

DySISmedical

DySIS Digital Colposcope Instructions for Use



DySIS v3 USA edition



CAUTION: Federal law restricts this device to sale by or on the order of a licensed health care provider

Notice

The information in this guide is subject to change without notice.

This guide contains information protected by copyright. No part of this guide may be duplicated or reproduced in any form without prior explicit written consent from DySIS Medical.

The manufacturer assumes no responsibility for any injury resulting from any illegal or improper use of the device; or from assembly operations, extensions, readjustments, modifications or repairs carried out by non-qualified personnel; or from not using the device according to the instructions, cautions, warnings, or statement of intended use published by the manufacturer; or from the electrical installation of the relevant room non complying with the relevant requirements for safety. Users must read and understand the warnings and precautions in this guide before using the equipment.

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



DySIS and DySISmap are trademarks of Forth Photonics Ltd, which is a subsidiary of DySIS Medical Ltd. Part No. 0230-53002 Rev 7

CONTENTS

| | |
|--|-----------|
| 1. INTRODUCTION | 8 |
| 1.1. General | 8 |
| 1.2. Indications for use | 8 |
| 1.3. Messages | 10 |
| 1.4. Summary of warnings and cautions | 11 |
| 1.5. Classification | 15 |
| 1.6. Repairs/maintenance and warranty | 16 |
| 1.7. Environmental conditions | 16 |
| 1.8. Usage restrictions | 17 |
| 2. GENERAL DESCRIPTION | 18 |
| 2.1. Installation | 18 |
| 2.2. Device layout | 18 |
| 2.3. Mounting arrangement - positioning arms | 20 |
| 2.4. Transporting, moving, positioning and braking | 20 |
| 2.5. Computing unit | 23 |
| 2.6. Touch screen | 23 |
| 2.7. Imaging head | 24 |
| 2.8. Connection ports | 25 |
| 2.9. Connecting a speculum | 27 |
| 2.10. Acetic acid applicator | 28 |
| 2.11. Power on/off | 29 |
| 2.12. Calibration | 30 |
| 3. DYSIS SOFTWARE APPLICATION | 31 |
| 3.1. The user interface | 31 |
| 3.2. Logging in | 31 |
| 3.3. Buttons | 32 |
| 3.4. Main Menu | 34 |
| 4. OPERATING DYSIS | 35 |
| 4.1. Overview | 35 |
| 4.2. Step 1 – Examination preparation | 35 |
| 4.3. Image brightness | 37 |
| 4.4. Digital filters | 38 |
| 4.5. Magnification | 38 |
| 4.6. Saving still images | 39 |
| 4.7. Capturing video streams | 39 |
| 4.8. Step 2 - Initiate Dynamic Imaging procedure | 40 |
| 4.9. Step 3 - Colposcopy during acetowhitening | 41 |

| | | |
|-----------|---|-----------|
| 4.10. | Step 4 - Marking biopsy points..... | 43 |
| 4.11. | Step 5 - Entering “initial” colposcopic impression | 44 |
| 4.12. | Step 6 - DySISmap | 45 |
| 4.13. | Step 7 - Final colposcopic impression | 49 |
| 4.14. | Step 8 - Selection of additional biopsy points | 49 |
| 4.15. | Closing the examination..... | 51 |
| 4.16. | Training mode | 51 |
| 5. | PATIENT AND DATA MANAGEMENT SYSTEM..... | 53 |
| 5.1. | General..... | 53 |
| 5.2. | Creating a new patient record | 53 |
| 5.3. | Appending an examination to a patient record | 54 |
| 5.4. | Opening a patient record | 54 |
| 5.5. | Modify patient information | 57 |
| 5.6. | New visit..... | 57 |
| 5.7. | New visit - referral information..... | 58 |
| 5.8. | New visit - colposcopic impression | 59 |
| 5.9. | New visit - memos..... | 59 |
| 5.10. | New visit - management plan | 60 |
| 5.11. | Histology results..... | 61 |
| 5.12. | DySIS report | 61 |
| 5.13. | Add history..... | 63 |
| 5.14. | Reviewing a visit..... | 65 |
| 5.15. | Reviewing images..... | 65 |
| 5.16. | Examination playback | 66 |
| 5.17. | Compare Mode | 68 |
| 5.18. | Exiting review | 68 |
| 6. | ADDITIONAL FUNCTIONS..... | 70 |
| 6.1. | Periodic calibration | 70 |
| 6.2. | Connecting USB devices | 74 |
| 6.3. | Exporting data | 74 |
| 6.4. | Printing images and reports | 75 |
| 6.5. | Uploading a logo for reports | 75 |
| 6.6. | Connecting to external databases..... | 78 |
| 6.7. | User Tools..... | 78 |
| 7. | CLEANING & MAINTENANCE..... | 80 |
| 7.1. | General..... | 80 |
| 7.2. | Housing and arm cleaning..... | 80 |
| 7.3. | Monitor cleaning..... | 80 |
| 7.4. | Cleaning the front imaging element of the imaging head..... | 80 |
| 7.5. | Disinfecting..... | 81 |
| 7.6. | Speculum..... | 81 |
| 7.7. | Acetic acid application kit | 81 |

| | | |
|------------|---|------------|
| 7.8. | Periodic cleaning and maintenance | 82 |
| 8. | ROUTINE ELECTRICAL TESTING | 82 |
| 9. | TROUBLESHOOTING AND SERVICING..... | 83 |
| 9.1. | Troubleshooting guide | 83 |
| 9.2. | Replacing fuses..... | 86 |
| 9.3. | Replacing the acetic acid application mechanism..... | 86 |
| 10. | DYSIS SERVICE, EXPECTED SERVICE LIFE AND RECYCLING | 88 |
| 11. | APPENDIX I: SOFTWARE MESSAGES..... | 89 |
| 12. | APPENDIX II: LABELING..... | 93 |
| 13. | APPENDIX III: QUICK REFERENCE CHART | 96 |
| 14. | APPENDIX IV: DYSIS TECHNICAL DESCRIPTION | 97 |
| 15. | APPENDIX V: DYSIS USER PRE-POWER UP CHECKLIST | 99 |
| 16. | APPENDIX VI: 60601-1-2 DATA | 100 |

| | |
|---|--|
|  | <p>When using this system, always conduct a thorough colposcopy examination, identifying and selecting areas for biopsy, before using the PCI feature to (possibly) select additional biopsy sites. The DySIS with PCI has not been shown to identify areas of cervical neoplasia. Therefore, never use this system to omit a biopsy selected on the basis of the conventional colposcopy examination.</p> |
|  | <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> |

The DySIS digital colposcope complies with:

EN 62471 (2008) Risk Group 2

FCC 47, CFR Part 15 - Subpart B (Class B)

EN 60601-1:2006+A12:2014 / EN 60601-1-6+A1:2015:2010

EN 62304:2006

EN ISO 13485:2012

EN ISO 17664:

EN ISO 14971:2012

EN ISO 11135-1:2007

EN ISO 11607-1:2009

EN ISO 10993-1:2009 / EN ISO 10993-5:2009 / EN ISO 10993-7:2008 /

EN ISO 10993-10:2010

EN ISO 15223-1:2012

EN ISO 14644-1:1999

BS EN 1041:2008+A1:2013

EN ISO 60601-2-18:1997

DySIS Medical operates a Quality Management System which complies with the requirements of ISO 13485: 2003

The CE mark on this product indicates it has been tested to and conforms to the provisions noted in the 93/42/EEC European Medical Device Directive.

USA Patent No 7749162

FDA 510(k) Clearance letter K092433

DySIS and DySISmap are trademarks of Forth Photonics Ltd, which is a subsidiary of DySIS Medical Ltd.

1. INTRODUCTION

Thank you for purchasing the DySIS Advanced Digital Colposcope and cervical imaging system (CAT#: DYS302) 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 colposcopy 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 color and spectral images.

- Three magnification scales - 6x, 11x, 16x

- Surface reflection (glare) elimination by polarized optics.

- Color-coded mapping of the tissue acetowhitening to assist evaluation, documentation and follow-up.

- Database for data storage, review and follow-up.

1.2. Indications for use

DySIS with Pseudo-Color Imaging (PCI) is a digital colposcope designed to image the cervix and lower genital tract under illumination and magnification.

Colposcopy is indicated for women with an abnormal Pap smear in order to affirm normality or detect abnormal appearances consistent with neoplasia, often with directed biopsy.

The PCI feature is an adjunctive tool for displaying areas of acetowhitening. 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: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

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-Color 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-Color Imaging (PCI).

General Clinical Guidance

The DySIS with Pseudo-Color Imaging (PCI) has not been shown to identify areas of cervical neoplasia. Therefore, never use this system to omit a biopsy selected on the basis of colposcopy examination.

Always/Never Use of Pseudo-Color Imaging (PCI) feature

The PCI feature analyzes synchronized still images of acetic acid application to present a false-color map overlay intended to help the colposcopist see acetowhitened areas of the cervix. However, no clinical trials have been conducted to demonstrate that the PCI feature improves detection of diseased tissue that would otherwise be overlooked.

Color coded areas of acetowhitening have not been shown to have diagnostic significance. Color coding only denotes relative difference in amount of acetowhitening.

Use of the PCI feature is NOT a substitute for the conventional colposcopic view. When using the DySIS with Pseudo-Color Imaging (PCI) you must ALWAYS first conduct a thorough colposcopic exam and identify and select areas for biopsy. You may then use the Pseudo-Color Imaging (PCI) feature to (possibly) identify one or more additional biopsy sites. NEVER cancel any of the biopsy sites initially identified with the conventional colposcopic view.

Optimal Use of the Pseudo-Color 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-color overlay Map.

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

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.

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 event 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.

Always engage the foot brake during an examination.

DySIS should be positioned on a flat floor, the base brake released and the arm brakes applied to prevent 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 hydraulic brakes of the arm 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 arm movement. |
| 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 power supply with protective grounding. |
| Only the DySIS medical grade 2 nd monitor 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. |
| <p>Sequence of actions to power up the device:</p> <ul style="list-style-type: none"> • Connect the main power cable to the appropriate outlet, or (if already connected) • Press the power button <p>The computing unit will power up and the software application will start.</p> <p>Sequence of actions to power down the device:</p> <ul style="list-style-type: none"> • Log out of the application and then click on Red Power Button (using the touch screen). DySIS will shut down automatically. <p>To avoid power consumption when idle, disconnect the power cable after the unit has completely shut down.</p> |
| The DySIS calibration card should be maintained so that it stays clean and in good condition. |

| |
|--|
| Make sure that any external data storage media have been checked for malware (viruses, trojans, etc.) 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 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. |











(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 or detached. |
| 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 color 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 from the side or from below, as this may distort the perception of the color and brightness. |
| | Before a DySISmap measurement, check that there is a sufficient volume of acetic acid solution 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 “Apply Agent” message 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, the annotations 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 labeling in section 12), the following warning labels are found on DySIS.

| | |
|---|--|
|  | The attachable speculum is a Type-BF applied part that provides protection against electric shock. |
|  | Follow DySIS operating instructions. |

| | |
|--|---|
|  | 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 at the location of this mark. |
|  | 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 millimeters or smaller in diameter.

The DySIS reusable metallic 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.

The DySIS pole and the patient monitor support module (available as an upgrade), not an applied part, could accidentally come in contact with the patient.

Mode of operation; DySIS is classified for continuous operation.

1.6. Repairs/maintenance and 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 repair center authorized by DySIS Medical.

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 Warranty for warranty statements and legal terms and conditions and the DySIS Service Agreement for service agreement options.

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 according to its 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.

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: 204-150W
- Rated Input Voltage: 110-230VAC

See the DySIS device label in Figure 62 at section 12 for the device label details.

Each DySIS system is accompanied by:

- DySIS acetic acid application kit
- DySIS declaration of conformity
- DySIS user manual
- DySIS calibration card

Accessories that can be used with DySIS are:

A speculum (reusable, different types and sizes)

USB data storage devices


USB printers and additional monitors

2. GENERAL DESCRIPTION

This section introduces DySIS and highlights the functionality of its different parts.

2.1. Installation

DySIS is always setup 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.

| | |
|---|---|
|  | <p>The power cable must always be positioned so as to minimize risk for tripping.</p> |
|---|---|

2.2. Device layout

DySIS can be seen in Figure 1 below.







Figure 1: The DySIS digital colposcope

DySIS can be further enhanced with the upgrade kit, which includes a medical-grade 19" Patient View or 2nd monitor and its positioning pole.



Figure 2: The DySIS digital colposcope with the Patient View or 2nd monitor installed


| Module Description | Module Function |
|---|--|
| Base | Stabilizing the unit Allows moving the device |
| Positioning arm | 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 |
| Patient View or 2 nd 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 enable 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 main power inlet is located on the rear of the computing unit.

| | |
|---|---|
|  | 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. |
|---|---|

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).

