applicable guidelines for colposcopy.

3. Intended Purpose/Use and Clinical Benefits

3.1. Intended Purpose and Use

DYSIS is a digital colposcope intended to provide magnified viewing of the vagina, cervix and external genitalia. DYSIS is used to diagnose abnormalities and select areas for biopsy. DYSIS acquires, displays and documents high resolution still and sequentially captured images and videos and provides colour coded mapping of the aceto-whitening effect to facilitate and assist assessment and documentation. Reviewing the DYSISmap should never replace the thorough evaluation of the cervix by clinicians.
The DYSIS Digital Colposcope does not quantitatively measure a physiological or anatomical parameter and is not used to measure the quantity or a quantifiable characteristic of energy or of substances (including medicinal products) delivered to or removed from the human body and therefore there is no result of measurement to display.

3.2. Clinical Benefits

The DYSIS Digital Colposcope provides to the user the means to magnify and view the vagina, cervix and external genitalia. Green filter along with a proprietary high contrast filter can be used to assist in the visualization and identification of abnormal vasculature and other tissue morphology. Digital annotations can be added at any time during the exam to indicate and document biopsy locations. DYSIS acquires, displays and documents high resolution still and sequentially captured images and videos and provides a color-coded mapping of the aceto-whitening effect to facilitate and assist the clinician with assessment and documentation. The examination replay can be used to review the exam at a later date and educate patients about their anatomy and findings of the examination.

4. Indications and Contra-Indications for Use

4.1. Indications for Use

The DYSIS Digital Colposcope with Pseudo-Color Imaging (PCI) is a digital colposcope designed to image the cervix and lower genital tract under illumination and magnification. Colposcopy is indicated for women with an abnormal Pap smear in order to affirm normality or detect abnormal appearances consistent with neoplasia, often with directed biopsy.

The PCI feature is an adjunctive tool for displaying areas of acetowhitening on the cervix. It is a tool that should NOT be used as a substitute for a thorough colposcopic evaluation.

Please read the following operating and maintenance instructions thoroughly before using your new digital colposcope. Following these instructions can help ensure many years of reliable service.

IMPORTANT: The material outlined in this manual should be reviewed and understood prior to operation of the equipment.

IMPORTANT: The user of this equipment should be thoroughly trained in the medical procedures appropriate to the instrumentation. Furthermore, time should be taken to read and understand these instructions before performing any procedures. Instructions for other equipment used in conjunction with the DYSIS Digital Colposcope (e.g., electrosurgical equipment) should also be read and understood. Failure to do so may result in injury to the patient and/or damage to the DYSIS Digital Colposcope.

4.2. Contraindications and Side Effects

There are no specific contraindications for the use of the DYSIS Digital Colposcope on patients, other than any relative contraindications to a patient having a colposcopic procedure in general. These have to be evaluated and determined by the healthcare provider and may include the patient's ability to tolerate a standard speculum examination, conditions that may be best treated in advance such as acute cervicitis and severe vaginitis, anticoagulant use, or heavy bleeding. The potential side effects of a colposcopic examination are in general mild and mostly experienced during the procedure, and include discomfort, pain, bleeding and anxiety.

A risk assessment has been performed for the DYSIS Digital Colposcopes and all residual risks have been assessed and reduced to as low as practicably possible. No undesirable side effects from using the DYSIS or acetic acid (acetowhitening process) have been identified.

5. Use of the Pseudo-Color Imaging (PCI) feature (DYSISmap™)

When using the PCI feature, please ensure biopsies have adequate surface area to account for possible image registration error (movement of the cervix while the patient is undergoing examination) in the pseudo-color overlay map.

During the dynamic imaging procedure, which is used to generate a pseudo-color map, it is important to instruct the patient to remain as still as possible, otherwise the system will not be able to generate a map.

6. Summary of Warnings and Cautions

6.1. Serious Incidents

If a serious incident occurs whilst using a DYSIS Medical product, it should be reported to DYSIS Medical (contact details, section 25) and the relevant regulatory authority e.g., FDA for US, competent authority of the Member State (EU) in which the user and/or patient is established.

6.2. Electromagnetic Interference

The DYSIS Digital Colposcope should only be connected to a grounded hospital grade outlet.

The use of diathermy equipment or electrosurgical units with the DYSIS Digital Colposcope may cause electromagnetic interference, which is witnessed as an interruption to the video stream or monitor. Using a galvanic isolation transformer between the main power supply and the DYSIS Digital Colposcope can successfully prevent the interference. However, if the interference continues in spite of the use of the transformer, it is recommended to use another colposcope for treatments.

Portable RF communications equipment, including antennas, can affect medical electrical equipment and should be used no closer than 30 cm to any part of the DYSIS Digital Colposcope. This includes cables specified by DYSIS Medical.

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.

6.3. Warnings and Cautions

	When using this system, always conduct a thorough colposcopy examination, identifying and selecting areas for biopsy, before using the PCI feature to (possibly) select additional biopsy sites. The DYSIS Digital Colposcope with PCI has not been shown to identify areas of neoplasia. Therefore, never use this system to omit a biopsy selected on the basis of the conventional colposcopy examination.
	Users of this equipment should be thoroughly trained in the appropriate medical procedures and must read this guide carefully before operating this device. Failure to do so may result in injury to the patient and/or damage to the device.

No modification of this equipment is allowed.

Do not use the DYSIS Digital Colposcope if it appears to be damaged or broken.

The power cable must always be positioned to minimize risk for tripping.

Do NOT position the device in a way that makes it difficult to disconnect the device from the main power supply. The power switch at the back of the device should always be kept easily accessible so that the power can be switched off.

Do not tilt, push, pull, or move the DYSIS Digital Colposcope in ways other than that described in this manual for its proper/optimal and safe use. The unit should be held at the top of the pole when it is being transported and should never be moved using the cables or imaging head as a handle. The unit should always be in the transport position and held/controlled while it is being moved.

Stepping and sitting on the device is prohibited.
Before using the DYSIS Digital Colposcope, make sure it is in optimal condition for use.

Do not spill any liquids on the device.

Use only cabling supplied or approved by DYSIS Medical. Using non-standard cables may result in user and/or patient hazard and/or device failure.

Prior to moving the DYSIS Ultra 2.0 and 3.0 Digital Colposcope, please ensure the touchscreen is secured and the arm(s) in a folded position.

There should be ample monitor cable length to allow for movement of the DYSIS View or disconnect the touchscreen monitor cable prior to moving DYSIS View.

Use your feet to release and engage the brakes.

Before moving the DYSIS Digital Colposcope, make sure that the braking system has been released and the wheels can move freely.

Always engage the braking system prior to starting an examination.

The DYSIS Digital Colposcope should be positioned on a flat surface and all brakes engaged to prevent movement and toppling.

Examine the functionality of the arm prior to examining a patient and ALWAYS before proceeding to connect a DYSIS speculum.

Connect only components that are specified in this guide as part of the DYSIS Digital Colposcope or that have been specified as being compatible with the devices.

To avoid the risk of electric shock, the DYSIS Digital Colposcope should only be connected to a power supply with protective grounding.

Never attach the DYSIS speculum to the imaging head before inserting it into the vagina.

Do not apply any force on top of the imaging head during an examination or at any other time (especially if a DYSIS speculum is connected).

Do not apply any force to the speculum connector of the imaging head. The speculum connector should never be used as a handle to move the device.

Sequence of actions to power up the device:

1. Connect the main power cable to the appropriate outlet.
2. Press the green power button.
3. The computing unit will power up and the software application will start.

Sequence of actions to power down the device:

1. Press the SHUT DOWN button (using the touchscreen) from the left panel. The colposcope will shut down automatically.
2. To avoid power consumption when idle, turn the green power button to the OFF position on the base after the unit has completely shut down.

The DYSIS Digital Colposcope calibration card should be maintained so it is clean and in good condition.

Ensure any external data storage media has been checked for malware (viruses, trojans, etc.) before connecting to the DYSIS Ultra 2.0 or Ultra 3.0 Digital Colposcope.

Do not spray solutions or liquids into air vents.

Do not immerse any part of the device in cleaning solutions and do not sterilize any part of the device.

If the device is accidentally contaminated during an exam, use the indicated disinfecting solution to clean based upon the contamination. Before disinfecting, the device needs to be powered down and the power cables should be disconnected.

Wear the proper Personal Protective Equipment (PPE) when disinfecting any part of the device.

 (This Caution Symbol Applies to the Safety Cautions Below)

Do not stare directly at the light source in the imaging head unit.

Using the handle of the imaging head to transport the device may result in a loss of device performance and stability and could cause injury to the user/patient.

To ensure optimal operation and safety, users should not remove any of the connectors on the colposcope.

The DYSISmap™ is not meant to replace conventional colposcopic assessment and decisions regarding biopsy treatment or diagnosis. The assessment of acetowhitening should be based on visual inspection of the entire set of the acetowhitening characteristics. The DYSISmap reflects a subset of them.

When using different concentrations of acetic acid, the acetowhitening characteristics may change and consequently the corresponding color coding of the DYSISmap to certain degrees of acetowhitening.

When adjusting the image brightness, the user should view the monitor directly and not from the side or from below, as this may distort the perception of the color and brightness.

DYSIS Ultra 2.0 Digital Colposcope: Before a DYSISmap measurement, check for a sufficient volume of acetic acid solution in the container. The acetic acid container holds 30cc of acetic acid and the software provides a prompt to the user to check its level after it has detected 15 spray cycles.

DYSIS View and Ultra 3.0 Digital Colposcope: Before a DYSISmap measurement, the syringe should be filled with 1.5cc of acetic acid and connected to the system.

While the DYSISmap measurement is in progress, do not obscure the light beam or the camera; patient movements should be minimized.

The user annotations are digital marks overlaid on the displayed image and do not follow the movements of the cervix. Therefore, the annotations should be used with caution if the cervix moves after marking.

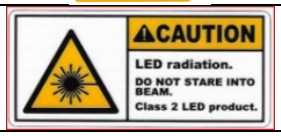
Unregistered users are restricted from accessing the database on the DYSIS digital Colposcope.

The “Required” fields in the “New Patient” form are mandatory. The patient data is saved only upon pressing **SAVE**.

DYSIS Ultra 2.0 Digital Colposcope: USB disks used for exporting data (images/report) should be formatted to the **exFAT** file format.

In addition to the device label, the following warning labels are found on DYSIS Digital Colposcopes or within this document:

	The disposable speculum is a Type-B applied part that provides protection against electric shock.
	The attachable speculum, if reusable, is a Type-BF applied part that provides protection against electric shock.
	CONSULT: Refer to instruction manual/booklet. NOTE: This symbol is used to signify the instruction manual/booklet must be read.
	General warning sign.
	Hand crush warning. (DYSIS Ultra 2.0 and Ultra 3.0 Digital Colposcope)
	Do not push (DYSIS Ultra 2.0 and Ultra3.0 Digital Colposcope)
	Do not step on the DYSIS Digital Colposcope.
	Do not sit on the Ultra 2.0 or Ultra 3.0 Digital Colposcope.

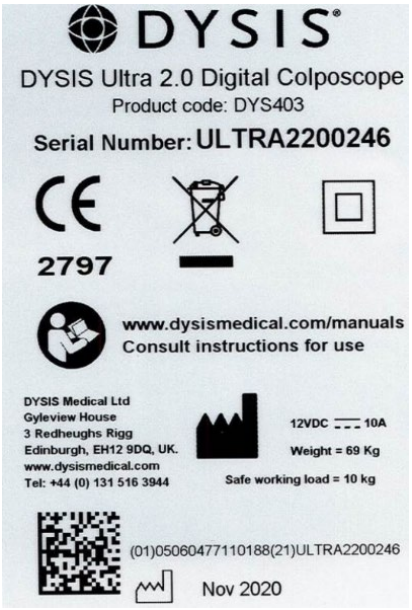
	LED emission.
	Class 2 LED product warning.

7. Location of Product Labels

7.1. DYSIS Ultra 2.0 Digital Colposcope

The product label (containing the device name, serial number, DYSIS Ultra 2.0 Digital Colposcope legal manufacturer address and Unique Device Identifier Barcode) and the warning labels are located on the back of the PC enclosure (Fig 1).

Product and warning labels are included on each device as shown in Fig 1a and b:



a) DYSIS ULTRA 2.0 product label located on the back of the device

b) DYSIS ULTRA 2.0 warning label located on the back of the device

Fig 1 (a and b): Images of product and warning labels applied to Ultra 2.0 devices.

7.2. DYSIS Ultra 3.0 Digital Colposcope

The product label (containing the device name, serial number, DYSIS Ultra 3.0 Digital Colposcope legal manufacturer address and Unique Device Identifier Barcode) and the warning labels are located on the back of the PC enclosure as shown below:

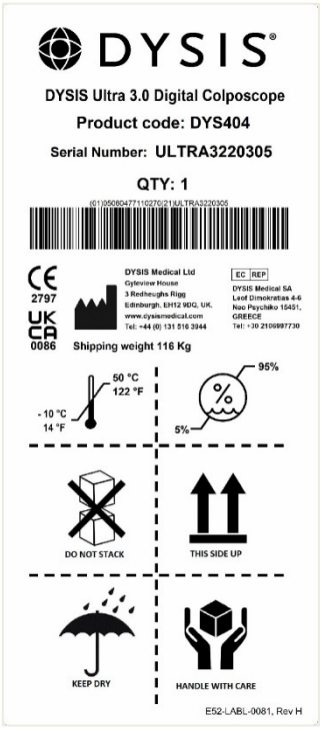
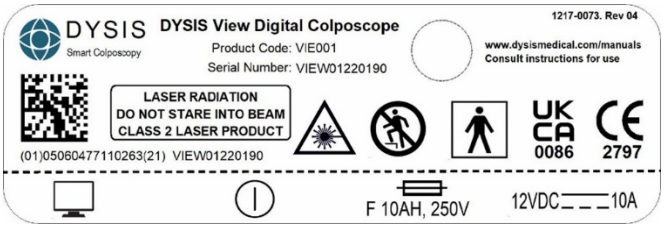


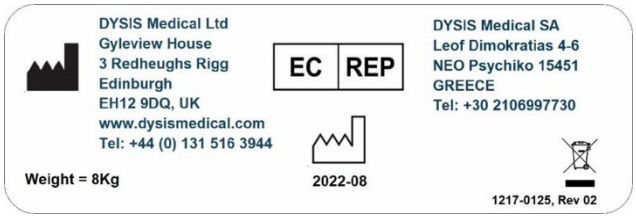
Fig 2 (a and b): Images of product and warning labels applied to DYSIS Ultra 3.0 devices.

7.3. DYSIS View

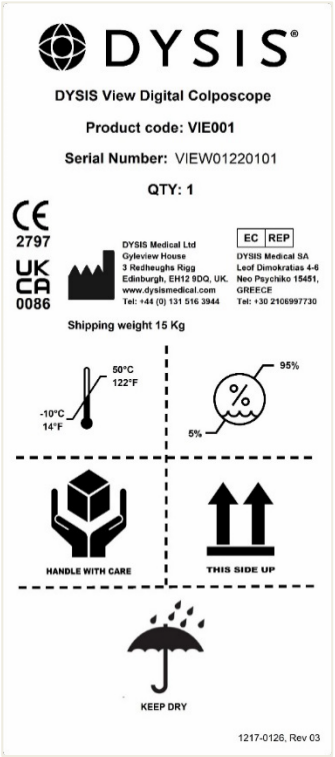
The product label (containing the device name, serial number, DYSIS View Digital Colposcope and Unique Device Identifier Barcode) is located on the side of the device base. The contact information label is located under the base (Fig 3).



a) DYSIS View product label located on the base of the device



b) DYSIS View contact information located under the base of the device



c) DYSIS View shipping label

Fig 3 (a, b and c): Images of product, contact information and shipping labels applied to DYSIS View devices.

8. Classifications

The following table summarizes the classification of the devices according to various regulatory standards:

Regulation / Standard	Details
Medical Device Regulation (2017/745)	Class IIa
FDA Classification (CFR Title 21)	Class II
IP Rating (IEC 60529)	00
Software Classification (IEC 62304)	Class A
LED Risk Group Rating (IEC 62471) photobiological safety)	Class II – do not stare directly at the beam
DYSIS Reusable Speculum (IEC 60601-1)	Type BF applied part
DYSIS Disposable Speculum (IEC 60601-1)	Type B applied part
Power Supply (class as per 60601-1)	Class II

9. Environmental Conditions

9.1. Storage

The DYSIS Digital Colposcopes should only be stored in environments where temperature ranges between 0°C and 50°C (32°F to 122°F) and humidity up to 95% (non-condensing).

9.2. Usage

The DYSIS Digital Colposcope should only be operated in environments where temperature ranges between 10°C and 40°C (50°F to 104°F) and humidity up to 90% (non-condensing).

9.3. Transportation

During shipping, the DYSIS Digital Colposcopes shall withstand a temperature range of -10°C to 50°C (14°F to 122°F) and humidity range of 5% to 95% (non- condensing).

9.4. Atmospheric Pressure

There is no impact from atmospheric pressure on the DYSIS Digital Colposcope and it does not require any gases to function.

10. Usage Restrictions

The DYSIS Digital Colposcopes are not meant to be used in any way other than the intended use stated by the manufacturer. Any effect on basic safety, reliability and performance of DYSIS Colposcopes is the manufacturer's responsibility only if:

- Appropriately trained DYSIS Medical personnel carry out assembly/test operations, extensions, readjustments, modifications or repairs;
- The electrical installation of the room complies with the electrical requirements of the hospital and the DYSIS Digital Colposcope is used in accordance with the instructions for use.

Users must read the instructions in this guide carefully before operating the device.

The colposcope must not be used if it appears to be damaged or broken.

There are no user replaceable parts on the device other than the DYSIS Acetic acid applicator and the fuses; the DYSIS Acetic acid applicator is recommended to be replaced every 30 days.

Apart from the speculum, the DYSIS Digital Colposcope is not intended to come into contact with the patient.

Users and Patients should not stare directly into the illumination source when the DYSIS Digital Colposcope is ON.

Air vents must be kept unobstructed.

11. Installation and Configuration of the DYSIS Colposcope

The DYSIS colposcopes should be installed by trained personnel using the following documents:

- 0231-85058 DYSIS Ultra 2.0 Installation Checklist
- 0231-84079 DYSIS View and Ultra 3.0 Installation checklist

For further configuration, such as connecting to a network, installing printers etc, please refer to:

- 0230-53138 DYSIS Ultra 2.0 Digital Colposcope Administrator Guide
- 0230-53163 DYSIS View and Ultra 3.0 Digital Colposcope Administrator Guide

12. DYSIS Ultra 2.0 and 3.0 Digital Colposcope System and Components

The components of the DYSIS Ultra 2.0 and 3.0 colposcope are shown in Fig 4 and Fig 5 and are described in the following section.

snip

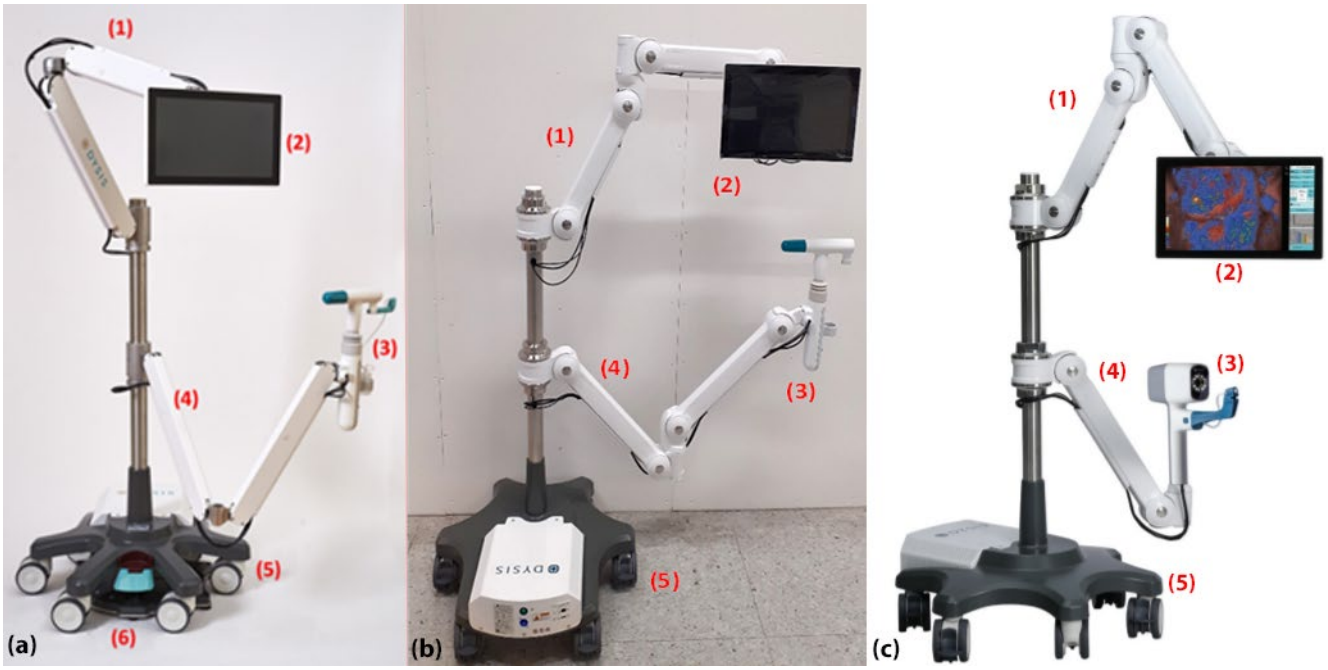


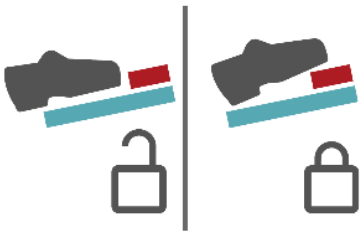
Fig 4: DYSIS Ultra 2.0 (a), (b) and DYSIS Ultra 3.0 (c) components: (1) Display Arm; (2) Clinician Monitor; (3) Imaging Head; (4) Optical Arm; (5) Base (including enclosure); (6) Foot Pedal/Brake (Ultra 2.0 only). Image (b) illustrates the Ultra 2.0 with the latest ARMS and BASE.

Fig 5: DYSIS Ultra 2.0 components: (1) Imaging Head; (2) Base and PC enclosure; (3) Disposable Speculum and speculum connector

13. DYSIS Ultra 3.0 and Ultra 2.0 Digital Colposcope System and Components

13.1. Base/Moving the Instrument

The braking system on the base is either a foot pedal which is used to engage / disengage the brake or wheels with independent braking mechanisms.
To move a DYSIS Ultra 2.0 device that has the foot pedal brake, this should be disengaged by pushing down the green pedal with your foot (Fig 6a). When in a suitable position, the red switch on the pedal should be pressed to engage the brake. Do not use your hands to engage the brake. For devices with independent wheel brakes, these should be engaged prior to using the device and disengaged for moving the colposcope (Fig 6b).



a) DYSIS Ultra 2.0 foot pedal label located on top of the base.

b) Individual Wheel brakes (DYSIS Ultra 2.0 and Ultra 3.0)

Fig 6: Braking mechanisms for the DYSIS Ultra 2.0 and 3.0

When moving the Colposcope, the user should release the brake and push the metal pole. Do not push the DYSIS Ultra 2.0 or Ultra 3.0 Digital Colposcope using the arms, imaging head or monitor. Care should be taken to protect exposed parts when maneuvering.

13.2. Display and Optical Arms

To place the DYSIS Ultra 2.0 or Ultra 3.0 Digital Colposcope in the most suitable position for use, the two arms (Fig 4) can be easily adjusted. It requires minimal effort for repositioning, and it is not required that it is locked in position.

