01 August 2017

DYSIS Medical Ltd
Gyleview House
3 Redheughs Rigg
Edinburgh
EH12 9DQ

Tel: +44 (0)131 516 3944
Email: info@dysismedical.com
Web: www.dysismedical.com

Dear Valued Customer

Re: FIELD SAFETY NOTICE (DYSFSN 2017-01) Routine Electrical Safety Testing for DYSIS v3

This letter contains important information pertaining to the routine electrical safety testing of the DYSIS Digital v3 Colposcope (DYS302). Please review this letter carefully and pass to the relevant department within your organisation to complete the necessary actions. This letter should be read in conjunction with the Instructions for Use for the system and seeks to address any ambiguity on routine testing.

Description of Issue:

A question has been raised regarding the appropriate routine electrical testing of the DYSIS v3 colposcope and whether earth bond testing can be performed. The DYSIS v3 colposcope has an isolated chassis and an internal, non-accessible Class 1 power supply. The earth bond test is performed as part of the IEC 60601-1 compliance testing of each manufactured unit and is therefore not appropriate or possible as part of routine electrical safety testing.

Root Cause

The root cause was identified as a potential misunderstanding by the user of electrical safety of the v3 colposcope. The Earth Bond in the instrument is performed on every device in manufacturing prior to release and DOES NOT need retested during routine electrical safety testing.

Advice on Action to be taken by the user:

As part of our improvement program for the DYSIS v3 colposcope, we have reviewed our procedure (0230-53074 - Electrical Safety Testing Note for DYSIS v3) to include information on the routine safety testing of the device. The revised procedure is attached within this communication – Attachment 1. This document was provided at the time of installation of each DYSIS v3 device but did not contain information on routine testing. This provides a number of tests that can be completed by competent personnel at the user's facility including the following:

- 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)

These tests verify that the external chassis remains electrically isolated despite wear and tear during routine use and are therefore compliant with the regulatory requirements for a Type BF Applied Part.

Please complete the attached acknowledgement form (Attachment 2) and return it to the Edinburgh address above.

If you have any questions on this issue, please do not hesitate to contact me or Amanda Durman (UK Sales & Marketing Director, amanda.durman@dysismedical.com) for additional information.

Yours sincerely,

Paul Houston
Quality and Regulatory Manager
paul.houston@dysismedical.com
07715 073327

Attachment 1

Electrical Safety Testing Note for NHS Medical Physics and EBME Departments – DYSIS v3, 0230-53074, Rev 01

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

A. 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.

B. Isolated Electrical System (Type BF Applied Part):

- Please note that an earth bond test cannot be performed without dismantling the instrument and this should only be conducted by representatives of the manufacturer.

	Isolated system! Chassis is NOT Earthed

For technical support please contact service@dysismedical.com

Attachment 2

Certificate of Acknowledgement DYSFA 2017-01

By signing below, I acknowledge that the required actions have been taken in accordance with the Field Safety Notice.

DYS302 Serial Number(s)		Number of Devices	

Printed Name		Signature	
Date		Telephone Number	
Facility Name			
Facility Address			

Note: This form must be returned to DYSIS Medical Ltd. before this action can be considered closed for your account.