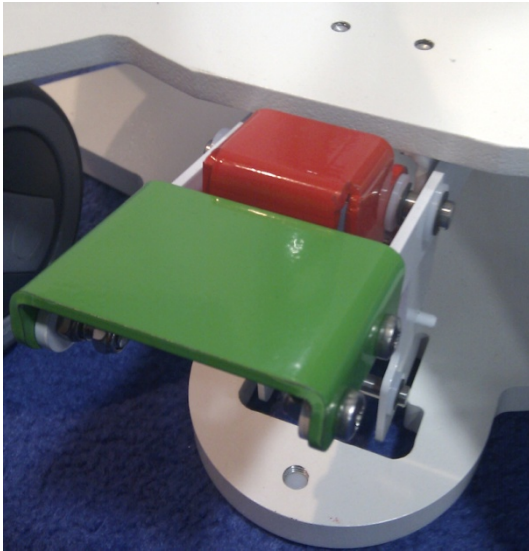






Figure 3: The foot brake pedal

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 castors. When transporting DySIS over a threshold, push DySIS 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 it rolls over it.

| | |
|---|--|
|  | 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. |



DySIS should be positioned on a flat floor, the base brake released and the arm brakes applied to prevent 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. Both knobs should be tightened during transporting.



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.

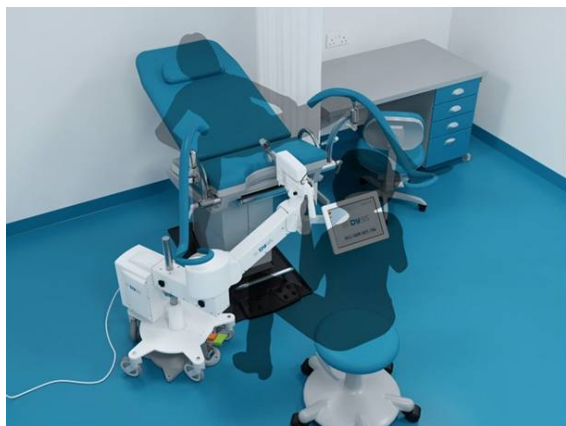



Figure 4: Typical positioning of DySIS in the clinic

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 longer operation time is needed.



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 arm movement.

| | |
|---|---|
|  | <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> |
|---|---|

By pressing the button under the imaging head, the user can point it easily in the desired direction. Note that this brake cannot be operated continuously for more than one minute. Release and repress if longer operation time is needed.

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 power inlet and the fuses.

2.6. Touch screen

The touch screen monitor is where the user interfaces with DySIS software and views the image. The user utilizes the touch screen capability to operate DySIS(*i.e.*,. 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 arm of the touch screen allows it to be moved to the left or right side of the imaging head, to facilitate use by left and right hand users. Its tilt can also be adjusted by releasing a knob at its rear.






Figure 5: The touch screen monitor

2.7. Imaging head

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



Figure 6: 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 has an isolated electrical system. To maintain patient safety, it is critical that all other devices connected to DySIS are electrically isolated (*i.e.*, have their own power source). 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.

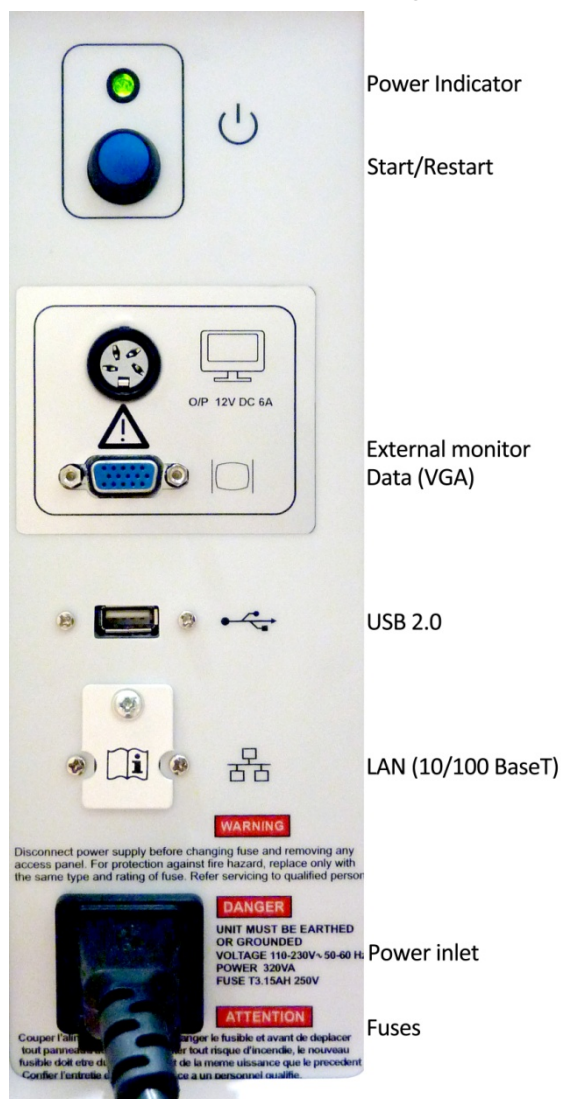




Figure 7: Computing unit connection ports

| | |
|---|--|
|  | 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 power supply with protective grounding. |

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 the device.

External Monitor

DySIS may be upgraded to include a Patient View or 2nd monitor (see Figure 2). The signal cable of the monitor (VGA) is connected to the computing unit as labeled.

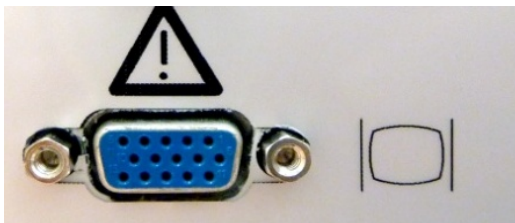



Figure 8: The VGA port for the connection of the additional monitor

| | |
|---|---|
|  | Only the DySIS medical grade 2 nd monitor should be connected to the VGA output of the computing unit. |
|---|---|


USB

The USB port is provided to allow the connection of external storage devices and printers. The DySIS USB port complies with the USB 2.0 standard (therefore, some USB 1.0 or 3.0 devices may not be recognized). Refer to Section 6.3 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 may 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 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

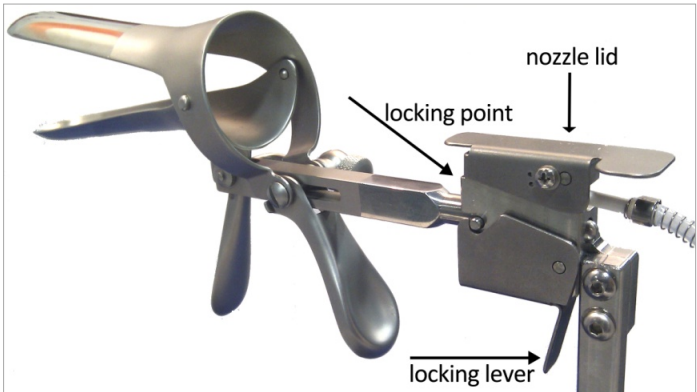




Figure 9: Speculum attachment

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

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

| | |
|---|---|
|  | 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). |

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

2.10. Acetic acid applicator

An acetic acid applicator is attached to the imaging head of DySIS, employing 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 identical holders, on the right and left of the imaging head, that allow the positioning of the applicator system according to the user's preferences.





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> <ul style="list-style-type: none">• Connect the power cable to the appropriate outlet, or (if already connected)• Press the power button <p>The computing unit will power up and the software application will start.</p> <p>Sequence of actions to power down the device:</p> <ul style="list-style-type: none">• Log out of the application and then click on CLOSE (using the touch screen). DySIS will shut down automatically. <p>To avoid power consumption when idle, disconnect the power cable after the unit has completed shut down.</p> |
|---|---|




Figure 11: The DySIS Power ON button and indicator

2.12. Calibration

To ensure consistent long-term operation, DySIS includes a weekly built-in calibration procedure that must be performed to ensure accurate results. A calibration card is provided with DySIS.

After a user logs into the system, a check is done on the date of the last calibration to determine the calibration requirement (a count-down label is also displayed on the main menu). If appropriate, the user will automatically be taken to the calibration screen and guided through the process (see Section 6.1 for details).

| | |
|--|--|
|  | <p>The DySIS calibration card should be maintained so that it stays clean and in good condition.</p> |
|--|--|

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 colposcopy 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 colposcopy examination and the storage and management of patient data are considerably simplified for improved documentation.

The functionality of the software varies slightly when DySIS is upgraded with the additional Patient View 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 (e.g., comments) |
| Numerical keyboard | Allows numerical entries |
| Date entry keypad | Allows quick date entry (e.g., date of birth) |
| Tick boxes | Allows quick selection of information (e.g., Blood Group) |
| Action buttons | Allows the user to perform a task (e.g., save an image) |
| Menu items | Allows the user to select an option (e.g., Review Exam) |
| Messages | Notifies or warns the user (e.g., to pull the syringe plunger) |
| Indicators | Informs the user about a current activity (e.g., video recording) |

3.2. Logging in

After turning 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 usernames and passwords are provided upon installation, and can

then be then 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 red “Shut down” button will turn DySIS off.

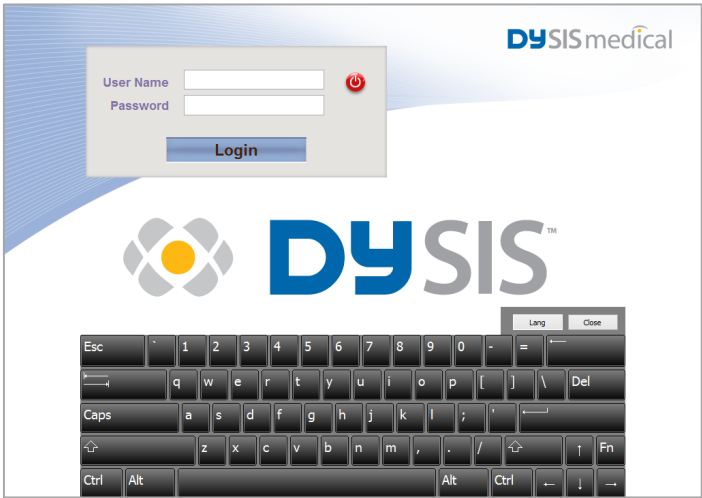
























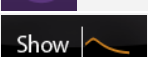






Figure 12: DySIS software user login screen

3.3. Buttons

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

| Button | Function | Button | Function |
|--|-----------------------------------|---|--|
| General | | | |
|  | Return to login screen |  | 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 image |  | Training mode |
|  | Magnification |  | Apply green filter |
|  | Apply blue filter |  | High contrast enhancement |
|  | Display full color image |  | Mark cervical OS |
|  | Mark biopsy point |  | Delete biopsy point |
| 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. It should be clearly indicated that the version running is marked “USA.”



Figure 13: The Main Menu of the DySIS software

4. OPERATING DYSIS

4.1. Overview

DySIS with Pseudo-Color Imaging (PCI, DySISmap) is a digital colposcope designed to image the cervix and lower genital tract under illumination and magnification. 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.

The PCI feature analyzes synchronized still images of acetic acid application to present a color-map overlay intended to help clinicians visualize acetowhitened areas of the cervix. Use of the PCI feature is NOT a substitute for the conventional colposcopic view. When using DySIS with DySISmap, you must ALWAYS first conduct a thorough colposcopy examination and identify and select areas for biopsy. You may then use the DySISmap feature to identify, where appropriate, one or more additional biopsy sites. NEVER cancel any of the biopsy sites initially identified with the conventional colposcopic view. The software embedded in DySIS has been designed to ensure that you comply with this requirement. Therefore, the examination process will proceed as follows:

1. Examination preparation
2. Initiate Dynamic Imaging procedure
3. Colposcopy examination (including acetic acid to observe acetowhitening effect)
4. Selection of biopsy points (after standard colposcopic assessment)
5. DySISmap
6. Selection of additional biopsy points

These steps are expanded in detail in the following sections:

4.2. Step 1 – Examination preparation

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 turned on and the practitioner can observe the image in the field of view of the camera both on the display monitor and the touch screen in order to perform a standard colposcopy examination.