When opening the arms, support must be given to the imaging head until the lower arm is in a “V” position where it will counterbalance. Failure to do this can result in the imaging head “dropping” a little, which could result in damage if it is close to other objects.

13.3. Clinician Monitor

The clinician monitor is a touchscreen monitor. It is used during the colposcopic examination to perform the procedure.

13.4. Imaging Head

DYSIS Ultra 2.0: The imaging head (Fig 5.1) consists of a camera with LED lighting and the DYSIS acetic acid applicator system. The DYSIS speculum is also attached to the imaging head using the speculum connector (Fig 5.3).

DYSIS Ultra 3.0: The imaging head consists of a camera with LED lighting and a DYSIS acetic acid platform system. The DYSIS speculum is also attached to the imaging head using the speculum connector – refer to Fig 16.

13.5. Camera and Light

The camera in the imaging head contains LEDs which provide illumination during the colposcopic examination.

This product meets the power requirements for a Class 2 LED product to IEC/EN 62471 under normal operating conditions and those of single fault failure.

The camera and the LEDs are automatically turned on when the DYSIS Ultra 2.0 and Ultra 3.0 Digital Colposcope is in examination mode.

13.6. Acetic Acid Applicator

13.6.1. DYSIS Ultra 2.0

The DYSIS Ultra 2.0 acetic acid applicator is comprised of a proprietary 1.5cc luer lock syringe, a fluid reservoir, tubing and a speculum connector with a diffusor. A spraying system is integrated into the imaging head (Fig 5) which is used for the application of acetic acid application and is controlled by software. The DYSIS acetic acid applicator kit (Fig 7) is filled by removing the bottle from its holder, unscrewing the lid and filling just below the shoulder level. Screw the base back into the lid and replace in its holder. Place a paper towel in front of the diffuser. Press the **PURGE** button from the MENU button on the HOME screen repeatedly until the acetic acid is sprayed from the spray nozzle, the syringe is fully filled and the air has been expelled from the tubing.

Fig 7: DYSIS Ultra 2.0 Acetic Acid kit

Please see Section 23.11 for instructions on how to replace the DYSIS Ultra 2.0 acetic acid applicator. A warning message will be displayed every 30 days prompting the DYSIS acetic acid applicator to be replaced. A warning message will also be displayed after 15 examinations, prompting the user to check the acetic acid level in the reservoir.

13.6.2. DYSIS Ultra 3.0 Acetic Acid applicator

Refer to DYSIS View (section 14.8).

13.7. Speculum Connector (coupling adapter)

The DYSIS speculum is attached to the imaging head (Fig 5.3) (Ultra 2.0 speculum connector pictured) following insertion to the connector that also houses the acetic acid diffuser. The speculum connector is considered a part of the DYSIS acetic acid applicator kit. The green coupling adapter (DYSIS Ultra 2.0) should be inserted into the optical head as shown in Fig 8 (CORRECT insertion) and not upside down as shown in Fig 9 (INCORRECT insertion).

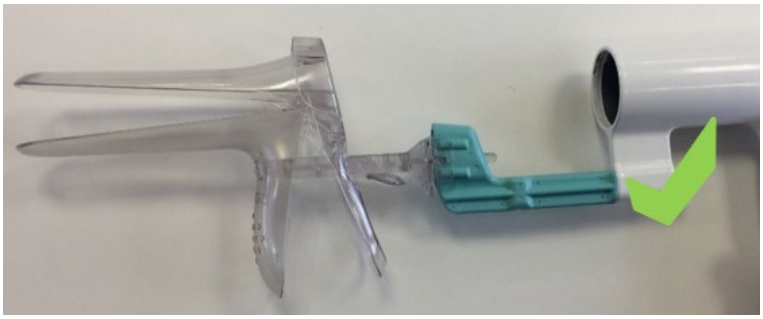


Fig 8: CORRECT insertion of the coupling adapter

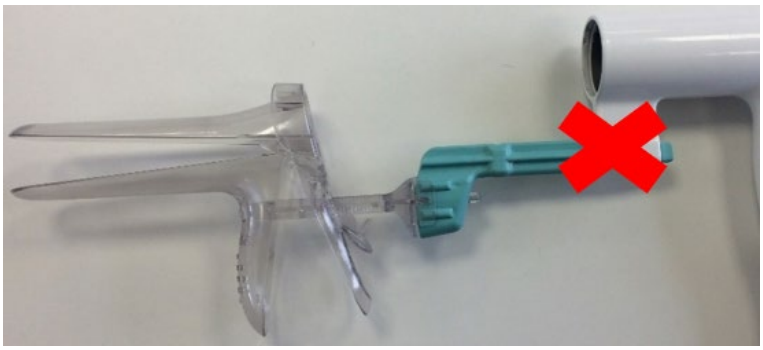


Fig 9: INCORRECT insertion of the coupling adapter

To release and remove the speculum from the connector (Fig: 10), hold the back of the speculum with one hand to stabilize it and place the thumb of your other hand on the back of the speculum connector (under the tubing); then, gently push the rear tip of the speculum from the insertion point.

Note – the disposable speculum is shown in the image below but removal of the reusable speculum follows exactly the same principle.

For the DYSIS Ultra 3.0 speculum connector (blue coupling adapter), refer to DYSIS View (section 14.8.1).

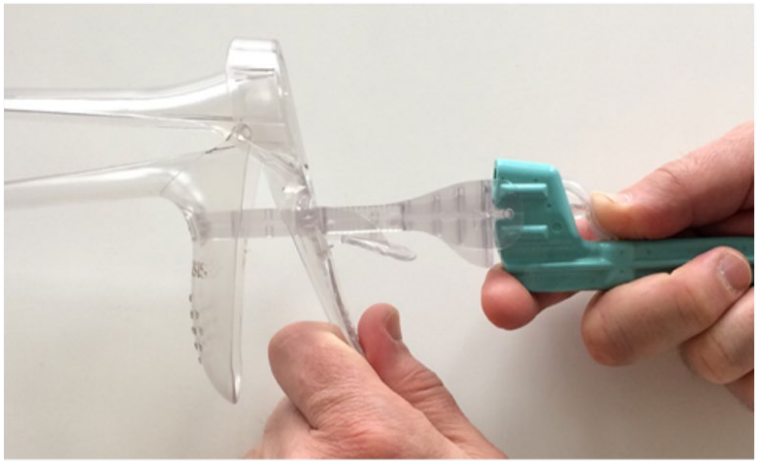


Fig: 10 Speculum removal

13.8. Power Cord and Power On/Off (including shutdown)

The DYSIS Ultra 2.0 and Ultra 3.0 Digital Colposcope should only be used with the supplied AC/DC power supply unit.

Device shutdown - the device should be isolated from the main power supply by switching the unit off.
To remove the power cord after DYSIS Ultra 2.0 or Ultra 3.0 Digital Colposcope is shut down, pull back on the yellow or silver tab, rotate 45 degrees to the left until the notches are lined up and then pull out.

13.9. Assembling and Inserting the Power Cord

Insert the end of the power cord into the power brick. To insert the power cord into the central processing unit (CPU), line up the notches and insert. Rotate the cord 45 degrees to the right until it locks into place (Fig 11). There will be an audible click as the silver / yellow tab moves into the locked position. It will be locked into the device.

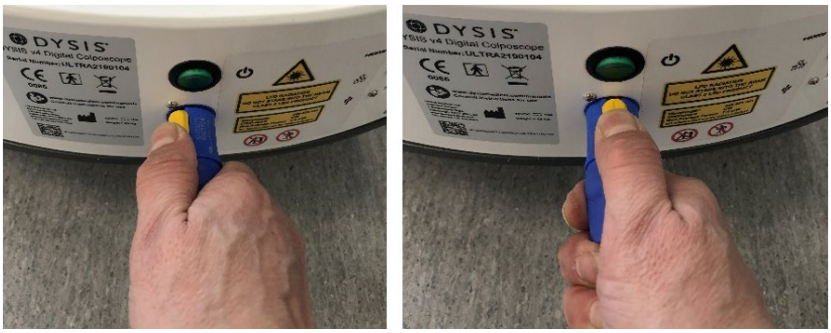


Fig 11: Inserting the power cord

13.10. Power On and Off

To power on the DYSIS Ultra 2.0 and Ultra 3.0 Digital Colposcope, ensure it is plugged into a power supply and that the power supply is connected to a suitable outlet. Press the green power button on the base (found above the power plug inlet as shown in Fig 12). The DYSIS software will launch automatically when powered on and the on/off button will illuminate green.

DO NOT TOUCH THE BUTTONS ON THE BACK OF THE MONITOR. FAILURE TO FOLLOW THESE RECOMMENDATIONS CAN RESULT IN MONITOR MALFUNCTION.

Fig 12: Green power button on base.

To turn off the DYSIS Ultra 2.0 and Ultra 3.0 Digital Colposcope, press SHUTDOWN from the left panel of the HOME screen or from the LOGIN screen and wait for the DYSIS Ultra 2.0 Digital Colposcope to shut down.

DO NOT SWITCH THE DYSIS Ultra 2.0 and Ultra 3.0 Digital Colposcope OFF BY UNPLUGGING THE POWER CORD OR BY TURNING OFF THE POWER SWITCH UNTIL IT HAS FULLY SHUTDOWN FROM THE TOUCHSCREEN. FAILURE TO FOLLOW THESE RECOMMENDATIONS CAN RESULT IN DATA LOSS.

14. DYSIS View System and Components

The components making up the DYSIS View colposcope are shown in Fig 13 & Fig 14 and are described in the sections below.

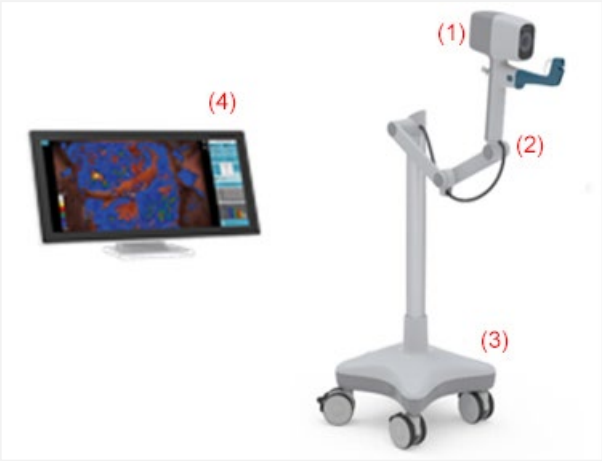


Fig 13: DYSIS View: (1) Imaging Head; (2) Arm; (3) Base (including PC and wheels with brakes); and (4) Clinician Touchscreen Monitor with stand

Fig 14: DYSIS View components: (1) Imaging Head with speculum connector; (2) Base and PC enclosure; (3) Wheels with brakes

14.1. Base / Moving the Instrument

The braking system on the base consists of four wheels with independent braking mechanisms. All foot brakes should be engaged prior to performing an examination and should be disengaged prior to moving the device.

14.2. Optical Arm

To place the DYSIS View in the most suitable position for use, the arm (Fig 13.2) can be easily adjusted. The arm requires minimal effort for repositioning and it is not required to be locked in position.

When opening the arm, support must be given to the imaging head. Failure to do this can result in the imaging head ‘dropping’ a little, which could result in damage if it is close to other objects.

14.3. Clinician Monitor

The clinician monitor is a touchscreen monitor. It is used during the colposcopic examination to perform the procedure.

14.4. Imaging Head

The imaging head consists of a camera with LED lighting and DYSIS acetic acid platform applicator. The speculum is also attached to the imaging head using the speculum connector – refer to Fig 5 and Fig 14.

14.5. Camera and Light

The camera in the imaging head contains LEDs which provide illumination during the colposcopic examination and execution of the DYSISmap.

This product meets the power requirements for a Class 2 LED product to IEC/EN 62471 under normal operating conditions and those of single fault failure.

The camera and the LEDs are automatically turned on when the DYSIS View Colposcope is in examination mode.

14.6. Assembling and Inserting the Power Cord and connecting the Monitor cable

Insert the end of the power cord into the power supply unit (PSU) or power brick (Fig 15). The power cord should be pushed straight into the back of the DYSIS View base. The monitor cable should be inserted into the port by aligning the ridge on the connector with the slot on the monitor cable port. When fully inserted, the monitor cable should be screwed into the port.

Fig 15: DYSIS View monitor cable, power On/Off button, fuse and power cord.

14.7. Power On and Off

To power on the DYSIS View Digital Colposcope, ensure that the monitor cable is connected, the device is plugged into a power supply and the power supply is connected to a suitable outlet. Press the green power button on the base (Fig 15). The DYSIS software will launch automatically when powered on and the on/off button will illuminate green.

DO NOT TOUCH THE BUTTONS ON THE BACK OF THE MONITOR. FAILURE TO FOLLOW THESE RECOMMENDATIONS CAN RESULT IN MONITOR MALFUNCTION.

To turn off the DYSIS View Digital Colposcope, press SHUTDOWN from the left panel of the HOME screen or from the LOGIN screen and wait for the device to shut down.

DO NOT SWITCH THE DYSIS View Digital Colposcope OFF BY UNPLUGGING THE POWER CORD OR BY TURNING OFF THE POWER SWITCH UNTIL IT HAS FULLY SHUTDOWN FROM THE TOUCHSCREEN. FAILURE TO FOLLOW THESE RECOMMENDATIONS CAN RESULT IN DATA LOSS.

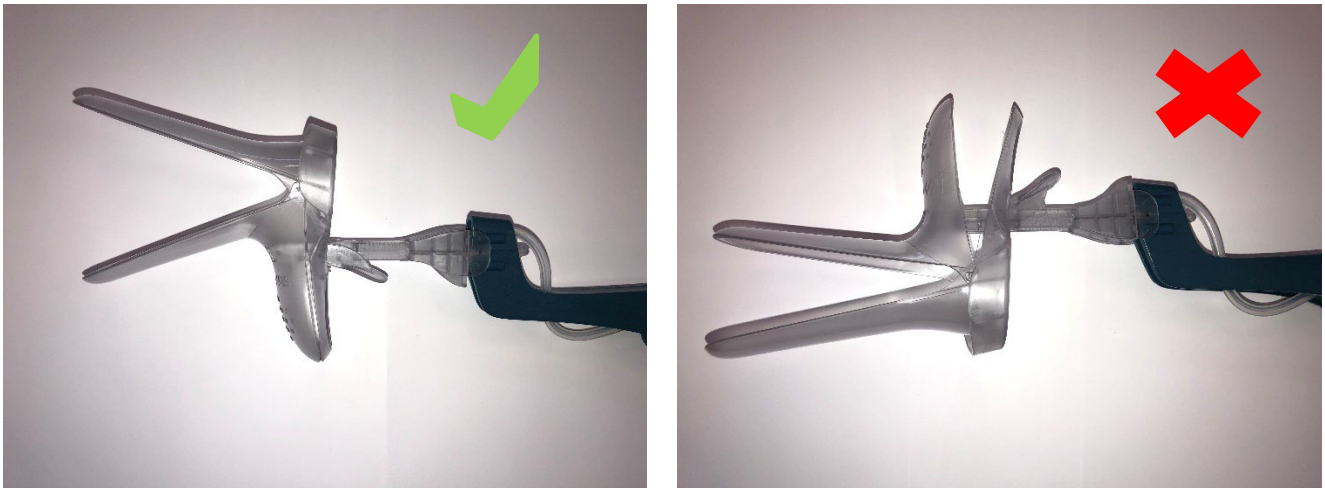
14.8. DYSIS View and DYSIS Ultra 3.0 Acetic Acid Platform Applicator

The DYSIS View acetic acid platform applicator is comprised of 2 parts, a proprietary 1.5 cc syringe and the speculum connector. A manual spray system is integrated into the imaging head (Fig 16), for the application of acetic acid. Acetic acid is manually applied by the user to start the DYSIS Exam. It consists of a 1.5cc syringe, tubing and a speculum connector with a diffusor. The DYSIS View acetic acid platform applicator is filled by unscrewing the syringe from the back of the imaging head. Pull up acetic acid into the syringe and screw into the back of the imaging head. Place a paper towel in front of the diffuser and depress the syringe to remove the air from the tubing prior to the exam. This will need to be performed a few times. Prior to starting the exam, ensure that air has been expelled from the tubing, the syringe is filled with acetic acid and is connected to the imaging head.

Fig 16: DYSIS View and Ultra 3.0 speculum connector and acetic acid platform applicator

14.8.1. Speculum Connector (coupling adapter)

The DYSIS speculum is attached to the imaging head following insertion to the connector that also houses the acetic acid diffuser. The speculum connector is considered a part of the DYSIS acetic acid platform applicator kit. The blue coupling adapter should be inserted into the optical head as shown in Fig 17 a) (CORRECT insertion) and not upside down as shown in Fig 17 b) (INCORRECT insertion).



a) Correct Insertion b) Incorrect Insertion

Fig 17: Insertion of speculum into the DYSIS View and Ultra 3.0 Coupling Adapter

To release and remove the speculum from the connector (Fig 18), hold the back of the speculum with one hand to stabilize it and place the thumb of your other hand on the back of the speculum connector (under the tubing); then, gently push the rear tip of the speculum from the insertion point.

Note: the disposable speculum is shown in the image below, but removal of the reusable speculum follows exactly the same principle.

Fig 18: Speculum removal

15. List of Additional Accessories for the DYSIS Digital Colposcopes

The only consumables (components) that are used with the DYSIS Digital Colposcope are the following and are designed to be specifically used with the DYSIS colposcope:

Acetic acid kit (ACE004) DYSIS Ultra 2.0 Digital Colposcope

Acetic acid (typically 3-5% concentration) is delivered to the patient's cervix by an automated spray system, which is controlled by the system software. The volume delivered is 1.5cc. The aim of using acetic acid is to

trigger acetowhitening that assists in the identification of abnormalities; this is a standard colposcopic procedure.

When using the acetic acid applicator, the acetic acid container should not be overfilled. Fill to the shoulder of the bottle.
Do not spray any liquids if the tubes of the spray mechanism have been disconnected or detached.

Acetic Acid Platform Applicator (ACE005) – DYSIS View and Ultra 3.0 Digital Colposcopes
Acetic acid (typically 3-5% concentration) is delivered to the patient's cervix by a manually operated syringe. The volume delivered is 1.5cc. The aim of using acetic acid is to trigger acetowhitening that assists in the identification of abnormalities; this is a standard colposcopic procedure.

Disposable speculum (DSP001, DSP002, DSP003)
The sterile disposable speculum (available in various sizes) is manufactured from Eastar™ Copolyester MN058.

Disposable treatment pipe (TRP001)
The DYSIS disposable diagnostic speculum can be immediately converted to a treatment speculum by the attachment of a sterile disposable treatment pipe. The disposable treatment pipe is a small plastic tube that is mechanically clipped to the diagnostic speculum offering efficiency advantages to the clinician and comfort advantages to the patient for smoke evacuation during treatments – the treatment pipe has no direct contact with the patient. Please refer to 0230-53050 DYSIS Disposable Specula IFU's. The disposable treatment pipe is manufactured from Polyprop 3020 SMB3.

Reusable speculum (RSP001-006)
The reusable speculum (available in various sizes) is manufactured from medical grade stainless steel by Surtex Instruments Ltd. This device should be cleaned and sterilized as per 0230-53004 DYSIS Reusable Care and Maintenance Instructions.

16. Positioning of the DYSIS Digital Colposcope

16.1. DYSIS Ultra 2.0 and Ultra 3.0 Digital Colposcope

To position the DYSIS Ultra 2.0 and Ultra 3.0 Digital Colposcope next to the examination table prior to operation, the considerations to be taken into account are:

- Space available
- Position of power outlets
- Left or right-handed operator
- Type of examination table

Ideally, the DYSIS Ultra 2.0 and Ultra 3.0 Digital Colposcope should be positioned next to the exam table with the optical arm under the patient's leg and the monitor arm over the patient's leg. The arms can be positioned easily and do not need to be locked into place.

The brake(s) should be accessible to the user or the team in order to be able to disengage and move it easily should the patient require emergency treatment at any time.

16.2. DYSIS View Digital Colposcope

Position the DYSIS View in front of the exam table. The optical arm can be positioned easily. The touchscreen monitor can be placed on a table or a stand (not provided with the DYSIS View) to the left or right side, outside of the stirrups.

After the speculum has been inserted, the imaging head connected to the speculum and a satisfactory field of view obtained, all brakes on the wheels should be engaged.

The brakes should be accessible to the user or the team in order to be able to disengage and move the DYSIS View easily should the patient require emergency treatment at any time.

17. The DYSIS Examination

The general flow of the examination process for the DYSIS Digital Colposcope is as follows:

- Patient preparation
- Initiation of examination
- Visual assessment (including application of acetic acid to observe acetowhitening effect)
- Selection of biopsy points (based on standard visual colposcopic assessment)
- Selection of initial colposcopic prediction
- Review of the DYSISmap
- Selection of final prediction
- Selection of additional biopsy points if appropriate
- Collection of all selected biopsy samples

18. DYSIS Software Application

18.1. General

The operation of the DYSIS Digital Colposcope uses a software application that is installed on the integrated computing unit. There are some differences in the functionality and clinical terminology depending on whether the device is being used in the US or outside of the US. US-specific options will be clearly indicated in the sections that follow. Non-US users have the option to have their devices configured in “Trial Mode”, which divides each colposcopic examination into two phases- one before the clinician reviews the DYSISmap and one after (see section 17). Notice the layout may vary depending upon the version of software installed.

The main functions of the software are:

- Control of the application by interacting with a graphical user interface on the touch screen
- The ability to run a colposcopic examination by controlling illumination, imaging, and display
- The ability to control the image by focusing, applying digital filters, changing magnification
- The ability to perform calibration of the optical system
- The ability to save images and videos and to perform the mapping of the acetowhitening
- A database that keeps patient records (identifiers, visit information, colposcopic examination images and other relevant information)
- The ability to review previous records and play back images
- Controlling access to the device (password protected login)
- Controlling the user access to functionality
- The ability to modify the mode of the device (UK vs US, Trial vs non-Trial, etc.)
- The ability to connect to a network to export images and reports

Note: DYSIS Medical does not have the ability to collect or process patient identifiable information.

18.2. Logging In

After turning the DYSIS Digital Colposcope on, the user must LOGIN to access the application (Fig 19). The application displays a keyboard on the touchscreen and prompts the user to provide a username and password (default usernames and passwords are provided upon installation and can then be customized). After completing the requested information, the user selects LOGIN to enter the HOME menu to access a patient record or proceed with an examination.

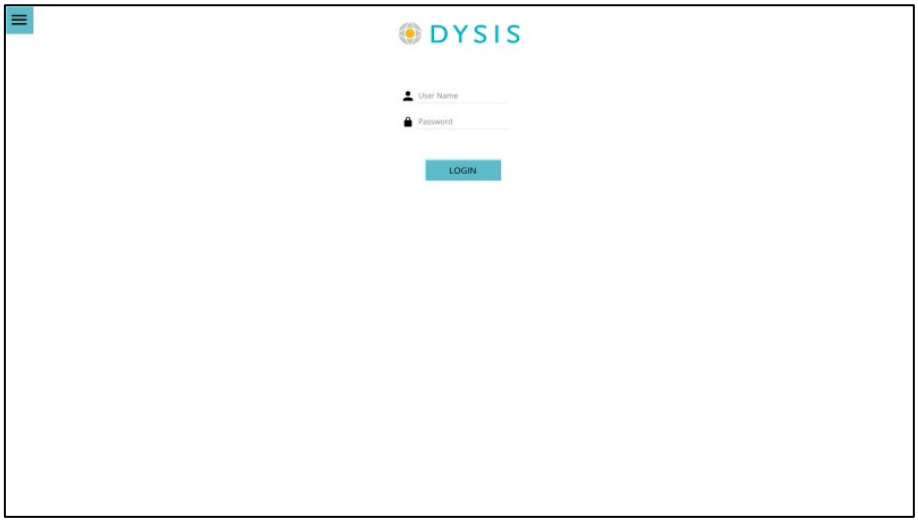


Fig 19: Login screen

18.3. HOME screen

The DYSIS HOME screen is the central navigation point of the software.

