

Implementation of the Dynamic Spectral Imaging System (DySIS)

Implementation of the Dynamic Spectral Imaging System (DySIS) as an adjunctive colposcopic technique for examination of the uterine cervix

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1. INTRODUCTION

The Dynamic Spectral Imaging System, or DySIS, is a digital video colposcope manufactured by DySIS Medical Ltd (Livingston, Scotland). It uses Dynamic Spectral Imaging technology to evaluate the acetowhitening phenomenon and to detect cancerous and precancerous cervical tissue. DySIS produces a quantified measurement of the rate, extent, and duration of the acetowhitening effect that is summarised in a graphical display, called DySISmap, overlaid on a live image of the cervix. DySISmap therefore provides the colposcopist with additional information that assists in the selection of biopsy sites.

DySIS should be used according to the standard colposcopic guidelines and process, but additional training is required to ensure that users understand the correct use and interpretation of the DySISmap. DySISmap should be used as an adjunct to standard colposcopic indicators.

NICE and the NHSCSP have evaluated the DySIS system and have concluded that the technology is suitable for use in NHS colposcopy clinics.¹ Clinical trials have demonstrated that, when combined with all other usual colposcopic indicators, DySIS colposcopy can detect high-grade lesions with 88% sensitivity, compared to the 55% achieved by conventional colposcopy.²

This document sets out practical requirements for using DySIS as an adjunct to conventional colposcopy in the NHS Cervical Screening Programme (NHSCSP) in England.

2. EQUIPMENT

2.1 Components

DySIS is a CE-marked* class IIa digital colposcope. It consists of the following parts:

- Wheeled base with braking system for moving the device and stabilising the unit.
- Central pole with two positioning arms for manoeuvring the imaging head.
- Onboard computer for data processing and image storage.
- 12" touchscreen monitor for image viewing and user interface.
- Imaging head that incorporates the illumination source, high definition digital camera, speculum connection point, and acetic acid applicator.

Upgraded software packages and a range of accessories are also available, including a large 19" medical grade monitor to assist with viewing live and recorded examination images.

The 12" touchscreen monitor is used for all data entry, instrument control, and image viewing activities.

*The CE (Conformité Européenne) label denotes that a product is compliant with European Union legislation and can be freely moved within the European market.

A range of control options are displayed on the right hand side of the DySIS touchscreen monitor including:

- Magnification (x6 - x27).
- Brightness control.
- Green and blue filters.
- Contrast control.
- Image (snapshot) capture.
- Biopsy point annotation.
- Biopsy video recording.

Standard colposcopic examinations can be performed using these DySIS functions.

An acetic acid applicator is included and can be attached to either side of the imaging head of DySIS. It consists of a syringe holder, acetic acid container, tubing, spray nozzle, and pre-aligned mount. Its function is to ensure that a measured amount of acid is delivered in a homogeneous pattern onto the cervix. In line with colposcopy guidelines, 3-5% acetic acid should be used with DySIS.

2.2 Specula

DySIS requires the use of specific specula, which are available in small, medium, and large sizes, as well as in normal and wide-billed widths. It is anticipated that plastic disposable specula and treatment specula will be made available during 2012. DySIS specula are similar to standard instruments but have an additional extension shaft that enables connection to the DySIS imaging head during the examination, allowing stable images to be captured for the production of the DySISmap.

The specula are supplied non-sterile and must be sterilized by HSDU prior to use, in accordance with standard cleaning procedures.

When integrating DySIS into a clinical service, consideration should be given to the number and size of DySIS specula required for the colposcopy clinic.

2.3 Manoeuvrability

The wheeled based allows the device to be moved within and between rooms in the clinical setting. A foot-operated brake mechanism can be engaged to provide greater stability during the examination. DySIS requires a mains power supply but is supplied with a long power cable, allowing it to be positioned in any area of the clinic room.

DySIS occupies approximately the same floor area as a conventional colposcope. It can be set up to the left or the right of the examination chair and operated with the left or right hand. The touchscreen monitor can also be positioned to accommodate left or right-handed practitioners, and the display angle can be further adjusted and tilted using a locking joint, so that the necessary functions and operations can be accessed.

Two positioning arms allow both vertical and horizontal movement, so that the imaging head can be positioned to ensure optimal visualisation of the cervix. The arm that supports the imaging head can be folded when not in use.

Training and familiarisation may be needed so that individual users can set up DySIS in a suitable ergonomic position to perform colposcopic examinations.