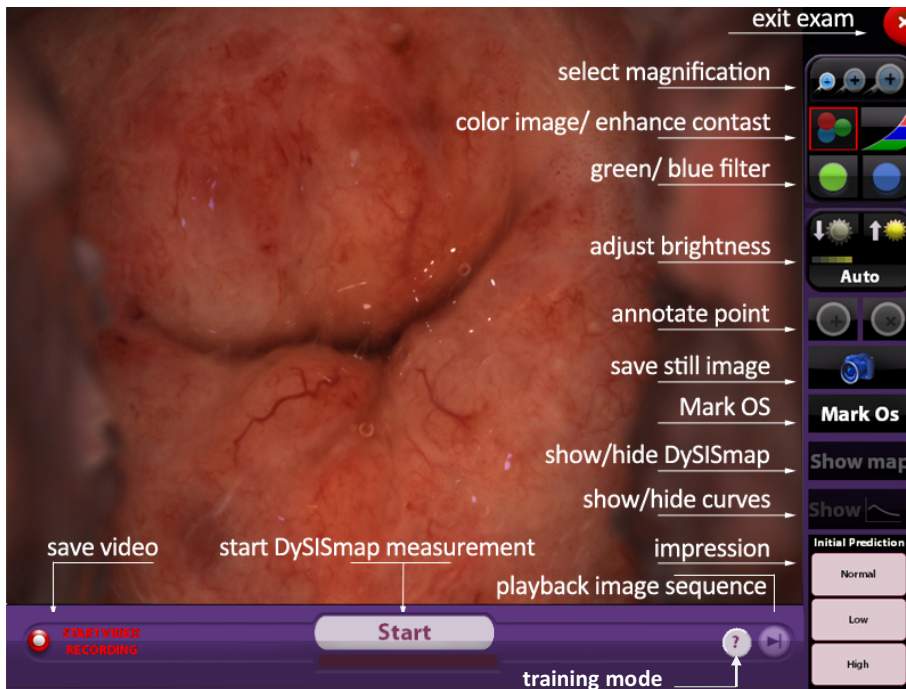








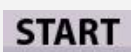


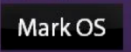


Figure 14: Examination screen with all basic functions indicated

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, lock the speculum (if required, see Section 2.9) and achieve a satisfactory field of view. Releasing the brake trigger ensures that the system will remain stable during the examination. The practitioner should use the black focusing knobs located on the handle of the imaging head to focus the image as displayed on the touch screen.


At this stage, several tools and options are available. During the examination, the user 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 filtered light of the color image |

| | | |
|---|-----------------|---|
|  | Blue Filter | Displays the blue filtered light of the color image |
|  | Color | Displays full-color image (default setting) |
|  | High 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 |
|  | Training mode | Enables/disables training mode (balloon messages) |
|  | START | Initiates Dynamic Imaging and the measurement of the DySISmap |
|  | Playback | Image playback (during/after DySISmap measurement) |
|  | Exit Exam | Terminates the examination |
|  | Mark OS | Allows a reference mark for the cervical OS. |

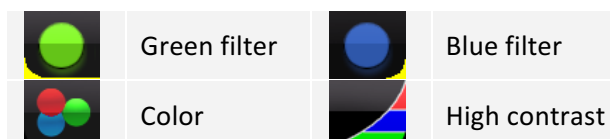
4.3. Image brightness

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 the screen is viewed directly and not from the side or from below, as this may distort color and brightness perception. |
|---|---|

4.4. Digital filters

The user can select to view the green or the blue filtered light of the color image in order to selectively enhance different features such as vascular patterns, atypical vessels, mosaics or punctation and improve the colposcopic imaging. Pressing the “High Contrast” button will often improve the contrast of the image further. After using these tools, the user can revert to the full color display by pressing the “Color” button.



4.5. Magnification

Pressing the different magnification ratios (6x, 11x and 16x) that are displayed on the touch screen results in a portion of the image being 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 and operate 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. When using DySIS with the Patient View monitor, the magnified image appears on both monitors and a green rectangle indicates the part of the image that is magnified.

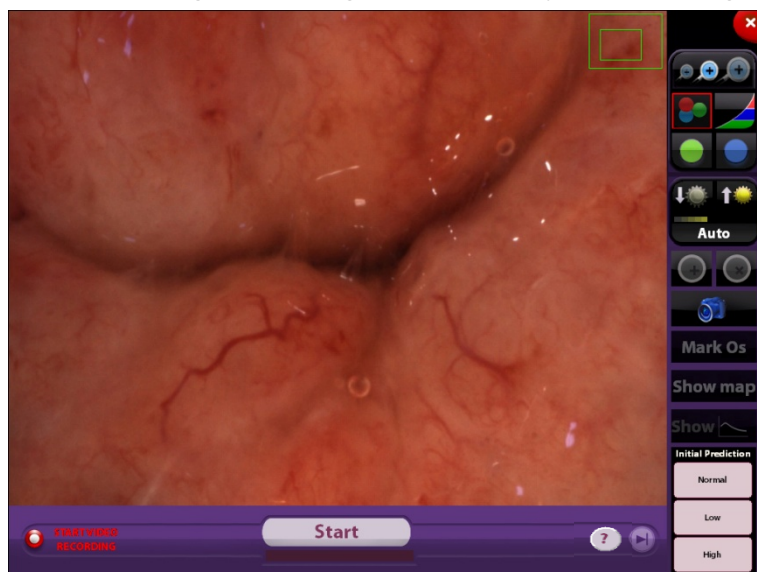


Figure 15: Image as seen on the touch screen of DySIS when the magnification is selected. The green box indicates the portion of the image that is displayed.

4.6. Saving still images

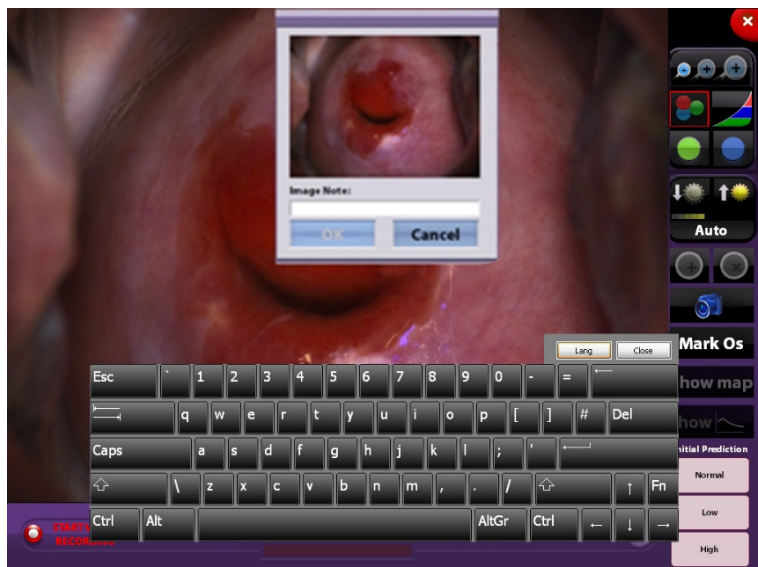


Figure 16: The dialog box for saving still images

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 a comment that will be included in the image 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.

PLEASE NOTE: The saved image will be that of the entire field of view, even if magnification or filters were on during capturing.

4.7. 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.”

PLEASE NOTE: The saved captured video will contain the images of the entire cervix, even if magnification is switched on.

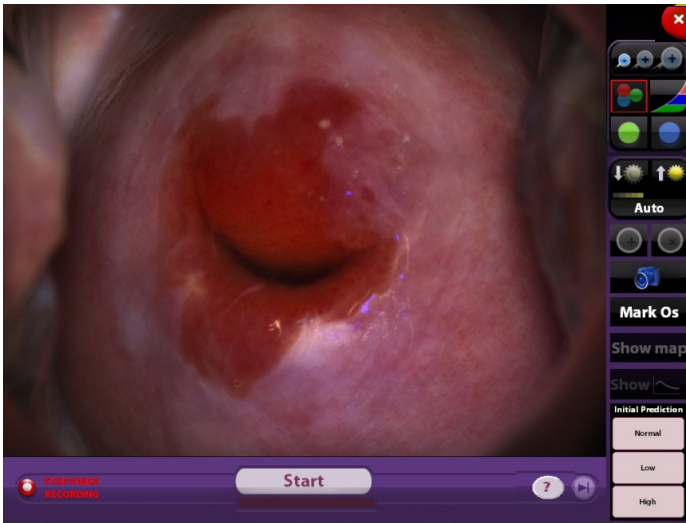


Figure 17: Recording a video clip

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

4.8. Step 2 - Initiate Dynamic Imaging procedure

DySIS will document the dynamic optical phenomena associated with the acetowhitening effect in a color-coded map (DySISmap). DySIS allows the capturing of a sequence of images at high-resolution. The images are automatically aligned to compensate for tissue micro-movements and are then used to calculate the DySISmap. Dynamic Imaging should be synchronized with the application of acetic acid. This synchronization may be done manually, or automatically, as described below.

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

The synchronized initiation of dynamic imaging should always be used in conjunction with the acetic acid application mechanism. Pull the syringe plunger to load it with acetic acid and press the “Start” button. After clicking on “Start,” the message “Apply Agent” is displayed and an audible sound is heard. At this stage the user must press the syringe plunger steadily and firmly to spray the full content. A sensor detects this process and

initiates image capturing. The user can stop the dynamic imaging acquisition procedure after a minimum of 130 seconds of data collection to display the DySISmap. Otherwise it is automatically terminated after 185 seconds.

4.9. Step 3 - Colposcopy during acetowhitening

During Dynamic Imaging, and as cervical acetowhitening is developing, the user can use the magnification and digital filter tools, capture still images and annotate points of interest to assist in the conventional colposcopy examination.



Figure 18: During image acquisition for the calculation of DySISmap, the green bar indicates progress.

| | |
|--|--|
| | Before synchronized Dynamic Imaging, check that there is a sufficient amount of acetic acid solution in the container. |
| | When performing a DySISmap measurement, do not use the acetic acid application mechanism before pressing "START." |
| | While Dynamic Imaging is in progress, do not obscure the light beam or the camera. |
| | While Dynamic Imaging is in progress, patient movements should be minimized. |










Image Sequence Review



Figure 19: Image sequence playback buttons

When using DySIS with the Patient View monitor, at any moment during Dynamic Imaging, the user can review the images that have been captured thus far, by clicking on the playback icon (see Figure 14).

The user can use forward/backward buttons displayed on the touch screen to scroll through the images manually, or let them play continuously and select the playback speed. The images can be reviewed on the second monitor, but the touch screen will always display the live image of the cervix. It is possible to view the captured images in their raw form or, after they have been aligned, by using the image sequence buttons. Click on the exit button to return to live view.

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

Marking the Cervical OS

DySIS provides a function to allow the user to mark the opening in the center of the ectocervix in order to provide a reference or landmark point that is visible on DySISmap. In order to do this, touch the screen in the appropriate place and then press the “Mark OS” function button (as shown below). The resulting reference mark is a cross as shown below.



Figure 20: Live view of the cervix with Cervical OS annotation.

4.10. Step 4 - Marking biopsy points

Throughout the examination, DySIS users can annotate points of interest that can serve as reference points to document areas of interest and to annotate potential biopsy areas as indicated by conventional colposcopy. To mark an area for biopsy, the user should click on the selected point of the image of the cervix 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 up to five points have been marked.





Figure 21: Image as seen on the touch screen with annotated points.

PLEASE NOTE: The user must **ALWAYS** select biopsy points based on the conventional colposcopy exam before the DySIS system will display DySISmap. If no biopsy points are indicated, when you press “Show Map” to view the DySISmap, a dialog box will appear asking you to confirm that no biopsy points are indicated by conventional examination.

4.11. Step 5 - Entering “initial” colposcopic impression

Throughout the examination, and before seeing the DySISmap, the user can enter the “initial colposcopic impression” using the options at the lower right bottom of the touch screen.



Figure 22: Image as seen on the touch screen with initial colposcopic impression selected.

4.12. Step 6 - DySISmap

Once all biopsy points indicated by standard colposcopy examination have been selected and marked on the image, users may access the DySISmap by pressing the “Show Map” button.

PLEASE NOTE: If no biopsy points were marked, DySIS will ask for confirmation from the user to proceed to DySISmap or to return to biopsy marking. If no “initial” colposcopic impression was entered, a pop up will prompt the user to select it before displaying the DySISmap.