Fig 20: Home screen

From the HOME screen, the user can enter a NEW PATIENT, start a DYSIS EXAM or access the PATIENT DATABASE to review previous visits or add a new visit to an existing patient record by selecting the corresponding button.

For users in the US, there is a message indicating the number of days remaining until the device will require calibration (see Section 22.3.3).

Additional options: Press the MENU button in the left upper corner (Fig 20) for additional options. This expands a side panel that enables the user to access the SETTINGS and set or change the device accessibility; PURGE the DYSIS acetic acid applicator (DYSIS Ultra 2.0 only); Calibrate (US only, see Section 18.5 below); LOG OUT; SHUT DOWN. (Fig 21 for Ultra 2.0 and Fig 22 for DYSIS View and Ultra 3.0)

The DYSIS View and Ultra 3.0 do not include the PURGE option as they have a manual applicator and also display an option for WiFi connection (DYSIS Ultra 2.0 does not support WiFi), as well as the system date/time.

Fig 21: Additional options menu DYSIS Ultra 2.0 Digital Colposcope

Fig 22: Additional options menu DYSIS View and Ultra 3.0 Digital Colposcope

18.4. General Navigation Buttons - DYSIS Digital Colposcopes

In some menus, the button will return the user to the previous screen. Alternatively, in other modes of use, the button will offer the option to return to the previous screen after a message has been acknowledged (i.e., during mapping).

enables returning to the HOME menu, dependent on the mode in use.

takes the user to the settings menu from the HOME menu. It will also allow the user to PURGE the DYSIS acetic acid applicator, LOGOUT and SHUTDOWN.

A different menu is available from the button when in examination mode. See Sections below.

Will close the menu and/or page in use.

18.5. Weekly Calibration (US only)

For users in the US, the system requires a weekly calibration. A message on the home screen displays when the current calibration expires. It is not possible to initiate the mapping procedure if the system calibration is not current or has failed. See Section 22.3.3 for instructions.

18.6. Creating a New Patient Record

To create a new patient record on the database (Fig 23), the user must select NEW PATIENT on the Home Screen and then use the touchscreen to enter personal identification information and additional demographic data. The cursor can be moved to any field by touching inside the text box or pressing the tab key on the keyboard. In addition, NEXT can be pressed on the touchscreen to move between data sets.

To successfully create a patient record, the fields marked "*Required*" must be completed and then press SAVE.

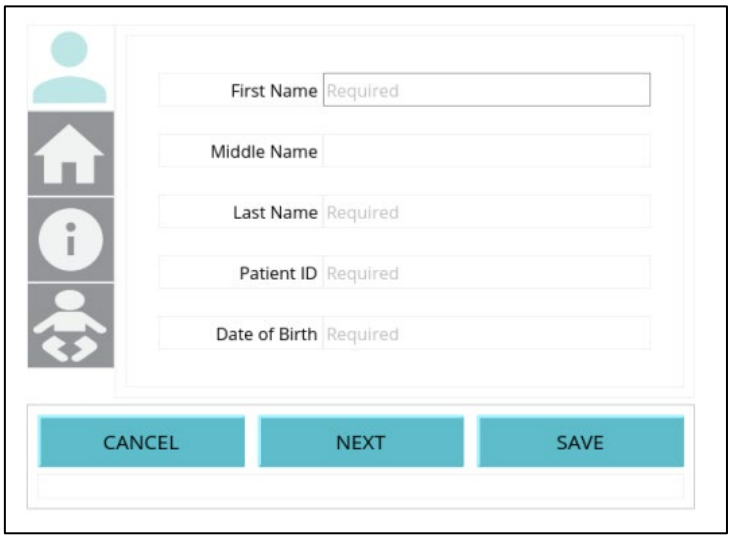


Fig 23: New Patient information

Additional information can be added by selecting each icon from the left panel of the NEW PATIENT screen including address, general information and obstetric history (Fig 24).

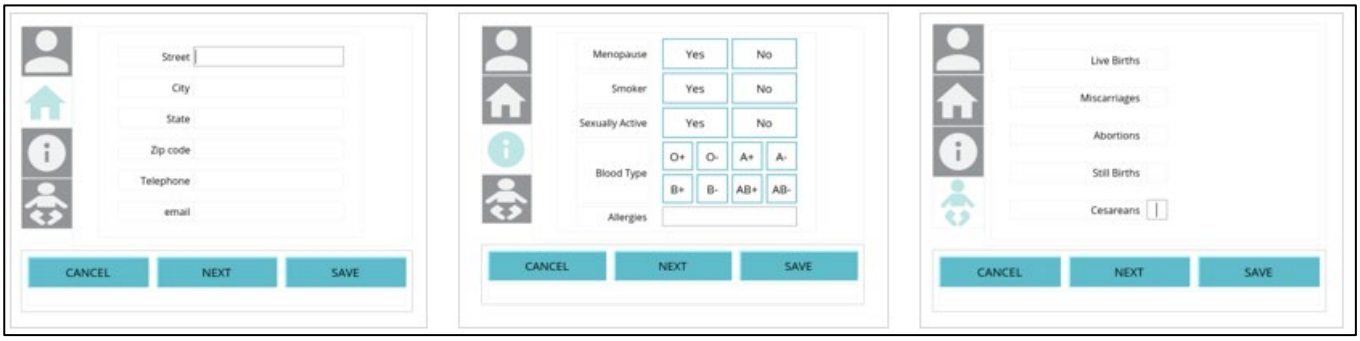


Fig 24: New Patient additional information

All information will be saved to the patient record upon pressing SAVE.

18.7. New Visit for an Existing Patient

To create a NEW VISIT for an existing patient, select the patient from the database by selecting PATIENT DATABASE from the home screen (Fig 20) and then selecting the patient by scrolling down the list which is alphabetical by LAST NAME (Fig 25). Alternatively, the database can be searched by entering information into the boxes above the columns of data, or by touching the column heading which will order the content alphabetically or numerically.

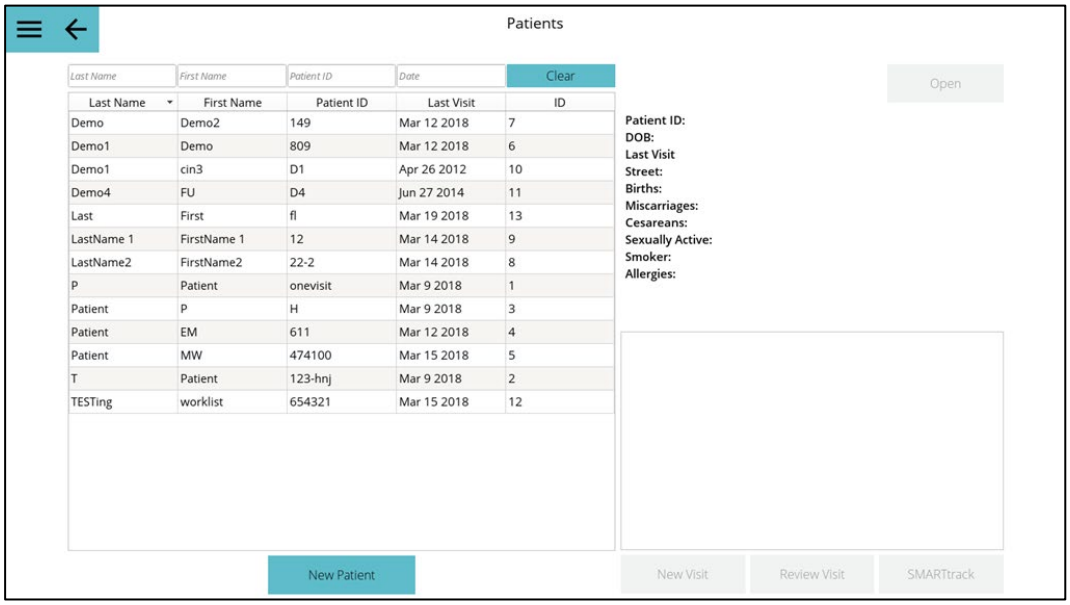


Fig 25: Database patient listing

After selecting the patient, select NEW VISIT from the boxes highlighted at the bottom right of the screen (Fig 26). A NEW VISIT record will be created. Information on the NEW VISIT can be entered in the same manner as described in Section 19.1 below.

Fig 26: New visit for a selected patient

19. Examination Preparation and Functions

19.1. Adding Data to a Patient Visit Record

Once the new patient visit record has been created and after the colposcopic examination has been completed, the user can enter additional information about the examination by selecting the corresponding box from the visit form (Fig 27). This includes the referral reason for the examination (Fig 28), additional information about the patient (Fig 30) and eventually the indicated management plan and histology results.

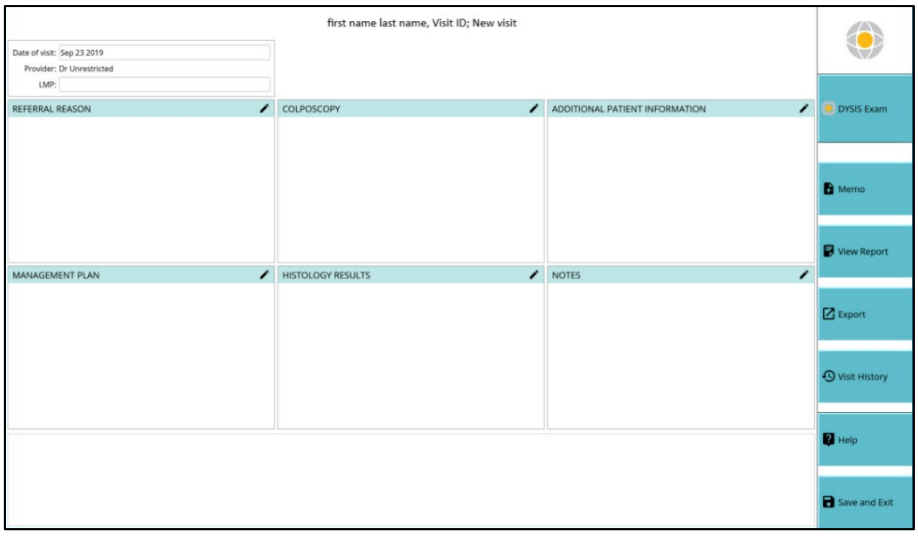


Fig 27: New visit form

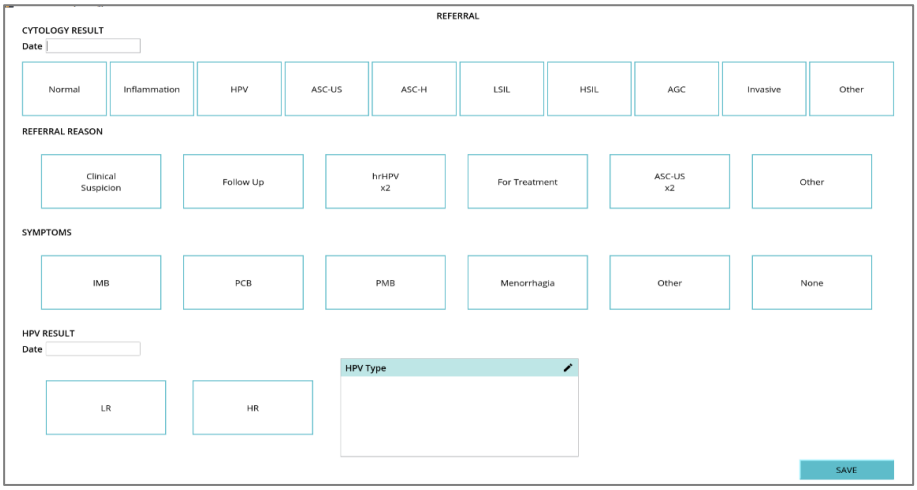


Fig 28: Referral reason (US and international)

Fig 29: Referral reason (UK)

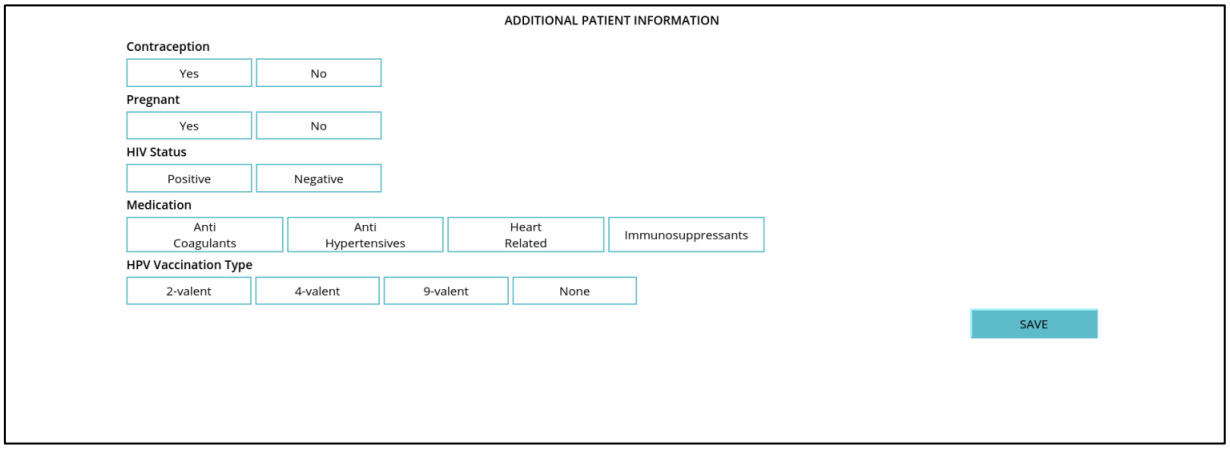


Fig 30: Additional patient information

19.2. Starting the Examination

After selecting DYSIS Exam, the imaging head is automatically turned on and the camera and light are operational. On View and Ultra 3.0, the LEDs turn on and off prior to the light illuminating. This is normal. User can observe the image in the field of view of the camera on the touchscreen and proceed with the examination.

19.3. Preparing the Patient

For non-cervical examinations (e.g., vulva, vagina, etc.) prepare the patient following standard practice.

For cervical examinations, follow standard clinical practice to prepare the patient and insert the speculum. Adjust the speculum to achieve the optimal field of view. Gently remove any mucous using a dry swab or saline. Avoid using acetic acid for cleaning, as this will start the acetowhitening process. Ensure the speculum connector is positioned posteriorly.

The DYSIS Digital Colposcope can be connected to the speculum via the speculum connector located at the front of the imaging head after insertion to stabilize the image during the examination. It is connected by pushing the end of the speculum into the opening on the connector rod of the imaging head (see Fig 8 and Fig 17). This does not fully lock but stabilizes the image during the examination.

19.4. Examination

The DYSIS monitor is a touchscreen. From the examination screen, the magnification can be increased or decreased by using the or by pinching or expanding the screen to zoom with your fingertips (Fig 31, Fig 32).

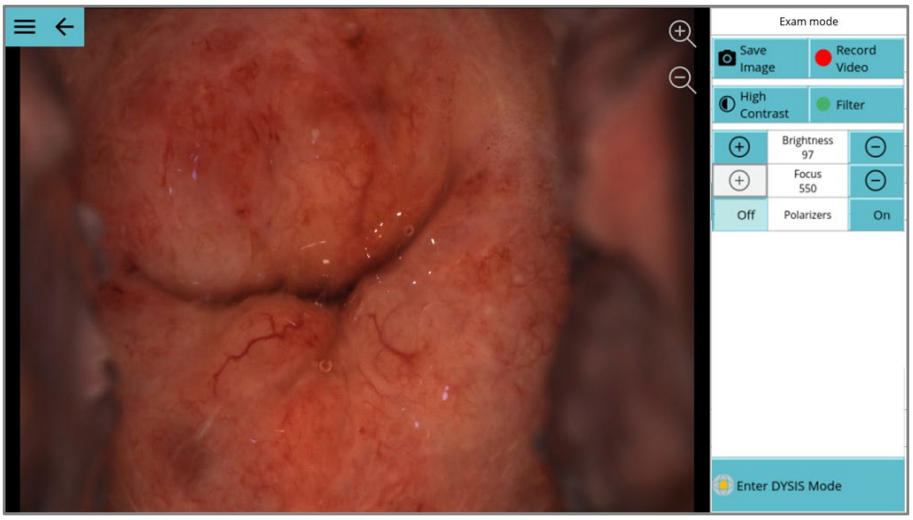


Fig 31: Examination screen (DYSIS Ultra 2.0)

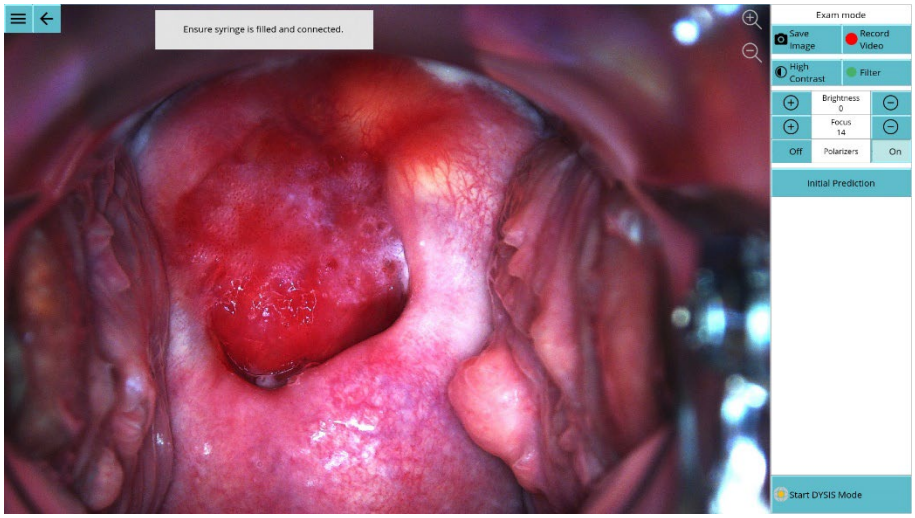
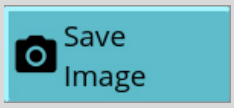
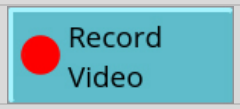
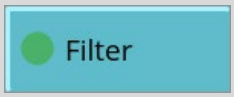
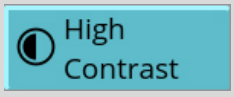
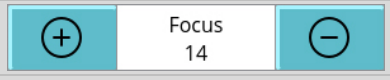
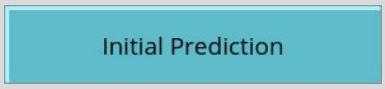
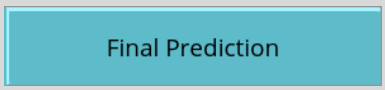
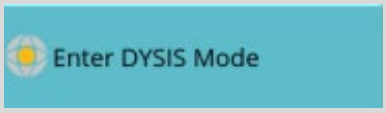
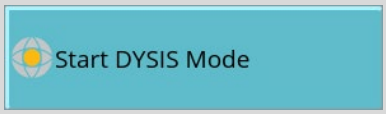


Fig 32: Examination screen (DYSIS View and Ultra 3.0)

Several operations and functions are available during the examination to facilitate the colposcopic evaluation:

Symbol	Function	Description
	Save Image	Takes a still image of the current view. Can be taken while filters are applied or when image is zoomed. This option can be used to document non-cervical examinations.
	Video Recording	Enables video recording. Touch to start and stop. Multiple clips may be recorded.
	Green Filter	Applies a green filter to the image. To deactivate and return to full color view, press the button again.
	High Contrast Filter	Enhances the contrast of the image. To deactivate, press the button again. Contrast enhancement is available for full color and green filter viewing.
	Brightness	Allows controlling the brightness of the image.
	Focus	Allows focusing.
	Initial Prediction*	By pressing this button, the user selects the “initial” colposcopic impression, i.e., before seeing the DYSISmap, selecting from Normal, Low and High. *Option available only to US users or devices configured to Trial Mode.
	Final Prediction*	By pressing this button, the user selects the “final” colposcopic impression, i.e., before seeing the DYSISmap, selecting from Normal, Low and High. *Option available only to US users or devices configured to Trial Mode.
	DYSIS mode	Press to prepare for the mapping process (DYSIS Ultra 2.0).
	Start DYSIS Mode	Press to start the mapping process (DYSIS View).
	Polarizers ON/OFF	Enable/disable the polarizers. Polarizers On: This mode is used during mapping. Surface reflections are eliminated.

		Polarizers Off: This mode may be used for general examination. It enhances depth perception and color vividness.
	Back Button	Exit the examination; an option to save any acquired data will be displayed.
	Additional Options	Opens an additional panel for viewing saved images, or to exit the examination.

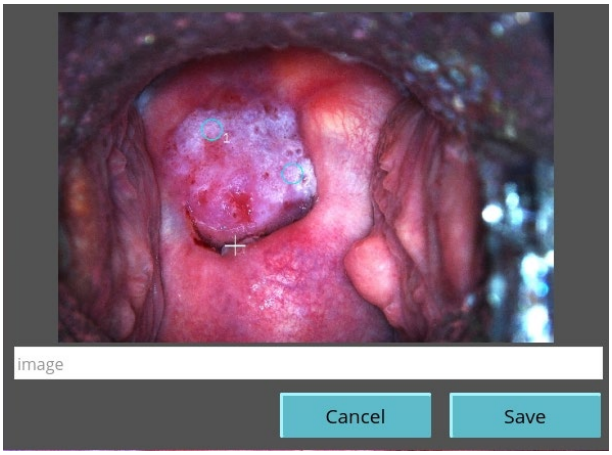


Fig 33: Capture Image

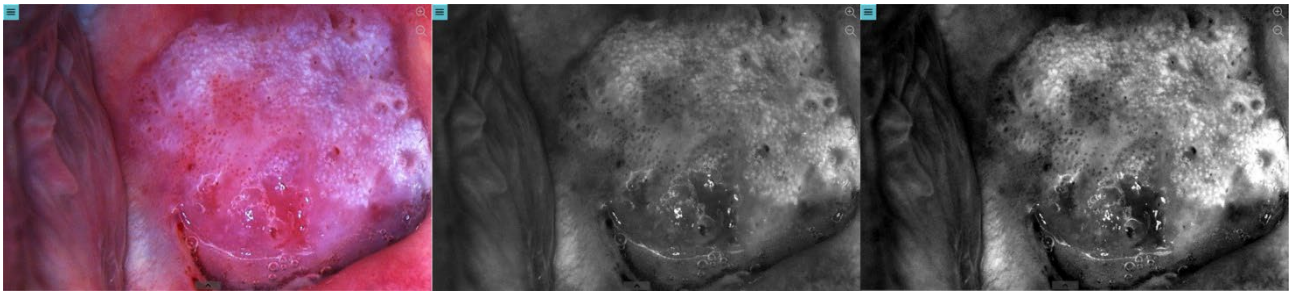


Fig 34: Magnified image; color image (default), Green Filter, Green Filter and High Contrast applied

19.5. Additional Options

Additional options are available by pressing ☰ during the examination (Fig 35).

