

DySISmedical

DySIS Digital Colposcope Instructions for Use



DySIS v3, International Edition

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Unless otherwise specified in this guide or in explicit written consent, no components other than those provided or recommended by the manufacturer should be used with the device.

The software described in this guide is furnished under a license agreement of nondisclosure. The software may be used or copied only in accordance with the terms of the agreement.

The FCC requires the user to be notified that any changes or modifications made to this device that are not expressly approved by DySIS Medical, may void the user's authority to operate the equipment.

Cable connections to this device must be made with shielded cables to maintain compliance with FCC Rules and Regulations.

Product names mentioned herein may be trademarks and/or registered trademarks of their respective companies.

This guide is a supplemental reference that takes the user further than the operational training with general information about DySIS, troubleshooting and diagnostics, as well as technical specifications.

For technical information and support regarding DySIS, email at service@dysismedical.com or contact your local representative. For general information regarding DySIS, contact DySIS Medical at info@dysismedical.com.

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	<p>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.</p>
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STANDARDS APPLIED

EN 60601-1:2006+A12:2014 Medical electrical equipment Part 1: General requirements for basic safety and essential performance

EN 60601-1-6+A1:2015:2010 Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

EN 62304:2006 Medical device software - Software life-cycle processes

EN ISO 13485:2012 Medical devices - Quality management systems - Requirements for regulatory purposes

EN ISO 17664:2004 Sterilization of medical devices - Information to be provided by the manufacturer for the processing of re-sterilisable medical devices

EN ISO 14971:2012 Medical devices - Application of risk management to medical devices

EN ISO 11135-1:2007 Sterilization of health care products. Ethylene oxide.

EN ISO 11607-1:2009 Packaging for Terminally Sterilized Medical Devices

EN ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

EN ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

EN ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals

EN ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

EN ISO 15223-1:2012 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

EN ISO 14644-1:1999 Cleanrooms and associated controlled environments.
Classification of air cleanliness

BS EN 1041:2008+A1:2013 Information supplied by the manufacturer of
medical devices

EN ISO 60601-2-18:1997 Medical electrical equipment. Particular requirements
for safety. Specification for endoscopic equipment. Section 2.18: Specification
for endoscopic equipment

The CE mark on this product indicates that it has been tested to and conforms
to the Essential Requirements of the Medical Device Directive 93/42/EEC as
amended by 2007/47/EC, the Low Voltage Directive 2006/95/EC & the
Electromagnetic Compatibility Directive 2008/104/EC

This device is a Risk Group 2 LED product according to EN 62471 (2008) that
covers photo-biological safety, under normal operating conditions and those of
single fault failure.

1. INTRODUCTION

Thank you for purchasing DySIS v3 (CAT#: DYS302), the advanced digital colposcope manufactured by DySIS Medical.

Please read this guide carefully before using your new equipment. DySIS has been designed to maximize safety and minimize strain for users and patients. However, certain precautions should be taken to further reduce the risk of personal injury or damage to the device. Be certain to follow the general precautions below and to note the cautions included in this guide. To maintain your DySIS in good working condition, please follow the operation and maintenance procedures described herein.

1.1. General

DySIS is a digital colposcope developed to assist clinicians in the *in vivo* evaluation, the documentation and the follow-up of cervical pathology. DySIS is meant to be used in hospitals and clinics by users trained in the relevant medical procedures. The DySIS intended operator is a medical professional allowed to perform colposcopic examinations. No particular technical expertise is required for operating DySIS.

DySIS integrates:

- Operation and image viewing on optimally placed touch-screen, improving ergonomics and clinical work-flow.
- Bright white-LED illumination for stable operation and long life-time.
- High resolution imaging sensor for crisp colour and spectral images.
- Three magnification scales.
- Surface reflections (glare) elimination by patented polarized optics.
- Colour-coded mapping of the tissue acetowhitening to assist evaluation, documentation and follow-up of cervical pathology.
- Data base for data storage, review and follow-up.

1.2. Indications for use

DySIS with Pseudo-Colour 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. It is a tool that should NOT be used as a substitute for a thorough colposcopic evaluation.

Warnings and precautions

Please read the following operating and maintenance instructions thoroughly before using your new digital colposcope. Following these instructions can help to 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 DySIS with Pseudo-Colour Imaging (PCI) (i.e. electrosurgical generators) should also be read and understood. Failure to do so may result in injury to the patient and/or damage to DySIS with Pseudo-Colour Imaging (PCI).

Optimal Use of the Pseudo-Colour Imaging (PCI) feature

When using the PCI feature, please ensure biopsies have adequate surface area to account for possible image registration error in the pseudo-colour overlay Map.

During the Dynamic Imaging procedure, which is used to generate a pseudo-colour 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.

DySIS 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 that is trained in, and qualified to perform, colposcopic procedures
- Language Understanding:
 - English
- Minimum Experience:
 - Experience in the colposcopic procedures
- Permissible Impairments:
 - As applied in regular colposcopic practice




Abbreviations

On first appearance and as necessary, abbreviations are enclosed in parentheses for clarity.

Note: Pseudo-Colour Imaging (PCI) and DySISmap are interchangeable terms


1.3. Messages

Messages are used to bring important information to your attention. Each type of message is identified below:

	WARNING: Warnings alert the user to the possibility of serious injury or other adverse reaction associated with the use or misuse of the device. Failure to follow Medical Equipment (ME) operating instructions could place the PATIENT or OPERATOR at RISK .
	CAUTION: consult accompanying documents. NOTE: This symbol advises the reader to consult the accompanying documents for important safety-related information such as warnings and precautions that cannot, for a variety of reasons, be presented on the device itself.
	CONSULT: Instructions for use. NOTE: This symbol advises the reader to consult the operating instructions for information needed for the proper/optimal use of the device.

1.4. Summary of warnings and cautions

The following table summarizes the warning, caution and information messages found in this guide.

 (This Warning Symbol Applies to the Safety Warnings Below)
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 DySIS if it appears to be damaged or broken.
The power cable must always be positioned so as to minimize risk for tripping
Do not tilt, push pull, or move DySIS in ways other than that described in this manual for its proper/optimal and safe use.
Stepping and sitting on the device is prohibited.
Before using DySIS, make sure that it is in optimal use condition, as presented at installation.

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.
Before moving DySIS, make sure that the arms and the touch screen are folded.
Never use your hands to engage or release the foot brake.
Before moving DySIS, make sure that the foot brake has been released and the wheels have been lowered.
Never use the foot brake during an examination.
When idle in the clinic, DySIS should be positioned on a flat floor surface, the base brake applied and the arm brakes applied to prevent undesired movement and toppling.
While controlling the arm with the brake, make sure to keep your fingers away from the arm joints as they may get trapped during the movement.
Make sure that you examine the functionality of the brakes every time you are about to examine a patient and ALWAYS before proceeding to connect a speculum. Pressing the button should not cause any undesired movement of the arm.
During operation of the brake, make sure you hold the handle firmly until after you have released the button and the brake is engaged.
Connect only items that are specified in this guide as part of DySIS or that have been specified as being compatible with DySIS
To avoid the risk of electric shock, DySIS must only be connected to a mains supply with protective earth grounding.
Only medical grade monitors should be connected to the VGA output of the computing unit.
A medical grade Local Area Network isolator must be used to connect to the DySIS LAN port.
Never attach the 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 speculum is connected).
Do not apply any force at the alignment bracket of the imaging head; the alignment bracket should never be treated as a handle to move the device.
Sequence of actions to power up the device: 1. The mains power cable should be connected to the appropriate outlet. 2. Press the power button; The computing unit will power up and the software application will start. Sequence of actions to power down the device:

1. The user must log out of the application and then click on CLOSE (using the touch screen). DySIS will shut down automatically.
2. To avoid power consumption when idle, disconnect the power cable after the unit has completed shut down.
Make sure that any external data storage media have been checked for malware (viruses, trojans, et) before connecting to DySIS.
Do not spray solutions or liquids into air vents.
Do not immerse any part of the device in cleaning solutions.
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 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.



(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 user/patient injury.
To ensure optimal operation and safety, users should not remove any of the connectors on DySIS.
When using the acetic acid spray mechanism, the acetic acid container should not be over-filled.
Do not spray any liquids if the tubes of the spray mechanism have been disconnected.
The DySISmap is not meant to replace conventional colposcopy and decisions regarding biopsy sampling, 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 correspondence of the DySISmap colour coding to certain degrees of acetowhitening.



(This Consultation Symbol Applies to Consultations Below)

When adjusting the image brightness, the practitioner should ensure viewing the monitor directly and not sideways or from below, as this may distort the colour and brightness perception.

Before a DySISmap measurement, check that there is sufficient acetic acid solution volume in the container.

When performing a DySISmap measurement, do not use the acetic acid application mechanism before pressing "START".

Apply the acetic acid only while the message "Apply Agent" is displayed.

While the DySISmap measurement is in progress, do not obscure the light beam or the camera.

While the DySISmap measurement is in progress, 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 they should be used with caution if the cervix moves after the marking.







Access to the database is restricted to registered users.

The underlined fields in the "New Patient" form are mandatory. The patient data is saved only upon pressing "OK".

To ensure the integrity of exported data and the safe removal of USB data storage devices, click on the USB icon on the touch screen before unplugging the USB device from DySIS.

Apart from the device label (see shipping and labelling in section 12 of this manual), the following warning labels are found on DySIS.

	<p>The instrument uses a Type-BF applied part and therefore provides protection against the risk of electrical shock.</p>
	<p>Follow DySIS operating instructions.</p>



	CONSULT: Refer to instruction manual/booklet NOTE: This symbol is used to signify that the instruction manual/booklet must be read
	General warning sign.
	Do not push DySIS.
	Do not sit on DySIS.
	Do not step on DySIS.
	Hand-crush warning.

1.5. Classification

- The DySIS digital colposcope is a Class-IIa device according to the 93/42/EEC Medical Device Directive and a Class-II device in the USA.
- DySIS is a Class-B Software Medical Electrical Equipment according to the possible effects on the patient, operator, or other people resulting from a HAZARD to which the SOFTWARE SYSTEM can contribute.
- DySIS is a Risk Group 2 LED product according to EN 62471 (2008) that covers photo-biological safety.
- According to IEN/EC 60529 DySIS is an IP20 medical device regarding the degree of protection against ingress of water and against foreign objects; DySIS is not protected against water ingress; DySIS is not protected against solid foreign objects of 5 millimetres or smaller in diameter.

- The DySIS reusable metal speculum is a Type BF applied part, per International Electro technical Commission (IEC 60601-1), according to the type of protection against electric shock.
- The DySIS Imaging Head is not an applied part (see Figure 1), but could accidentally come in contact with the patient. The imaging head and the positioning arm are protected by double insulation that prevents the patient to come into contact with the electrical system. The power supply inside DySIS is Class I. Refer to technical documentation for more information on electrical safety per IEC 60601-1.
- Mode of operation; DySIS is classified for continuous operation.

1.6. Repairs / maintenance & warranty

	No modification of this equipment is allowed
	Do not use DySIS if it appears to be damaged or broken

- All service, repairs or upgrades to the device must be performed by DySIS Medical or by a DySIS Medical authorized repair centre;
- Disassembling or repairing DySIS by unauthorized personnel voids the manufacturer's warranty;
- Do not attempt to clean DySIS in ways other than those specified in this guide;
- Do not use DySIS if it appears to be damaged or broken;
- See *DySIS Service Agreement* for service agreement details and *DySIS Warranty* for warranty statements and legal terms and conditions;
- See section 7 (Cleaning & Maintenance) of this guide for system cleaning and maintenance information and section 8 for troubleshooting and servicing.

1.7. Environmental conditions

Storage

DySIS 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).

Usage

DySIS 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).

1.8. Usage restrictions

- DySIS is 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 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 relevant room complies with the appropriate requirements;
 - DySIS is used in accordance with the instructions for use.
- Users must read the instructions in this guide carefully before operating the device.
- DySIS must not be used if it appears to be damaged or broken.
- There are no user replaceable parts in DySIS other than the acetic acid spray mechanism and the fuses; acetic acid spraying kit (ACE001) is recommended to be replaced on a monthly basis.
- DySIS is not intended to come into contact with patients, apart from the speculum.
- Users and Patients should not stare directly into the illumination source when DySIS is ON.
- Air vents must be kept unobstructed.
- Do not sit, lean or step on DySIS; do not place any items (such as instruments, coffee, weights, etc. on DySIS); do not push or pull DySIS in a way other than the way instructed by DySIS Medical for proper operation.
- DySIS should only be connected to a grounded hospital grade outlet.
 - Frequency: 50/60Hz
 - Power Input: 150-310W
 - Rated Input Voltage: 100-230VAC

See the DySIS device label in Figure 44 at section 12 of this guide for the device label details.