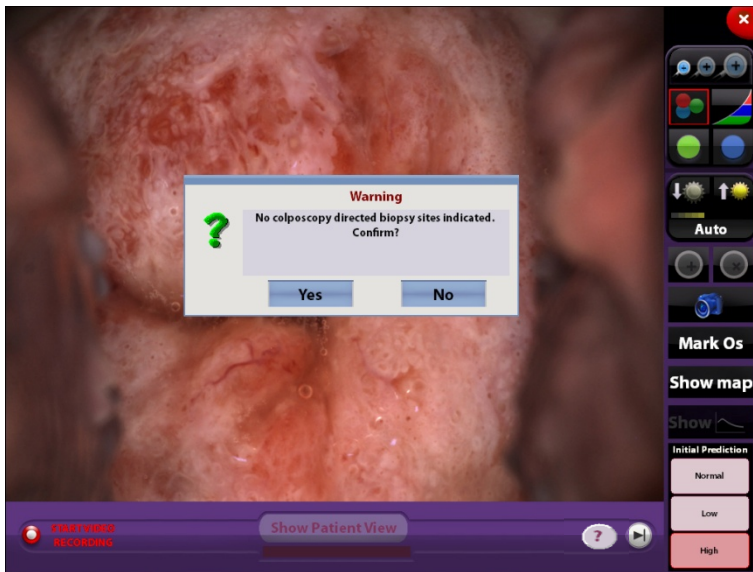


Figure 23: DySIS will ask for confirmation that the initial colposcopy impression indicated no biopsy points were selected before making the DySISmap visible.



Figure 24: Live image view of the cervix with Cervical OS annotation and colposcopy indicated biopsy points marked. The “Show Map” button is enabled.

After pressing “Show Map” the DySISmap is displayed.

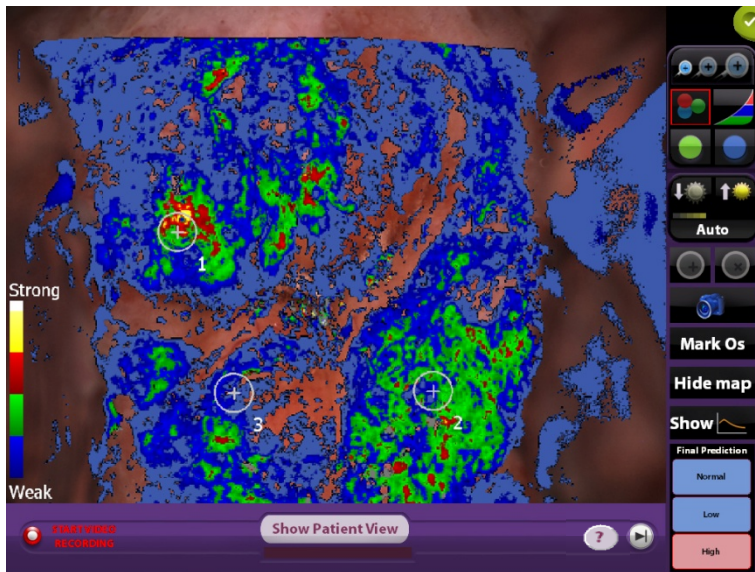



Figure 25: After “Show Map” has been pressed, the DySISmap is shown. Note that the biopsy points marked before seeing the DySISmap are now shown in grey and cannot be edited.

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

IMPORTANT: Color-coded areas of acetowhitening have NOT been shown to have clinical significance with regard to how well the biopsy sites selected using PCI correspond to the level of cervical disease as determined by pathology results. Color coding only denotes the relative difference in the amount of whiteness on the image as determined by DySIS.

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

| Color coding | | Whitening |
|--------------|---|-----------------|
| No Color | | Very weak/ None |
| Cyan |  | Weak |
| Blue | | |
| Green | | Strong |
| Red | | |
| Yellow | | Intense |
| White | | |



Dynamic curves

After Dynamic Imaging, users can also review the dynamics of the acetowhitening response of the tissue at any location on the cervix, by pressing “Show Curves” (see Figure 14). This displays a graph on the upper left part of the display, where the vertical axis represents the acetowhitening intensity and the horizontal axis represents the time since application of acetic acid.



Figure 26: Live image of the cervix with the acetowhitening 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 tool can facilitate the review of the acetowhitening phenomenon at different locations, simply by monitoring the variations in acetowhitening intensity (curve height) over time.

| | |
|---|---|
|  | The assessment of acetowhitening should be based solely on visual inspection of the entire set of the acetowhitening characteristics. PCI documents a subset of these characteristics referring to acetowhitening color changes. |
|  | Using different concentrations of acetic acid may change the acetowhitening characteristics. Higher concentrations of acetic acid lead to larger acetowhitening changes. These larger acetowhitening changes are reflected in stronger signals on the DySIS PCI map. The DySIS PCI map has only been shown to be capable of depicting the acetowhitening changes generated by the application of 3% and 5% acetic acid. |

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

4.13. Step 7 - Final colposcopic impression

After seeing the map and before closing the examination, the user must enter the “final” colposcopic impression (see Figure 25). At this stage, additional biopsy points may also be annotated (see next page). If a second monitor is connected, the “Patient View” option becomes available, which removes the image of the cervix from the second screen so that it only includes the map and some information that may be used for patient education (see Figure 25).

4.14. Step 8 - Selection of additional biopsy points

Additional biopsy points may now be added to those already selected under the conventional colposcopy review using the tools described above. Please note that the colposcopy indicated biopsy points cannot be adjusted (and are now shown in grey). New biopsy markers are added in yellow.

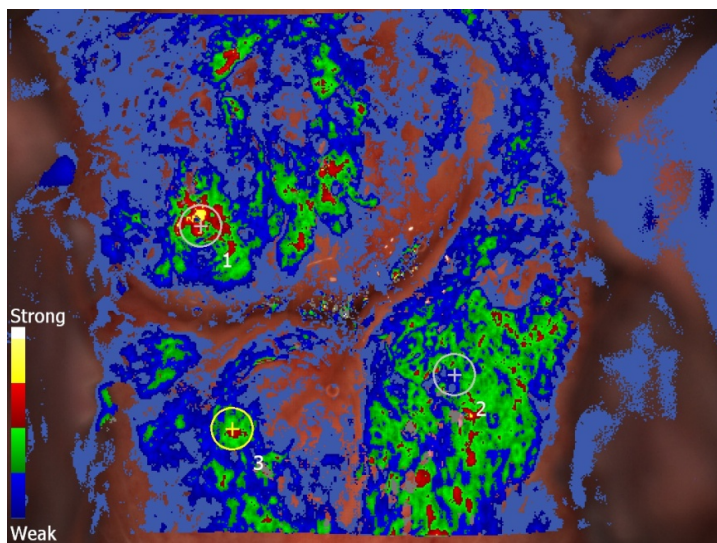



Figure 27: Additional biopsy points (#3, shown in yellow) can be added after the DySISmap has been viewed.

Biopsy point annotation

As described above, throughout the examination (i.e., before, during and after Dynamic Imaging), users can annotate points of interest or for biopsy using the “Mark Point” option (see Figure 14).

| | |
|---|--|
|  | <p>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.</p> |
|---|--|

Biopsy point viewing

In order to assist the biopsy procedure, the “Hide Map” button can be pressed and the DySISmap will be removed from view, leaving the biopsy points visible on the live image of the cervix.

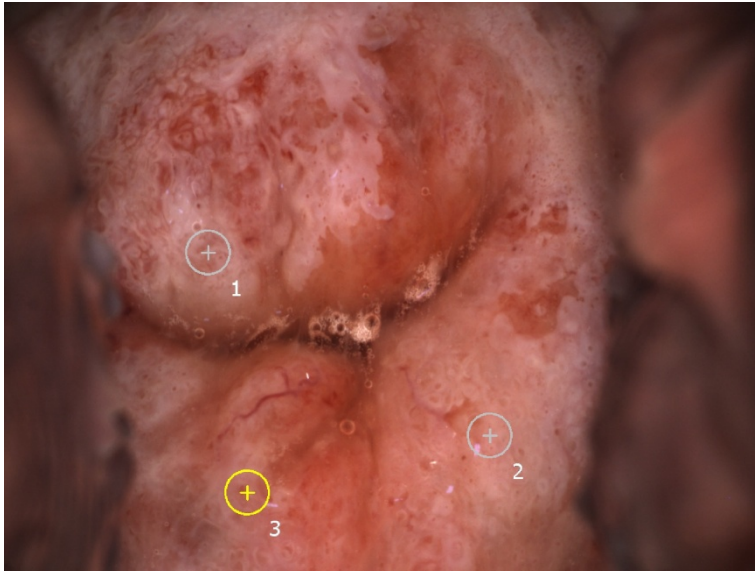
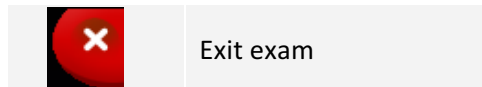


Figure 28: Biopsy points as viewed by selecting “Hide map”

4.15. Closing the examination

To finish the examination after all desired data has been recorded and operations (e.g., biopsy sample collection) completed, the user must press the exit exam button on the upper right of the screen.



PLEASE NOTE: If no “final” colposcopic impression was entered, a window will prompt the user to select it before closing the exam.

4.16. 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 and highlight areas on the interface, guiding the user through the steps to allow the calculation of the map.

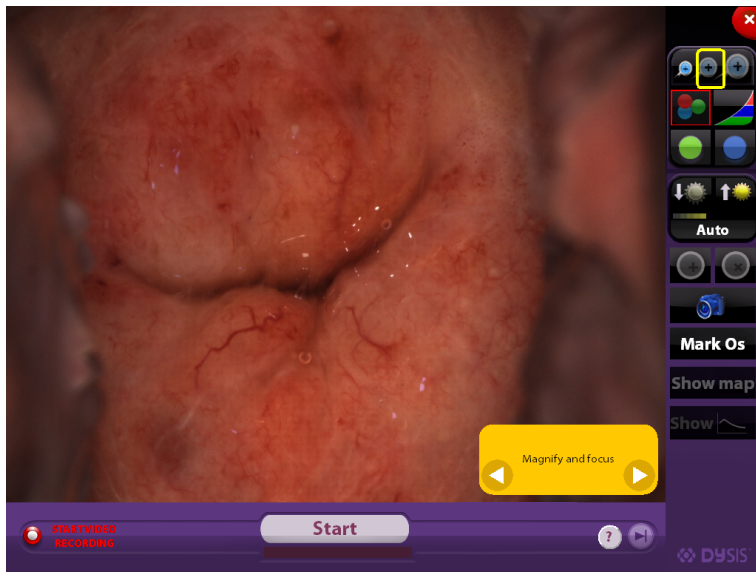


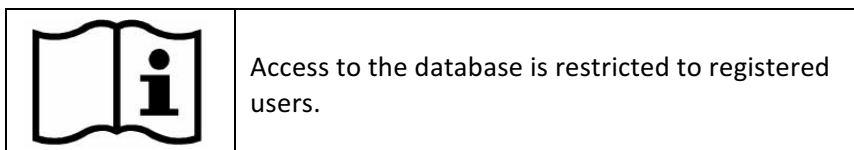
Figure 29: Training mode enabled with balloon messages displayed & highlighting the relative button to be pressed.

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.

5. PATIENT AND DATA MANAGEMENT SYSTEM

5.1. General

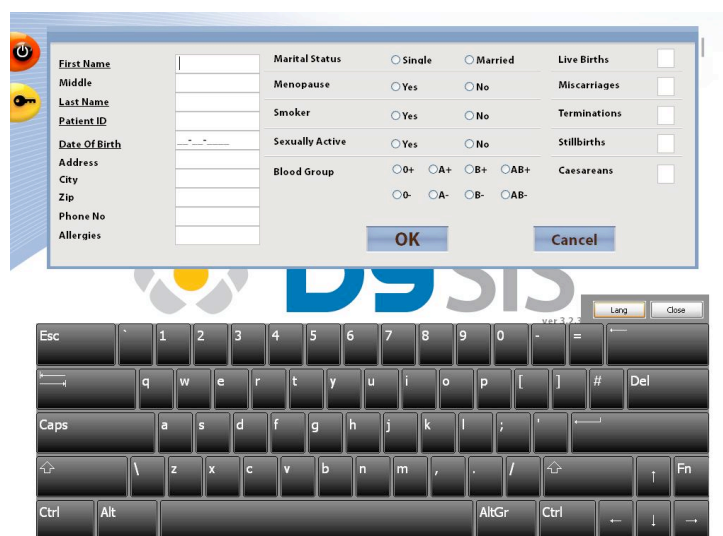
The patient and data management system enables users to maintain a record for each patient, including personal data, medical history information and data collected during the examination(s) performed with DySIS.



5.2. Creating a new patient record

Typically, before proceeding with examining a new patient, a patient 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 from the Main Menu, the user must press the “New Patient” button. The user 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 to choose the correct selection. Alternatively a new patient can be created while the user is viewing the database records. Mandatory fields are underlined and include the patient’s first and last name, patient ID and date of birth. The other fields may be entered if desired.