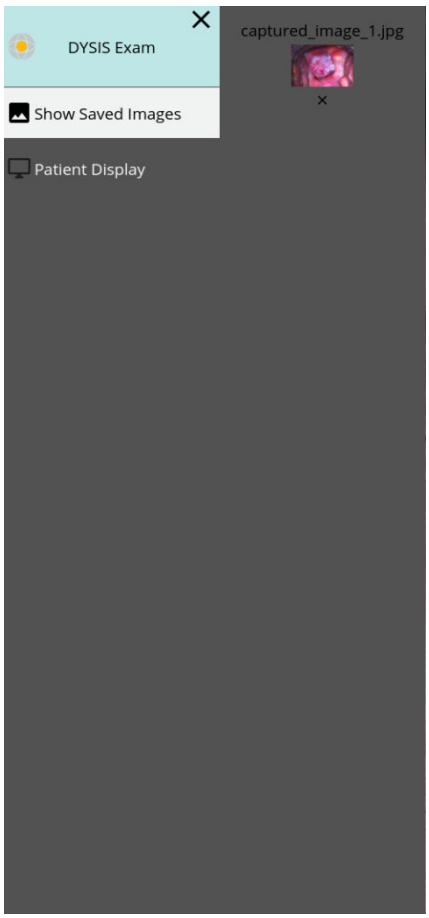
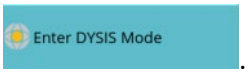


Fig 35: Additional options menu (patient display not available on DYSIS View, optional on Ultra 2.0 or Ultra 3.0)

Show Saved Images	Show Saved Images	Displays images that have already been saved. Pressing x on the image deletes it.
Cancel Exam	Cancel Exam	Exits the examination and saves all data.

20. DYSIS mapping

20.1. Initiating the mapping process (DYSIS Ultra 2.0)

To Enter DYSIS mapping mode and then start the DYSIS mapping, select 

. This opens additional examination options (Fig 36).

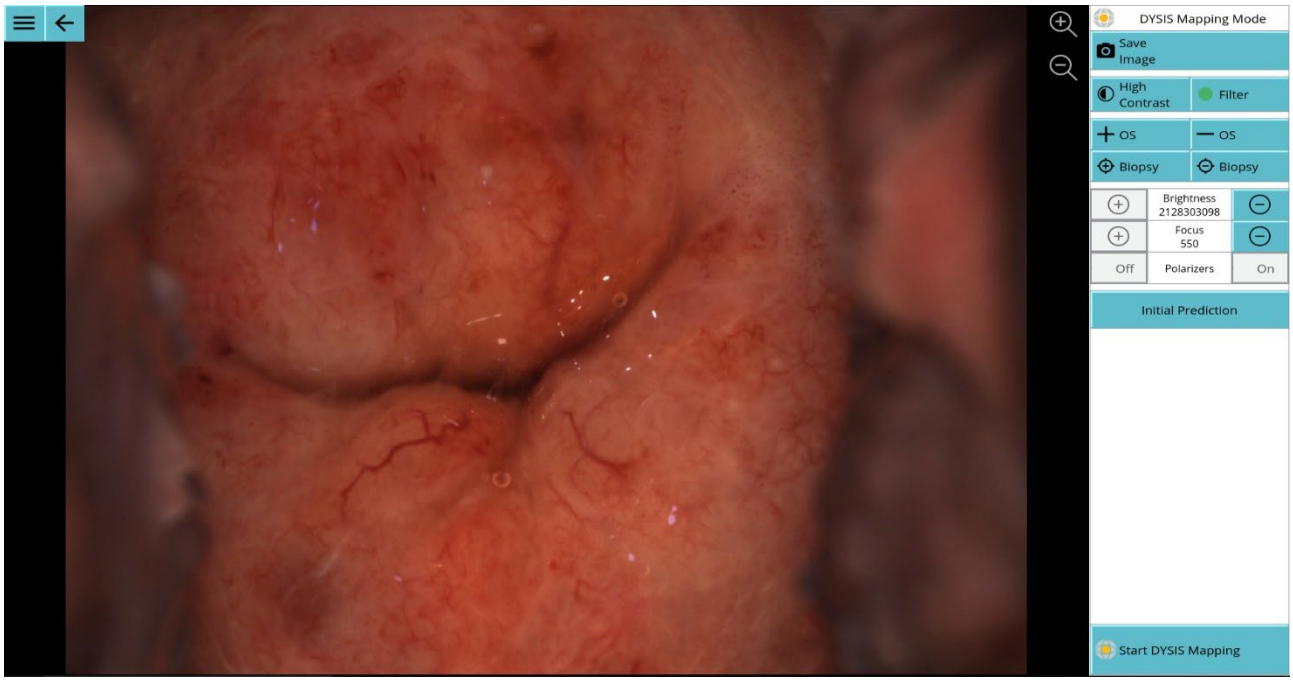


Fig 36: Examination screen (after selecting Enter DYSIS Mode)

Prior to initiating the DYSIS mapping, the patient should be instructed to remain as still as possible. Upon pressing Start DYSIS Mapping, 1.5 cc of acetic acid will be diffused homogenously over the cervix and the mapping process will begin. Refrain from placing anything in the field of view of the camera while the device is mapping or a map may not be calculated.

20.2. Initiating the mapping process (DYSIS View and Ultra 3.0)

The syringe should be filled with acetic acid and connected to the imaging head before starting the mapping process. Prior to initiating the mapping, the patient should be instructed to remain as still as possible, the image should be focused, and the brightness set to the desired level and the polarizers on. To start the DYSIS mapping process, press **Start DYSIS Mode**. At this stage imaging begins and the Start DYSIS Mode button is hidden (Fig 37). Brightness, Focus and Polarizer controls are disabled, and the system is waiting for the application of acetic acid. Make sure that movements are minimized and that nothing obstructs the camera view. If any corrections are required prior to the start of the exam, use the Back arrow to exit and restart the examination.

Depress the syringe plunger fully to spray the acetic acid onto the cervix and the mapping process will begin.

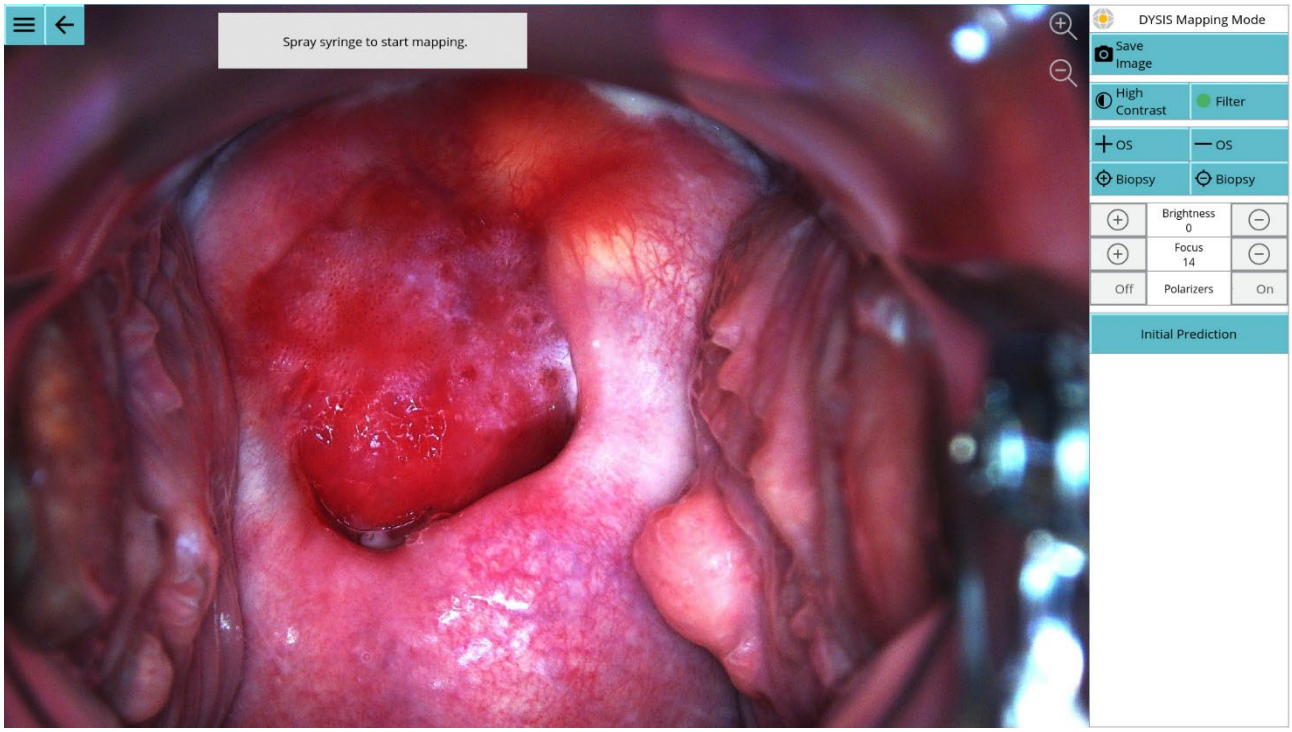


Fig 37: Examination screen (after having pressed Start DYSIS Mode)

20.3. DYSIS Mapping (Continued)

Refrain from placing anything in the field of view of the camera while the device is mapping or a map may not be calculated.

While the system collects images for the mapping, a thorough visual colposcopic assessment should be completed. Areas can be magnified during the examination, filters applied to enhance visualization of different features such as vascular patterns, atypical vessels, mosaics or punctation, etc. Biopsy markers and os can be added or deleted using the relevant buttons.

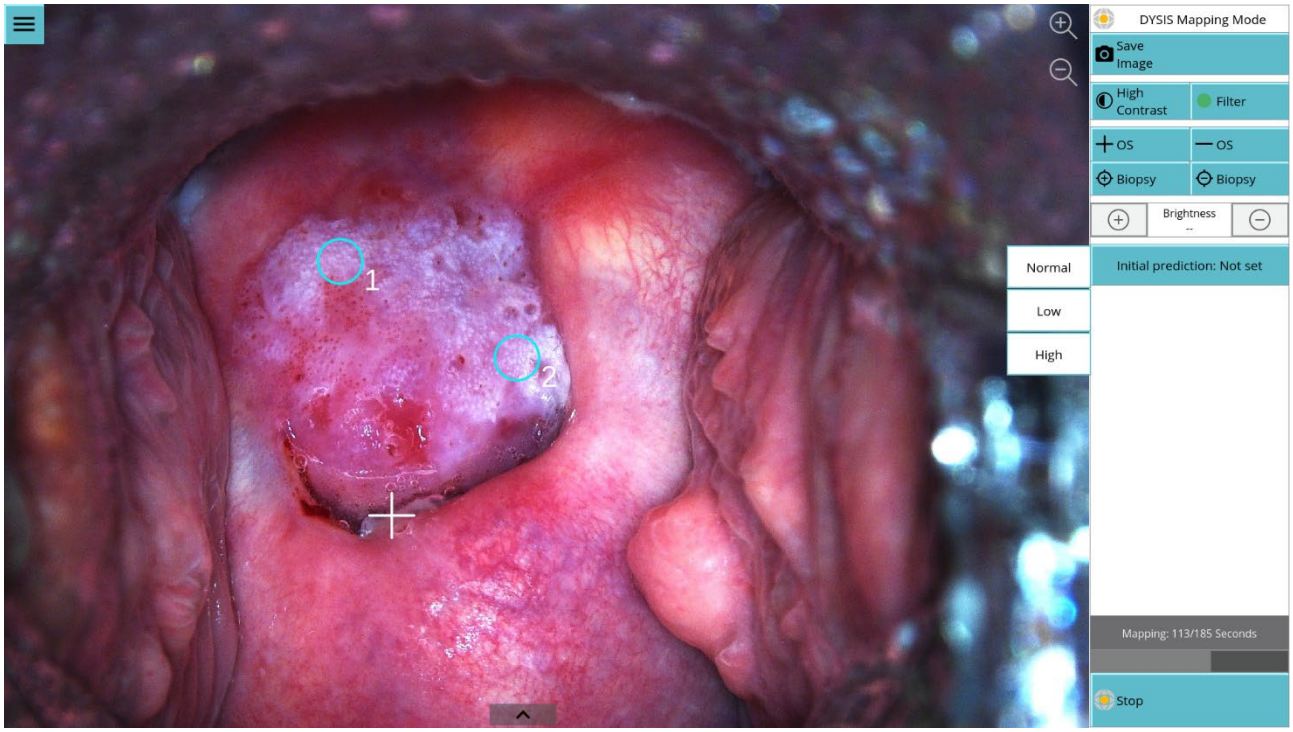


Fig 38: Examination screen (DYSIS mapping in progress)

During mapping, a timer will display in the lower right corner of the screen. It requires at least 125 seconds of information for the map to be calculated, and the process will automatically stop at 185 seconds. The progress bar will turn green when the timer reaches 126 seconds, a map will be calculated if the Stop button is selected.

The examination can be stopped manually at any moment by pressing 

.

A message will be displayed asking for confirmation (Fig 39). If this is done prior to having enough images recorded, no map will be calculated, and a warning message will be displayed.

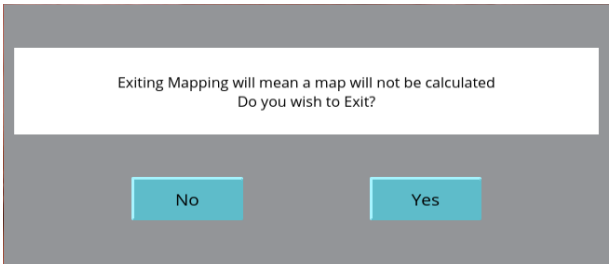
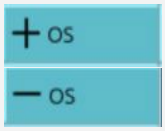


Fig 39: Confirmation message

Additional options become available upon initiation of mapping:

Symbol	Function	Description
	Os Marker	Add or remove a digital marker for the os. First touch the option then select the area on the touchscreen.
	Biopsy Markers	Add or remove digital biopsy markers during/after mapping.

For users in the US and devices configured in Trial Mode: During the mapping process, and in any case before selecting to view the DYSISmap, the user must enter the colposcopic impression or prediction of the examination– selecting from NORMAL, LOW or HIGH (Fig 38). Similarly, after seeing the map, the user will have to enter a final impression before closing the examination (Fig 41 below).

When using the DYSIS Colposcope, at any moment during dynamic imaging, the user can review the images that have been captured thus far (instant replay) by pressing the playback icon. The playback can be accessed by selecting the  button at the bottom of the screen in live viewing. A set of controls allows the user to advance the images at 2x normal speed, 5x normal speed and individually.

The user can use the forward/backward buttons displayed on the touchscreen to scroll through the images manually or play continuously and select the playback speed. The replay screen can be moved on the touchscreen by touching the white bar at the top and dragging to the desired location.

Click on the  button to close this preview window and return to full-screen live view (Fig 40).

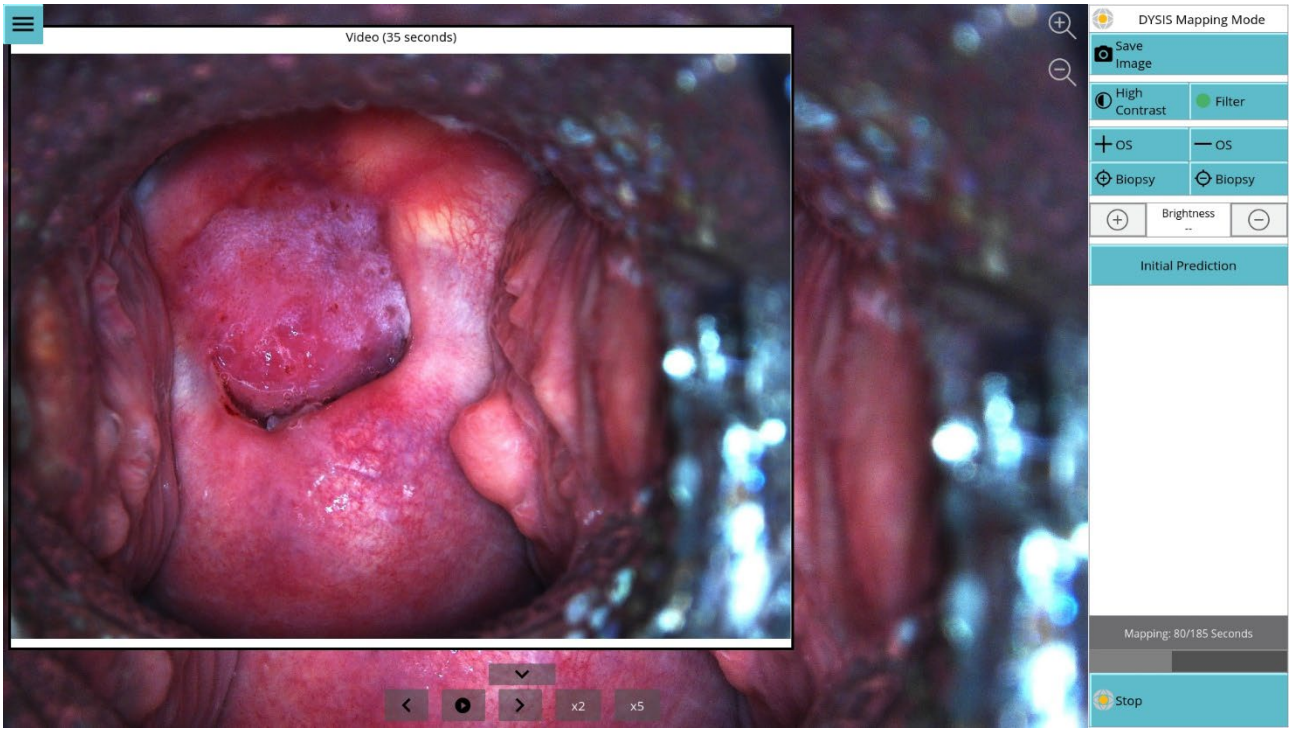


Fig 40: Examination screen with the preview panel shown

After mapping is completed, brightness and focus adjustments, the button for enabling/disabling polarized view and video recording will be available again.

USERS IN THE USA PLEASE NOTE:
The user must ALWAYS select biopsy points based on the conventional colposcopic examination before viewing the DYSISmap. If no biopsy points are indicated, when "Show Map" is selected to view the DYSISmap, a dialog box will appear asking to confirm that no biopsy points are indicated by conventional examination.

20.4. The DYSISmap

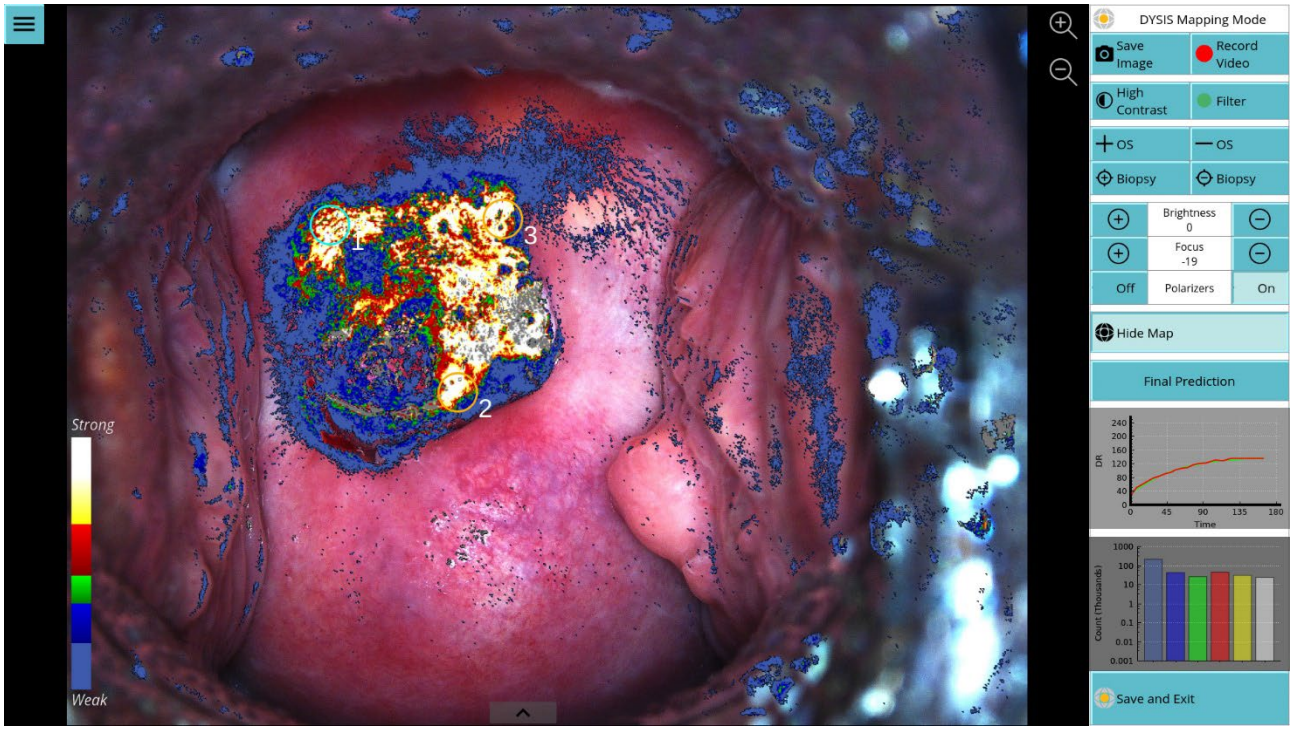


Fig 41: Examination screen with DYSISmap displayed

The DYSIS Digital Colposcope will document the dynamic optical phenomena associated with the cervical acetowhitening in a color-coded map. The DYSIS Digital Colposcope captures high-resolution, sequential images. The images are automatically aligned to compensate for small tissue movements and contractions and then are used to calculate the DYSISmap (see example in Fig 41).

The mapping feature should be used as an adjunct to the colposcopic examination and always after the user has examined the patient and has selected biopsy sites (if applicable) based on standard practice guidelines. Additional biopsy sites may be selected after viewing the color-coded map but viewing the DYSISmap should never lead to the cancellation of biopsy sites selected during the conventional colposcopic exam.

The DYSISmap captures and documents the tissue acetowhitening dynamics (intensity or diffuse reflectance over time). The continuum of colors of the DYSISmap ranges from cyan to blue to green to red to yellow to white and denotes a progressively stronger acetowhitening response.

The DYSISmap is not intended to be used on non-cervical tissue.

The table below represents the color code used to document the tissue acetowhitening dynamics as depicted by the DYSIS Digital Colposcope. This color assignment is based on combining the intensity and duration of acetowhitening over the time period of the dynamic imaging procedure.

Color coding		Whitening
White		Intense
Yellow		
Red		Strong
Green		Moderate
Dark blue		Weak
Cyan		Very Weak
No Color		Very Weak/ None

In the example of Fig 41 above, one can observe the gradual change of colors from Blue/Green to Red/Yellow/White indicating a progressively stronger response in the DYSISmap, that the colposcopist may want to consider as part of the overall colposcopic assessment and the selection of appropriate areas for biopsy sampling.

20.5. Dynamic Curves

After Dynamic Imaging, users can also review the dynamics of the acetowhitening response of the tissue (Fig 42). The graphs are displayed at the lower right part of the screen (Fig 42).

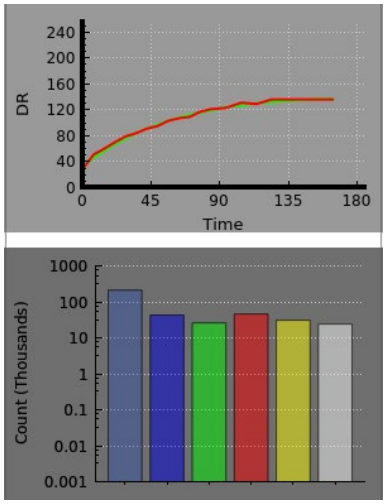


Fig 42: DYSISmap graphs

By touching the screen at different sites on the cervix, it is possible to view and compare the response at different parts of the cervix. This tool can facilitate the review of the acetowhitening phenomenon at different locations simply by monitoring the variations in acetowhitening intensity (curve height) and persistence. The vertical axis represents the acetowhitening intensity and the horizontal axis represents the time since application of acetic acid. This function is only available after the map has been calculated and viewed.