- Each DySIS system is accompanied by:
 - DySIS speculum*
 - DySIS acetic acid application kit*
 - DySIS declaration of conformity, EUR*
 - DySIS practical tips laminated sheet, EUR*
 - DySIS calibration card*

Accessories that can be used with DySIS are:

- A speculum (single use or reusable, different types and sizes)
- USB data storage devices
- USB printers
- Additional monitors

2. GENERAL DESCRIPTION

This section introduces DySIS and highlights their respective functions.

2.1. Installation

DySIS is always set-up and installed by qualified personnel. During installation, the DySIS modules are unpacked from their shipping boxes, the device is assembled and the system start-up and quality check procedures are completed.



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

2.2. Device layout





DySIS can be seen in Figure 1 below.



Figure 1: The DySIS digital colposcope

DySIS can be further upgraded by a kit that includes a medical-grade 19" TFT monitor and its positioning pole.


Module Description	Module Function
Base	Stabilizing the unit Allows moving the device
Positioning arms	Positioning the imaging head
Computing unit	Data processing and storage
Touch Screen Monitor	Image viewing User Interface
Imaging Head	Illumination Source Imaging parts Braking control Speculum connection point Acetic acid applicator holder
TFT monitor (upgrade)	Magnified image viewing, patient viewing

	Do not tilt, push pull, or move DySIS in ways other than that described in this manual for its proper/optimal and safe use.
	Stepping and sitting on the device is prohibited.
	Before using DySIS, make sure that it is in optimal use condition, as presented at installation.
	Do not spill any liquids on the device.

2.3. Mounting arrangement - positioning arms

The imaging head is mounted on a double arm structure to allow independent vertical and horizontal movements and allow the unit to be arranged in several positions.

The DySIS base (Figure 1) supports the positioning arms and the computing unit. The mains power inlet is located on the rear of the computing unit.

	<p>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.</p>
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2.4. Transporting, moving, positioning and braking

The wheeled base allows DySIS to be moved freely. To engage the brake that stabilizes the base, gently step on the foot brake (red pedal). Before transporting the instrument, the wheels have to be lowered and the brake released (gently step on the green pedal). The arms and the touch screen monitor arm must be folded during moving (see Figure 1 above).

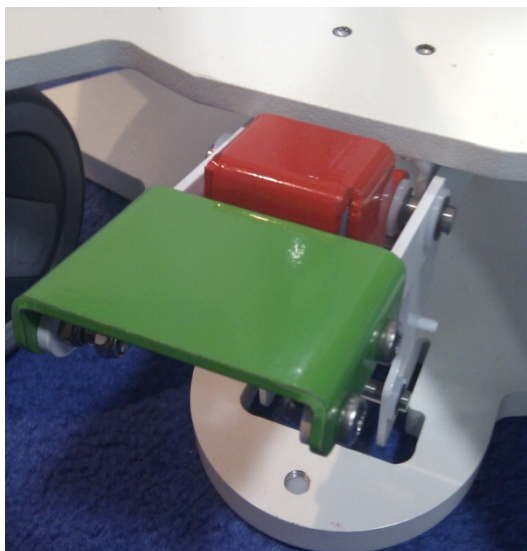








Figure 2: The foot brake pedal

When transporting DySIS, the base brake system must be disengaged via the foot pedal. When transporting DySIS on a level floor, push DySIS at the metal stump (or the lower part of the monitor pole if included) so that it rolls over the floor on its casters. When moving DySIS over a threshold, push at the metal stump (or the lower part of the monitor pole if included) and carefully apply a force at the base using a foot to assist DySIS over the threshold, so that it rolls over the threshold on its wheels.

	<p>Before moving DySIS, make sure that the arms and the touch screen are folded.</p>
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	Never use your hands to engage or release the foot brake.
	Before moving DySIS, make sure that the foot brake has been released and the wheels have been lowered.
	Never use the foot brake during an examination.
	When idle in the clinic, DySIS should be positioned on a flat floor surface, the base brake applied and the arm brakes applied to prevent undesired movement and toppling.

The combined movement of the two arms allows the positioning of the imaging head. Both arms can be locked using the corresponding knobs. The range of motions allows DySIS to be placed to the right or the left of the examination chair.

	While controlling the arm with the brake, make sure to keep your fingers away from the arm joints as they may get trapped during the movement.
--	--

The mount that holds the touch screen can rotate around the imaging head, so that the touch screen can be positioned on either side to facilitate its operation by right and left handed users.

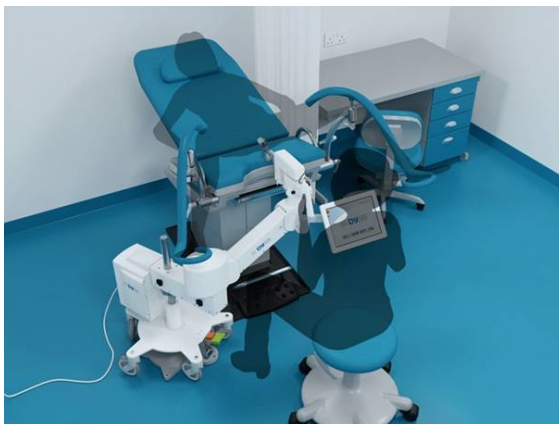




Figure 3: Typical positioning of DySIS in the clinic

After the imaging head has been brought into position facing the patient, the user can press the button on the handle to release the brakes of the vertical and pan/tilt motions of the imaging head unit. By keeping the button pressed, and by holding the handle, the user can point the imaging head easily to the desired direction. Note that this brake cannot be operated continuously for more than one minute. Release and repress if you need longer operation time.

	<p>Make sure that you examine the functionality of the brakes every time you are about to examine a patient and ALWAYS before proceeding to connect a speculum. Pressing the button should not cause any undesired movement of the arm.</p>
	<p>During operation of the brake, make sure you hold the handle firmly until after you have released the button and the brake is engaged.</p>

2.5. Computing unit

The computing unit hosts the data and image processing and storage components, the USB port, the LAN port, the external video port, the mains inlet and the fuses.

2.6. Touch screen

The touch screen monitor is the point where the user interfaces with DySIS software and views the image. The user utilizes the touch screen capability to operate DySIS, *e.g.* enter patient personal and clinical data, results of the examination and other diagnostic information, initiate an examination, guide magnification tools to the area(s) of interest, etc. The holder of the touch screen allows it to be flipped to the left or the right side of the imaging head, to facilitate use by left and right hand users.



Figure 4: The touch-screen monitor

2.7. Imaging head



The imaging head hosts the illumination source (LED), the imaging sensor (camera), high quality imaging elements and the image fine-focusing mechanism. It also hosts the two holders (left-right) for the acetic acid container and applicator as well as an arm where the suitable speculum can be attached for increased stability during the examination.



Figure 5: Imaging Head Unit



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 user/patient injury.
	Do not use the alignment bracket to move the imaging head, as this part is fragile.

2.8. Connection ports

DySIS is a Class IIa medical device and has an isolated electrical system. To maintain patient safety it is critical that all other devices connected to DySIS are electrically isolated. Please contact DySIS Medical for further details.

Several connection ports are found on the rear of the computing unit, together with the inlet for the mains and the housing of the fuses.

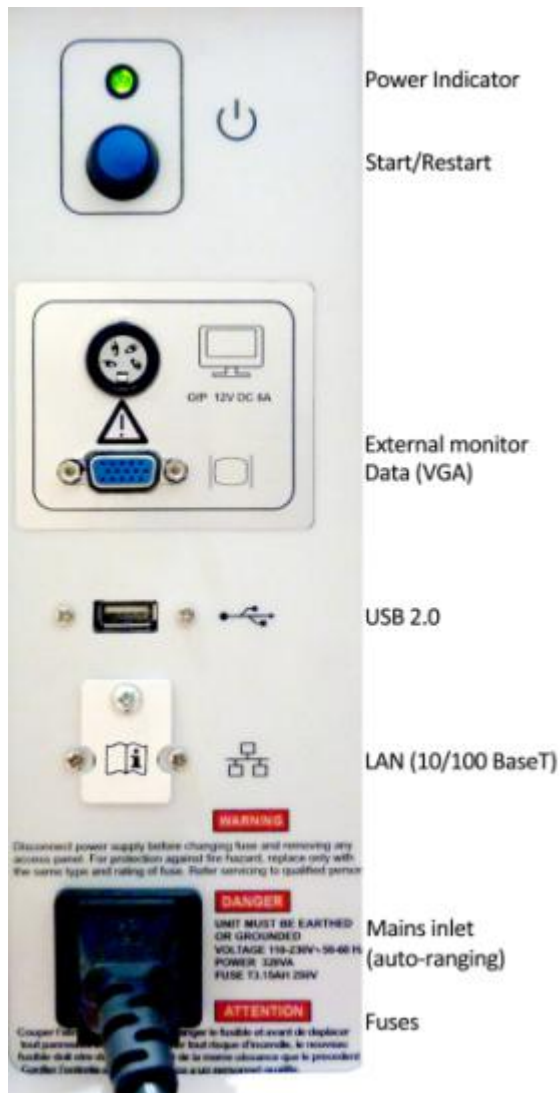




Figure 6: Computing unit connection ports

	<p>Connect only items that are specified in this guide as part of DySIS or that have been specified as being compatible with DySIS.</p>
	<p>To avoid the risk of electric shock, DySIS must only be connected to a mains supply with protective earth grounding.</p>

Only grounded hospital grade power should be input to the device to maintain the system in a good working condition. The power cable provided by DySIS Medical should be used to power up the device.

External Monitor

DySIS may be upgraded to include a patient monitor, as shown in the image below. The signal cable of the monitor (VGA) is connected to the computing unit as labelled.



Figure 7: DySIS upgraded with additional monitor

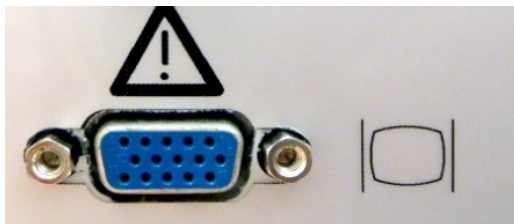



Figure 8: The VGA port for the connection of an external monitor (upgrade)


	<p>Only medical grade monitors should be connected to the VGA output of the computing unit.</p>
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USB

The USB port is provided to allow the connection of external storage devices and printers only. The DySIS USB port complies with the USB 2.0 standard (therefore, USB 1.0 devices may not be recognized). Please see Section 6 for further details of exporting data.


Local Area Network

DySIS may be connected to a Local Area Network (LAN) to facilitate data communication and printing. However, it is critical that any LAN connection to DySIS is electrically isolated. This can be achieved by the use of a Medical Grade LAN isolator between DySIS and the main network. Contact DySIS Medical for further details. Access to the LAN connector can be achieved by removing the LAN cover (held in position by a single screw) once isolation provision has been made.

	<p>A medical grade Local Area Network isolator must be used to connect to the DySIS LAN port.</p>
---	---

Imaging head connections

Located underneath the imaging head is the data transfer cable and the cables for powering and controlling its components. A connector on the rear of the imaging head controls the acetic acid applicator sensor.

	<p>To ensure optimal operation and safety, users should not remove any of the connectors on DySIS.</p>
---	--

2.9. Connecting a speculum

A speculum with an extension shaft should be connected to the device (Figure 9) during an examination to stabilize the field-of-view, especially during a DySISmap measurement, and whenever hands-free operation is desired. The user must first insert the appropriate speculum into the vagina following the standard clinical procedures, and then:

- Rotate the DySIS arm so that the imaging head is facing the examination area
- Press the trigger on the imaging head handle to release the brakes and position it so that the docking point is aligned with the speculum extension shaft
- Carefully move the imaging head forward while holding the speculum, and engage the speculum extension shaft until a positive lock is achieved

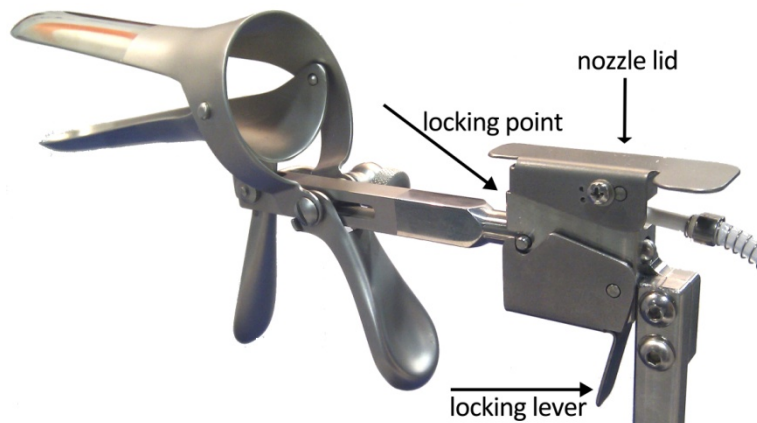


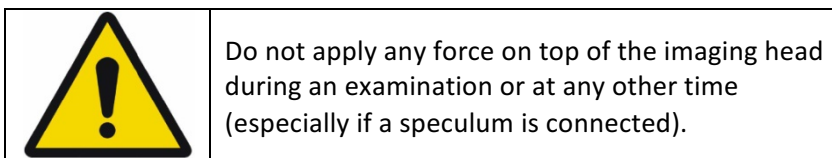
Figure 9: Speculum attachment

To detach the speculum from DySIS and retract it from the vagina, the user must:

- Unlock the knobs on the arm to allow movement
- Unlock the speculum by holding its locking lever
- While holding the speculum, press the button on the handle to release the brake and carefully slide the imaging head back and away from the speculum until it is fully disengaged; the speculum is then free to be removed as normal in colposcopic practice.