The screenshot displays the DySIS software interface. On the left, there is a sidebar with a power button icon and a key icon. The main area shows a patient form with the following fields and options:

- First Name: Text input field
- Middle: Text input field
- Last Name: Text input field
- Patient ID: Text input field
- Date Of Birth: Date picker (MM/DD/YYYY)
- Address: Text input field
- City: Text input field
- Zip: Text input field
- Phone No: Text input field
- Allergies: Text input field
- Marital Status: Radio buttons for Single, Married
- Menopause: Radio buttons for Yes, No
- Smoker: Radio buttons for Yes, No
- Sexually Active: Radio buttons for Yes, No
- Blood Group: Radio buttons for O+, A+, B+, AB+, O-, A-, B-, AB-
- Live Births: Check box
- Miscarriages: Check box
- Terminations: Check box
- Stillbirths: Check box
- Caesareans: Check box

At the bottom of the form are "OK" and "Cancel" buttons. Below the form is a virtual keyboard with a "Lang" button and a "Close" button. The keyboard includes standard QWERTY keys, a numeric keypad, and function keys like Ctrl, Alt, and Fn.

Figure 30: New patient information entry

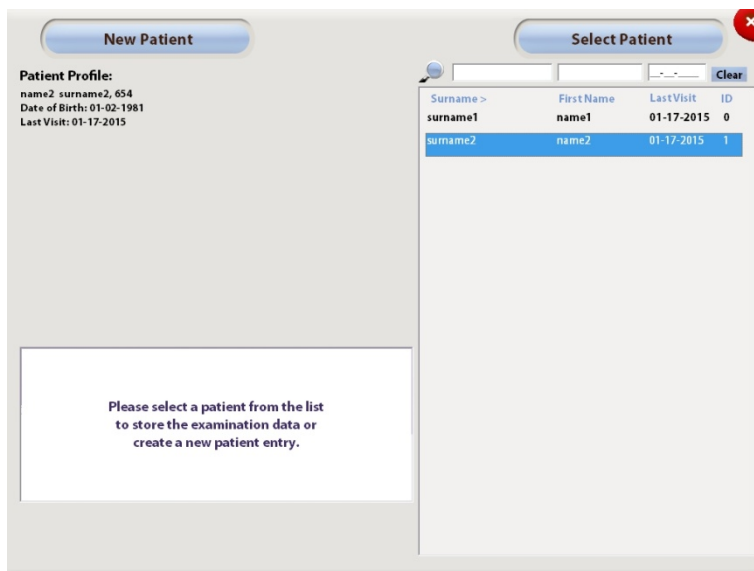
After completing the necessary information, the user can press **OK** to save the new patient record. Pressing **Cancel** discards the entered information and the application returns to the Main Menu. After creating a new patient, DySIS will automatically creating a new visit for the patient.



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

5.3. Appending an examination to a patient record

After completing an examination that has been performed directly from the Main Menu (see section 3.4) without first selecting a patient, the user will be prompted to either select an existing patient from the database or create a new patient record. It is also possible to exit, in which case all examination data will be deleted.



New Patient

Patient Profile:
name2 surname2, 654
Date of Birth: 01-02-1981
Last Visit: 01-17-2015

Please select a patient from the list to store the examination data or create a new patient entry.

Select Patient

| Surname> | FirstName | LastVisit | ID |
|----------|-----------|------------|----|
| surname1 | name1 | 01-17-2015 | 0 |
| surname2 | name2 | 01-17-2015 | 1 |

Figure 31: After completing an exam from the Main Menu, the user may append the examination to an existing patient or create a new patient.

5.4. 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 patient file, the user must open the correct patient record. While in the Main Menu, the user 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.

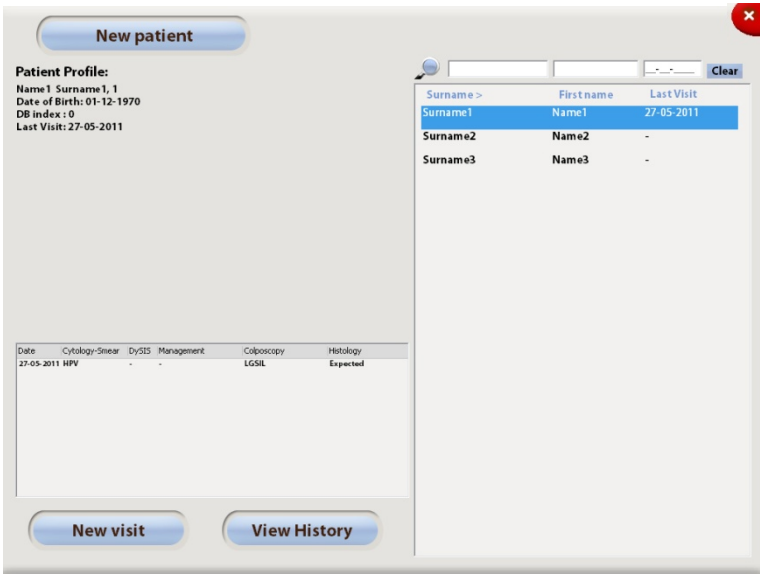


Figure 32: Patients list; the bottom panel displays a summary of the visits of the highlighted patient

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

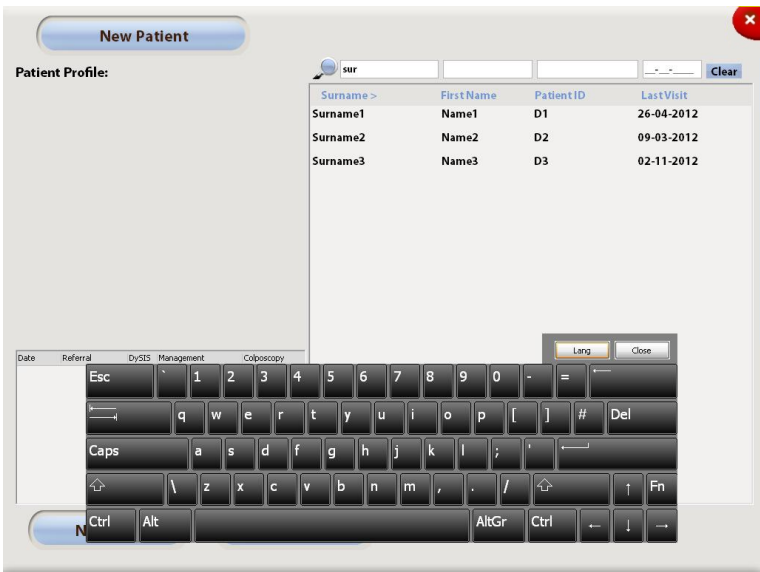



Figure 33: Patient search

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).

| Date | Cytology-Smear | DySIS | Management Plan | Colposcopy | Histology | Media |
|------------|----------------|-------|-----------------|--------------|-----------|-------|
| 27-05-2011 | Borderline | YES | - | HGSIL, LGSIL | Expected | Yes |
| 27-05-2011 | HPV | - | - | LGSIL | Expected | Yes |

Figure 34: 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 (from the same patient) |
| Edit | The user can edit the patient personal information |
|  | The user can view the patient personal information |

5.5. 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 “View History ”

Inside the patient card the user has to:

- Press “Edit”
- Modify information as desired
- Press “OK”; Patient information is now updated.

5.6. New visit

It is possible to start a new visit for a patient either directly after highlighting the patient in the patient 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 | Date of last menstrual period |
| Contraception | Yes/no |

Figure 35: New Visit

5.7. New visit - referral information

Figure 36: 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 (e.g., Smear, Symptoms, HPV test). On this screen, the user can enter examination dates, select multiple fields and type additional comments in the text boxes. In addition, the user can click on “Type” to select from a list of specific HPV types when known.

5.8. New visit - colposcopic impression

After a colposcopy examination, DySIS allows practitioners to fully record their colposcopic impression by recording information on clinical findings, morphological characteristics, test results, etc. Along with the initial and final impression, the form allows entering the colposcopic impression per biopsy point that has been marked.

| Point | Normal | Metaplasia | Ectropion | Inflammation | HPV | LSIL | HSIL | Glandular Abnormal | Invasion | Other |
|-------|--------|------------|-----------|--------------|-----|------|------|--------------------|----------|-------|
| 1 | | | | | | | | | | |
| 2 | | | | | | | | | | |
| 3 | | | | | | | | | | |

Figure 37: Completing the colposcopic impression after an examination

5.9. New visit - memos

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

Figure 38: Drag your finger on the touch screen to create a sketch. Pressing “Clear” clears the display.

5.10. 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 conveniently by clicking on the relevant fields that include the reason for discharge, intended follow-up by cytology and/or colposcopy, treatment suggestions, medication and additional comments.

The screenshot shows a 'Management Plan' dialog box overlaid on a patient record interface. The patient's name is 'Name1 Surname1'. The dialog box contains several sections for data entry:

- 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' (highlighted in red), '12 Months', and 'Other'.
- Follow up for Colposcopy:** Four buttons: '3 Months', '6 Months' (highlighted in red), '12 Months', and 'Other'.
- Follow up note:** A text input field.
- Treatment:** A grid of buttons including 'None', 'Laser Vaporization', 'LEEP', 'Laser Cone', 'Knife Cone', 'Hysterectomy', and 'Other'.
- Note:** A text input field at the bottom.

The background interface shows fields for 'Date of Visit', 'Doctor:', 'LMP:', 'Contraception', 'Referral Reason', 'Smear: Borderline', 'HPV Test: HR', and a 'Management Plan' section with a 'Management P' button. On the right, there are buttons for 'Playback', 'Report', 'emo', and 'port'.

Figure 39: The management plan dialog box

5.11. Histology results

Figure 40 shows the Histology dialog box. It includes a 'Results date' field set to 15-05-2010, a 'Biopsy' section with buttons for 'Core', 'Punch', and 'See and Treat', and a 'Notes' text area. The main section displays a grid of histology results buttons. The first row includes 'Normal', 'Unspec.', 'Metap.', 'Infl.', 'HPV', 'CNI', 'CNII', 'CNIII', 'CGNI', 'CGNI-II', 'Invas.', and 'Other'. The 'CNIII' button is highlighted. Below this is a 'Per point Histology' section with two rows of buttons. The first row has buttons for 'Normal', 'Unspec.', 'Metap.', 'Infl.', 'HPV', 'CNI', 'CNII', 'CNIII', 'CGNI', 'CGNI-II', 'Invas.', and 'Other'. The 'CNIII' button is highlighted. The second row has buttons for 'Normal', 'Unspec.', 'Metap.', 'Infl.', 'HPV', 'CNI', 'CNII', 'CNIII', 'CGNI', 'CGNI-II', 'Invas.', and 'Other'. The 'CNII' button is highlighted. At the bottom of the dialog box, there are four checkboxes, each labeled 'include in the report'.

Figure 40: Use the histology dialog box to enter biopsy results for the specific examination

After the 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.

5.12. 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's personal and medical information and the recorded colposcopic impression. The report also includes the DySISmap (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 in the report, click on the image to select it and then on the check box that indicates "include in the report."

Name1 Surname1
1

Date of Visit: 27-05-2011
Doctor: 1
LMP:
Contraception: ☐ Yes ☐ No

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

Notes:

Referral Reason
Review
Smear: Borderline

Colposcopy
Review
Punctations: None
Abnormal Vessels: Yes
Gland Openings: No
Mosaics: None
Prediction: HGSIL
Prediction for point 1: HGSIL
Prediction for point 2: LGSIL

Management Plan
Review
Colposcopy follow-up: 3 Months

Histology Results
Edit
Result: CNIII
Result for point 1: CNIII
Result for point 2: CNII

DYSIS Exam
Exam Playback
View Report
Memo
Export

Scopy Video Clip: VIDEO
☐ Include in the report

Image 1
Export to USB
☐ Include in the report

Image 2
☒ Include in the report

Image 3
☐ Include in the report

Notes
☐ Include in the report

Figure 41: Checked images will be included in the report.

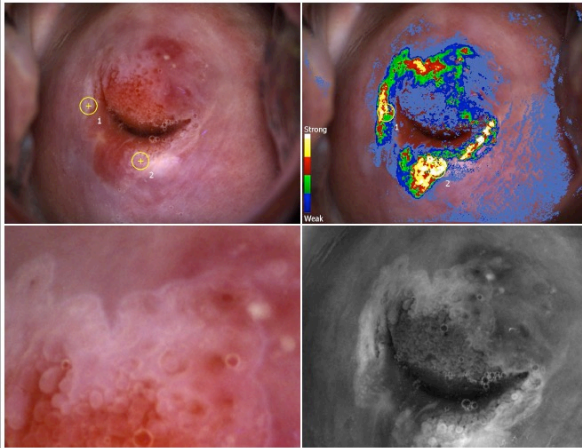
DYSIS™

Patient Name: surname2 name2
Date of Birth: 1-2-1981
Doctor: 1
Date of Visit: 01-18-2015

Referral Reason
Smear: LGSIL
HPV Test: HR, 16

DYSIS Colposcopy
Biopsy: Punch
Gland Openings: Yes
Initial Prediction: Low
Final Prediction: High
Prediction for point 1: HGSIL
Prediction for point 2: HGSIL

Colposcopic Images:



Annotations:

1
2

DySISmap:

Strong
Weak

Figure 42: DySIS report with patient personal information, the recorded colposcopic impression and colposcopic images, including annotations and the DySISmap.