The histogram represents the count of each color on the map in a logarithmic scale.

Additional biopsy markers can be added (and removed if required) after the DYSISmap has been displayed. Biopsy markers that were added prior to the map will be displayed in bright blue (and can no longer be removed); those chosen after the map will be orange (see biopsies #2 and #3 in Fig 43). A maximum of 5 biopsy markers can be added.

Prior to the biopsy procedure, the “Hide Map” button can be selected and the DYSISmap will be removed from view, leaving the biopsy points visible on the live image of the cervix for reference and guidance.

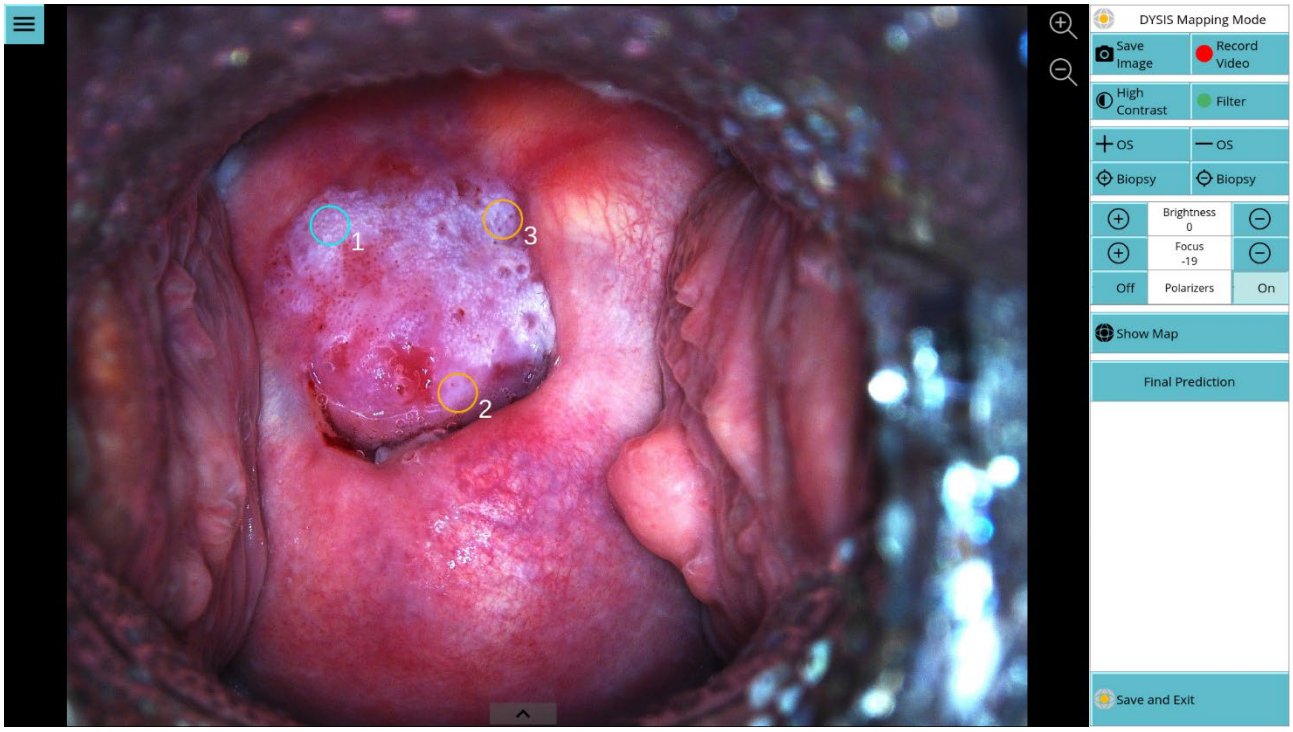


Fig 43: Examination screen with biopsy markers shown

The user annotations are digital marks overlaid on the displayed image and do not follow the movements of the cervix. Therefore, they should be used with caution if the cervix moves after marking. The biopsy markers maintain their location when the image of the cervix is magnified.

20.6. Exiting the Exam

To complete and exit the examination after all desired observations have been made, data has been recorded and operations completed, the user must press the 

button on the lower right corner of the screen. US users or users of devices configured in Trial Mode must first select a Final Prediction; otherwise the system will prompt for its selection upon exiting the exam.

20.7. Assigning to a patient after a DYSIS Exam initiated directly from the HOME screen

After saving images, videos or having performed an examination, exit the DYSIS exam screen and the following screen will appear (Fig 44):

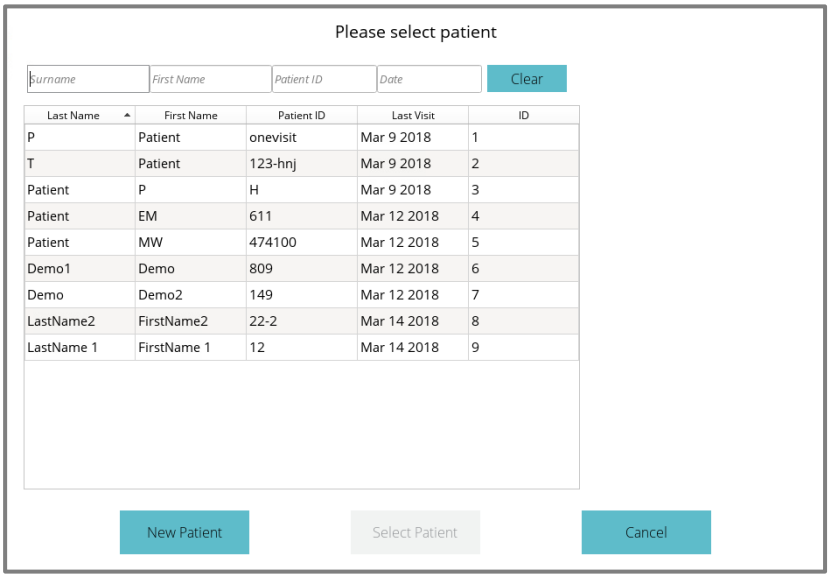


Fig 44: Select patient

The user can either create a new patient where the examination will be saved, select an existing one or press CANCEL. By selecting CANCEL, the examination will be discarded, and a confirmation message will be displayed.

20.8. Examination documentation

Clinical findings of the colposcopic examination and management plan can be documented by selecting the Colposcopy section and choosing from the available options (see Fig 45).

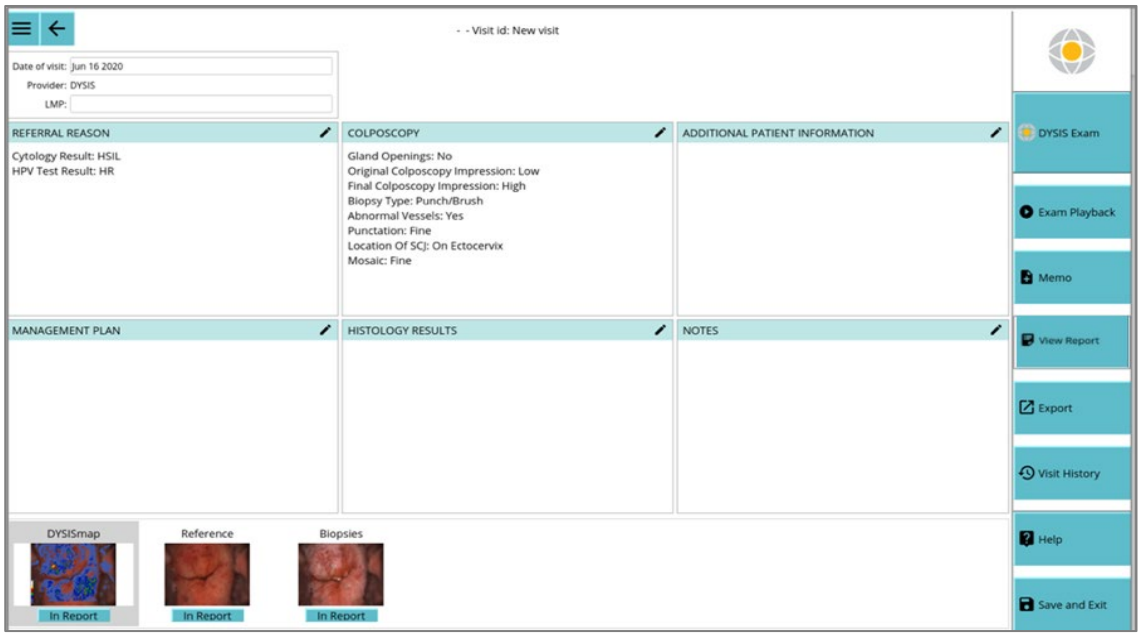


Fig 45: Patient visit record

In addition, notes and sketches can be entered free hand by selecting Memo and then using the touchscreen.

Additional colposcopic findings can be documented following the examination. The COLPOSCOPY screen is automatically displayed after exiting the examination (Fig 46).

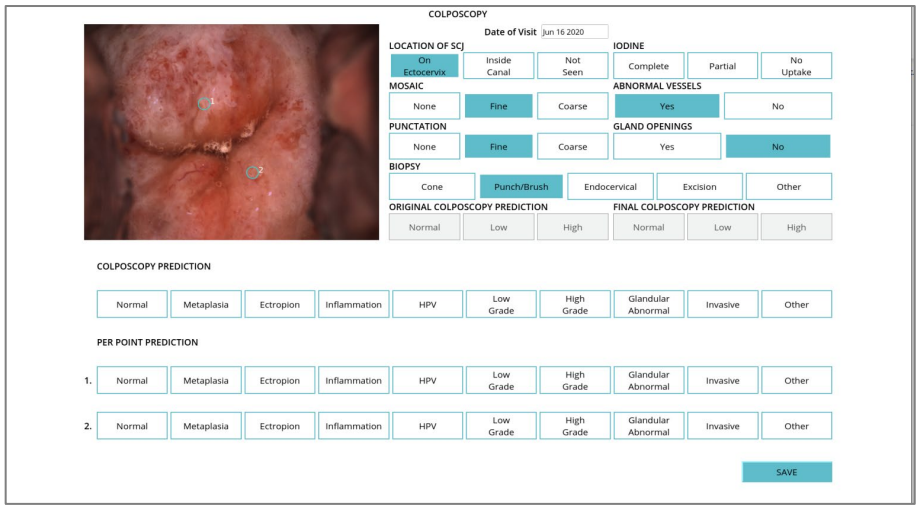


Fig 46: Colposcopy form

The user can complete the management plan (Fig 47) following the examination. Additional management plan options and may be entered after the histology results have been made available.

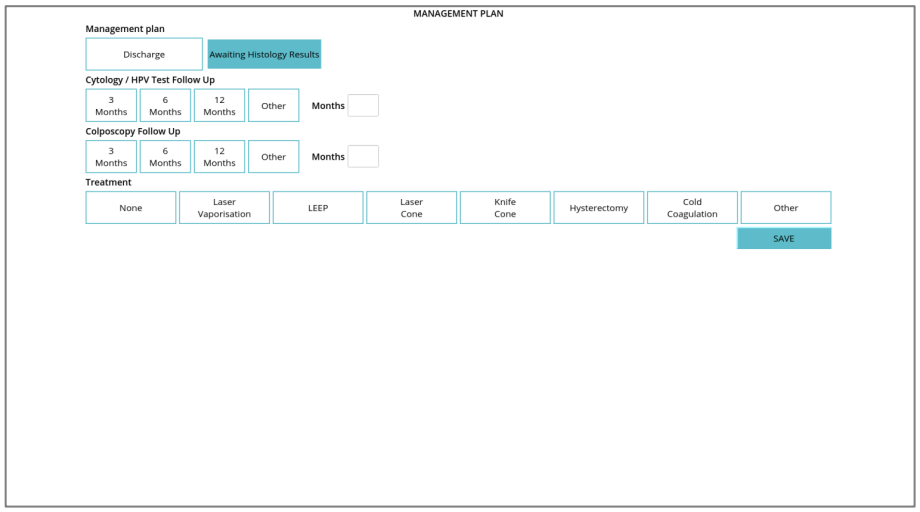


Fig 47: Management plan form (US and International)

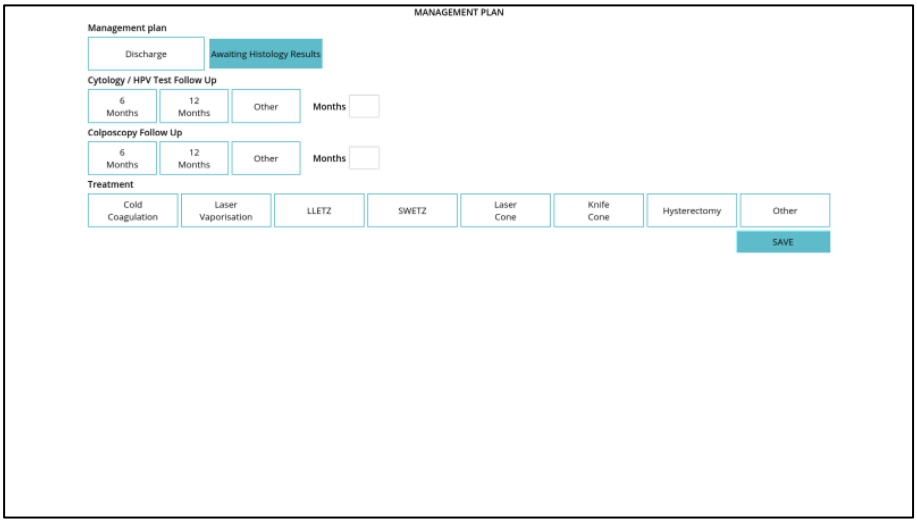


Fig 48: Management plan form (UK)

The HISTOLOGY form allows the documentation of the most severe histological finding, and in addition, it is possible to enter per-point results for any biopsies that have been annotated (Fig 49).

Fig 49: Histology results form

Additional information can be added into the visit record by using the on-screen keyboard within the NOTES section (Fig 50).

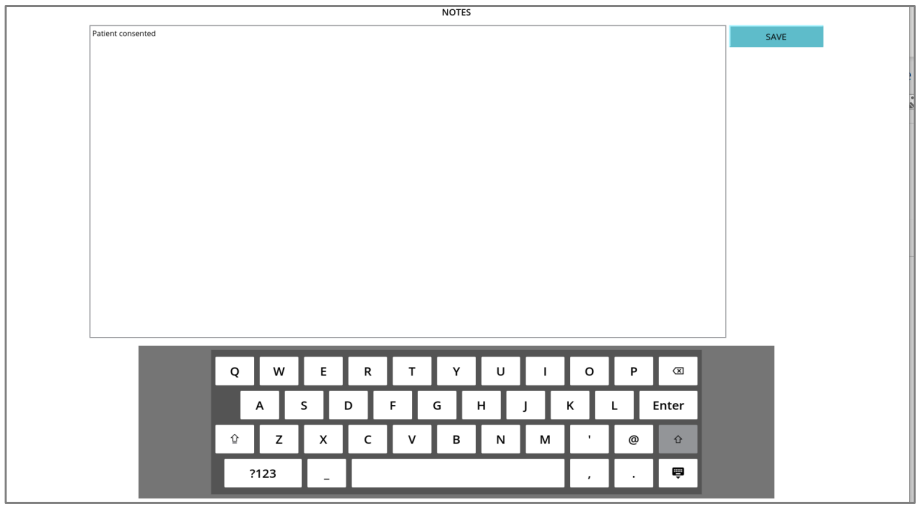
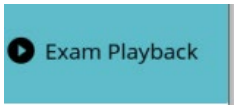
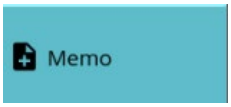
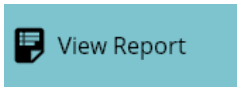
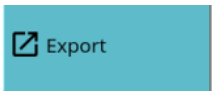
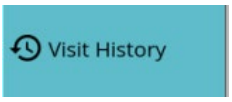
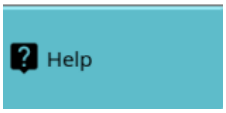
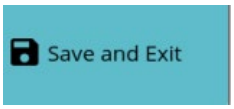


Fig 50: Notes form

The right side of the screen offers additional options after the examination:

	Replays the DYSIS exam (all the sequential images that were automatically captured for the mapping).
	Allows the user to draw freehand on the DYSIS touchscreen.
	Allows the user to view the visit report.
	Exports the entire visit to a USB or network location.
	A record of any additional information entered after the patient record had been closed.
	Guidance for the clinician.
	Save all data and exit the patient visit record.

21. Patient Database

21.1. DYSIS Ultra 2.0 and Ultra 3.0

The patient database can host >10,000 DYSIS examinations (the exact storage capacity will vary according to the length of videos, number of maps generated, etc.).

21.2. DYSIS View

The patient database can host >2,000 DYSIS examinations (the exact storage capacity will vary according to the length of videos, number of maps generated, etc.).

21.3. Reviewing a Visit

To access the database from the HOME screen, press PATIENT DATABASE. Patients' names will be listed in their order of entry (Fig 51).

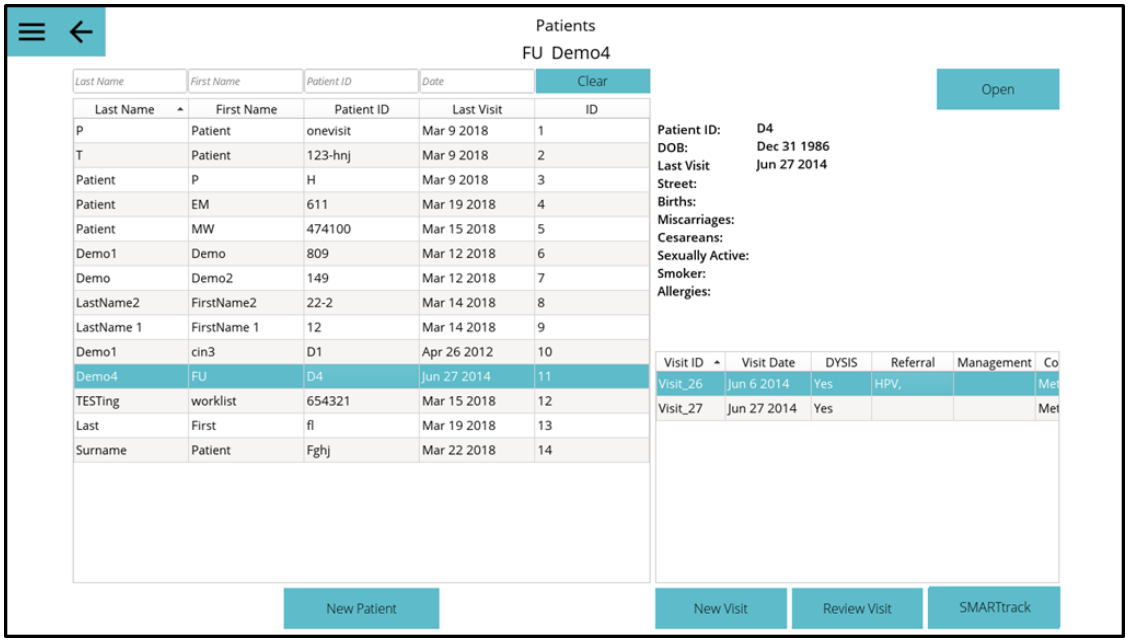


Fig 51: Database patient listing

To search the PATIENT DATABASE, the user can click on the LAST NAME, FIRST NAME, PATIENT ID or LAST VISIT tabs which will then sort the visits alphabetically or numerically in that column.

Alternatively, by selecting the text field above any of these columns, the touchscreen keyboard appears, and the patient database can be searched more specifically by completing any of these fields.

Click on a patient name in the database to select their record (patient is highlighted). Patient information and previous visits are shown on the panel on the right. Press OPEN (top right corner) to access the patient's record. It is also possible to EDIT a patient's details. Click on a specific visit on the list to select it (visit is highlighted) and press REVIEW VISIT to access for review.

21.4. Examination playback

From the visit record, the user can use EXAM PLAYBACK (Fig 52) to review the images and the DYSISmap (when available).

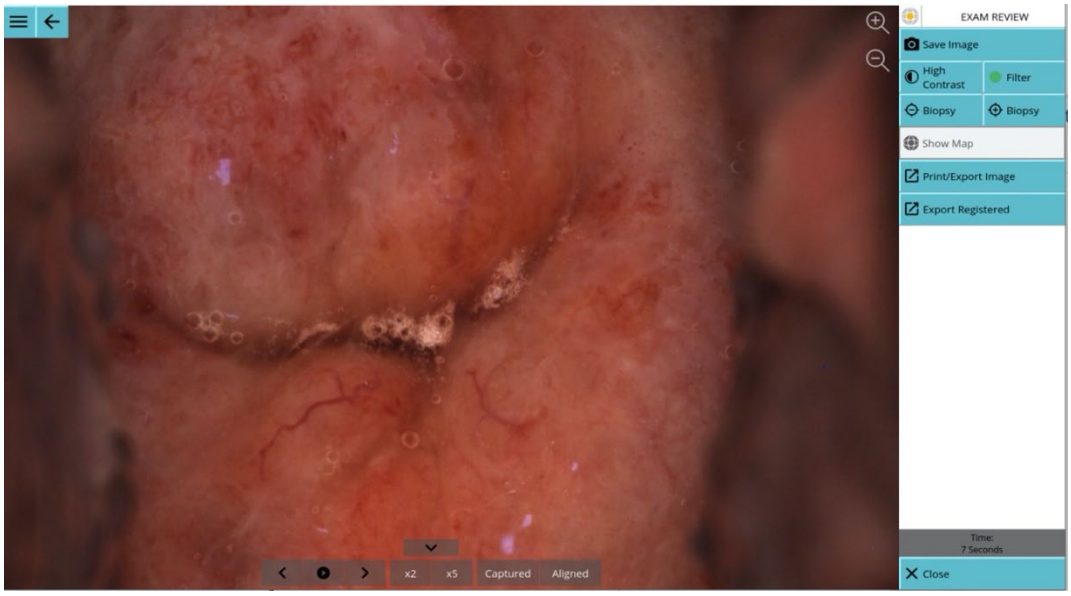


Fig 52: Examination playback

Filters can be applied, and additional images may be saved while reviewing previous visits. The DYSISmap histogram is available when a map is available. Selecting “Captured” displays the original images (best for details) and selecting “Aligned” displays the processed images for DYSISmap viewing.

21.5. Visit History

The DYSIS patient records can be amended at any time after a visit and those changes will be logged (Fig 53).

For example, if a patient’s referral reason was not available at the time of examination but the result is to be entered later, the information can be entered by selecting the appropriate boxes in each section. When the record is closed, a box will appear asking the user to confirm the entry and the reason for it. By selecting NEW INFO or ERROR, the user confirms the reason for the change entered. It can then be confirmed or discarded.

Fig 53: Visit history log

Following confirmation, the new information will appear in the VISIT HISTORY section of the patient record.

21.6. SMARTtrack

SMARTtrack allows the user to compare 2 patient visits side-by-side, enabling longitudinal tracking (Fig 54).

To use SMARTtrack, first select the patient from the PATIENT DATABASE. Highlight a specific visit to include in the visits for review and press SMARTtrack. Then select the second visit from the list of visits at the lower right-side panel.