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



Before use, any speculum should be checked to ensure there are no unintended rough surfaces, sharp edges or protrusion which may injure a patient.



2.10. Acetic acid applicator

An acetic acid applicator is attached to the imaging head of DySIS. This system includes a syringe holder, a container, a nozzle and a pre-aligned mount (Figure 10). The user can achieve uniform application of acetic acid over the entire field of view through the rear opening of the speculum and synchronization with dynamic imaging, if desired, using the acetic acid applicator properly. In that case, the nozzle should be fixed on the pre-aligned mount and connected to the container and the syringe, which should be placed in the syringe holder. There are two holders, on the right and left of the imaging head, that allow the positioning of the applicator system according to the preference of the user.



Figure 10: The acetic acid application mechanism

The spraying mechanism should be primed every time the container is refilled with acetic acid to prevent the formation of air bubbles and ensure homogeneous coverage of the cervix. Priming is performed by spraying the contents of the syringe a few times until no bubbles are observed in the tubing. Acetic acid must be prepared and used following standard safety medical practice; note, that in general, colposcopic guidelines indicate the use of 3-5% acetic acid.

	When using the acetic acid spray mechanism, the acetic acid container should not be over-filled.
	Do not spray any liquids if the tubes of the spray mechanism have been disconnected.

2.11. Power on/off

Before using DySIS, make sure that it is in optimal use condition, as presented at installation. Check all cables connections as in previous sections and follow safety procedures before pressing the power button to switch DySIS ON.

To start the device, see below.


	<p>Sequence of actions to power up the device:</p> <ol style="list-style-type: none"> 1. The mains power cable should be connected to the appropriate outlet. 2. Press the power button; The computing unit will power up and the software application will start. <p>Sequence of actions to power down the device:</p> <ol style="list-style-type: none"> 1. The user must log out of the application and then click on CLOSE (using the touch screen). DySIS will shut down automatically. 2. To avoid power consumption when idle, disconnect the power cable after the unit has completed shut down.
--	--



Figure 11: The DySIS Power ON button and indicator

The operation of DySIS is detailed in the sections that follow.

3. DYSIS SOFTWARE APPLICATION

The operation of DySIS is based on a software application that includes:

- A graphical user interface for controlling the device and its operations
- Tools to conduct and document a colposcopic examination
- Tools for reviewing and comparing data from previous examinations
- A patient management system to store personal and medical data

Using the DySIS application, the colposcopic examination and the storage and management of patient data are considerably simplified and better documented.

The functionality of the software varies slightly when DySIS is upgraded with the additional TFT monitor; the differences will be noted in the corresponding places.

3.1. The user interface

The graphical user interface simplifies the operation of DySIS, makes database entries easy and allows users to perform a series of tasks during an examination. The interface utilizes (in graphical form):

Full text keyboard	Allows text entries inside relevant fields (<i>e.g.</i> comments)
Numerical keyboard	Allows numerical entries
Date entry keypad	Allows quick date entry (<i>e.g.</i> date of birth)
Tick boxes	Allows quick selection of information (<i>e.g.</i> Blood Group)
Action buttons	Allows the user to perform a task (<i>e.g.</i> save an image)
Menu items	Allows the user to select an option (<i>e.g.</i> Review Exam)
Messages	Notifies or warns the user (<i>e.g.</i> to pull the syringe plunger)
Indicators	Informs the user about a current activity (<i>e.g.</i> video recording)

3.2. Logging in

After switching DySIS on, the user must Login to access the application. The application displays a keyboard on the touch-screen and prompts the user to provide username and password (default user names and passwords are

provided upon installation, and can then be customized). After completing the requested information the user has to press “OK” to enter the main menu, from where it is possible to access a patient’s record or proceed with an examination. Selecting “Shut down” will switch DySIS off.

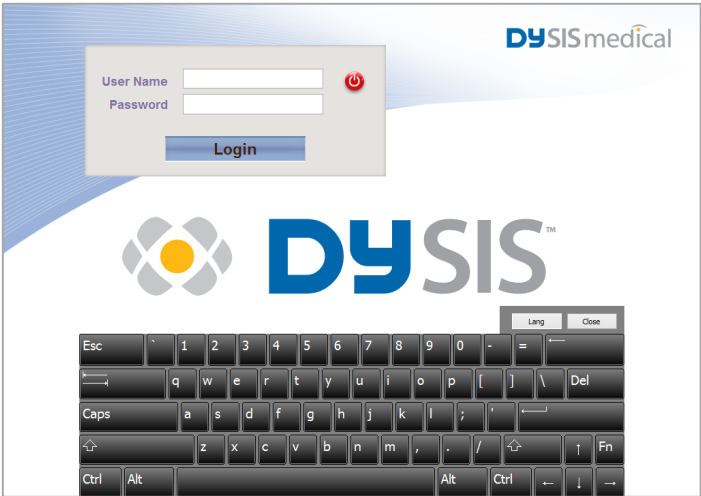





















Figure 12: Login screen

3.3. Buttons

The graphical buttons that are used in the application are listed below.

Button	Function	Button	Function
General			
	Log out		Terminate function
 	Shut down		Close/ return button
	View patient personal information		USB device connected/ press to disconnect device
During an examination			
	Increase Brightness		Decrease Brightness
	Capture mage		Magnification

	Apply green filter		Apply blue filter
	Display full colour image		Contrast enhancement
	Mark point		Delete point
	Change curve		
During image sequence playback			
	Enter playback mode		Play sequence
	Display previous image		Display next image
	Pause		Show curves
	Standard playback speed		High playback speed
	Show aligned images		Show captured images

3.4. Main Menu

The DySIS Main Menu is the central navigation point of the software and allows users to access the patient records, start an examination, create a new patient record or access the tools page. The version of the software that is installed on the device is displayed on that screen.



Figure 13: The Main Menu

4. OPERATING DYSIS

4.1. Performing an examination

The practitioner can start an examination by selecting “DySIS Exam” either from the main menu (without entering patient information), or after initiating a new visit of a specific patient (see section 5.2). When the examination is initiated from the main menu, the practitioner will be prompted to append the examination data to a patient record after the completion of the examination.

After selecting “DySIS Exam” the illumination is automatically switched on and the practitioner can observe the image in the field of view of the camera on the touch-screen (and the additional monitor when one is connected).

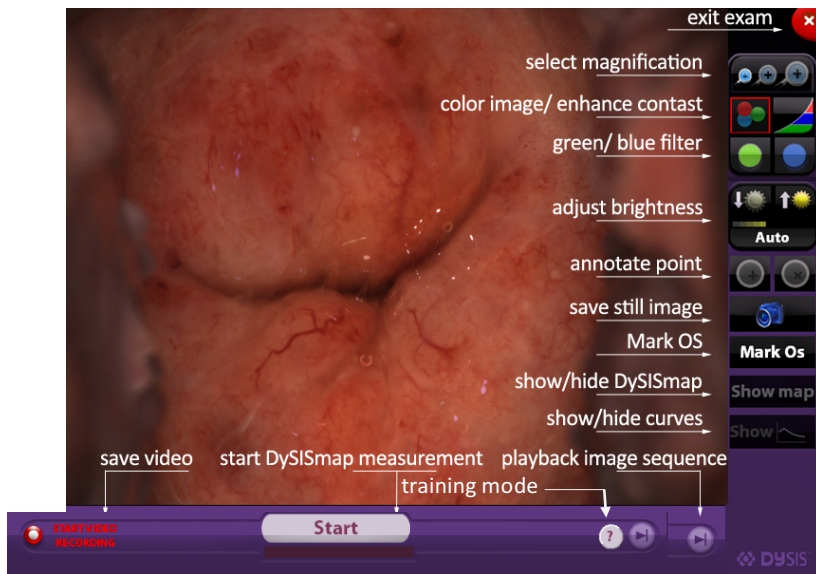







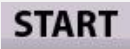




Figure 14: Examination screen


The user should use the movements of the two arms to bring the imaging head in front of the examination area and the brake trigger should be pressed to adjust the position of the imaging head and achieve a satisfactory field of view. The practitioner should use the knobs of the micrometric translation control, found under the imaging head, to fine-adjust the focus by observing the display. Releasing the brake trigger and locking the arm positions with the corresponding knobs ensures that the system will remain stable during the examination.

At this stage, several tools and options are available. During the examination, the operator has access to the operations/functions outlined below.

Symbol	Function	Description
	Brightness Control	Controls the brightness of the image. Selecting Auto adjusts brightness automatically within factory settings
	Green Filter	Displays the green channel of the colour image
	Blue Filter	Displays the blue channel of the colour image
	Colour	Displays full-colour image (default setting)
	Contrast	Enhances the contrast of the image
	Magnification	Enables image magnification
	Capture Image	Saves a snapshot of the image
	Video Recording	Saves a video clip
	START	Initiates a DySISmap measurement
	Playback	Image playback (during/after DySISmap measurement)
	Exit Exam	Terminates the examination

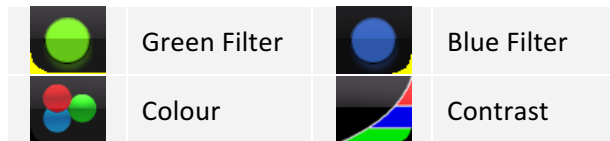
4.2. Image brightness

The brightness of the image can be adjusted by using the brightness control buttons, either automatically or manually. A bar below the buttons indicates the setting.

	When adjusting the image brightness, the practitioner should ensure viewing the screen directly and not sideways or from below, as this may distort colour and brightness perception.
---	---

4.3. Digital filters

The user can select to view the green or the blue channel of the colour image in order to selectively enhance different features such as vascular patterns, atypical vessels, mosaics or punctuation and improve the colposcopic impression. Pressing the contrast button will often improve the contrast of the image further. After using these tools, the user can revert to the full colour display by pressing on the “Colour” button.



4.4. Magnification

Pressing on the different magnification ratios that are displayed on the touch screen, a portion of the image is magnified and displayed. The area to be magnified is selected by dragging on the touch-screen. While magnified viewing is activated, the digital filters are available operating as described above.

Three magnification scales are available; the user can switch between them simply by pressing on the corresponding indication.

Drag your finger on the touch screen display to view a different area in magnification. A green rectangular indicates the part of the image that is magnified.

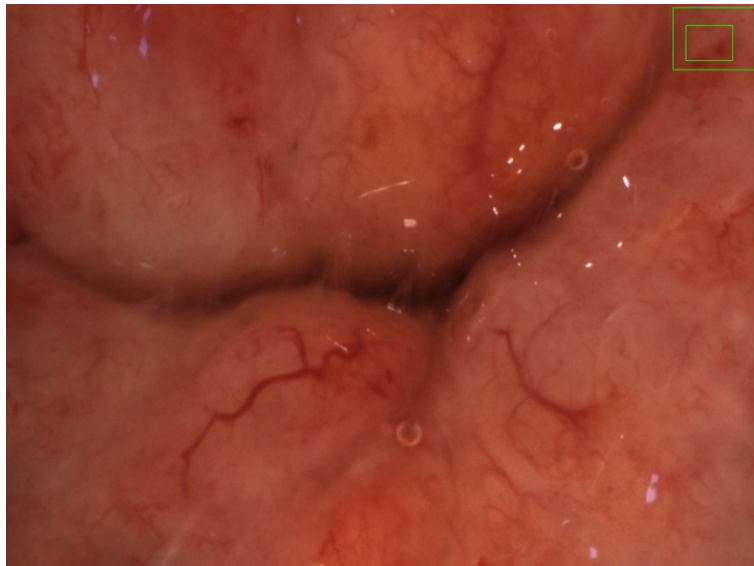


Figure 15: Image as seen when the magnification is selected. The green box indicates the area that appears magnified.