5.13. 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. The "Add History" section can be accessed from the patient record.

The "Add History" dialog box is a window for entering patient medical history. It features a title bar with a close button. The main content area is divided into three sections: Cytology, Treatment, and HPV Test. Each section includes an "Exam Date" field, a set of buttons for selecting results, and a "Notes" text area. The Cytology section has buttons for Normal, Inflammation, HPV, ASC-US, ASC-H, LSIL, HSIL, AGC, Invasive, and Other. The Treatment section has buttons for None, Laser Vaporization, LEEP, Laser Cone, Knife Cone, Hysterectomy, and Other. The HPV Test section has buttons for LR and HR, and an "HPV Type" button. Below these sections are two large text areas for "Colposcopy" and "Histology Results", each with an "Edit" button. A "Close" button is located in the top right corner.

Figure 43: The "Add History" dialog box

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

Colposcopy

Exam. Date: 03-07-2009

Speculum

| | | |
|----------|---------|-----------|
| Complete | Partial | Not taken |
|----------|---------|-----------|

Insertion

| | | |
|------|------|--------|
| None | Fine | Coarse |
|------|------|--------|

Cloud Openings

| | |
|-----|----|
| Yes | No |
|-----|----|

Biopsy

| | | |
|------|-------|-------------|
| Cone | Punch | Second Tact |
|------|-------|-------------|

Biopsy

| | | |
|------|------|--------|
| None | Fine | Coarse |
|------|------|--------|

Abnormal Vessels

| | |
|-----|----|
| Yes | No |
|-----|----|

Notes:

Location of SC?

| | | |
|---------------|--------------|----------|
| Directocervix | Inside canal | Not seen |
|---------------|--------------|----------|

Colposcopy Prediction

| | | | | | | | | | |
|--------|------------|-----------|---------|-----|------|-------|--------------------|----------|-------|
| Normal | Metaplasia | Ectropion | Inflam. | HPV | LSIL | HGSIL | Glandular Abnormal | Invasion | Other |
|--------|------------|-----------|---------|-----|------|-------|--------------------|----------|-------|

Per Point Prediction

| | | | | | | | | | | |
|---|--------|------------|-----------|---------|-----|------|-------|--------------------|----------|-------|
| 1 | Normal | Metaplasia | Ectropion | Inflam. | HPV | LSIL | HGSIL | Glandular Abnormal | Invasion | Other |
|---|--------|------------|-----------|---------|-----|------|-------|--------------------|----------|-------|

Figure 44: The dialog box for entering older colposcopy examination results

The user can use a wide range of options to record the colposcopic impression. To record biopsy site 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, the user must click on the “Delete” button and then in the vicinity of the point.

Histology

Results date: 10-03-2008

Histology

| | | | | | | | | | | | |
|--------|-------|---------|---------|-----|-----|------|-------|------|-----------|--------|-------|
| Normal | Unsm. | Metapl. | Inflam. | HPV | CNI | CNII | CNIII | CGNI | CGNII-III | Invas. | Other |
|--------|-------|---------|---------|-----|-----|------|-------|------|-----------|--------|-------|

Per point Histology

| | | | | | | | | | | | | |
|---|--------|-------|---------|---------|-----|-----|------|-------|------|-----------|--------|-------|
| 1 | Normal | Unsm. | Metapl. | Inflam. | HPV | CNI | CNII | CNIII | CGNI | CGNII-III | Invas. | Other |
| 2 | Normal | Unsm. | Metapl. | Inflam. | HPV | CNI | CNII | CNIII | CGNI | CGNII-III | Invas. | Other |

Figure 45: The Histology dialog box

In a similar way, the user can also record histology results from previous examinations. To record biopsy sites locations, the user must click on the “Add” button and then on any point on the circular cervix.

5.14. Reviewing a visit

All data and information recorded during a visit is saved in the database and can be reviewed at a later stage. To review a visit, select the patient from the patient list, then highlight the specific visit from the list of visits and select “Review Visit.” While reviewing a visit, all information recorded is available for review by clicking on the corresponding fields. Notice that it is not possible to edit any information, except for the information of the most recent visit recorded with DySIS and the histology results (see section 5.11) for every visit, which can be edited once.

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).

5.15. Reviewing images

Images saved during a colposcopy 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 46: Image review

5.16. 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 47: 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.

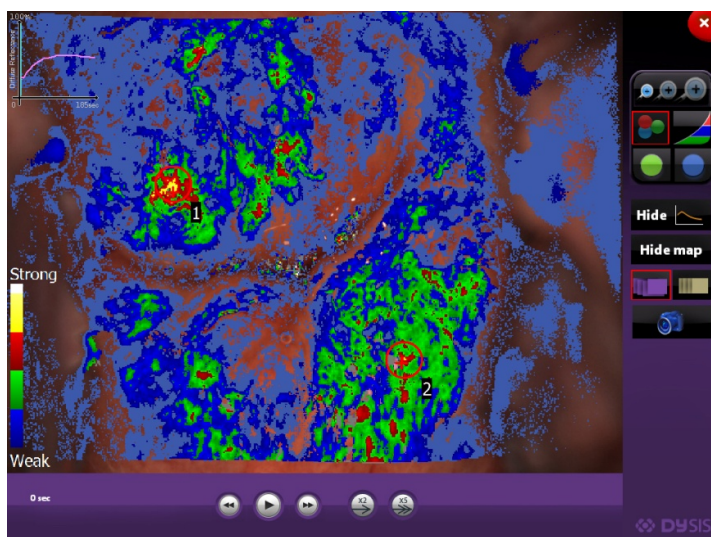


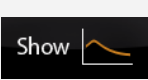


Figure 48: DySISmap and graph view, during review

When playing back the sequence of images, it is possible to display the raw or the aligned images. In addition, 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 color image |
| | Blue filter | Displays the blue channel of the color image |
| | High Contrast | Enhances the contrast |
| | Color | Enables the color mode (default setting) |
| | Capture image | Saves a snapshot of the displayed image. |
| | Show captured images | Displays the captured images |

| | | |
|---|--------------------|---|
|  | Show aligned mages | 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) |

5.17. Compare Mode

To compare images that were obtained during two different examinations 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.” Now, the image sequences of those two visits are available to be displayed side by side for comparison. Press “Play” after selecting a visit to start the image playback with full review capacity.

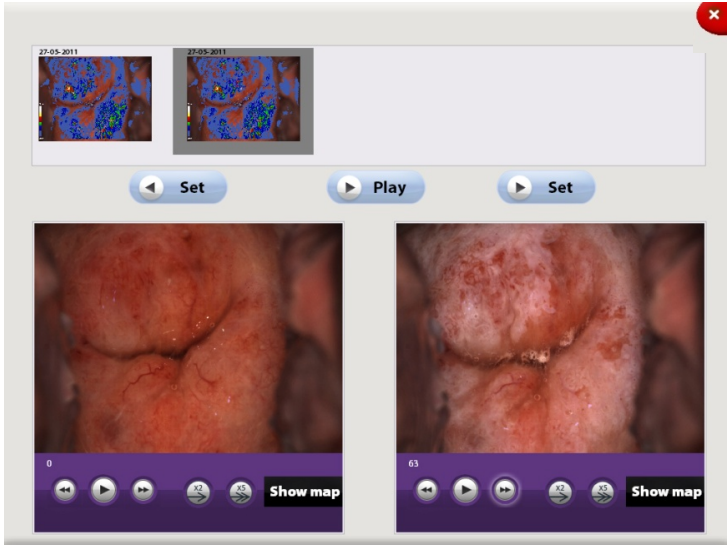
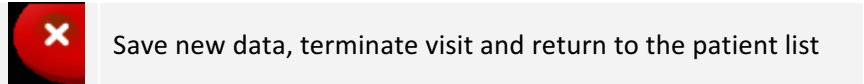


Figure 49: Comparing images from two examinations of the same patient

5.18. Exiting review

After reviewing a visit, to return to the patient list users can terminate the review by pressing the return button on the upper right corner of the touch screen.



6. ADDITIONAL FUNCTIONS

6.1. Periodic calibration

DySIS requires calibration on a weekly basis to ensure the repeatability of the mapping procedure. A countdown will display upon start up to communicate the number of days until calibration is needed. When calibration is needed, a message will appear at the first startup of that day.

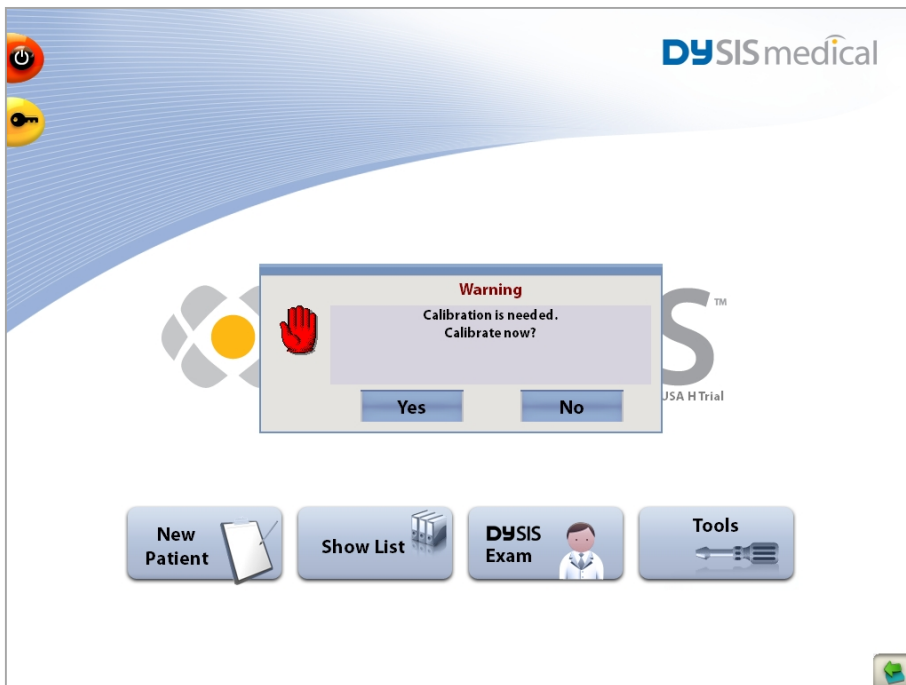


Figure 50: Message on the Main Menu prompting for system calibration

If the user selects to bypass calibration, the Dynamic Imaging functionality will be disabled and the mapping of the acetowhitening will not be possible; all other examination features (magnification, filters, image and video capture, etc.) will be available.



Figure 51: Message displayed on the Main Menu informing that the current calibration is out of date

If the user selects to perform system calibration, the system will display the calibration screen, which includes step-by-step instructions on how to use the DySIS calibration card. A calibration option is available in the Tools menu.

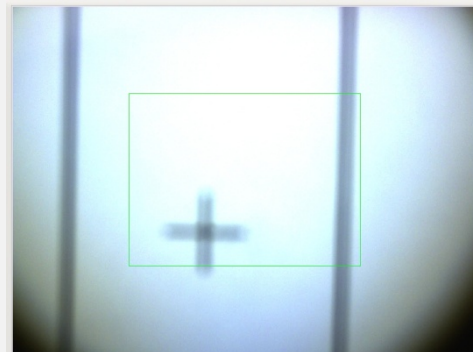
The procedure is described in detail in the following pages.

Placing the DySIS calibration card

Secure the calibration card on a vertical surface, consider using double-sided tape) within reach of the camera to start the calibration procedure.