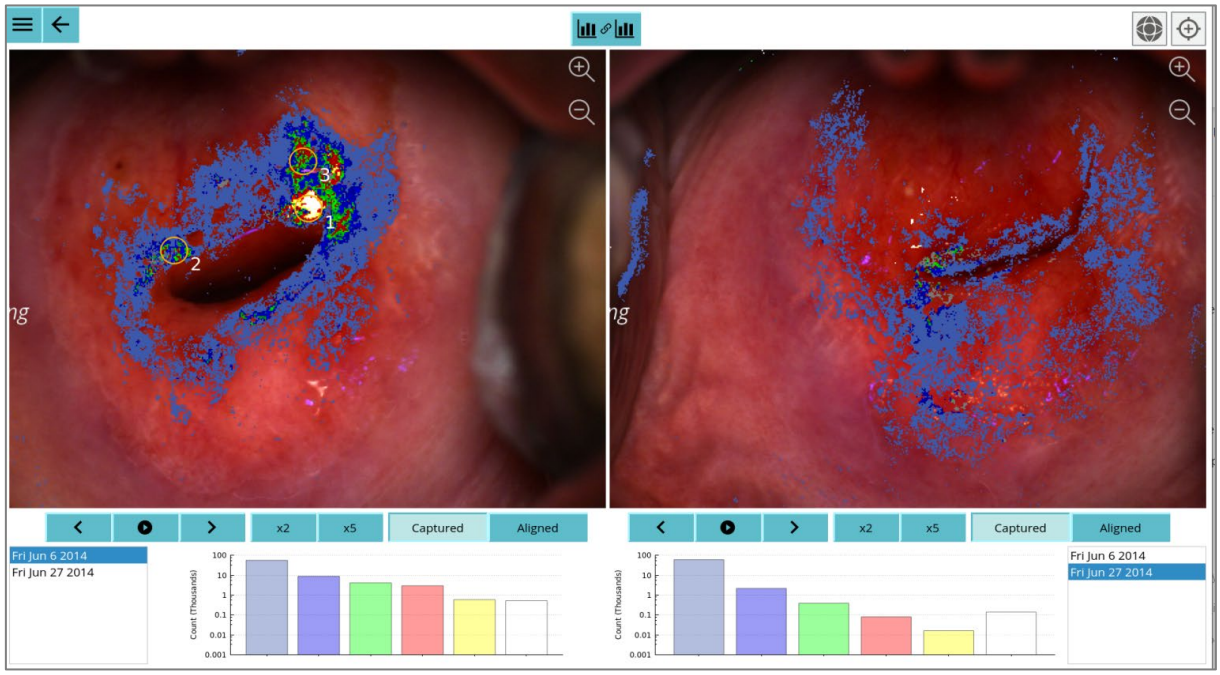


Fig 54: SMARTtrack

When  is displayed, the two visits can be reviewed independently. When this symbol is aqua and unlinked, both sides can be manually replayed and images paused or advanced separately. Each visit is controlled by a set of buttons below each image and the map histogram is displayed respectively below each visit.

When the chain links are locked  the images will play, move and magnify simultaneously, controlled by a single set of buttons at the bottom of the screen.

The buttons below each image allow images to be advanced individually frame by frame (taken at 7 second intervals), at  normal speed and  normal speed, by selecting the appropriate option.

Using  and  buttons, the images can be advanced or reversed individually. The time of each image capture is displayed on the right side of each screen.

Switching between Captured and Aligned images (Fig 55) allows to view the raw images as captured (best for details), or the images aligned by the software for the map calculation. The images need to be aligned in order to view the DYSISmap.

When viewing the aligned images, two additional buttons become available:  .

By selecting , the map will be displayed or hidden over the reference image. By selecting , the biopsy annotations will be displayed and hidden over the reference image.

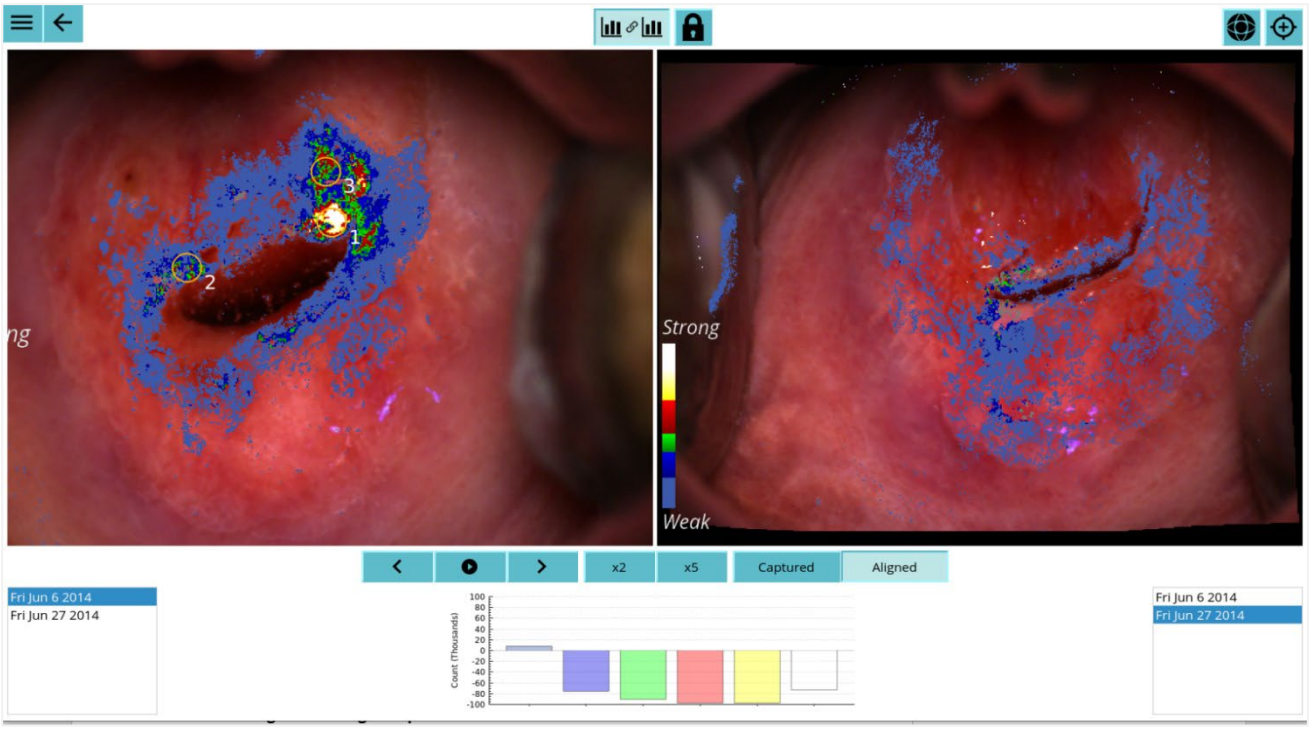


Fig 55: SMARTtrack with comparison displayed

To change the exams for comparison, select a visit from the box below each image and select the exam to review. They will be uploaded into the viewing area.

When viewing images in SMARTtrack, a graph is displayed below the images. The graph illustrates changes in the map over the two visits. The user should select each viewing area on the images to review.

For example, a map which shows a reduction in a strong acetowhite response and a reduction in red, yellow and white will show a negative value below the center line, illustrating the amount of reduction in each color.

If the acetowhite response is greater between the two visits, the graph will show a positive value above the center line.

The graph will represent only what can be seen in the view on the touchscreen. This feature eliminates less relevant characteristics and acetowhite values from the graph.

21.7. DYSIS Report

To generate, print or download a patient report, select the patient from the patient database then select the desired visit (Fig 56).

Select individual images from the tray at the bottom of the screen by pressing Add To Report then select REVIEW REPORT. Images that have been captured independent of the mapping process by the operator and at specific intervals by DYSIS will be automatically included in the report. To deselect these images, press the In Report button to remove them from the report (Fig 56).

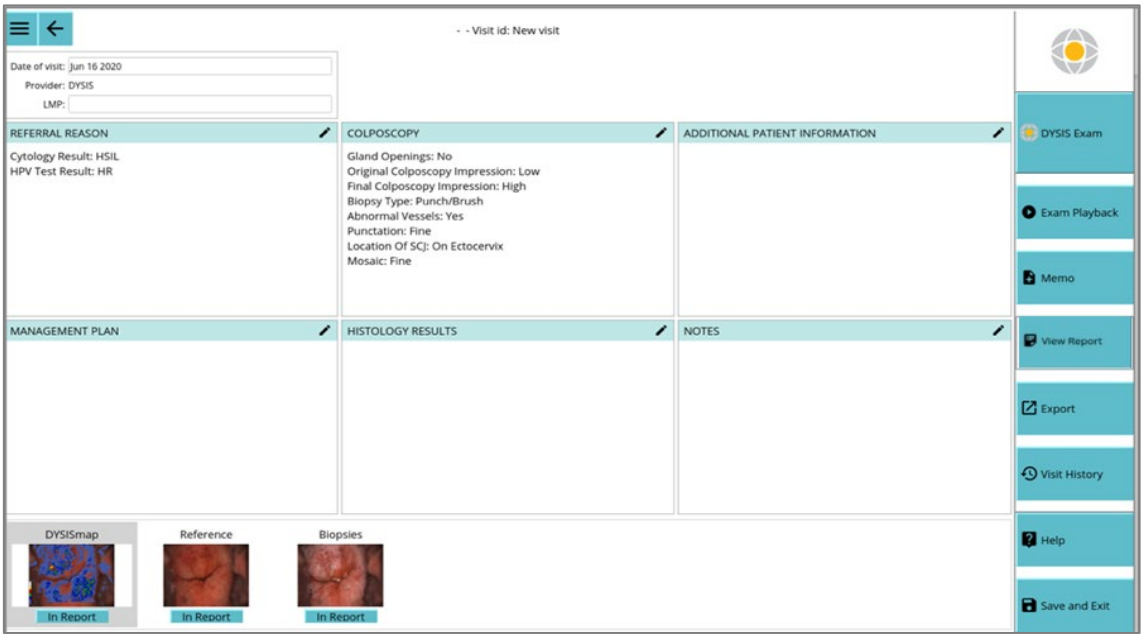


Fig 56: Images included in report

The report will be displayed including patient demographics, REFERRAL REASON, COLPOSCOPY findings, MANAGEMENT PLAN and HISTOLOGY RESULTS. It will also include any images selected and any notes entered in the NOTES section of the patients visit record.

By selecting EXPORT TO PDF, PRINT REPORT or CLOSE (Fig 57), the report can be exported to a USB stick (Ultra 2.0 and 3.0 Digital Colposcope) a network shared folder, or printed if a printer has been connected (through Ethernet or USB port on the DYSIS Ultra 2.0 and Ultra 3.0 or wirelessly for the DYSIS View and Ultra 3.0 Digital Colposcope) or closed.

Fig 57: DYSIS report

22. Additional Functions

In the menu, there are additional features and settings available to the Administrator and the common user based upon the role assigned.

22.1. Simulator trainer

The simulator contains 5 patient cases which allows the clinician to use the software on full patient cases prior to use on a patient. This may be used for training on the DYSIS Colposcope.

To start the simulation case, select Simulator to access all of the functionality of the user interface and perform a simulated patient exam. Refer to Section 19 on how to perform a DYSIS Exam.

22.2. Purge syringe (Ultra 2.0 only)

The purge syringe option is used to expel any air in the tubing. When this is selected, the acetic acid applicator will activate and spray acetic acid from the diffusor located on the speculum connector. To minimize spray, place a paper towel in front of the diffusor. Press Purge until the air has been expelled from the tubing.

22.3. Settings

The following are available under Settings.

22.3.1. Info

The INFO tab displays the versions of the DYSIS software components. In addition, serial numbers of components, such as the camera, are displayed. It is important to know this information when contacting the DYSIS service and maintenance team.

22.3.2. Password (Ultra 2.0), Users (View and Ultra 3.0)

Users may change their own password. The passwords are case sensitive and need to be at least five characters long. Users of DYSIS View and DYSIS Ultra 3.0 can also change their real name.

22.3.3. Calibration (US only)

The calibration function can be accessed through the left panel of the HOME screen (Fig 58).

Fig 58: Calibrate option

If calibration has expired, a message will appear to prompt the user to calibrate the system (Fig 59). Acknowledge the message by selecting OK and access the CALIBRATE option from the left panel of the HOME screen.

Fig 59: Calibration message

For the calibration procedure, the user should place the provided grey card on its mount (jig) and then connect it to the speculum connector (DYSIS Ultra 2.0 set-up shown in Fig 60, set-up is similar for the DYSIS View and Ultra 3.0).

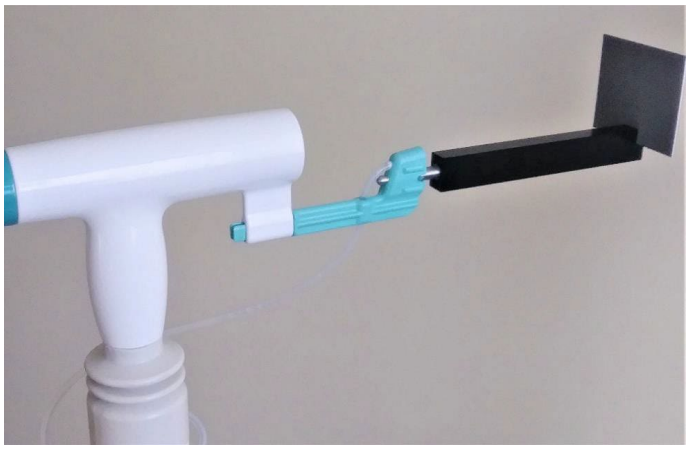


Fig 60: Calibration set up

By pressing the CALIBRATE button, the following screen appears (Fig 61):

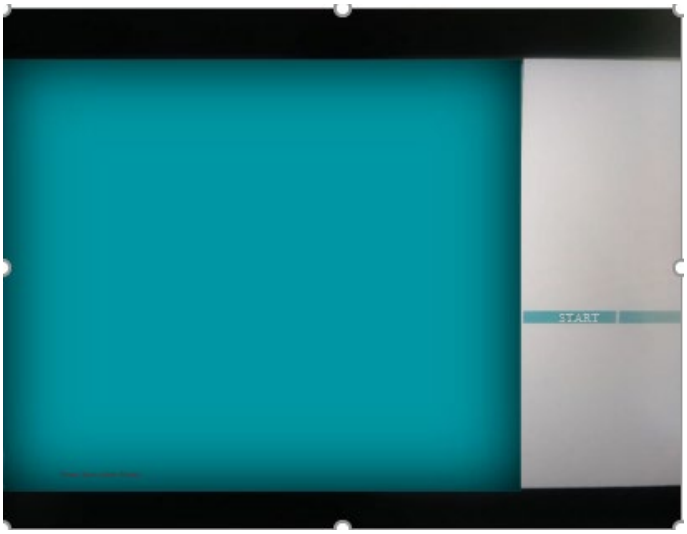


Fig 61: Calibration screen

After pressing START, the user should follow the instructions as three sequential messages are displayed (Fig 62). The first asks the user to confirm the 8 LEDs are on; the second message prompts to turn the room lights off, and the third message prompts the user to place the card on the jig and connect the jig to the camera.

Fig 62: Calibration prompts

After confirmation of the above messages, the software will start calibration. On the DYSIS Ultra 3,.0 and the DYSIS View, there will be a 2 minute camera preparation time and a green progress bar. Upon completion, the "Calibration Completed Successfully" (Fig 63) message will be displayed. The CLOSE button should be pressed to return to the HOME screen.

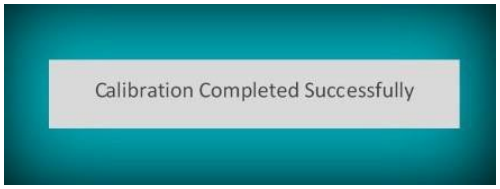


Fig 63: Calibration success message

23. Care, Maintenance and Troubleshooting

23.1. General

Prior to cleaning the DYSIS Digital Colposcope, turn off the power by shutting down DYSIS Digital Colposcope and turning off and unplugging the colposcope from the main power outlet.

Do not immerse any part of DYSIS Colposcope into cleaning solutions.

	Do not immerse any part of the device in cleaning solutions.

When not in use, the DYSIS Digital Colposcope should be stored with the arm(s) folded towards the pole. This will ensure that when the DYSIS Digital Colposcope is moved, the imaging head is protected.

23.2. Replacement Parts

Certain parts of the DYSIS Digital Colposcope are replaceable including the arm(s) and imaging head (Ultra 2.0 and Ultra 3.0). This operation should only be performed by DYSIS Medical representatives.

23.3. Arm(s), Base and Computer Housing Cleaning

To remove stains, wipe the DYSIS Digital Colposcope with a soft cloth lightly moistened with a mild detergent solution. Do not spray solutions on to the device. Be particularly careful to ensure there is no ingress into air vents on the back of the CPU or connection ports, switches, and buttons.

	Do not spray solutions or liquids into air vents.

See below for cleaning the monitor touchscreen and imaging head.

23.4. Touchscreen Monitor Cleaning

The touchscreen monitor can be cleaned with commercially available disinfectant/antiviral cleaning wipes or a damp cloth moistened with a mild detergent/antiviral solution and dried. Do not use excessive moisture and do not apply excessive pressure.

23.5. Cleaning and disinfection

The user should clean and maintain the DYSIS Digital Colposcope (monitor, base, imaging head, arm(s), pole etc.) on a monthly basis as per cleaning instructions.

The imaging head can be cleaned by wiping with a damp cloth moistened with mild detergent/antiviral solution.

The glass cover over the camera lens at the front of the imaging head can be cleaned with a cotton cloth or lens tissue moistened with a lens cleaner. Pay special attention not to scratch the surface during cleaning.

IMPORTANT NOTE: DO NOT USE A CIRCULAR MOTION WHEN WIPING THE IMAGING HEAD WINDOW; USE ONLY STRAIGHT MOVEMENTS – EITHER UP AND DOWN OR SIDE TO SIDE.

	Do not sterilize any part of the device.
	If the device is accidentally contaminated during an exam use indicated disinfecting solution to cleanse it. Before attempting this disinfecting action, the device needs to be powered down and the power cables should be disconnected.
	Wear the correct Personal Protective Equipment (PPE) when disinfecting any part of the device and speculum.

If needed, the DYSIS Digital Colposcope can be wiped with a soft cloth dampened with 70% isopropanol alcohol, disinfectant wipes (chlorhexidine for viral control) and similar substances. DYSIS Digital Colposcope is not intended to be sterilized.

23.6. DYSIS Acetic Acid Applicator

The acetic acid applicator does not come into contact with the patient at any time.

DYSIS Ultra 2.0 Digital Colposcope: The applicator kit should be purged with acetic acid prior to use, accessible from ☰ on the HOME menu on the DYSIS Ultra 2.0 Digital Colposcope.

DYSIS View and Ultra 3.0 Digital Colposcope: The applicator kit should be purged with acetic acid prior to use. See Section 14.8.

The acetic acid solution should be labeled and discarded/changed per facility protocol. If daily or periodic cleaning is required per facility protocol and is not required to be a sterile solution, the acetic acid solution can be poured out of the acetic acid reservoir and the reservoir rinsed and dried. To rinse the tubing, pour 10cc of water into the reservoir. The tubing can be flushed by pulling back and depressing the syringe while holding a

paper towel in front of the diffuser. The bottle should be removed and dried, the tubing should be dried by depressing the syringe several times to expel any remaining fluid.

The DYSIS acetic acid applicator should be replaced on a monthly basis (please see Section 23.6).

The DYSIS acetic acid applicator consists of an acetic acid reservoir (DYSIS Ultra 2.0 Digital Colposcope), proprietary luer lock syringe, spray nozzle, speculum connector and silicon tubing. The DYSIS View acetic acid applicator consists of a proprietary luer lock syringe, spray nozzle speculum connector and silicone tubing. If the local clinical practice is to store and maintain acetic acid in sterile conditions, it is strongly recommended the kit is high level disinfected prior to use. This can be achieved by using a commercial high level disinfection fluid, which should be used according to the manufacturer's instructions. Ensure the liquid reaches all parts of the kit, by filling the reservoir with the liquid and then drawing and pressing the syringe plunger to fill the tubing (repeat until the tubing is filled and liquid is sprayed from the nozzle). Purge the fluid from the applicator by repeating these steps using sterile saline or sterile water until cleared.

23.7. Routine Electrical Testing

The DYSIS Digital Colposcope electrical system consists of two parts: 1) the 240v double insulated (⧈) power brick and 2) the 12v DYSIS Digital Colposcope. The power pack can be tested to meet current electrical testing requirements for Class 2, double insulated devices. The DYSIS Digital Colposcope is below the SELV limits of 50 V AC and therefore does not require any routine electrical testing to be performed.

23.8. Connecting an External Monitor (DYSIS Ultra 2.0 and Ultra 3.0)

The DYSIS Ultra 2.0 and Ultra 3.0 Digital Colposcope can be connected to an HDMI monitor, via the HDMI port (Fig 64), but only if a suitable medical grade isolator is used.

To remove the cover plate, remove one screw at a time. When the DYSIS HDMI port is exposed, the isolator should then be connected directly. The external monitor should be connected to the isolator.

After having connected the external monitor, both monitors will be functional with the next DYSIS Ultra 2.0 or Ultra 3.0 Digital Colposcope start-up.

Fig 64: HDMI port (DYSIS Ultra 2.0 and Ultra3.05 Digital Colposcopes)

23.9. Troubleshooting

DYSIS Medical discourages the performance of any maintenance, troubleshooting or service actions on a DYSIS Digital Colposcopes other than those specified in this guide. If a DYSIS Digital Colposcope malfunctions, or if there is a suspicion that it underperforms, please follow the guidelines below before contacting the DYSIS Medical service department. This will facilitate and expedite identification and solutions to the problem.

Before performing any troubleshooting action, please make sure the power cord is connected and note if the green power button in the rear of the main unit is lit.

The following table lists specific issues which may be experienced with the DYSIS Digital Colposcope. Observe all safety precautions and warnings and make sure to carefully read and fully understand the instructions for use before attempting any troubleshooting. Make sure the instrument is shut down, disconnect it from the power source and restart it to confirm the issue persists, before contacting technical support. If any of the suggested actions fail to solve the issue, please contact the DYSIS Medical service department at 844-DYSISMED.

23.9.1. Troubleshooting Guide

Description	Possible Cause	User Action
The imaging head does not maintain its position	Arm is not extended enough/extended too much	Make sure that the arm is extended enough so that it is in a "V" position.
Image is fuzzy, unclear or dark	Front imaging element may be dirty	Clean front glass (See Section 23.5).
	Imaging head malfunction	Contact DYSIS Medical service department.
No image on the touch screen	Buttons on the back of the touchscreen have been pressed (status LED is black instead of green)	Press the power button on the back of the monitor so that the LED indicator is green; shut down the system and restart without pressing any buttons on the back of the touchscreen monitor.
	The signal or power cable is disconnected or damaged	Contact DYSIS Medical service department.
	Graphics card malfunction	Contact DYSIS Medical service department.
CPU does not turn ON when power button is pressed	Cables going into the power brick or into DYSIS Digital Colposcope may be loose/disconnected	Check connections; if problem persists, contact DYSIS Medical service department.
	Computing unit malfunction	Contact DYSIS Medical service department.
CPU turns on, the software functions, but the DYSIS Exam button is disabled	Camera malfunction	Shut down the device and restart. If the problem persists, contact DYSIS Medical service department.
Dynamic imaging cannot be initiated	Error in plunger	Check that there is sufficient acetic acid solution in the container. From the home menu, press "purge syringe." (Ultra 2.0 only). If problem persists, contact DYSIS Medical service department.
	Weekly calibration is required (US only)	Calibrate the system.
Image is displayed, but the lights do not turn on	Illumination source malfunction	Contact DYSIS Medical service department.