4.5. Saving still images

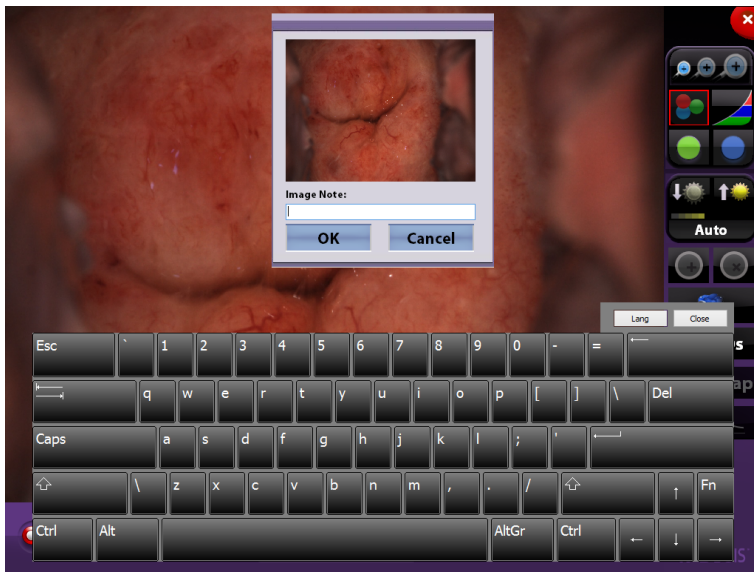


Figure 16: The dialog box for saving still images

High-resolution still images can be saved by clicking on the camera button; a dialog box with an image preview and a keyboard on the touch-screen prompt the user to enter the desired filename (by default, the images are sequentially numbered). Images are saved in a high resolution and quality jpg (*.jpg) format that can be later exported to a USB data storage medium or printed. Note that the saved image will be that of the entire field of view, even if magnification or filters were switched on during capturing.

4.6. Capturing video streams

The user can save a video stream to document a medical procedure; this is possible by clicking on "Start Video Recording". While recording the indication "Video Recording" is flashing and to terminate the procedure the user must click on "Stop Video recording". Note that the saved captured video will contain the images of the entire cervix, even if magnification is switched on.



Figure 17: Recording a video clip

To avoid the accidental recording of very long video streams, a message appears after 4 minutes of video recording, prompting the user to confirm whether this is intentional. If the user fails to confirm within 30 seconds, then the video recording stops automatically. During video recording, practitioners can use the filters and the magnification tool. Note though that the video clip will contain the entire image in full colour.

4.7. DySISmap

DySIS offers the option of documenting and quantifying the dynamic colour changes that may appear on the cervix after the application of dilute acetic acid (acetowhitening), in a colour-coded map. DySIS allows the capturing of a sequence of images at high-resolution; while capturing is in progress, the images are automatically aligned to compensate for tissue micro-movements and are then used to calculate the DySISmap.

Initiating the measurement

If the acetic acid applicator syringe is loaded, the **Start** button on the examination screen will be active. The DySIS user must click **Start** to set the system in stand-by mode; then DySIS displays the message “Apply Agent” and gives a repetitive sound. If the system detects that the brightness is off-limits, it prompts the user to use the brightness settings.

While “Apply Agent” is displayed, the user should press the syringe plunger steadily and firmly to spray the full content onto the cervix; a sensor detects this process and initiates image capturing.

Image Acquisition

During image acquisition, the user can use the magnification and digital filter tools and capture still images. Special attention should be paid to keep the movements of the patient and the cervix to a minimum. If the movements of the cervix are too large to be compensated by the software, a message will be displayed, notifying the user. Image acquisition will continue.

The procedure will complete after three minutes, but if needed, can be terminated by the user at any point by pressing **Stop**. However, at least 125 seconds of image acquisition are needed for the calculation of the DySISmap. The captured images are automatically aligned to compensate for tissue micro movements. At the end of the procedure the DySISmap becomes available.



Figure 18: During image acquisition - calculating DySISmap. The green bar indicates progress.

	<p>Before a DySISmap measurement, check that there is sufficient acetic acid solution volume in the container.</p>
--	--





	When performing a DySISmap measurement, do not use the acetic acid application mechanism before pressing Start .
	Apply the acetic acid only while the message “Apply Agent” is displayed.
	While the DySISmap measurement is in progress, do not obscure the light beam or the camera.
	While the DySISmap measurement is in progress, patient movements should be minimized.










Image Sequence Review



Figure 19: Image sequence playback buttons

In DySIS with the upgrade kit, at any moment during image acquisition, the user can select to review the images that have been captured thus far, by clicking on the playback button. These images are displayed on the TFT monitor, while the touch-screen displays the live image and the playback buttons, which allow the user to scroll through the images manually (using the forward/backward buttons) or let them play continuously and select the playback speed. It is

possible to view the images in their raw form or, after they have been aligned, by selecting accordingly using the image sequence buttons. Click on the exit button to return to live view. This feature can be used when in doubt about the colour of the cervix before acetic acid was applied, or to review the progress of the acetowhitening.

	Enter playback mode		
	Display previous image		Display next image
	Play sequence		Pause
	Standard playback speed		High playback speed
	Show aligned images		Show captured images

Dynamic curves

During image acquisition, users can monitor the acetowhitening response of the tissue at any location on the cervix using the dynamic curves graph that appears on the upper left part of the display. In this graph, the vertical axis represents the measured intensity and the horizontal axis the time that has passed since the application of acetic acid.

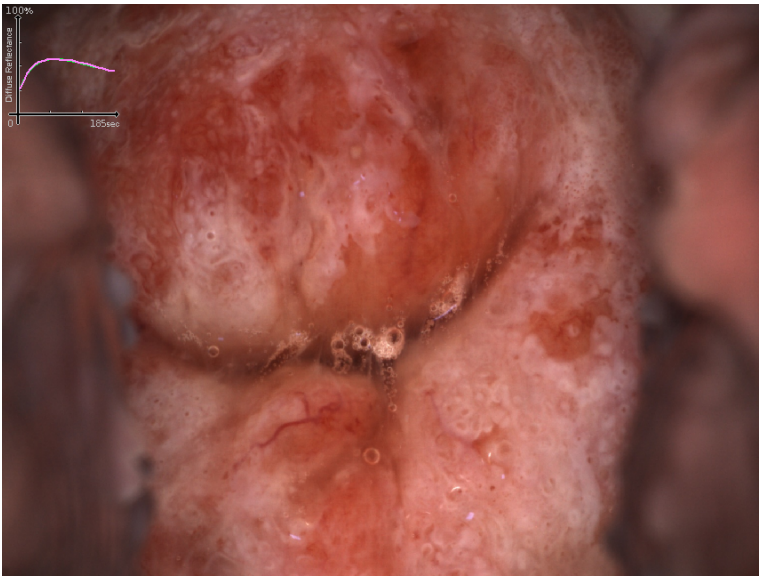


Figure 20: Image with curves as displayed on the monitor

By pointing at different sites on the cervix using the image on the touch screen, it is possible to view the response at different sites. This graphical tool can assist the evaluation of the acetowhitening phenomenon on every tissue location, simply by monitoring the variations in acetowhitening intensity (curve height) over time. Their display is controlled by using the **Show Curves** and **Hide Curves** buttons.

DySISmap

When the image acquisition is completed, the dynamic curve data are used for the calculation of a single numerical index (the CB value), which takes into account both the intensity and the duration of acetowhitening. As the acetowhitening response varies across the cervix, the parameter takes different values. In general, the higher the CB value, the most intense or durable the acetowhitening is at a specific location. This information is used for the calculation of the DySISmap that is displayed overlaid on the real-time image on the monitor. By pressing on **Hide Map** users can remove the map from the display and view the live image of the cervix.

The DySISmap captures the tissue acetowhitening dynamic behaviour (intensity over time). The continuum of pseudo-colours of DySIS map ranges from cyan to blue to green to red to yellow to white and designate progressively stronger response.

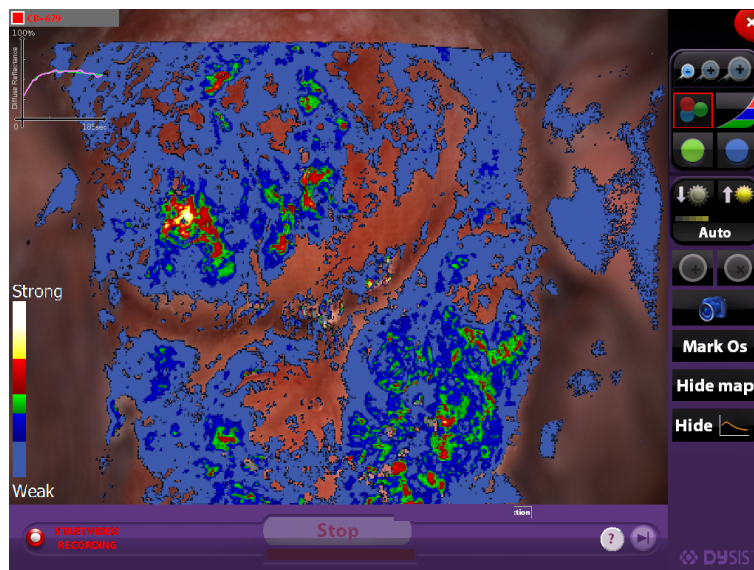


Figure 21: DySISmap overlaid on the image of the cervix, with the colour bar and the graph in view.

The following table summarizes the colour coding of the DySISmap.

Colour coding		Whitening
No Colour		very weak/ none
Cyan		
Blue		weak
Green		
Red		strong
Yellow		
White		intense

The magnification and the digital filter tools, still images capture, video recording and points of interest annotation are available to the user to complete the examination.

Image sequence playback

When the measurement is completed, the user can playback the sequence of captured images and select to view either the aligned or the raw ones at different speeds, as described above. This feature is available in the upgraded version only. Note that during subsequent entries to the examination, this feature is disabled.

Point annotation

After reviewing the images and the DySISmap, DySIS users can annotate points of interest that can serve as guidance marks during biopsy sampling as well as for documentation. After clicking at the selected point on the cervix image that is displayed on the touch screen and then on the “Mark Point” button, an annotation is overlaid on the image. If desired, the procedure can be repeated until five points have been marked.

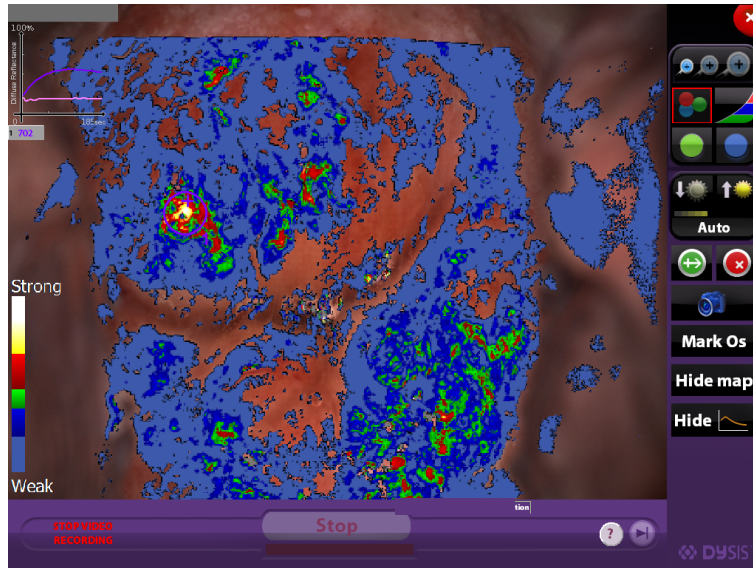


Figure 22: DySISmap and annotation controls on the touch screen





For every annotated point, a dynamic curve is also recorded and displayed on the graph. The curve displayed for each of the points is only one of those that fall inside the area of the mark; if for documentation reasons the user wishes to change to another curve from the same area (e.g. in the case of an artefact that distorts some of the curves), then the user can point inside the mark on the touch screen and then use the “Change Curve” button that is displayed until a satisfactory/representative curve is displayed.

To delete one of the marks, the user should first point inside the mark on the touch screen and then press on the “Delete Point” button.

	Mark Point
	Delete point
	Change curve

After marking a point, video recording starts automatically to document the biopsy sampling procedure and is indicated by the video recording sign, which is flashing. The video is available for review or export from the record of the visit.