2.4 Duration of DySIS Examination

The examination time for DySIS compares favourably with that for conventional colposcopy. DySIS measures the acetowhitening process over the 2-3 minute development time and then automatically produces a DySISmap of the cervix. For patients with a clear presentation, the mapping process can be halted prematurely if necessary, but no DySISmap will then be stored in the patient record system.

3. TRAINING

DySIS Medical provides product training, and the cost of this is included in equipment procurement. Individuals operating DySIS must be trained and certified by a company representative or product trainer. The training programme includes device setup and maintenance, operating instructions and procedures, and troubleshooting. The company also provides a selection of training materials and guides, and DySIS training courses are under development in the UK.

New users can be trained in the use of DySIS, and in interpreting the DySISmap, in 2-4 hours. However, there will be an initial learning curve as individuals become accustomed to using the system. **During this initial familiarisation period (which is estimated to last 2-4 weeks) it may be necessary for clinics to reduce the number of patients seen.**

4. PATIENT DATABASE, IMAGE STORAGE, IT CONNECTIVITY, AND REPORTS

4.1 Onboard Database

DySIS includes an onboard patient database that enables practitioners to maintain a record for each patient, including patient details, medical history, images collected during the examination, biopsy annotations, histology results, and the post-treatment management plan.

DySIS stores all high-definition images and video clips produced during the patient examination so that these can be reviewed at a later time. The images stored include a baseline/reference image of the cervix, the acetowhitening sequence, biopsy annotations and video, and the DySISmap.

4.2 IT Connectivity

Patient records and images can be manually or automatically imported/exported via a USB stick (for manual transfers) or via Ethernet (for automatic transfers). Protocols regarding the confidentiality of sensitive or patient identifiable information must be observed.

DySIS has a standard software interface through which Electronic Medical Record (EMR) systems may connect and exchange information. Patient examination data and images produced and stored in DySIS can be exported and integrated into existing colposcopy databases. IT work may be required to enable DySIS to connect with these databases, but DySIS Medical will work with the hospital or provider to ensure compatibility.

Achieving connectivity between DySIS and colposcopy databases ensures that use of DySIS will not interfere with the production of KC65 reports.

4.2 Reports & Patient Records

At any point after an examination, DySIS can create a standardised patient report, containing patient details, medical information, and a summary of the examination data. Specific images can be selected and included by the user. The report can be printed directly or exported to a USB storage device as a PDF file.

5. TREATMENT

After users have been trained and have familiarised themselves with DySIS as a diagnostic tool, they may be able to use the system to perform colposcopy treatments, such as LLETZ/LEEP. However, because the DySIS imaging head is a different shape to a traditional colposcope, DySIS operators will need to learn new techniques to manipulate biopsy forceps and treatment wands. Because the cervix is viewed on a 2D screen, treatment procedures are similar to those of endoscopy practice. The Optical Working Distance for DySIS is reported to be 30 cm, equivalent to most traditional colposcopes.

Some colposcopists may prefer to use DySIS solely for diagnostic purposes. In such cases, either clinics will need to be configured into diagnostic and treatment sessions, or a conventional colposcope will need to be available to allow treatment. In both scenarios, the need to provide sufficient clinical space must be considered.

6. SERVICE AND MAINTENANCE

The DySIS colposcope requires basic daily maintenance. No part of the system other than the speculum is intended to come into contact with the patient. Standard cleaning and disinfecting procedures are outlined in the DySIS User Manual.

DySIS reusable specula require cleaning and decontamination/sterilisation between uses. The manufacturer provides instructions, which follow standard MHRA requirements for HSDU sterilisation.

Only the first year of service & maintenance for DySIS is included in the purchase price. Subsequent contracts may be purchased from DySIS Medical on an annual basis.

7. PROCUREMENT AND COSTING TEMPLATE

The DySIS digital video colposcope can be purchased directly from DySIS Medical Ltd, either as a capital purchase or through a service leasing agreement.

NICE have produced a costing template that can be used to assess the impact of implementing DySIS:

<http://guidance.nice.org.uk/DG4/CostingTemplate/xls/English>

The standard assumptions used in the template can be altered to reflect local circumstances. This resource is an implementation tool and should be used alongside published guidance.

8. REFERENCES

1. *Adjunctive colposcopy technologies for examination of the uterine cervix - DySIS and Niris Imaging System*. London: NICE, 2012.
2. Louwers J, Zaal A, Kocken M, ter Harmsel et al. Dynamic spectral imaging colposcopy: higher sensitivity for detection of premalignant cervical lesions. *BJOG*, 2011, 118: 309–318.

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