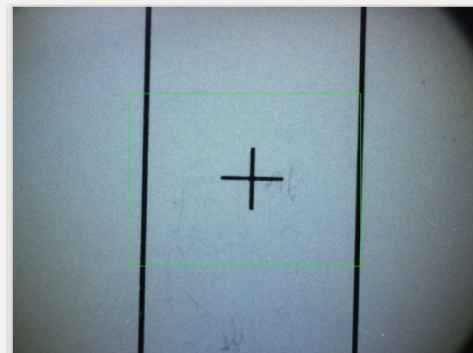
Adjust the imaging head

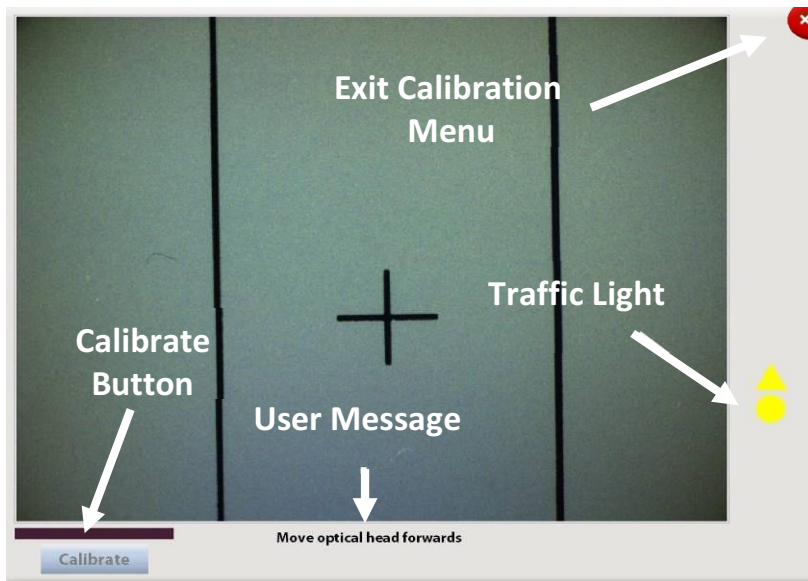
- Position the camera to point squarely on the calibration card.
- Adjust the camera position to ensure the plus sign is centered in the image.
- Focus the camera on the plus sign. At this stage, focusing doesn't need to be accurate.
- Observe the color of the "traffic light" on the lower right side of the screen. If it is red, then move the device until it is yellow and ready for fine focusing.



Complete the Calibration

- When the "traffic light" is green, press the "Calibrate" button.
- A progress bar will indicate the level of completion. Do not move the camera or the card during calibration.
- The message "Calibration completed successfully" should appear within a few seconds. Press "OK" to confirm.
- To exit the calibration menu, press the exit button at the top right corner of the screen.









| Traffic Light Indications | | | |
|--|---|---|---|
|  |  |  |  |
| No Calibration Card in front of the device or the card is placed too far from or too close to the camera | Move the Camera towards the card | Move the Camera backwards | The Camera is focused and the device is ready for calibration |



Figure 52: Calibration screen with instructions and “traffic light” assistance

6.2. Connecting USB devices

DySIS features a USB port that can be used to connect external devices, such as printers, hard drives, or memory sticks. Whenever an external data storage device is connected, the USB connection icon is displayed in the lower right corner of the touch screen to indicate the connection and the “Export to USB” options (throughout the software) are active. Before removing a USB device, users should press 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, etc.) 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. |

6.3. 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 later be found inside a folder named “DySIS_Export” and are categorized by patient. Images and video clips are in standard formats and can be directly inserted into 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.

When DySIS is connected to a network, a folder may be selected to be used for exporting the data as above. Export to USB will always have priority, so to export the data to the network folder, no USB storage medium should be connected to DySIS.

6.4. Printing images and reports

DySIS can print high quality colposcopic images and reports. A printer can be installed on the DySIS. Please inquire for more details.

6.5. Uploading a logo for reports

A logo can be uploaded to DySIS and included in the patient report.

To upload a logo:

A bitmap version of the logo must be created. Microsoft™ (MS) Paint can be used to accomplish this.

- First, on a computer that already has the logo, open the MS Paint program and then select “Open” to open the file that contains the logo.

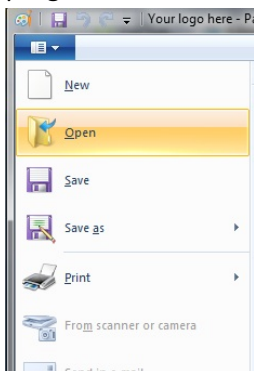


Figure 53: MS paint menu

- Select “Save as” to save the image in .bmp format to the main folder of the USB.

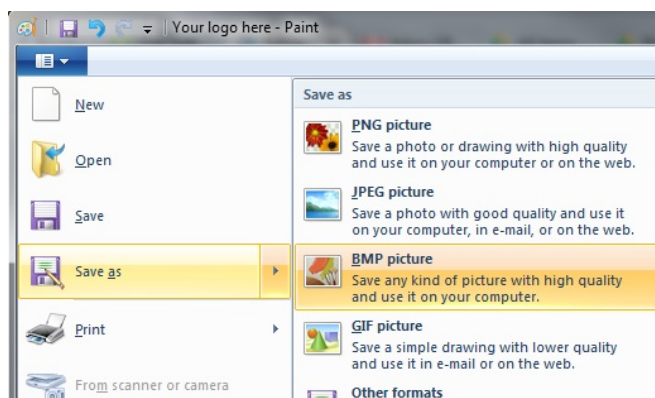


Figure 54: Save image as .bmp picture

- Now, insert the USB containing the logo into DySIS.

- A green arrow icon will displayed in the lower right corner of the touch screen to indicate recognition of the USB.
- From the Main Menu, select “Tools.”
- Select “Import pictures from USB.”

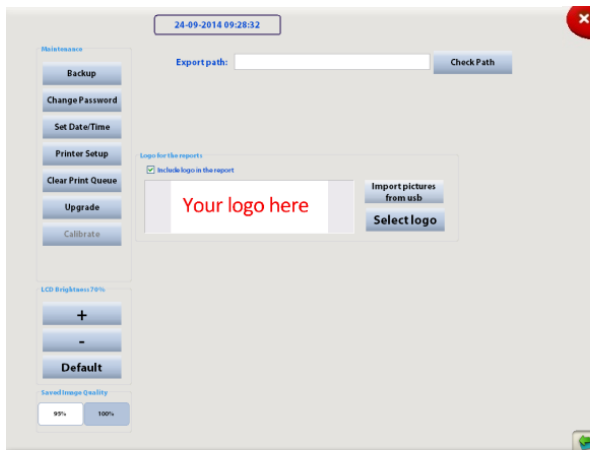


Figure 55: Tools page for importing logo

- A preview of all .bmp images on the USB will be displayed in the preview window.

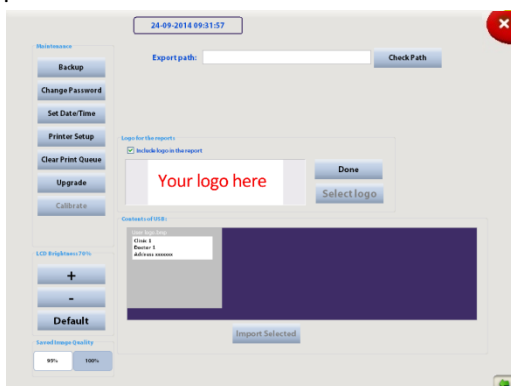


Figure 56: Preview of .bmp images

- Select the .bmp image to be included in the report and choose “Import Selected.” After the image is imported, the list of images contained on the USB will not be visible anymore.

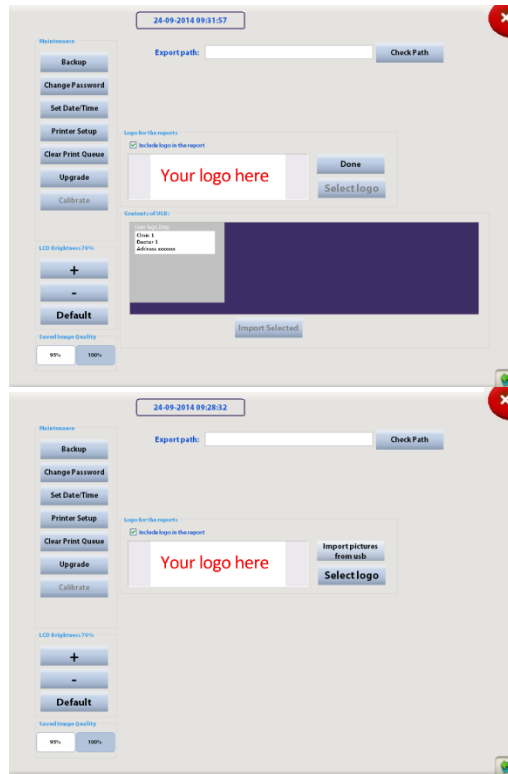


Figure 57: Import selected logo

- Choose “Select logo” to review the stored logos.
- Choose the logo to be used and choose “Use Selected.”



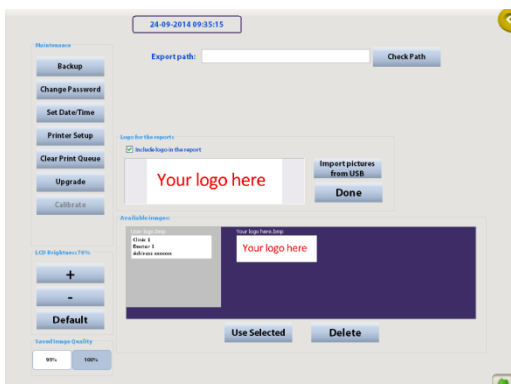


Figure 58: Selecting logo and choosing to use selected logo

- Press “Done.” The logo will be updated. If the logo is to be included in the reports, select “Include logo to the report” and ensure the box is checked.

6.6. Connecting to external databases

The DySIS onboard patient and data management system can be integrated with EMR systems that are compatible with HL7 and DICOM standards. Please contact your DySIS representative for additional information.

6.7. User Tools

Selecting “Tools” from the Main Menu allows the DySIS user to perform the following functions:

Backup

The option to back up the entire database of DySIS is available when a USB storage medium is connected to the device. A high capacity USB external hard drive should be used. After connecting the USB hard 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 significant time in the case of a large database. After backup is complete, click on the USB icon before disconnecting the USB device. It is advised to backup the database regularly.

Change password

Use this option to change username and password through a simple interface. Administrators can also add user from this option.

Set time/date

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

Printer Setup

Provides access to the printer setup menu of the operating system.

Clear Print Queue

Use this to clear the printer queue.

Upgrade

The option to upgrade the software version on DySIS is available when a USB storage medium that contains the upgrade files is connected to the device.

Calibrate

Manually start the calibration procedure (see section 6.1 for details).

LCD brightness

Use the controls to adjust the brightness of the touch screen monitor or return to the default setting.

Saved 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.

Export path, Check path

Allows the configuration and checking of a network folder to where data can be exported.

Sync with agent

Allows users to switch off the automated synchronization between the acetic acid applicator and the image acquisition of the Dynamic Imaging process, and do it manually. The default setting is that it sync is activated.

Import pictures from USB

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

Select Logo



Select one of the uploaded images to be used in the report.

7. CLEANING & MAINTENANCE

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 and 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 only 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 by 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 by immersing or autoclaving. |
|  | If the device is accidentally contaminated during an exam, only use an 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 the speculum. |

No part of DySIS – other than the speculum – is intended to come into direct contact with patients. If needed, DySIS may be cleaned with a soft, damp cloth using Vircon, 70% propan-2-ol (isopropanol), sterilization 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 the US. Refer to the specula instruction sheet for more details.

Single-use specula should be used according to their instructions for use and disposed of properly after use according to regulations.

7.7. Acetic acid application 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.

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)

| | |
|---|--|
|  | <p>Isolated system! Chassis is NOT Earthed</p> |
|---|--|

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 lit.

The following table lists specific issues that may be experienced with DySIS. Observe all safety precautions and warnings and make sure you carefully read and fully understand the instructions for use before attempting any of the troubleshooting below.

Make sure you shut down, disconnect from the power outlet 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 (service@dysismedical.com) or your local DySIS Medical representative.

| 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 Patient View monitor | The Patient View monitor power and/or signal cable may be disconnected or damaged | Check the cables in the rear of the monitor and the rear of the main unit |
| | The power on Patient View monitor may be off | Check the power button on the front panel of the monitor to ensure it is 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 |

| | | |
|---|--|--|
| Dynamic Imaging cannot be initiated | Sensor cable disconnected or loose | Make sure the sensor jack on the right of the imaging head handle is fully inserted in place |
| | Syringe plunger is not pulled and the Sync Snapshot button is inactive | Pull the syringe plunger to load the spray mechanism with acetic acid |
| Image is displayed, but illumination does not turn on | Illumination source malfunction | Contact service support |
| DySIS doesn't turn on | Main power cable is disconnected | Make sure that the main power switch is OFF and reconnect the main power cable. Turn the main 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 |
| Calibration cannot be performed | The card is not at the right distance | Try focusing accurately |
| | The card is very dirty | Contact service support |
| | System malfunction | Contact service support |
| Software update cannot be performed | The USB stick is not recognized | Try using another USB stick or a USB hub |
| | The DySIS software upgrade is not on the USB stick | Follow software update instructions carefully. The upgrade file should not be embedded in a folder on the USB. |
| | System malfunction | Contact service support |

9.2. Replacing fuses

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



Figure 59: 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 main 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 into 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

It is recommended the acetic acid assembly is replaced monthly for best ongoing performance.