The user can remove the DySISmap from the display (press **Hide Map**), or use the colour filters and magnification; image capture and video recording options to fully document the procedures.

	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 the marking.
	DySISmap is not meant to replace conventional colposcopy and decisions regarding biopsy sampling, treatment or diagnosis.
	The assessment of acetowhitening should be based on visual inspection of the entire set of the acetowhitening characteristics. DySISmap reflects a subset of them.
	When using different concentrations of acetic acid, the acetowhitening characteristics may change and consequently the correspondence of the DySISmap colour coding to certain degrees of acetowhitening.

4.8. Training mode

The user can enable/disable training messages anytime during the live imaging, simply by pressing the “?” icon. When the training mode is enabled, balloon messages will be displayed, guiding the user through the steps to allow the calculation of the map.

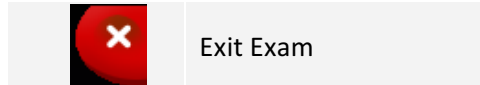


Figure 23: Training mode enabled with balloon messages displayed & highlighting the relative button to be pressed.

NOTE: the messages displayed are not displayed automatically; the user should manually press the next or previous step by using the arrows on the balloons.

4.9. Closing the examination

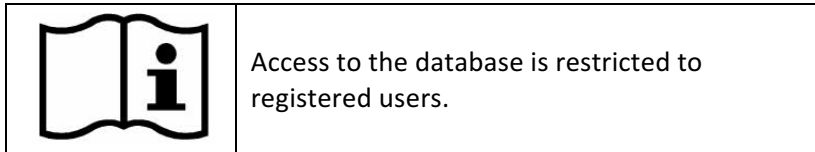
To finish the examination after all desired data has been recorded, the user must press the exit exam button on the upper right of the screen.



5. PATIENT AND DATA MANAGEMENT SYSTEM

5.1. General

The patient and data management system enables practitioners to maintain a record for each patient, including personal data, medical history information and data collected during the examination(s) performed with DySIS.




5.2. Creating a new patient record

Typically, before proceeding with examining a new patient, a personal record should be created; alternatively, the user may proceed directly with the examination and enter the personal data after the completion of the examination, or select to discard all the collected data.

To create a new patient record, starting from the Main Menu, the practitioner must press the “New Patient” button. The practitioner can fill-in all the available information in the new patient form using the keyboard displayed on the touch-screen when a data field is clicked. Note that for certain fields a numeric keypad appears, whereas for others, the user has just to pick the correct selection. Alternatively a new patient can be created while the user is viewing the data base records.

Figure 24: New patient information entry

After filling-in the available data, the practitioner can press **OK** to save the new patient record. Pressing **Cancel** discards the entered information and the application returns to the Main Menu. After creating a new patient, DySIS is automatically opening a new visit for the patient.



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

5.3. Opening a patient record

Before performing a DySIS examination on a patient who is already in the database, or to update and review an existing medical file, the practitioner must open the correct patient record. Whilst in the Main Menu, the practitioner can select “Show List” to view the database and display the list of patients in alphabetical order. Highlighting a patient name displays the list of records available for that patient. Pressing “View History” opens the patient record.

New Patient

Patient Profile:
cin3 Demo1, D1
Date of Birth: 01-01-1972
Last Visit: 04-26-2012

Surname >	First Name	Patient ID	Last Visit
Demo1	cin3	D1	04-26-2012
Demo2	bxvideo	D2	03-09-2012
Demo3	focalhigh	D3	11-02-2012
Demo4	FU	D4	06-06-2014
Demo5	CIN2	D5	06-06-2014
test	test	test	11-05-2015

Date	Referral	DySIS	Management	Colposcopy
2012-04-26	Moderate Dysk...	YES	LLETZ	HGSIL

New Visit **View History**

Figure 25: Patients list; the bottom panel displays a summary of the visits of the highlighted patient

To search for a patient in the database, users can enter the desired characters in the search boxes that appear above the patient Surname, First Name and Last Visit. DySIS filters and displays the patient records accordingly.

New Patient

Patient Profile:
cin3 Demo1, D1
Date of Birth: 01-01-1972
Last Visit: 04-26-2012

Surname >	First Name	Patient ID	Last Visit
Demo1	cin3	D1	04-26-2012
Demo2	bxvideo	D2	03-09-2012
Demo3	focalhigh	D3	11-02-2012
Demo4	FU	D4	06-06-2014
Demo5	CIN2	D5	06-06-2014
test	test	test	11-05-2015

Lang Close

Esc 1 2 3 4 5 6 7 8 9 0 - =

q w e r t y u i o p [] \ Del

Caps a s d f g h j k l ; ' " \

z x c v b n m , . / ~

Ctrl Alt AltGr Ctrl

Figure 26: Search Patient

When a patient name has been highlighted, the user can proceed with starting a new visit or by viewing the patient's existing records (from where it is also possible to start a new visit).

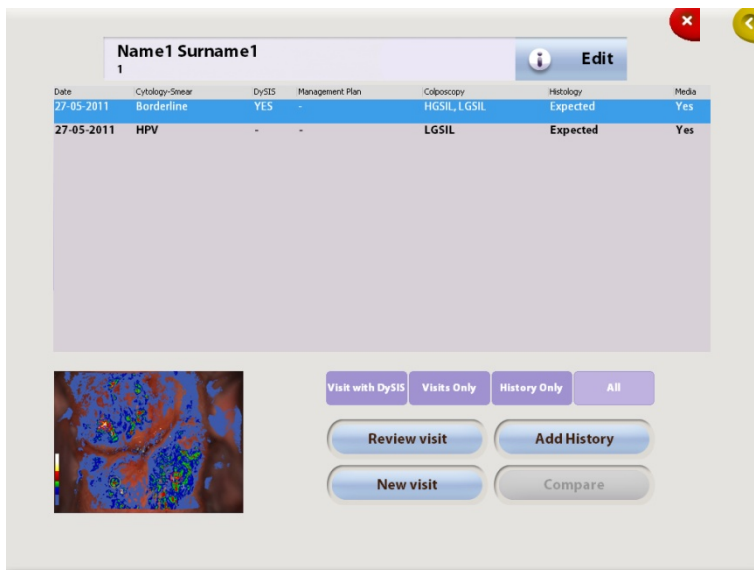



Figure 27: Patient Card

After a patient record has been entered, the user can proceed with:

Review Visit	Review the selected visit (provides access to the data collected during the selected visit)
New Visit	Initiates a new visit, which may or may not include an examination
Add History	Allows the user to enter information on the medical history of the patient
Compare	The user can compare data from two visits of the patient
Edit	The user can edit the patient personal information
	The user can view the patient personal information

5.4. Modify patient information

To update or correct the patient information, open the patient card starting from the “Main Menu”:

- Press “Show List”
- Highlight the desired patient
- Press “Show History”

Inside the “Patient card” the user has to:

- Press “Edit”
- Modify information as desired

- Press “OK”; Patient information is now updated.

5.5. New visit

It is possible to start a new visit for a patient either directly after highlighting the patient in the patients list or after entering the patient record. Inside a new visit, users can fill-in information in the following fields

Referral Reason	The reason for referral to the current visit
Management Plan	The management suggested after this visit
Colposcopy	The colposcopic impression at this visit
Histology	Histology results from biopsy samples collected during this visit
Medication	Anti-coagulants, anti-hypertensives, heart-related, immunosuppressants
LMP date	Last menstrual period date
Contraception	Yes/no
Currently Pregnant	Yes/no
HIV Status	Positive / Negative

The screenshot shows a web-based form for entering a new patient visit. At the top, the patient's name 'Name1 Surname1' and ID '1' are displayed. Below this, there are input fields for 'Date of Visit' (set to 11-17-2015), 'Doctor' (set to demo), 'LMP' (set to --/--/), 'Contraception' (radio buttons for Yes/No), 'Currently Pregnant' (radio buttons for Yes/No), 'HIV Status' (radio buttons for Positive/Negative), and 'Medication' (checkboxes for Anti-coagulants, Anti Hypertensives, Heart related, and Immunosuppressants). A 'Notes' text area is also present. The form is organized into a grid with four main sections: 'Referral Reason - Edit', 'Management Plan - Edit', 'Colposcopy - Edit', and 'Histology - Edit'. On the right side, there are buttons for 'Exam Playback', 'View Report', 'Memo', and 'Export', along with a 'DYSIS Exam' logo. A large dark blue bar is at the bottom of the form.

Figure 28: New Visit

5.6. New visit- referral information

The screenshot displays the DySIS Exam software interface. At the top, a header bar shows 'Name1 Surname1' and a patient ID '1'. Below this, there are fields for 'Date of Visit' (27-03-2011), 'Doctor:', 'LMP:', and 'Contraception:'. A 'Referral' dialog box is open in the center, featuring a 'Close' button at the top right. The dialog box is divided into several sections: 'Entry Date' with a date picker; 'Clinical Suspicion' and 'Follow Up' buttons; 'Smear' section with an 'Exam Date' field and a grid of buttons for 'Normal', 'Inflammation', 'HPV', 'Borderline', 'Mild Dyskaryosis', 'Moder. Dyskaryosis', 'Severe Dyskaryosis', 'Glandular Neoplasia', 'Invasive', and 'Other'; 'Symptoms' section with buttons for 'IMB', 'PCB', 'PMB', 'Menorrhagia', 'None', and 'Other'; and 'HPV Test' section with 'Exam Date' and 'HPV Type' fields, and 'LR' and 'HR' buttons. To the right of the dialog box, there is a 'DySIS Exam' logo and a vertical stack of buttons: 'Exam Playback', 'View Report', 'Memo', and 'Export'.

Figure 29: The Referral dialog box inside a new visit

After opening the Referral dialog box, the user can use the touch screen to enter specific information on the referral reason for the current visit: Smear, Symptoms, HPV test. It is possible to enter examination dates, to select multiple fields, and text boxes allow the entry of additional comments. Click on “Typing” to select from a list of specific HPV types when known.

5.7. New visit- colposcopic impression

After a colposcopic examination, DySIS allows practitioners to fully record their colposcopic impression by recording information on clinical findings, morphological characteristics, test results, etc.

Name1 Surname1
1

Date of Visit: 27-05-2011

Doctor: [blank]
LMP: [blank]
Contraception: [blank]
Referral Reason: [blank]
Smear: Borderline
HPV Test: HR

Colposcopy

Exam Date: 27-05-2011

Colposcopy Image

Findings:

Complete **Partial** **No uptake** **None** **Fine** **Coarse** **Yes** **No**

Biopsy **Cone** **Punch** **Second Test** **None** **Fine** **Coarse** **Yes** **No**

Notes:

Location of SCI

On ectocervix **Inside canal** **Not seen**

Colposcopy Prediction

Normal **Metaplasia** **Ectropion** **Inflam.** **HPV** **LGSIL** **HGSIL** **Glandular Abnormal** **Invasion** **Other**

Per Point Prediction

1 **Normal** **Metaplasia** **Ectropion** **Inflam.** **HPV** **LGSIL** **HGSIL** **Glandular Abnormal** **Invasion** **Other**

2 **Normal** **Metaplasia** **Ectropion** **Inflam.** **HPV** **LGSIL** **HGSIL** **Glandular Abnormal** **Invasion** **Other**

Close

Figure 30: Completing the colposcopic impression after an examination

5.8. New visit- memos

DySIS offers the option to create a digital sketch that can serve as a memo, with any notes. Simply press “Memo” while in the New Visit to open the sketching pad.

Name1 Surname1
1

Date of Visit: 27-05-2011

Doctor: [blank]
LMP: [blank]
Contraception: [blank]
Referral Reason: [blank]
Smear: Borderline
HPV Test: HR

Memos

Sketching Area

Notes:

Close

Clear

Figure 31: Drag your finger on the touch screen to create a sketch. Pressing “Clear” clears the display.

5.9. New visit- management plan

DySIS offers the option to fully record the intended management plan for the patient after a visit. Information can be entered very conveniently by clicking on the relevant fields that include the reason for discharge, intended follow-up by cytology and/or colposcopy, treatment suggestions and additional comments.

The screenshot shows the 'Management Plan' dialog box overlaid on the main patient record interface. The background interface includes fields for 'Name1 Surname1', 'Date of Visit' (11-17-2015), 'Doctor' (demo), 'Medication' (Anti-coagulants, Anti Hypertensives), 'Notes', 'LMP', 'Contraception', and 'Currently Pregnant'. The 'Management Plan' dialog box contains the following sections:

- Discharge:** Two buttons: 'No evidence of disease' and 'Disease Regressed Spontaneously'. A 'Close' button is also present.
- Follow up for Smear:** Four buttons: '3 Months', '6 Months', '12 Months', and 'Other' with an adjacent text input field.
- Follow up for Colposcopy:** Four buttons: '3 Months', '6 Months', '12 Months', and 'Other' with an adjacent text input field.
- Follow up note:** A text input field.
- Treatment:** A grid of buttons including 'None', 'Laser Vaporization', 'LLETZ', 'Laser Cone', 'Knife Cone', 'Hysterectomy', and 'Other'.
- Note:** A text input field at the bottom.