The DYSIS Digital Colposcope doesn't turn on	Main power cable is disconnected	Ensure the power switch is OFF and reconnect the main power cable to the power brick and the power cable is locked into the DYSIS Digital Colposcope base. Turn the main power switch ON.
	Outlet has no electricity	Ensure the electrical outlet is operational.
	System malfunction	Contact DYSIS Medical service department.
Calibration cannot be performed (US only) or Calibration has failed	The card is very dirty	Contact DYSIS Medical service department.
	The card is not placed at the right distance	Use the calibration jig
	System malfunction	Contact DYSIS Medical service department.
Software update cannot be performed (DYSIS Ultra 2.0 Digital Colposcope)	The USB stick is not recognized	Use another USB stick formatted to exFAT.
	The configured network path with the upgrade package is not accessible	Check connections through the connectivity tab in SETTINGS to ensure the configured network path is accessible.
	The DYSIS Ultra 2.0 Digital Colposcope software upgrade files are not on the USB stick	Follow software update instructions carefully. The upgrade file should not be embedded in a folder on the USB.
	System malfunction	Contact DYSIS Medical service department.
Power cable cannot be plugged in to DYSIS Ultra 2.0 and Ultra 3.0 Digital Colposcope	The inner circle is pressed, and power cable cannot lock into DYSIS Ultra 2.0 Digital Colposcope	Hold the outer circle and pull back the inner circle to connect the power cable.

23.9.2. Software Messages

Message	Possible Cause/User Action
15 Spray cycles have completed. Check acetic acid level (DYSIS Ultra 2.0 only)	Make sure that there is enough acetic acid in the reservoir. If not, please refill the container.
All visit data/images will be discarded. Press OK to confirm	A message shown when CANCEL is pressed after a direct DYSIS exam. By selecting OK, all data from the visit will be discarded.
An error has been detected in the camera/syringe. Please contact DYSIS (Ultra 2.0 Digital Colposcope)	When this message is displayed, DYSIS Exam is disabled. Shut down the DYSIS Ultra 2.0 Digital Colposcope and then start it up again. If message persists, please contact DYSIS Medical service department.
An error has been detected in the camera. Please contact DYSIS (DYSIS View and Ultra 3.0 Digital Colposcopes)	When this message is displayed, DYSIS Exam is disabled. Shut down the DYSIS View or Ultra 3.0 Digital Colposcope and then start it up again. If message persists, please contact DYSIS Medical service department.
An error has been detected: Code: XXXX Press OK to shutdown	Please contact the Administrator to export logs and forward the logs to DYSIS Medical service department for investigation.
Are you sure you want to delete image?	By selecting OK, the selected image will be deleted.
Due to excessive movements, no map will be calculated	There were too many micro-movements, causing failure in image alignment and inability to calculate the map
Failed to export report. Can't access export directory	Please check the export directory is valid and accessible through an Administrator account.
Failed to export report. Please config an export path in settings	Please check the export directory is valid and accessible through an Administrator account.
It has been xx days since the last calibration. Please calibrate now (US Only)	Weekly calibration is required. This message will be displayed to perform the calibration. No mapping will be available until DYSIS Digital Colposcope has been calibrated.
It has been 30 days since the acetic acid consumables were changed. Please change now (DYSIS Ultra 2.0 only).	Please change the DYSIS acetic acid kit.
No colposcopy directed biopsy sites indicated. Confirm?	This message is displayed when Show Map is selected without having added any biopsy points. By selecting OK, you confirm no biopsy points need to be added and the map will be displayed. By pressing cancel, you have the option to add biopsy markers.
No initial prediction selected. Please select prediction to continue	Please select the Initial Predication from the right-side menu for the colposcopy examination.
No final prediction selected. Please select Prediction to continue	Please select a Final Prediction from the right-side menu for the colposcopy examination.

No map will be calculated. Do you still wish to exit?	This message is displayed when STOP is selected during the mapping procedure. No map will be calculated since not enough images were recorded. For the map to be calculated, please press NO.
No printer currently configured. Please contact an administrator.	Please contact the Administrator to check the printer is accessible and DYSIS Digital Colposcope is configured for the printer.
Please enter the number of months for the colposcopy follow up	The option "Other" has been selected. Please indicate the number of months for the colposcopy follow up.
Please enter the number of months for the cytology follow up	The option "Other" has been selected. Please indicate the number of months for the cytology/HPV follow up.
Image registration failure. Not enough images to calculate map	No map will be calculated due to a failure to align the images accurately.
Syringe purge has completed successfully (Ultra 2.0 Digital Colposcope)	Purge syringe was pressed through the left side menu.
There has been a problem connecting to the DICOM Server. Please contact a System Administrator	Please contact the Administrator to check the DICOM server is accessible. No data will be sent to the PACS server until this error message is resolved.
There has been an issue with the configured export network share. Check network connection	Please contact the Administrator to check the configured network path is accessible. No data will be exported to the configured network path until this message is resolved.
There is a problem with the USB memory stick (Ultra 2.0 and Ultra 3.0 Digital Colposcope)	Please check that the USB memory stick is working properly and plug it again. Ensure the USB drive is formatted as exFAT; if this message is displayed again, please use another USB memory stick.
Unable to connect to DICOM Server. Please contact System Administrator	Please contact the Administrator to check the DICOM server is accessible.
Unable to print to printer: xxx Please contact an Administrator	Please contact the Administrator to check the printer is installed properly and is accessible.
Unable to write report to export directory. Please contact an Administrator	Please contact the Administrator to check the export path is accessible.
Video has recorded for xx minutes. Stop or continue	This message is displayed after recording a video for four minutes.
You have selected to terminate the acquisition process. Are you sure?	This message is displayed after selecting STOP during the mapping procedure. The map will be calculated since enough images were recorded.

23.10. Networking and Connectivity

Please refer to *0230-53138 DYSIS Ultra 2.0 Colposcope Administrator's Guide* and *0230-53163 DYSIS View and Ultra 3.0 Digital Colposcope Administrator Guide* for instructions for adding users, networking, connectivity and installing a printer.

23.11. Replacing the DYSIS Acetic Acid Applicator (DYSIS Ultra 2.0 Digital Colposcope)

23.11.1. Removing the existing Acetic Acid Applicator Kit:

1. Push the container upwards from the bottom in order to remove it from the holder (Fig 65).
2. Hold the container and gently pull the two sides of the T-valve from its holder until the syringe detaches from its position.
3. Gently squeeze the pins together on the rear end of the speculum connector rod and remove it from its mount.

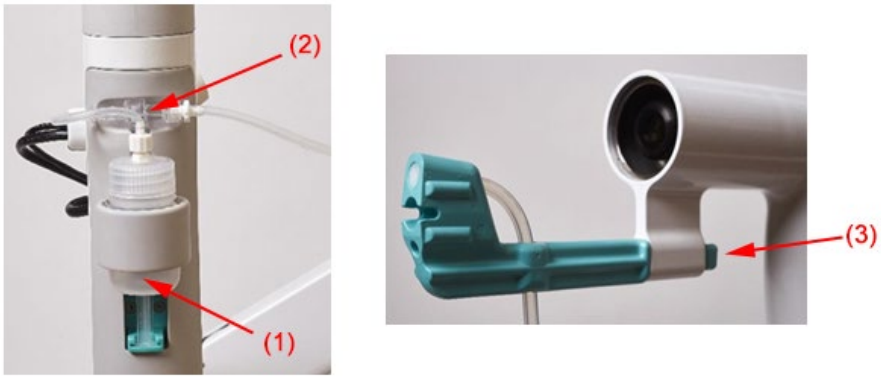
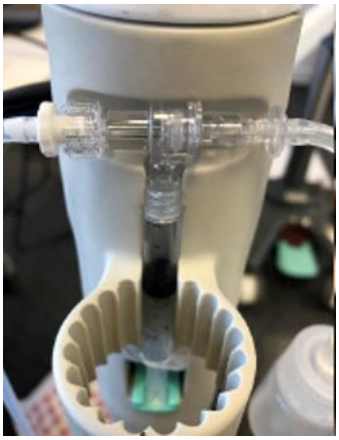


Fig 65: Removing the acetic acid kit.

23.11.2. Connecting the Acetic Acid Applicator Kit (DYSIS Ultra 2.0 Digital Colposcope)

1. Insert the speculum connector into the slot in front of the camera housing.
2. Pull the plunger of the syringe and snap into the syringe port located on the front of the rubber housing cover (Fig 66Fig 66).
3. Place the acetic acid reservoir into the holder

(1)



(2)

(3)

Fig 66: Placing the reservoir

23.11.3. Filling the DYSIS Ultra Acetic Acid Applicator

Remove the reservoir from its holder. Unscrew the bottle and fill it with acetic acid just below the shoulder level. Screw the base back into the lid and replace in its holder. Press the PURGE button from the ☰ button on the home screen and repeat until the acetic acid is sprayed from the spray nozzle, the syringe and the tubing are fully filled, and the air is expelled from the tubing.

23.12. Replacing the DYSIS Acetic Acid Applicator (DYSIS View and Ultra 3.0

To replace the DYSIS View and Ultra 3.0 acetic acid kits, unscrew and remove the syringe from the back of the imaging head (Fig 67). Press the 2 blue tabs located in front of the imaging head on the side of the speculum connector and pull to remove the connector. Replace the speculum connector and screw the syringe into the back of the imaging head. Ensure the diffusor is up. Refer to section 14.8.1 for correct and incorrect insertion.

a) Side view of syringe and speculum connector

b) Front view of syringe

Fig 67: Replacing the DYSIS View and Ultra 3.0 Acetic Acid Platform Applicator.

24. Warranty, Service, Expected Service Life, Recycling and Disposal

DYSIS provides a one-year manufacturer's warranty, covering parts and labor. Customers should contact their local representative for servicing the colposcope and for information on extended service contracts.

The DYSIS Digital Colposcopes have an expected service life (lifecycle) of 10 years from the date the system was installed. Metal parts, such as the movable base and the pole can be recycled in metal recycling facilities. Electronic components such as monitor, CPU components and imaging head modules can be recycled at specialty electronic components recycling centers.

DYSIS products are designed to ensure that all of the equipment can be dismantled and the components and materials are recoverable. Disposal of electronic equipment is governed by the Environmental Protection Agency (EPA). Refer to state and local regulations for disposal of the colposcope.

The symbol on the product or its intended use indicates this product must not be disposed with other household waste. Instead, it is the user's responsibility to dispose of waste equipment at a designated collection point for the recycling of electrical and electronic equipment waste. The separate collection and recycling of waste equipment at the time of disposal will help conserve natural resources and ensure it is recycled in a manner which protects human health and the environment.

25. Contact Information

UK Address
DYSIS Medical Ltd
Gyleview House,
3 Redheughs Rigg,
Edinburgh, EH12 9DQ, UK.
www.dysismedical.com
Tel: +44 (0) 131 516 3944

US Address
DYSIS Medical
24 Superior Dr.
4th Floor
Natick, MA 01760
Tel: 844-DYSISMED

EC REP
DYSIS Medical SA
Leof Dimokratias 4-6,
Neo Psychiko 15451,
GREECE
Tel: +30 2106997730

26. Essential Performance

DYSIS Digital colposcopes enable clinicians to illuminate and visualize the cervix uteri so that they perform a colposcopic examination. Typically, colposcopy is performed on women that have been referred after a screening test (cytology and/or HPV) indicated suspicion for disease. The purpose of colposcopy is to visually evaluate the cervix, perform a series of assessments (most importantly, the assessment of: acetowhitening, iodine staining, vessel morphology, lesion morphology) and then decide (following national and local guidelines) the appropriate management. Management options may include biopsy sampling for histopathological diagnosis, discharge to routine screening, surveillance or immediate treatment. Diagnosis is only provided by histopathology review of biopsy samples, and with respect to biopsy, the role of the colposcopist is to decide which locations on the cervix should be biopsied and then take the samples.

Failure to perform a colposcopy does not introduce a significant risk to the patient's well-being as it can be repeated at a later time. The progression of cervical disease is rather slow, so a few hours or days of delay do not introduce a risk.

The DYSISmap, included as a distinct additional feature on the DYSIS device, provides clinicians a means to obtain an objective impression of the acetowhitening in a simple-to-read way. Clinicians may (or may choose not to) include the DYSISmap information in their assessment (i.e., as an element added to the list above). The DYSISmap is an adjunctive tool that does not suggest a diagnosis of a cervical condition and never obliviates the need for a thorough visual colposcopy. Furthermore, biopsies chosen based on visual colposcopy should never be canceled because of the DYSISmap.

The DYSISmap is an adjunct, and as such, a thorough colposcopic examination is performed irrespective of it. Furthermore, the DYSISmap is not used to cancel an otherwise appropriate biopsy, so disease will not be missed because of a DYSISmap failure.

Neither the DYSIS Digital Colposcope nor the DYSISmap are diagnosis aids, and even more so, as colposcopy that they are used for is not intended to provide a direct diagnosis of a patient's condition.

In conclusion, use of DYSIS Digital Colposcopes does not depend on essential performance.

27. Technical Description

27.1. DYSIS Ultra 2.0

General Information:

- Product Name: DYSIS Ultra 2.0 Digital Colposcope
- EC Product Class: Class IIa, FDA Product Class II

Mechanical:

- Monitor Arm (ARMD) - 5 degrees of freedom (X, Y, Z, tilt and yaw)
- Optical Head Arm (ARMO) – 5 degrees of freedom (X, Y, Z, tilt and yaw)
- Main Stand with 6 axis wheelbase (BASE)

PC Unit and Monitor:

- DYSIS proprietary software running on Linux operating system
- Motherboard: 8th Generation core i3 CPU; on-board GPU
- RAM: 8GB, HDD: 1 TB, SSD: 256GB
- 1 x USB port
- 1 x HDMI port
- 1 x Ethernet port
- Monitor - 15” touchscreen monitor Full HD 1920x1080P pixels max resolution @ 60Hz

Imaging Head Unit:

- CMOS sensor
- Resolution: 2802 x 2100 pixels, >20 frames per second, ~20-line pairs per mm resolution
- Digital interface: USB3

DYSIS Ultra 2.0 Digital Colposcope Power/Operation:

- Frequency: 50/60Hz
- Rated Input Voltage: 100-240VAC
- Rated Output: 12VDC
- Start Up Time to Operation < 1 min
- Operational Footprint Length, Width, Height (cm): 125 x 70 x 165
- Idle Footprint - Length, Width, Height (cm): 70 x 70 x 165
- DYSIS Ultra 2.0 Product Weight: 69 Kg (Plus packaging 104 Kg)
- Packaging dimensions - Length, Width, Height (cm): 83 x 83 x 143

Each DYSIS Ultra 2.0 Digital Colposcope system is accompanied by:

- DYSIS acetic acid applicator
- DYSIS declaration of conformity, EUR
- DYSIS Ultra 2.0 Digital Colposcope quick reference guide
- DYSIS calibration card
- DYSIS calibration jig

27.2. DYSIS Ultra 3.0

General Information:

- Product Name: DYSIS Ultra 3.0 Digital Colposcope

- EC Product Class: Class IIa, FDA Product Class II

Mechanical:

- Monitor Arm (ARMD) - 5 degrees of freedom (X, Y, Z, tilt and yaw)
- Optical Head Arm (ARMO) – 5 degrees of freedom (X, Y, Z, tilt and yaw)
- Main Stand with 6 axis wheelbase (BASE)

PC Unit and Monitor:

- DYSIS proprietary software running on Linux operating system
- Motherboard: 8th Generation core i3 CPU; on-board GPU
- RAM: 8GB, HDD: 1 TB, SSD: 256GB
- 1 x USB port
- 1 x HDMI port
- 1 x Ethernet port
- Monitor - 15” touchscreen monitor Full HD 1920x1080P pixels max resolution @ 60Hz

Imaging Head Unit:

- CMOS sensor
- Resolution: 2802 x 2100 pixels, >20 frames per second, ~20-line pairs per mm resolution
- Digital interface: USB3

DYSIS Ultra 3.0 Digital Colposcope Power/Operation:

- Frequency: 50/60Hz
- Rated Input Voltage: 100-240VAC
- Rated Output: 12VDC
- Start Up Time to Operation < 1 min
- Operational Footprint Length, Width, Height (cm): 125 x 70 x 165
- Idle Footprint - Length, Width, Height (cm): 70 x 70 x 165
- DYSIS Ultra 3.0 Product Weight: 81 Kg (Plus packaging 116 Kg)
- Packaging dimensions - Length, Width, Height (cm): 83 x 83 x 143

Each DYSIS Ultra 3.0 Digital Colposcope system is accompanied by:

- DYSIS acetic acid applicator
- DYSIS declaration of conformity, EUR
- DYSIS Ultra 3.0 Digital Colposcope quick reference guide
- DYSIS calibration card
- DYSIS calibration jig

27.3. DYSIS View

General Information:

- Product Name: DYSIS View Digital Colposcope
- EC Product Class: Class IIa, FDA Product Class II

Mechanical:

- Optical Head Arm – 2 degrees of freedom (Y, Z)

PC Unit and Monitor:

- DYSIS proprietary software running on Linux operating system
- Motherboard: 10th Generation core i3 CPU; on-board GPU
- RAM: 8GB, SSD: 128Gb
- 1 x multi port to connect to the touch screen monitor
- Monitor - 15” touchscreen monitor Full HD 1920x1080P pixels max resolution @ 50Hz
- WiFi: Intel® Wi-Fi 6 AX201 (Gig+), 802.11ax

Imaging Head Unit:

- CMOS sensor
- Resolution: 2768 x 2076 pixels, >20 frames per second, ~20 line pairs per mm resolution
- Digital interface: USB3

DYSIS View Digital Colposcope Power/Operation:

- Frequency: 50/60Hz
- Rated Input Voltage: 100-240VAC
- Rated Output: 12VDC
- Fuse: 12VDC, 10A, operating speed and breaking capacity
- Start Up Time to Operation <1 min
- Operational Footprint Length, Width, Height (cm): 43 x 32 x 85
- Idle Footprint - Length, Width, Height (cm): 32 x 32 x 85
- DYSIS View Product Weight: 8Kg (Plus packaging 15 Kg)
- Packaging dimensions - Length, Width, Height (cm): 94 x 44 x 36

Each DYSIS View Digital Colposcope system is accompanied by:

- DYSIS acetic acid platform applicator
- DYSIS declaration of conformity, EUR
- DYSIS calibration card
- DYSIS calibration jig

28. 60601-1-2 DATA (DYSIS Ultra 2.0)

Tables of guidance and manufacturer's declaration regarding electromagnetic emissions and immunity as per EN 60601-1-2:2015. Data extracted from Eurofins York EMC Test Report 5110TR2 as summarized in Test certificate 5109TC1.

EN60601-1-2: 2015 **Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances – Requirements and tests** **For Professional Healthcare Facility Environment**		
Reference Standard	**Levels**	**Result**
Emissions		
Conducted RF emission EN55011:2009+ A1:2010	Class A Mode 1 Mode 2 At 230V 50Hz and 110V 60Hz	Pass
Radiated RF emission (Enclosure) EN55011:2009+ A1:2010	Class A Mode 1 Mode 2	Pass
Harmonic Distortion EN61000-3-2+A1:2009+A2:2009	A Mode 1	Pass
Voltage Fluctuations and Flicker EN61000-3-3: 2013	Plt Pst Dmax Mode 1	Pass
Immunity		
Enclosure Port		
Electrostatic Discharge EN61000-4-2: 2009	±2, 4, 8, 15kV air ±2, 4, 6, 8kV contact Mode 1	Pass
Radiated RF EM fields EN61000-4-3: 2006+A1:2008+ IS1:2009+A2: 2010	3V/m 80-2700MHz Mode 1	Pass
Proximity fields from RF wireless protos equipment EN61000-4-3: 2006+A1:2008+ IS1:2009+A2: 2010	As detailed below and in section 8.10 of standard Mode 1	Pass

EN60601-1-2: 2015
Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances – Requirements and tests
For Professional Healthcare Facility Environment

Reference Standard				**Levels**		**Result**
Test frequency (MHz)	**Band (MHz)**	**Service**	**Modulation**	**Maximum Power (W)**	**Distance (m)**	**Immunity Test Level (V/m)**
385	380-390	TETRA	Pulse Modulation 18Hz	1.8	0.3	27
450	430-470	GMRS 460 FRS460	FM ±5kHz deviation 1kHz sinewave	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse Modulation 217Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE Band 5	Pulse Modulation 18Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse Modulation 217Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation 217Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse Modulation 217Hz	0.2	0.3	9
5500						
5785						
RATED power frequency magnetic fields EN 61000-4-8:2010				30A/m No magnetically sensitive parts		N/A
Input a.c. power Port						
Electrical Fast Transients / Bursts EN61000-4-4:2012				±2kV 100kHz repetition frequency Mode 1		Pass
Surges EN61000-4-5:2006				±0.5 and 1kV line to line ±0.5, 1 and 2kV line to earth Mode 1		Pass

EN60601-1-2: 2015 **Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances – Requirements and tests** **For Professional Healthcare Facility Environment**		
Reference Standard	**Levels**	**Result**
Conducted disturbances induced by RF fields EN 61000-4-6: 2014	3Vrms 0.15-80MHz 6Vrms in ISM bands between 0.15MHz and 80MHz. The ISM (industrial, scientific and medical) bands between 0.15MHz and 80MHz are 6.765MHz to 6.795 MHz; 13.553MHz to 13.567MHz; 26.957MHz to 27.283MHz; and 40.66MHz to 40.70MHz Mode 1	Pass
Voltage Dips and Interrupts EN 61000-4-11:2004	0 % U_T; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle And 70 % U_T; 25/30 cycles Single phase: at 0° 0 % U_T; 250/300 cycle Mode 1 230V and 100V	Pass
Input DC Power Port		
Electrical Fast Transients / Bursts EN61000-4-4:2012	±2kV 100kHz repetition frequency No DC port	N/A
Surges EN61000-4-5:2006	±0.5 and ±1kV line to line ±0.5, 1 and 2kV line to earth No DC port	N/A
Conducted disturbances induced by RF fields EN 61000-4-6: 2014	3Vrms 0.15-80MHz 6Vrms in ISM bands between 0.15MHz and 80MHz. No DC port	N/A
Electrical Transient conduction along supply lines ISO7637-2	Not applicable	N/A
Patient coupling port		
Electrostc Discharge EN61000-4-2: 2009	±2, 4, 8, 15kV air ±2, 4, 6, 8kV contact No patient coupling port	N/A

EN60601-1-2: 2015 **Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances – Requirements and tests** **For Professional Healthcare Facility Environment**		
Reference Standard	**Levels**	**Result**
Conducted disturbances induced by RF fields EN 61000-4-6: 2014	3Vrms 0.15-80MHz 6Vrms in ISM bands between 0.15MHz and 80MHz. No patient coupling port	N/A
Signal input/output parts Port		
Electrostatic Discharge EN61000-4-2: 2009	±2, 4, 8, 15kV air ±2, 4, 6, 8kV contact Mode 1	Pass
Electrical Fast Transients / Bursts EN61000-4-4:2012	±1kV 100kHz repetition frequency Mode 1	Pass
Surges EN61000-4-5:2006	±0.5 and ±1kV line to line ±0.5, 1 and 2kV line to earth No outdoor cables	N/A
Conducted disturbances induced by RF fields EN 61000-4-6: 2014	3Vrms 0.15-80MHz 6Vrms in ISM bands between 0.15MHz and 80MHz. The ISM (industrial, scientific and medical) bands between 0.15MHz and 80MHz are 6.765MHz to 6.795 MHz; 13.553MHz to 13.567MHz; 26.957MHz to 27.283MHz; and 40.66MHz to 40.70MHz Mode 1	Pass

29. 60601-1-2 DATA (DYSIS Ultra 3.0)

Tables of guidance and manufacturer's declaration regarding electromagnetic emissions and immunity as per EN 60601-1-2:2015. Data extracted from Eurofins York EMC Test Report 6017TR1 as summarized in Test certificate 6018TC1.