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 the system is turned OFF

- Remove the power cable from the main 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 counterclockwise
Slide the black collar off the other side of the luer lock tubing
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 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



Figure 60: The acetic acid assembly and holder

10. DYSIS SERVICE, EXPECTED SERVICE LIFE AND RECYCLING







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.

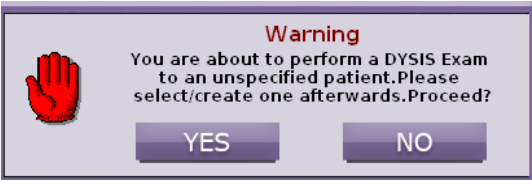
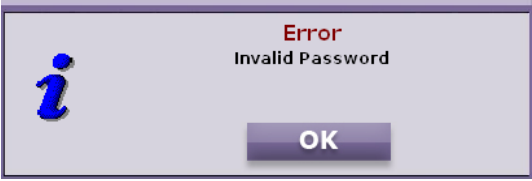
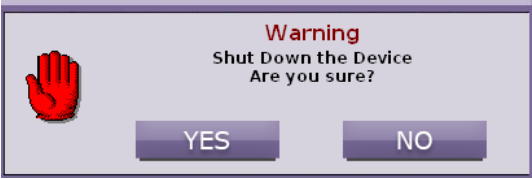
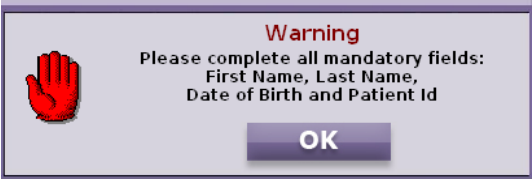
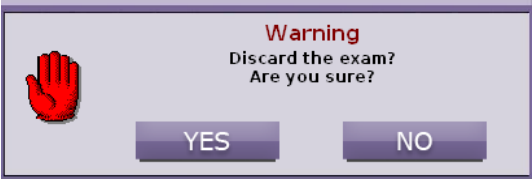
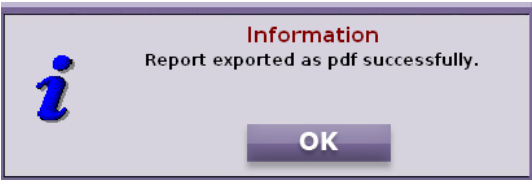
Metal parts, such as the movable base and the Patient View monitor pole, can be recycled in metal recycling facilities. Electrical components (such as Patient View monitor, touch screen, computer components and imaging head modules) can be recycled at specialty electrical components recycling stores or facilities.







11. APPENDIX I: SOFTWARE MESSAGES

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

| | |
|--|---|
|  <p>Warning Failed to start Camera Please contact technical support</p> <p>OK</p> | <p>Camera connection failure; contact technical support.</p> |
|  <p>Information Exam exported successfully.</p> <p>OK</p> | <p>Confirmation that exporting the examination data has been successful.</p> |
|  <p>Warning 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 NO and adjust the brightness, either automatically or manually, or press YES to ignore it.</p> |
|  <p>Warning 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 NO and adjust the brightness, either automatically or manually, or press YES to ignore it</p> |
|  <p>Warning 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 You have selected to terminate the acquisition process. Are you sure ?</p> <p>YES NO</p> | <p>During dynamic imaging, STOP was pressed. Please confirm.</p> |

| | |
|--|---|
|  <p>Information You have selected to terminate the acquisition process. No map will be calculated. Are you sure ?</p> <p>YES NO</p> | <p>During dynamic imaging, STOP was pressed; the collected data is not sufficient for the calculation of the map. Please confirm.</p> |
|  <p>Warning 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 image sequence will be available for review.</p> |
|  <p>Warning Due to excessive motions the pseudocolor map will be computed using images up to ### second. Image acquisition</p> <p>OK</p> | <p>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.</p> |
|  <p>Warning You are recording a long video clip. Continue?</p> <p>YES NO</p> | <p>The video recording has exceeded 4 minutes. Please confirm if you wish to continue.</p> |
|  <p>Warning Video stopped</p> <p>OK</p> | <p>The video recording has stopped.</p> |
|  <p>Error Please Insert a USB device and try again</p> <p>OK</p> | <p>Problem with export of data. Retry with a new USB data storage device.</p> |

| | |
|---|---|
|  | <p>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.</p> |
|  | <p>The username or password you entered is wrong.</p> |
|  | <p>Confirm that you wish to turn DySIS off.</p> |
|  | <p>You have not completed all the fields that are compulsory for the creation of a new patient.</p> |
|  | <p>You have selected to discard all examination data. Press YES to confirm and NO for more options.</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 username.</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 backup. 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 database backup has successfully completed.</p> |

12. APPENDIX II: LABELING

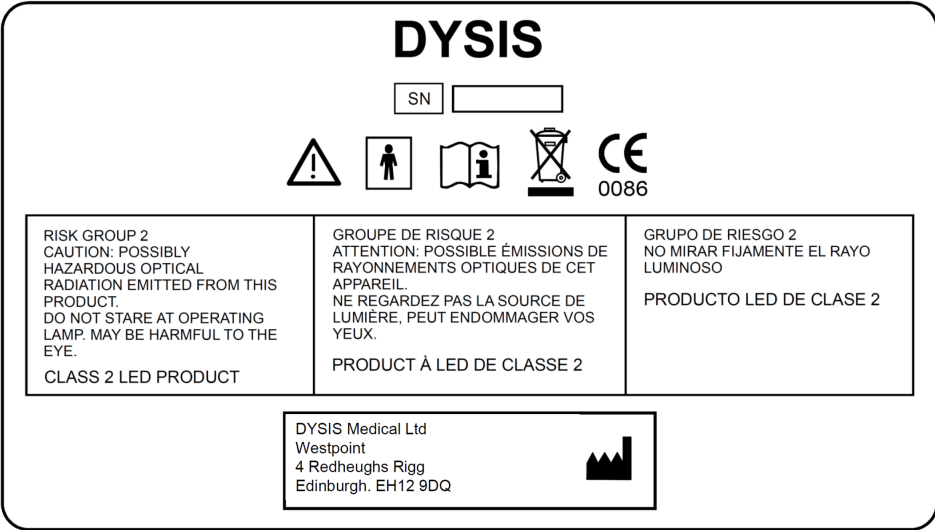


Figure 61: The main device label where the Serial Number (SN) and labeling information can be found

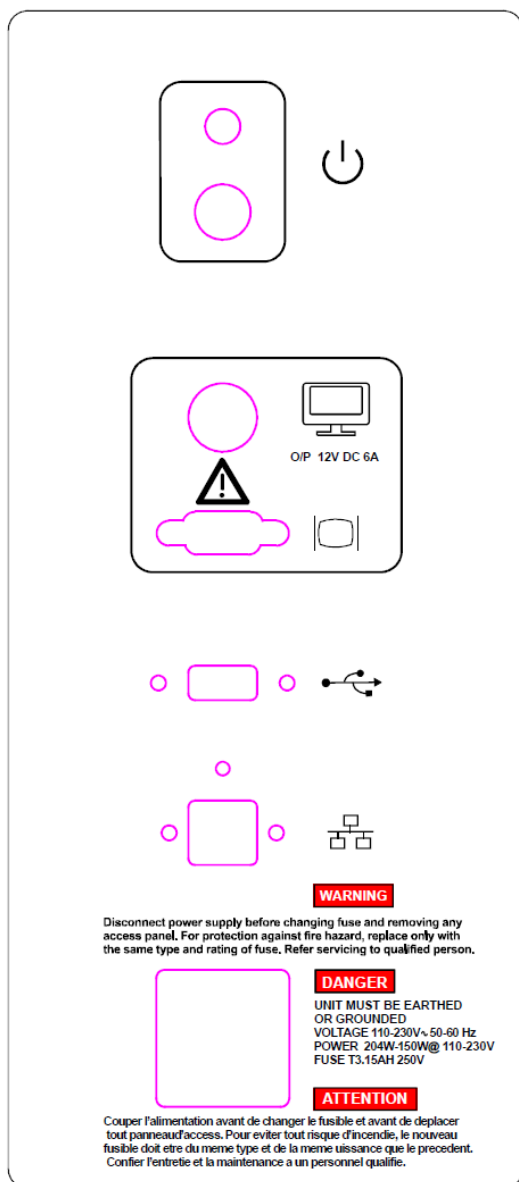


Figure 62: The label found on the DySIS computing unit

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

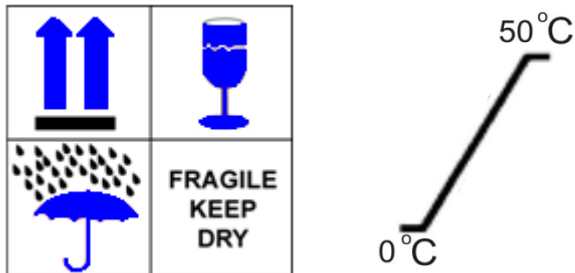


Figure 63: DySIS shipment packaging labels

The labels found on the DySIS packages used for shipment (Figure 63) include the following: which side is UP, contents are FRAGILE and contents 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 gynecological chair. Maintain DySIS 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 ON/OFF button on the back of the computer
- Wait for the LOGIN screen to appear
- Enter a valid USERNAME/ 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's 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
- Clean the cervix to remove any mucous.
- Use the fine focusing mechanism for optimization of visualization of the cervix
- Filters, magnification and documentation tools are available
- Pull back the plunger of the syringe to fill with acetic acid solution
- Press **Start** and spray the acetic acid when prompted to perform acetowhitening mapping
- Press the **EXIT** button to terminate the examination
- Provide assessment and management plan (optional)

To turn DySIS off:

- Select **SHUT DOWN or red X** from the main menu and wait for the device to shut down

14. APPENDIX IV: DYSIS TECHNICAL DESCRIPTION

DySIS Product Description:

Name: DySIS v3

Class: EC Class IIa, FDA Product Class II

PC Unit and Monitors:

Motherboard: Pentium Core i5 CPU; on-board GPU

RAM: 2GB, HDD: 250GB

1x USB 2.0 port, 1x VGA port

Touch screen: 12.1", 1024x768 pixels, max resolution @ 60Hz

Patient View monitor (upgrade): 19", 1280x1024 pixels, max resolution @ 60Hz

Imaging Unit:

CMOS sensor

Resolution: 1600x1200 pixels

Digital interface: Gigabit Ethernet

DySIS Power/Operation:

Frequency: 50/60Hz

Power Input: 204 to 150W

Rated Input Voltage: 110-230VAC

Fuse Information: T3.15AH, 250V ceramic tube (2 pcs)

Start Up Time to Operation: < 1 min

Operational Footprint Length, Width, Height (in): 59x24x28

(with TFT Upgrade kit 59x24x67)

Idle Footprint Length, Width, Height (in): 27x24x28

(with Patient View Monitor Upgrade kit 27x24x67)

DySIS System Weight (lbs): 135 (with Patient View upgrade kit, 150)

DySIS shipping weight (lbs): 238 (2 pieces)

Patient View Monitor upgrade kit shipping weight (lbs): 33 (1 piece)

DySIS can be fully isolated from a main power supply by pulling out the main power cable from the main inlet power receptacle.

Manufacturer information:

DySIS v3 is manufactured for DySIS Medical by
Integrated Technologies Ltd Ashford, Kent, TN23 6NF, UK

Company contact information:

E-mail: info@dysismedical.com, Web: www.dysismedical.com

Global HQ:

DySIS Medical Ltd.,
Gyleview House,
3 Redheughs Rigg,
Edinburgh,
EH12 9DQ
Phone: +44 (0)131 516 3944,

USA office:

DySIS Medical Inc.,
3001 N. Rocky Point Drive East,
Suite 200, Tampa, FL 33607, USA.
Phone: (844) DYSISMED or (813) 367-3564

15. APPENDIX V: DYSIS USER PRE-POWER UP CHECKLIST

Check that the power 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 mishandling of the device.

Check that all brakes on the system work properly as described in the instructions for use.

Check that the spray mechanism is connected, the acetic acid container is filled and that it works properly.

Visually inspect the device safety labels and see that none 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. | | | |

Legal Manufacturer information:

DYSIS Medical Ltd.,

Gyleview House,

3 Redheughs Rigg,

Edinburgh,

EH12 9DQ

E-mail: info@dysismedical.com, Phone: +44 (0)131 516 3944,

Web: www.dysismedical.com