On the right side of the background interface, there is a sidebar with the 'DySIS Exam' logo and buttons for 'Exam Playback', 'View Report', 'Memo', and 'Export'.

Figure 32: The management plan dialog box

5.10. Histology results

Figure 33 shows a screenshot of the 'Histology' dialog box in a medical software interface. The dialog box is titled 'Histology' and has a 'Close' button in the top right. It contains a 'Results date' field with the value '15-05-2010'. Below this is a 'Biopsy' section with three buttons: 'Cone', 'Punch', and 'See and Treat'. There is a 'Notes' text area. The main part of the dialog is a grid of buttons for histology results, organized into two rows. The first row has buttons for 'Normal', 'Unsm.', 'Metapl.', 'Inflam.', 'HPV', 'CNI', 'CNI', 'CNI', 'CGNI', 'CGNI-II', 'Invas.', and 'Other'. The second row has buttons for 'Normal', 'Unsm.', 'Metapl.', 'Inflam.', 'HPV', 'CNI', 'CNI', 'CNI', 'CGNI', 'CGNI-II', 'Invas.', and 'Other'. The 'CNI' button in the second row is highlighted. At the bottom of the dialog, there are four checkboxes, each labeled 'include in the report'.

Figure 33: Use the histology dialog box to enter biopsy results for the specific examination

After the histology review results from the samples of a specific visit are available, it is possible to enter the results using the Histology option inside the record of that visit.

5.11. DySIS report

DySIS users can create a standardized report that can be printed or exported to a USB data storage device as a “pdf” file. After completing the examination, or at any later point while reviewing that visit, the practitioner can create and review a report with the patient personal and medical information and the recorded colposcopic impression. The report also includes the DySISmap (when available) and the acetowhitening dynamic curves at the annotated biopsy points (when available). Furthermore, the user can select among images captured during the examination or the sketch, which will be included in the report. To include one of them to the report, users have to simply click on the image to select it and then on the tick box that indicates “Include in the report”.

cin3 Demo1

D1 (0-0)

Review Only

Date of Visit: 04-26-2012

Doctor: portia

LMP: -

Contraception: ☐ Yes ☐ No

Currently Pregnant: ☐ Yes ☐ No

Medication

☐ Anti-coagulants
☐ Anti Hypertensives
☐ Heart related
☐ Immunosuppressants

HIV Status: ☐ Positive ☐ Negative

Notes:

Referral Reason - Review

Sweat: Moderate Dyskaryosis

Colposcopy - Review

Prediction: HSIL

Management Plan - Review

Treatment: LLETZ

Histology - Review

Result: CIN3

Image 1

Map

Reference

☒ Include in the report

☒ Include in the report

☒ Include in the report

DYSIS Exam

Exam Playback

View Report

Memo

Export

Figure 34: Ticked images will be included in the report.

The DySIS report can be modified and reproduced at any time, also during review of the examination (see sections below).

Your logo here

DYSIS

Patient Name: Brown, Alex

Patient ID: 01

Patient Date: 04-26-2012

Doctor: portia

Doctor Date: 04-26-2012

Referral Reason

Sweat: Moderate Dyskaryosis

Management Plan

Treatment: LLETZ

Colposcopy

Prediction: HSIL

Histology Results

Result: CIN 3

Image 1

Map

Reference

Figure 35: DySIS report with patient personal information, the recorded colposcopic impression, the DySISmap and two selected images. Note the option to customize the logo on the upper left corner.

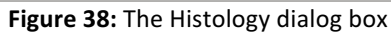
5.12. Add History

DySIS allows users to complete a patient's medical record in the database by entering medical information such as results from previous examinations. "Add History" can be accessed from the patient record.

Figure 36: The "Add History" dialog box

In a few simple steps, the user can enter information on cytology and HPV results (high/low risk, typing), information on a previous treatment as well as detailed information on previous colposcopic examinations and histology results.

The user can use a wide range of options, to record the colposcopic impression. To record biopsy sites locations, the user must click on the “Add” button and then on any point on the circular cervix. Up to 5 points can be entered and the colposcopic prediction can be completed per point. To remove a point, users must click on the “Delete” button and then in the vicinity of the point.



5.13. Reviewing a visit

During review, it is possible to generate and view a DySIS report, view the images and video clips recorded during that visit (highlight an image on the touch screen and it will be displayed on the monitor). It is also possible to

connect a USB data storage device and export the saved data. It is also possible to play back the sequence of images if one was recorded and then reproduce the entire procedure (see below).

5.14. Reviewing Images

Images saved during a colposcopic examination are available for review from the media pane of the visit form.

Clicking on the selected image once more opens the image review window, which allows the user to apply filters and magnify portions of the image, as during the examination.

If a USB data storage device is connected, the option “Export to USB” appears. Clicking on this option exports the image.



Figure 39: Image review

5.15. Examination Playback

The “Exam Playback” is an integrated examination review tool that allows the review of the images collected during the DySIS acetowhitening assessment.

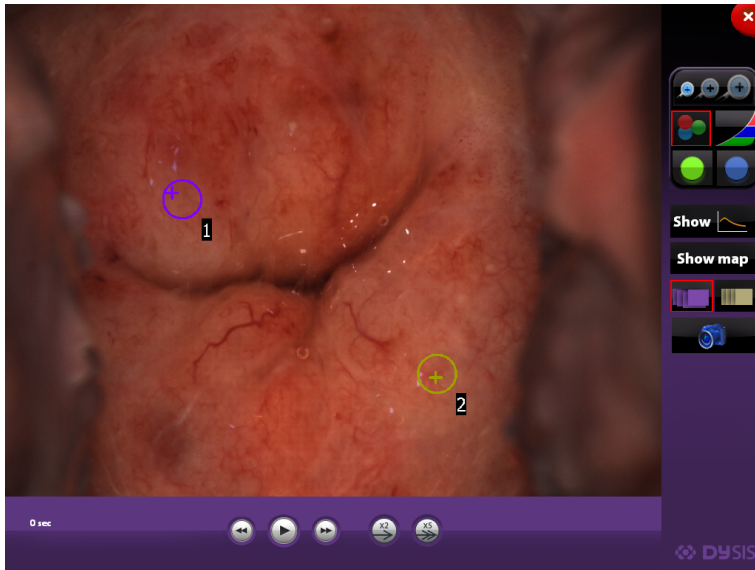


Figure 40: Examination playback

Several tools, as described earlier (see section 4), are available and allow the user to perform magnification and digital filtering on the captured images, play them back in sequence, view or hide DySISmap, view the annotated points and save screen images.

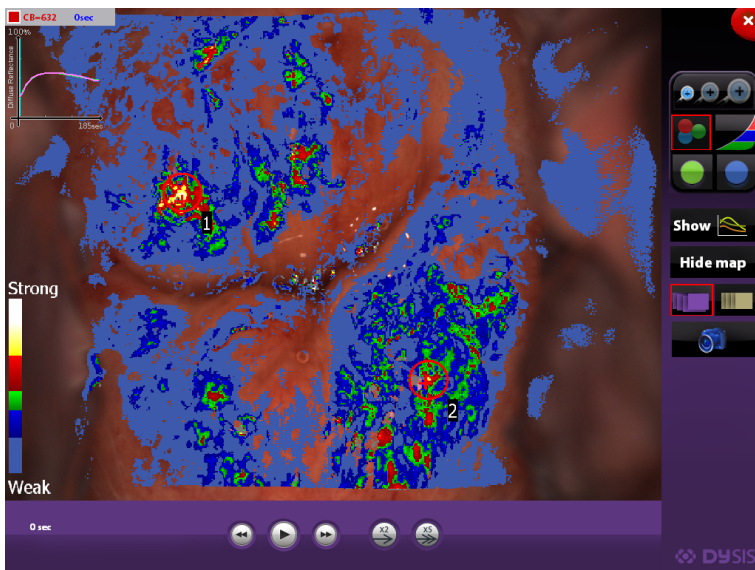













Figure 41: DySISmap and graph view, during review

When playing back the sequence of images it is possible to select to display the raw or the aligned images; the playback speed can be varied using the x2 and

x5 buttons, and arrows allow the moving back/forward by one image. Furthermore, the user can view DySISmap and the dynamic curves (if available).

The following tools are available to the user during playback:

Symbol	Function	Description
	Digital Zoom	Enables image magnification
	Green Filter	Displays the green channel of the colour image within the magnification window
	Blue Filter	Displays the blue channel of the colour image within the magnification window
	Contrast	Enhances the contrast when a digital filter is active, within the magnification window
	Colour	Enables the colour mode (default setting)
	Capture Image	Saves a snapshot of the displayed image.
	Playback buttons	Allow playback of the images, either continuous or manual (forwards/backwards)
	Show Captured Images	Displays the captured images
	Show Aligned images	Displays the aligned images
	Show Map	Displays DySISmap (only while viewing the aligned images)
	Show curves	Display the acetowhitening dynamic curves (only while viewing the aligned images)

5.16. Compare

To compare images that were obtained during two separate exams of the same patient, select “Compare” after selecting the patient. Then select which visits to display by highlighting one visit and selecting “Set Left” and then highlighting another one and selecting “Set Right”. The image sequences of those two visits are available to be displayed side by side for comparison. Note that this feature is available in the DySIS upgraded version only. Press Play after selecting a visit, and will start the image playback with full review capacity.

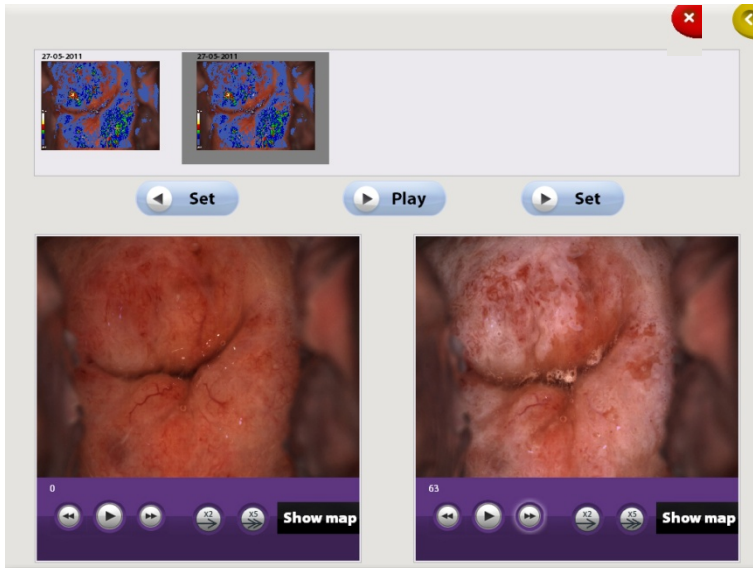


Figure 42: Comparing images from two examinations

5.17. Exiting review

After reviewing a visit, users can return to the previous screen by pressing at the return button on the upper right corner of the touch screen.



Save new Data, terminate visit and return to the patients' list

6. ADDITIONAL FUNCTIONS

6.1. Connecting USB devices

DySIS features a USB port that can be used to connect external devices, such as printers, wireless transmitters, hard-disks, or memory sticks. Whenever an external data storage device is connected, the USB connection icon is displayed at the lower right corner of the touch screen that indicates the connection and the “Export to USB” options become active. Before removing a USB device, users should point on this icon to ensure data integrity and the safe removal of the device.



USB device connected/ press to disconnect device

	Make sure that any external data storage media have been checked for malware (viruses, trojans, et) before connecting to DySIS.
	To ensure the integrity of exported data and the safe removal of USB data storage devices, click on the USB icon on the touch screen before unplugging the USB device from DySIS.

6.2. Exporting data

When a USB data storage device is connected to DySIS it is possible to export images saved during an examination, examination reports or entire examinations. Exported data can be later found inside a folder named “DySIS_Export”, and are categorized per patient. Images, and video clips are in standard formats and can be directly inserted in most software applications (*e.g.* presentation software). When exporting an entire visit, a folder is created that can be later reviewed on the DySISviewer™ software.

6.3. Printing images and reports

DySIS can print high quality colposcopic images and reports. Upon request, a qualified engineer can install a printer. Please inquire for more details.

6.4. Connecting to external databases

DySIS enables connectivity with external databases through standard protocols. Please inquire for more details.