IEC 60601-1-2: 2014 + A1:2020 **EN 6060-1-2: 2015 + A1: 2021** **Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance -Collateral standard: Electromagnetic disturbances – Requirements and tests** **For Professional Healthcare Facility Environment**		
Reference Standard	**Levels**	**Result**
Emissions		
Conducted RF emission EN55011:2016+ A1:2017+ A11: 2020	Class B *Tested in Modes 1 & 2*	Pass
Radiated RF emission (Enclosure) EN55011:2016+ A1:2017+ A11: 2020	Class B *Tested in Modes 1 & 2*	Pass
Harmonic Distortion EN61000-3-2: 2019	A *Tested in Modes 1 & 2*	Pass
Voltage Fluctuations and Flicker EN61000-3-3: 2013	Plt Pst Dmax *Tested in Modes 1 & 2*	Pass
Immunity		
Enclosure Port		
Reference Standard	**Levels**	**Results**
Electrostatic Discharge EN61000-4-2: 2009	±2, 4, 8, 15kV air ±8kV contact *Tested in Modes 1 & 2*	Pass
Radiated RF EM fields EN61000-4-3: 2006+A1:2008+ IS1:2009+A2: 2010	3V/m 80-2700MHz *Tested in Modes 1 & 2*	Pass
Proximity fields from RF wireless communicationsequipment EN61000-4-3: 2006+A1:2008+ IS1:2009+A2: 2010	As detailed below and in section 8.10 of standard *Tested in Modes 1 & 2*	Pass

IEC 60601-1-2: 2014 + A1:2020
EN 6060-1-2: 2015 + A1: 2021
Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance -Collateral standard: Electromagnetic disturbances – Requirements and tests
For Professional Healthcare Facility Environment

Reference Standard			**Levels**			**Result**
Test frequency (MHz)	**Band (MHz)**	**Service**	**Modulation**	**Maximum Power (W)**	**Distance (m)**	**ImmunityTest Level (V/m)**
385	380-390	TETRA	Pulse Modulation 18Hz	1.8	0.3	27
450	430-470	GMRS 460 FRS460	FM ±5kHz deviation 1kHz sinewave	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse Modulation 217Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE Band 5	Pulse Modulation 18Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse Modulation 217Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation 217Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse Modulation 217Hz	0.2	0.3	9
5500						
5785						
RATED power frequency magnetic fields EN 61000-4-8:2010			30A/m *Not applicable – no magnetically sensitive devices*			N/A

IEC 60601-1-2: 2014 + A1:2020 **EN 6060-1-2: 2015 + A1: 2021** **Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance -Collateral standard: Electromagnetic disturbances – Requirements and tests** **For Professional Healthcare Facility Environment**		
Reference Standard	**Levels**	**Result**
Proximity magnetic fields IEC 61000-4-39:2017 EN 61000-4-39:2017 (Not UKAS accredited)	As detailed below and in section 8.11 of standard (Table 11) *Tested in Modes 1 & 2*	Pass
Input a.c. power Port		
Electrical Fast Transients / Bursts EN61000-4-4:2012	±2kV 100kHz repetition frequency *Tested in Modes 1 & 2*	Pass
Surges EN61000-4-5:2014 + a1: 2017	±0.5 and 1kV line to line ±0.5, 1 and 2kV line to earth *Tested in Modes 1 & 2*	Pass
Conducted disturbances induced by RF fields EN 61000-4-6: 2014	3Vrms 0.15-80MHz 6Vrms in ISM bands between 0.15MHz and 80MHz. The ISM (industrial, scientific and medical) bands between 0.15MHz and 80MHz are 6.765MHz to 6.795 MHz; 13.553MHz to 13.567MHz; 26.957MHz to 27.283MHz; and 40.66MHz to 40.70MHz *Tested in Modes 1 & 2*	Pass
Voltage Dips and Interrupts EN 61000-4-11:2004	0 % UT; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25 cycles Single phase: at 0° 0 % UT; 250 cycle *Tested in Modes 1 & 2*	Pass

Input DC Power Port		
Electrical Fast Transients / Bursts EN61000-4-4:2012	±2kV 100kHz repetition frequency *Not applicable - No DC ports*	N/A
Surges EN61000-4-5:2006	±0.5 and ±1kV line to line ±0.5, 1 and 2kV line to earth *Not applicable - No DC ports*	N/A

IEC 60601-1-2: 2014 + A1:2020
EN 6060-1-2: 2015 + A1: 2021
Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance -Collateral standard: Electromagnetic disturbances – Requirements and tests
For Professional Healthcare Facility Environment

Reference Standard	Levels	Result
Conducted disturbances induced by RF fields EN 61000-4-6: 2014	3Vrms 0.15-80MHz 6Vrms in ISM bands between 0.15MHz and 80MHz. The ISM (industrial, scientific and medical) bands between 0.15MHz and 80MHz are 6.765MHz to 6.795 MHz; 13.553MHz to 13.567MHz; 26.957MHz to 27.283MHz; and 40.66MHz to 40.70MHz *Not applicable - No DC ports*	N/A
Electrical Transient conduction along supply linesISO7637-2	Not to be fitted in a vehicle	N/A
Patient coupling port		
Electrosta tic Discharge EN61000- 4-2: 2009	⍰2, 4, 8, 15kV air ⍰8kV contact *Not applicable - No patient coupling ports*	N/A
Conducted disturbances induced by RF fields EN 61000-4-6: 2014	3Vrms 0.15-80MHz 6Vrms in ISM bands between 0.15MHz and 80MHz. The ISM (industrial, scientific and medical) bands between 0.15MHz and 80MHz are 6.765MHz to 6.795 MHz; 13.553MHz to 13.567MHz; 26.957MHz to 27.283MHz; and 40.66MHz to 40.70MHz *Not applicable - No patient coupling ports*	N/A
Signal input/output parts Port		

Electrostatic DischargeEN61000-4-2: 2009	±2, 4, 8, 15kV air ±8kV contact *Not applicable – no cables >3m*	N/A
Electrical Fast Transients / Bursts EN61000-4-4:2012	±1kV 100kHz repetition frequency *Not applicable – no cables >3m*	N/A
Surges EN61000-4-5:2006 This test applies only to output lines intended toconnect directly to outdoor cables	±0.5 and ±1kV line to line ±0.5, 1 and 2kV line to earth *Not applicable - No outdoor cables*	N/A
Conducted disturbances induced by RF fields EN 61000-4-6: 2014	3Vrms 0.15-80MHz 6Vrms in ISM bands between 0.15MHz and 80MHz. The ISM (industrial, scientific and medical) bands between 0.15MHz and 80MHz are 6.765MHz to 6.795 MHz; 13.553MHz to 13.567MHz; 26.957MHz to 27.283MHz; and 40.66MHz to 40.70MHz *Not applicable – no cables >3m*	N/A

EN 301 489-1 V2.2.3 (2019-11) Electromagnetic compatibility and Radio Spectrum Matters (ERM);
Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements
EN 301 489-17 V3.2.4 (2020-09) Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems
Harmonised Standard for Electromagnetic compatibility

Test	**Class/limit/level**	**Result**
EN 301 489-17 Table A1 Conducted RF emission, (AC power port) EN55032: 2015 (Dated Standard)	EN301-489-1 clause 8.4 Class B Limits 0.15-0.5MHz 66-56dB±V QP 0.5-5MHz 56dB±V QP 5-30MHz 60dB±V QP 0.15-0.5MHz 56-46dB±V Ave 0.5-5MHz 46dB±V Ave 5-30MHz 50dB±V Ave Alternatively, for ancillary equipment intended to be used exclusively in an industrial environment or telecommunicationcentres, the class A limits given in EN 55032 may be used. *Tested in Mode 2*	Pass

EN 301 489-17 Table A1 Conducted RF emission, (Wired network port) EN55032: 2015 (Dated Standard)	EN301-489-1 clause 8.7.3 Class B Limits 0.15-0.5MHz 84-74dB□V QP 0.5-30MHz 74dB□V QP 0.15-0.5MHz 74-64dB□V Ave 0.5-30MHz 64dB□V Ave Alternatively, for ancillary equipment intended to be used exclusively in an industrial environment or telecommunicationcentres, the class A limits given in EN 55032 may be used. *Not applicable – no Telecoms line*	N/A
EN 301 489-17 Table A1 Mains Harmonics, (AC power port) EN61000-3-2: 2019 (Dated Standard)	EN301-489-1 clause 8.5 A *Tested in Mode 2*	Pass
EN 301 489-17 Clause 7.1 Voltage fluctuations, (AC power port) EN61000-3-3: 2013 + A1: 2019 (Dated Standard)	EN301-489-1 clause 8.6 Plt Dmax *Tested in Mode 2*	Pass
EN 301 489-17 Table A1 Radiated RF immunity, (Enclosure) EN61000-4-3: 2006 +A1, A2 (Dated Standard)	EN301-489-1 clause 9.2 3V/m 80-6000MHz 1kHz 80% AM Please refer to 301 489-17 section 4.3 for exclusion bands *Tested in Mode 2*	Pass

EN 301 489-1 V2.2.3 (2019-11) Electromagnetic compatibility and Radio Spectrum Matters (ERM); Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements

EN 301 489-17 V3.2.4 (2020-09) Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems
Harmonised Standard for Electromagnetic compatibility

Test	**Class/limit/level**	**Result**
EN 301 489-17 Table A.1 Electrostatic discharge EN61000-4-2: 2009 (Dated Standard)	EN301-489-1 clause 9.3 +/-8kV air discharge +/-4kV direct discharge *Tested in Mode 2*	Pass
EN 301 489-17 Table A.1 Fast transients common mode EN61000-4-4: 2012 (Dated Standard)	EN301-489-1 clause 9.4 0.5kV signal lines, input & dc ports 1kV ac power ports Not applicable to signal ports where cables are <3m *Tested in Mode 2*	Pass
EN 301 489-17 Table A.1 Conducted RF immunity (AC, DC, Signal & Earth lines) EN61000-4-6: 2014 (Dated Standard)	EN301-489-1 clause 9.5 3Vrms 1kHz 80%AM 0.15-80MHz *Tested in Mode 2*	Pass
EN 301 489-17 Table A.1 Transient and surges (Vehicular DC power line)ISO7637-1/2	EN301-489-1 clause 9.6	N/A

EN 301 489-17 Table A.1 Voltage dips & interruptions (AC power line) EN61000-4-11: 2004 (Dated Standard)	EN301-489-1 clause 9.7 0% @ 0.5 cycles 0% @ 1 cycle 70% @ 25 cycles 0% @ 250 cycles *Tested in Mode 2*	Pass
EN 301 489-17 Table A1 Transient Com & Differential mode (AC power line) EN61000-4-5: 2014 + A1 (Dated Standard)	EN301-489-1 clause 9.8 0.5kV line to line 1kV line to earth *Tested in Mode 2*	Pass

30. 60601-1-2 DATA (DYSIS View)

Tables of guidance and manufacturer's declaration regarding electromagnetic emissions and immunity as per EN 60601-1-2:2015. Data extracted from Eurofins York EMC Test Report 5657TR1 as summarized in Test certificate G5658TC1.

EN60601-1-2: 2015
Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance -Collateral standard: Electromagnetic disturbances – Requirements and tests
For Professional Healthcare Facility Environment

Reference Standard	**Levels**	**Result**
Emissions		
Conducted RF emission EN55011:2009+ A1:2010	Class B *Tested in Modes 1 & 2*	Pass
Radiated RF emission (Enclosure)EN55011:2009+ A1:2010	Class B *Tested in Modes 1 & 2*	Pass
Harmonic Distortion EN61000-3-2+A1:2009+A2:2009	A *Tested in Modes 1 & 2*	Pass
Voltage Fluctuations and FlickerEN61000-3-3: 2013	Plt Pst Dmax *Tested in Modes 1 & 2*	Pass
Immunity		
Enclosure Port		
Reference Standard	**Levels**	**Results**
Electrostatic Discharge EN61000-4-2: 2009	±2, 4, 8, 15kV air ±2, 4, 6, 8kV contact *Tested in Modes 1 & 2*	Pass
Radiated RF EM fields EN61000-4-3: 2006+A1:2008+ IS1:2009+A2: 2010	3V/m 80-2700MHz *Tested in Modes 1 & 2*	Pass
Proximity fields from RF wireless communications equipment EN61000-4-3: 2006+A1:2008+ IS1:2009+A2: 2010	As detailed below and in section 8.10 ofstandard *Tested in Modes 1 & 2*	Pass

EN60601-1-2: 2015
Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance -Collateral standard: Electromagnetic disturbances – Requirements and tests
For Professional Healthcare Facility Environment

Reference Standard			**Levels**			**Result**
Test frequency (MHz)	**Band (MHz)**	**Service**	**Modulation**	**Maximum Power (W)**	**Distance (m)**	**Immunity Test Level (V/m)**
385	380-390	TETRA	Pulse Modulation 18Hz	1.8	0.3	27
450	430-470	GMRS 460 FRS460	FM ±5kHz deviation 1kHz sinewave	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse Modulation 217Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE Band 5	Pulse Modulation 18Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band1, 3, 4, 25; UMTS	Pulse Modulation 217Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation 217Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse Modulation 217Hz	0.2	0.3	9
5500						
5785						
RATED power frequency magnetic fieldsEN 61000-4-8:2010			30A/m *Not applicable – no magnetically sensitive devices*			N/A
Input a.c. power Port						
Electrical Fast Transients / Bursts EN61000-4-4:2012 ±2kV			100kHz repetition frequency *Tested in Modes 1 & 2*			Pass
Surges EN61000-4-5:2006			±0.5 and 1kV line to line ±0.5, 1 and 2kV line to earth *Tested in Modes 1 & 2*			Pass

EN60601-1-2: 2015 **Medical electrical equipment Part 1-2: General requirements for basic safety andCollateral standard: Electromagnetic disturbances – Requirements and tests** **For Professional Healthcare Facility Environment essential performance**		
Reference Standard	**Levels**	**Result**
Conducted disturbances induced by RF fields EN 61000-4-6: 2014	3Vrms 0.15-80MHz 6Vrms in ISM bands between 0.15MHz and80MHz. The ISM (industrial, scientific and medical) bands between 0.15MHz and 80MHz are 6.765MHz to 6.795 MHz; 13.553MHz to 13.567MHz; 26.957MHz to 27.283MHz; and 40.66MHz to 40.70MHz *Tested in Modes 1 & 2*	Pass
Voltage Dips and Interrupts EN 61000-4-11:2004	0 % U_T; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25 cycles Single phase: at 0° 0 % U_T; 250 cycle *Tested in Modes 1 & 2*	Pass
Input DC Power Port		
Electrical Fast Transients / Bursts EN61000-4-4:2012	±2kV 100kHz repetition frequency *Not applicable - No DC ports*	N/A
Surges EN61000-4-5:2006	±0.5 and ±1kV line to line ±0.5, 1 and 2kV line to earth *Not applicable - No DC ports*	N/A
Conducted disturbances induced by RF fields EN 61000-4-6: 2014	3Vrms 0.15-80MHz 6Vrms in ISM bands between 0.15MHz and80MHz. The ISM (industrial, scientific and medical) bands between 0.15MHz and 80MHz are 6.765MHz to 6.795 MHz; 13.553MHz to 13.567MHz; 26.957MHz to 27.283MHz; and 40.66MHz to 40.70MHz *Not applicable - No DC ports*	N/A
Electrical Transient conduction along supply lines ISO7637-2	Not applicable	N/A

EN60601-1-2: 2015
Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance -Collateral standard: Electromagnetic disturbances – Requirements and tests
For Professional Healthcare Facility Environment

Reference Standard	Levels	Result
Patient coupling port		
Electrostatic Discharge EN61000-4-2: 2009	±2, 4, 8, 15kV air ±2, 4, 6, 8kV contact *Not applicable - No patient coupling ports*	N/A
Conducted disturbances induced by RF fields EN 61000-4-6: 2014	3Vrms 0.15-80MHz 6Vrms in ISM bands between 0.15MHz and80MHz. The ISM (industrial, scientific and medical) bandsbetween 0.15MHz and 80MHz are 6.765MHz to 6.795 MHz; 13.553MHz to 13.567MHz; 26.957MHz to 27.283MHz; and 40.66MHz to 40.70MHz *Not applicable - No patient coupling ports*	N/A
Signal input/output parts Port		
Electrostatic Discharge EN61000-4-2: 2009	±2, 4, 8, 15kV air ±2, 4, 6, 8kV contact *Not applicable – no cables >3m*	N/A
Electrical Fast Transients / Bursts EN61000-4-4:2012	±1kV 100kHz repetition frequency *Not applicable – no cables >3m*	N/A
Surges EN61000-4-5:2006 This test applies only to output lines intended toconnect directly to outdoor cables	±0.5 and ±1kV line to line ±0.5, 1 and 2kV line to earth *Not applicable - No outdoor cables*	N/A
Conducted disturbances induced by RF fields EN 61000-4-6: 2014	3Vrms 0.15-80MHz 6Vrms in ISM bands between 0.15MHz and80MHz. The ISM (industrial, scientific and medical) bandsbetween 0.15MHz and 80MHz are 6.765MHz to 6.795 MHz; 13.553MHz to 13.567MHz; 26.957MHz to 27.283MHz; and 40.66MHz to 40.70MHz *Not applicable – no cables >3m*	N/A

Radio Testing – EMC

EN 301 489-1 V2.1.1 Electromagnetic compatibility and Radio Spectrum Matters (ERM);
Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements

Draft EN 301 489-17 V3.2.0 Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 17:Specific conditions for Broadband Data Transmission Systems
Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU (Not UKAS Accredited)

Test	Class/limit/level	Result
EN 301 489-17 Clause 7.1 Radiated RF emission (Enclosure) EN55032: 2015 (Dated Standard)	EN301-489-1 clause 8.2 Class B Limits 30-230MHz 40dBµV/m QP 230-1000MHz 47dBµV/m QP Alternatively, for ancillary equipment intended to be used exclusively in an industrial environment or telecommunication centres, the class A limitsgiven in EN 55032 may be used. *Tested in Modes 2*	Pass
	EN301-489-1 clause 8.2 Class B Limits 1-3GHz 50dBµV/m Ave 3-6GHz 54dBµV/m Ave 1-3GHz 70dBµV/m Peak 3-6GHz 74dBµV/m Peak *Tested in Modes 2*	Pass
EN 301 489-17 Clause 7.1 Conducted RF emission, (DC power port) EN55032: 2015 (Dated Standard)	EN301-489-1 clause 8.3 Class B Limits 0.15-0.5MHz 66-56dBµV QP 0.5-5MHz 56dBµV QP 5-30MHz 60dB□V QP 0.15-0.5MHz 56-46dBµV Ave 0.5-5MHz 46dBµV Ave 5-30MHz 50dBµV Ave Alternatively, for ancillary equipment intended tobe used exclusively in an industrial environment or telecommunication centres, the class A limitsgiven in EN 55032 may be used. *Not applicable - No DC ports*	N/A

EN 301 489-1 V2.1.1 Electromagnetic compatibility and Radio Spectrum Matters (ERM); Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements **Draft EN 301 489-17 V3.2.0 Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 17:Specific conditions for Broadband Data Transmission Systems** **Harmonised Standard covering the essential requirements article 3.1(b) of Directive 2014/53/EU (Not UKAS Accredited)**		
Test	**Class/limit/level**	**Result**
EN 301 489-17 Clause 7.1 Conducted RF emission, (AC power port) EN55032: 2015 (Dated Standard)	EN301-489-1 clause 8.4 Class B Limits 0.15-0.5MHz 66-56dBµV QP 0.5-5MHz 56dBµV QP 5-30MHz 60dBµV QP 0.15-0.5MHz 56-46dBµV Ave 0.5-5MHz 46dBµV Ave 5-30MHz 50dBµV Ave Alternatively, for ancillary equipment intended tobe used exclusively in an industrial environment or telecommunication centres, the class A limitsgiven in EN 55032 may be used. *Tested in Mode 2*	Pass
EN 301 489-17 Clause 7.1 Conducted RF emission, (Wired networkport) EN55032: 2015 (Dated Standard)	EN301-489-1 clause 8.7.3 Class B Limits 0.15-0.5MHz 84-74dBµV QP 0.5-30MHz 74dBµV QP 0.15-0.5MHz 74-64dBµV Ave 0.5-30MHz 64dBµV Ave *Not applicable – no Telecoms line*	N/A
EN 301 489-17 Clause 7.1 Mains Harmonics, (AC power port) EN 61000-3-2: 2006 +A1, A2 (EN61000-3-2: 2014), (Dated Standard)	EN301-489-1 clause 8.5 A *Tested in Mode 2*	Pass
EN 301 489-17 Clause 7.1 Voltage fluctuations, (AC power port) EN61000-3-3: 2013 (Dated Standard)	EN301-489-1 clause 8.6 Plt Pst Dmax *Tested in Mode 2*	Pass

EN 301 489-1 V2.1.1 Electromagnetic compatibility and Radio Spectrum Matters (ERM); Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements **Draft EN 301 489-17 V3.2.0 Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 17:Specific conditions for Broadband Data Transmission Systems** **Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU (Not UKAS Accredited)**		
Test	**Class/limit/level**	**Result**
EN 301 489-17 Table A1 Radiated RF immunity, (Enclosure) EN61000-4-3: 2006 +A1, A2 (Dated Standard)	See EN50121-4 EN301-489-1 clause 9.2 3V/m 80-6000MHz 1kHz 80% AM Please refer to 301 489-17 section 4.3 for exclusion bands (*Tested on mode 2)*	Pass
EN 301 489-17 Table A.1 Electrostatic discharge EN61000-4-2: 2009 (Dated Standard)	EN301-489-1 clause 9.3 +/-8kV air discharge +/-4kV direct discharge *Tested in Mode 2*	Pass
EN 301 489-17 Table A.1 Fast transients common mode EN61000-4-4: 2012 (Dated Standard)	EN301-489-1 clause 9.4 0.5kV signal lines, input & dc ports 1kV ac power ports Not applicable to signal ports where cables are <3m *Tested in Mode 2*	Pass
EN 301 489-17 Table A.1 Conducted RF immunity (AC, DC, Signal & Earth lines) EN61000-4-6: 2009 (Dated Standard)	EN301-489-1 clause 9.5 3Vrms 1kHz 80%AM 0.15-80MHz *Tested in Mode 2*	Pass
EN 301 489-17 Table A.1 Transient and surges (Vehicular DC power line) ISO7637-1/2	EN301-489-1 clause 9.6	N/A
EN 301 489-17 Table A.1 Voltage dips & interruptions (AC power line) EN61000-4-11: 2004 (Dated Standard)	EN301-489-1 clause 9.7 0% @ 0.5 cycles 0% @ 1 cycle 70% @ 25 cycles 0% @ 250 cycles *Tested in Mode 2*	Pass

EN 301 489-1 V2.1.1 Electromagnetic compatibility and Radio Spectrum Matters (ERM); Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements **Draft EN 301 489-17 V3.2.0 Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 17:Specific conditions for Broadband Data Transmission Systems** **Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU (Not UKAS Accredited)**		
Test	**Class/limit/level**	**Result**
EN 301 489-17 Clause 7.2 Transient Com & Differential mode (AC power line)	EN301-489-1 clause 9.8 0.5kV line to line 1kV line to earth	Pass