6.5. User Tools

Selecting “Tools” from the Main Menu, the DySIS user can:

Backup database

Select “Back Up” from the Tools option in the Main Menu to save a copy of the entire database. A high capacity USB hard disk drive should be used. After connecting the USB disk drive, make sure that the USB icon appears at the lower right side of the touch screen to indicate proper communication. Note that backing up may take more than 30 minutes in case of a large data base. After back up is complete click on the USB icon before disconnecting the USB drive. It is advised to back up the data base regularly.

Upload logo image

Use this option to upload an image, such as a hospital logo, in standard bitmap (*.bmp) format to be included in the report.

Set time/date

Use this option to change/adjust the time and date setting of the computer in DySIS.

Modify user name and password

Use this option to change user name and password.

Adjust touch-screen brightness

Use the controls to adjust the brightness of the touch screen monitor.

Set jpg image quality



The quality of the images saved as jpg can be set to 100% or 95%. The default setting is 95%; saving images at 100% increases their file size significantly.

7. CLEANING & MAINTAINANCE

7.1. General

When not in use, cover DySIS with a dust cover. Prior to cleaning DySIS, turn the power off and unplug the power cord from the electrical outlet.

7.2. Housing & arm cleaning

	Do not spray solutions or liquids into air vents.
	Do not immerse any part of the device in cleaning solutions.

To clean DySIS from stains, wipe with a soft lightly moistened cloth using a mild detergent. Do not spray any solutions in the air vents. During cleaning, pay special attention to prevent liquid ingress into the device or moistening of the connection ports and switches/buttons. See below for special instructions regarding the cleaning of the monitors and the front imaging element.




7.3. Monitor cleaning

The touch-screen monitor display surface can be cleaned with a soft cloth, such as cotton or lens paper. If necessary, persistent stains can be removed by moistening part of the cloth with warm soap water. To remove stains from the enclosures, wipe with a soft lightly moistened cloth using a mild detergent. Specialized cleaning products should not be used (or used according to instructions).

7.4. Cleaning the front imaging element of the Imaging head

If needed, the front imaging element of the imaging head may be cleaned with a soft cloth, such as cotton or lens paper dampened slightly on isopropyl alcohol or any commercial lens cleaner. Pay special attention to not scratch its surface during cleaning.

7.5. Disinfecting

	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.

No part of DySIS, other than the speculum is intended to come into contact with patients. If needed, DySIS may be cleaned with a soft damp cloth using Vircon, 70% propan-2-ol (isopropanol), sterilisation wipes (chlorahexadine for viral control) and similar substances. DySIS is not intended to be sterilized. A speculum, acetic acid applicator, or any other equipment used with DySIS should be cleaned, disinfected or sterilized according to its manufacturer's instructions for use.

7.6. Speculum

Reusable specula used with DySIS should be prepared (cleaned and decontaminated/sterilized) according to clinical practice, standards and regulations applicable in your country. Refer to the manufacturer's instruction sheet for more details.

Single-use specula should be used according to their manufacturer's instructions and disposed after use according to hospital practice.

7.7. Acetic acid applicator kit

The acetic acid application kit consists of the syringe, the acetic acid reservoir, the luer lock, the spray nozzle, and the silicon tubing. If the local clinical practice is to store and maintain acetic acid in sterile conditions, it is strongly recommended that the kit is sterilized before use. This can be achieved by using a commercial sterilization fluid, which should be used according to the manufacturer's instructions.

Ensure that the sterilization liquid reaches all parts of the kit, by filling the reservoir with the sterilization liquid and then draw and press the syringe plunger to fill the tubing (repeat until the tubing is filled and liquid is sprayed from the nozzle).

The acetic acid assembly should be replaced on a monthly basis. 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. To clean the tubing, pour 10 ml of water into the reservoir. The tubing can be flushed by pulling back the syringe, depressing the syringe while holding a paper towel in front of the diffuser.

7.8. Periodic Cleaning and Maintenance

The user should, on a monthly basis, clean/maintain DySIS (clean monitors, imaging head front glass, pole, base, etc.) per cleaning and maintenance instructions as described in this section (7).

8. ROUTINE ELECTRICAL TESTING

IMPORTANT: Please read carefully before performing any routine electrical safety test on the DYSIS Digital Colposcope (v3).

An Integrated Computer System:

- The computer integrated within the DYSIS colposcope will start to boot-up as soon as the system is powered.
- Please make sure that you always allow the device enough time to boot-up completely (typically 1 minute), until the user log-in screen is displayed on the touch screen.
- To shut down, use the button on the touch screen.
- Please allow the device / computer enough time to shut down fully.
- If you need to perform a 'stop test', please make sure that the computer has booted up completely before switching off the power.

Isolated Electrical System (Type BF Applied Part):

Please note that the DYSIS Digital Colposcope is an electrically isolated system and an earth bond test is not possible. Earth bond testing is not a safety critical test for this instrument. The following should be performed as routine safety testing:

- Applied Part Insulation breakdown
- Medical Earth Leakage
- Medical Touch current testing
- Patient Leakage Testing (BF Applied Part)
- Patient Auxiliary Leakage Testing (BF Applied Part)
- Patient F-Type Leakage Testing (BF Applied Part)



Isolated system! Chassis is NOT Earthed

For technical support please contact service@dysismedical.com

9. TROUBLESHOOTING AND SERVICING

DySIS Medical discourages the performance of any maintenance, troubleshooting or service actions on DySIS other than those specified in this guide. If DySIS 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 the identification and the solution of the problem.

9.1. Troubleshooting guide

Before performing any troubleshooting action, please make sure that the power cord is connected and note if the indicator light in the rear of the main unit is alight.

The following table lists specific issues that may be experienced with DySIS. Observe all safety precautions and warnings and make sure you read carefully and fully understand the instructions for use before attempting any of the troubleshooting below. Make sure you shut down, disconnect from mains power and restart the unit before contacting technical support. If any of the suggested actions fail to solve the problem, please contact the DySIS Medical service department.

Description	Possible Cause(s)	User Action
The imaging module does not maintain its position when brakes are activated	Brake system components may be excessively worn or dirty	Contact service support
Image is fuzzy, unclear or dark	Front imaging element may be very dirty	Clean front glass element (See section 7.4)
	Spray nozzle cover is lifted	Make sure that the metallic cover of the spray nozzle is in the lower position
No image on the TFT monitor	The TFT monitor power and/or signal cable may be disconnected or damaged	Check the VGA cable connections at the rear of the TFT monitor and the rear of the main unit; check that the power cable is properly connected to the mains supply
	The power on TFT monitor may be off	Check the power button on the front panel of the TFT monitor to be ON

	Graphics card settings may have been lost	Contact service support
No image on the touch screen	The signal or power cable is disconnected or damaged	Contact service support
	Graphics card malfunction	
Computing unit does not turn ON when power button is pressed	Cabling going into the computing unit may be loose/disconnected	Contact service support
	Computing unit malfunction	Contact service support
Computing unit turns on, the software functions, but the DySIS Exam button is disabled	Camera malfunction	Contact service support
Image is displayed but illumination does not turn on	Illumination source malfunction	Contact service support
DySIS doesn't turn on	Mains power cable is disconnected	Make sure that the mains power switch is OFF and reconnect the mains power cable. Switch the mains power ON.
	Outlet has no electricity	Make sure there is the appropriate supply at that outlet
	Blown fuse(s)	Replace fuses (see section 9.2)
	System malfunction	Contact service support

9.2. Replacing fuses

The fuses of the device are located underneath the mains power inlet.



Figure 43: Power inlet and fuses

Follow the procedure below to check and replace them, if needed. Note that replacing fuses is the only service action that can be performed by the user. If you are not familiar with the procedure do not proceed, and contact your local representative.

- Make sure that the system is turned OFF
- Remove the power cable from the mains power inlet
- Gently press on the clip and pull the fuse cover to remove it
- Pull out and remove both fuses from their holders
- Use T3.15 AH, 250V ceramic tube fuses for replacement (always replace both fuses)
- Re-insert and press the protective cover to fix it in place
- Reconnect the power cable and start-up the system. If the system fails to start up, please contact the DySIS Medical service support

9.3. Replacing the acetic acid application mechanism

Follow the procedure to remove the acetic acid spray mechanism (spare parts to be purchased separately from DySIS Medical, Part No ACE001). When performing the replacement make sure that no liquids are spilled on the device.

- Make sure that the system is turned OFF
- Remove the power cable from the mains power inlet
- Lift the protecting cap and remove the spray nozzle from its holder
 - Remove the mechanism from its holder
 - Unscrew the syringe luer lock by gently rotating it anti-clockwise
 - Slide the black collar off the end of the syringe
 - Safely dispose of the used acetic acid kit

To assemble and install the replacement kit:

- Unscrew the syringe
- Place the sensor collar over the end of the new syringe
- Screw the syringe back into the luer lock on top of the acetic acid bottle
- Place the assembly back into the clip on the side of the imaging head.
- Fit the spray nozzle back into its holder and press the protective cap back down.

10. DYSIS WARRANTY, SERVICE, EXPECTED SERVICE LIFE AND RECYCLING


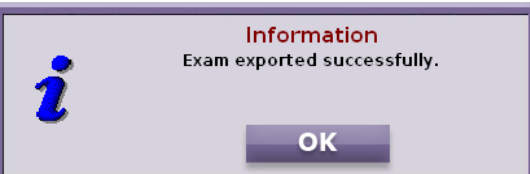
DySIS is offered with a one-year full warranty, covering parts and labour. Customers should contact their local representative for servicing DySIS and for information on service contracts.

DySIS has an expected service life, and so lifecycle, of 10 years from the date that the system was shipped to the customer.

Metal parts, such as the movable base and the TFT pole can be recycled in metal recycling facilities. Electronic components such as TFT monitor, touch screen, CPU components, imaging head modules can be recycled at specialty electronic components recycling stores.

11. APPENDIX I: SOFTWARE MESSAGES

The following table lists the information, warning and error messages that may appear during the use of DySIS.

	Camera connection failure; contact technical support.
	Confirmation that exporting the examination data has been successful.



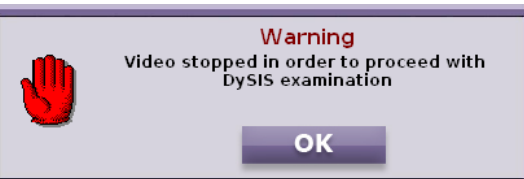
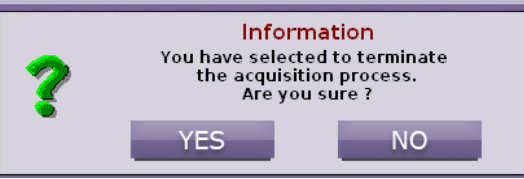
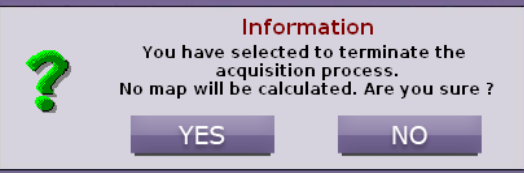
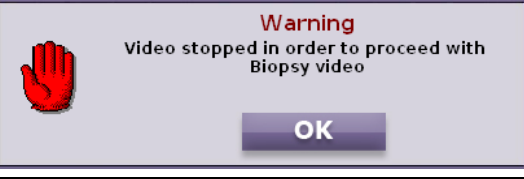
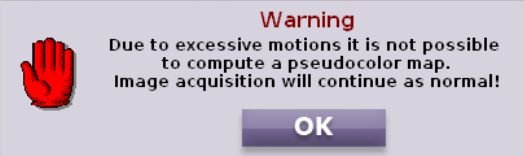

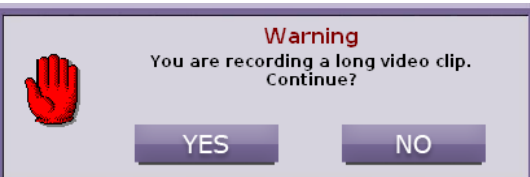
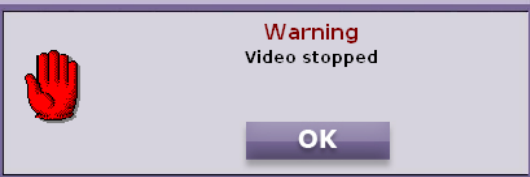
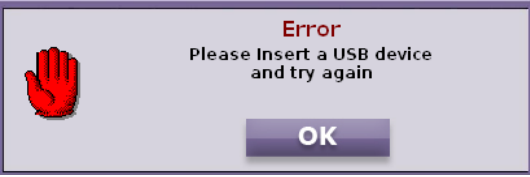
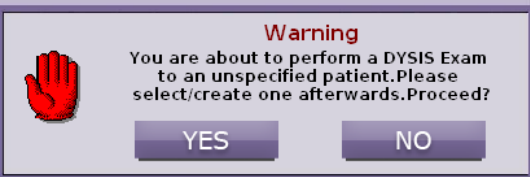
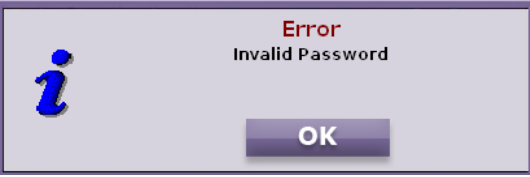










 <p>Warning</p> <p>Excessive image brightness detected. Press YES to ignore it or NO for "Brightness Control" adjustments</p> <p>Yes No</p>	<p>After pressing START; the image brightness may be too high. Press OK and adjust the brightness, either automatically or manually.</p>
 <p>Warning</p> <p>Low image brightness detected. Press YES to ignore it or NO for "Brightness Control" adjustments</p> <p>Yes No</p>	<p>After pressing START; the image brightness may be too low. Press OK and adjust the brightness, either automatically or manually.</p>
 <p>Warning</p> <p>Video stopped in order to proceed with DySIS examination</p> <p>OK</p>	<p>START was pressed during video recording. Video recording has been terminated. All data has been saved.</p>
 <p>Information</p> <p>You have selected to terminate the acquisition process. Are you sure ?</p> <p>YES NO</p>	<p>During image acquisition, STOP was pressed; please confirm.</p>
 <p>Information</p> <p>You have selected to terminate the acquisition process. No map will be calculated. Are you sure ?</p> <p>YES NO</p>	<p>During image acquisition, STOP was pressed; the collected data are not sufficient for the calculation of the map. Please confirm.</p>
 <p>Warning</p> <p>Video stopped in order to proceed with Biopsy video</p> <p>OK</p>	<p>During video recording a point was marked. The video recording was stopped, and a new video clip is being recorded.</p>
 <p>Warning</p> <p>Due to excessive motions it is not possible to compute a pseudocolor map. Image acquisition will continue as normal!</p> <p>OK</p>	<p>Due to excessive movements, DySIS cannot calculate a map. However, image acquisition will continue normally. The</p>

	image sequence will be available for review.
	Due to excessive movements, the map will be calculated using images collected for ### seconds only. Image acquisition will continue normally. The image sequence will be available for review.
	The video recording has exceeded 4 minutes. Please confirm you wish to continue.
	The video recording has stopped
	Problem with export of data. Retry with a new USB data storage device.
	Confirm that you wish to perform an examination without entering patient information first. After the examination, you will be prompted to create a new patient record, to append the data to an existing record or to discard all data.
	The user name or password you entered is wrong

 <p>Warning Shut Down the Device Are you sure?</p> <p>YES NO</p>	<p>Confirm that you wish to turn DySIS off.</p>
 <p>Warning Please complete all mandatory fields: First Name, Last Name, Date of Birth and Patient Id</p> <p>OK</p>	<p>You have not completed all the fields that are compulsory for the creation of a new patient.</p>
 <p>Warning Discard the exam? Are you sure?</p> <p>YES NO</p>	<p>You have selected to discard all examination data. Press YES to confirm and NO for more options.</p>
 <p>Information Report exported as pdf successfully.</p> <p>OK</p>	<p>The report of the examination has been exported on the USB data device successfully.</p>
 <p>Error New Passwords are different! Please re-type</p> <p>OK</p>	<p>The new password has not been entered successfully. Please retry.</p>
 <p>Error The New Password fields can not be empty</p> <p>OK</p>	<p>You must provide a new password.</p>
 <p>Warning You are about to change your username Are you sure?</p> <p>YES NO</p>	<p>Please confirm you wish to change your user name.</p>

 <p>Error The available disk size is not sufficient!</p> <p>OK</p>	<p>The storage space available is not enough. Please check disk or use a larger one.</p>
 <p>Error Back-up Error! Please check USB connection and try again!</p> <p>OK</p>	<p>Error during data back-up. Check that the USB storage medium is connected correctly and that there is enough available space before trying again!</p>
 <p>Information Back-up concluded successfully.</p> <p>OK</p>	<p>The data base backup has been successful.</p>

12. APPENDIX II: LABELING

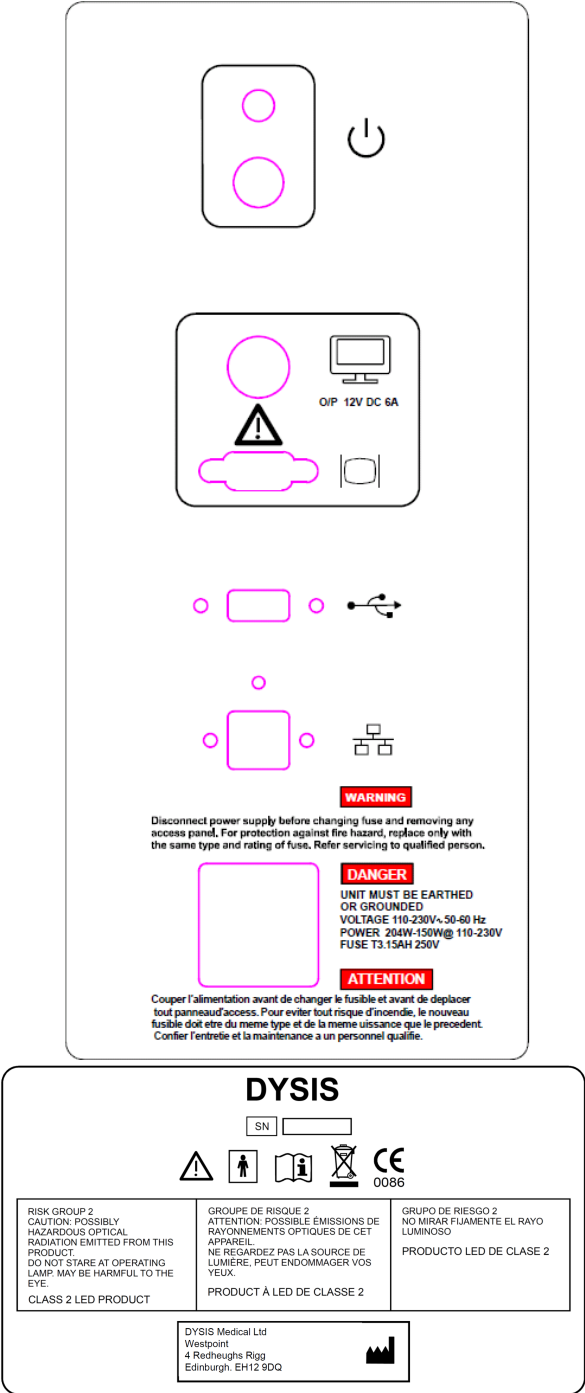


Figure 44: The labels found on DySIS

The labels found on DySIS (Figure 44) provide the information necessary to identify and contact the manufacturer, as well as information on the specifications of the device.

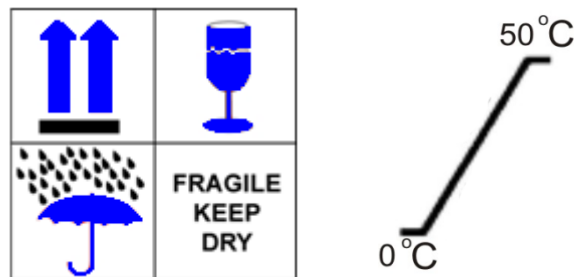


Figure 45: DySIS Shipment packaging labels

The labels found on the DySIS packages used for shipment (Figure 45) advice which side is UP, that the contents are FRAGILE and that they have to be kept DRY. For DySIS the environmental storing temperature is in the range of 0-50°C.



13. APPENDIX III: QUICK REFERENCE CHART

The following guide outlines the steps that can be followed for operating DySIS; please refer to the previous sections of the instructions for use for a more detailed description and explanation of the individual steps.

DySIS is installed at the optimum position for examination next to the gynaecological chair. Maintain DySIS is in its idle position, until the patient has been prepared for an examination following standard safety and medical practice;

To start DySIS:

- Start DySIS by pressing the button on the computer pod
- Wait for the LOGIN screen to appear
- Provide a valid USER NAME/ PASSWORD combination and press LOGIN

To record the visit of a patient:

- Highlight the patient name on the database then press NEW VISIT
- Select referral reason information (optional)
Or
- Select NEW PATIENT from the main menu, provide the patient personal information and press OK
- Select referral reason information (optional)

For the examination, use the rotating arms to bring the imaging head facing the examination area; if desired use their knobs to stabilize the position.

To perform and document an examination:

- Press DySIS EXAM to switch the illumination ON; live image is displayed on the touch screen
- Prepare the patient and insert the appropriate speculum
- Press the trigger to release the pan and tilt brakes, and bring the imaging head to face the examination site; connect to the speculum with soft movements
- Use the fine focusing mechanism for optimization
- Filters, magnification and documentation tools are available
- Pull the plunger to load the spray mechanism and press START to perform acetowhitening mapping
- Press the EXIT button to terminate the examination
- Provide assessment and management plan (optional)

To switch DySIS off:

- Select SHUT DOWN from the main menu and wait for the device to shut down

14. APPENDIX IV: DYSIS TECHNICAL DESCRIPTION

DySIS Product Description:

- Product Name: DySIS v3
- EC Product Class: Class IIa, FDA Product Class II

PC Unit and Monitors:

- Motherboard: Pentium Core i5 CPU; on-board GPU
- RAM: 2GB, HDD: 250GB
- 1 x USB 2.0 port
- 1x VGA port
- Touch screen: 12.1", 1024 x 768 pixels max resolution @ 60Hz
- TFT monitor (upgrade): 19", 1280 x 1024 pixels max resolution @ 60Hz

Imaging Head Unit:

- CMOS sensor
- Resolution: 1600 x 1200 pixels
- Digital interface: Gigabit Ethernet

DySIS Power/Operation:

- Frequency: 50/60Hz
- Power Input: 20 to 310W
- Rated Input Voltage: 110- 230VAC
- Power Consumption (fully operational): 125 W, (when upgraded with the TFT monitor, 150W)
- Fuse Information: T3.15AH, 250V ceramic tube (2 pcs)
- Start Up Time to Operation < 1 min
Operational Footprint Length, Width, Height (cm): 150x60x70
(with TFT Upgrade kit 150x60x170)
- Idle Footprint Length, Width, Height (cm): 31x60x70
(with TFT Upgrade kit 31x60x170)
DySIS System Weight (Kg): 61 (with TFT upgrade kit 68)
- DySIS shipping weight (kg): 150 (2 pcs)
- DySIS can be fully isolated from mains power supply by pulling out the mains power cable from the mains inlet power plug.

15. APPENDIX VI: DYSIS USERS PRE-POWER UP CHECKLIST

- Check that the mains cable is connected as specified in the user's manual.
- Check that cables are securely connected and visually inspect that the cables are not abused or cut.
- Visually inspect that all DySIS enclosures are intact, unbroken and in position.
- Visually inspect that no liquids are spilled on DySIS.
- Visually inspect that the front window of the imaging head is clean and nothing obstructs its field of view.
- Visually inspect the device to be free of debris and of any foreign objects and see that there is no abuse or miss-handling of the device.
- Check that all brakes on the system work properly as described in the instructions of use.
- Check and see if the spray mechanism is connected and that it works properly.
- Visually inspect the device safety labels and see that are not worn out or missing.
- Check that the device label is not abused and that the device warranty, service and maintenance records are up to date and there is no neglect in the device optimal running condition.

16. APPENDIX VI: 60601-1-2 DATA

Tables of guidance and manufacturer’s declaration regarding electromagnetic emissions and immunity as per by EN 60601-1-2:2007 (clauses 5.2.2.1 and 5.2.2.2).

15.1 Guidance and manufacturer’s declaration on electromagnetic emissions

The DySIS Digital Colposcope is intended for use in the electromagnetic environment specified below. The customer or the user of the DySIS Digital Colposcope should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The DySIS Digital Colposcope uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The DySIS Digital Colposcope is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

15.2 Guidance and manufacturer's declaration on electromagnetic immunity

The DySIS Digital Colposcope is intended for use in the electromagnetic environment specified below. The customer or the user of the DySIS Digital Colposcope should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV differential Mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the DySIS V3 colposcope requires continued operation during power mains interruptions, it is recommended that the DySIS V3 colposcope be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	N/A EUT contains no devices susceptible to magnetic fields.	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

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