Children's Health Ireland

FLEXIBLE ENDOSCOPE TRACEABILITY	
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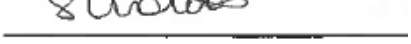
Authorised By Name: Sandra Morton Title: Clinical Nurse Manager III	*Signature:*  *Date: 14/2/2020*
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Document Review History		
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Document Change History	
Change to Document	***Reason for Change***
New HSE Standards	To bring in line with new standards
Updated the following sections: Purpose, Definition of Terms, Responsibility, Guideline, Procedure, Reference & Appendices	

CONTENTS

1.0 Purpose

To ensure all Reusable Invasive Medical Devices (RIMD) sets (including flexible scopes) are traced through the decontamination process (inclusive of storage of the endoscopes in the extended storage cabinet and VAC packing) to the service user. This is achieved through the identification and recording of the unique serial number and barcode of each scope used for each patient. This is necessary for future contact tracing when possible endoscopic transmission of disease is being investigated. *"A comprehensive traceability system delivers a complete electronic record of all reprocessing stages for the decontamination of RIMD including Endoscopes and their associated accessories used for patient treatment. Track and Trace systems provide evidence that endoscopes and their associated accessories used in clinical procedures have been decontaminated prior to and after use. A track and trace system enables timely identification of reprocessed endoscopes and their accessories to facilitate recall / withdrawal of potential faulty or contaminated endoscopes or accessories from use. In addition, the system must facilitate timely identification of service users exposed to specific endoscopes and accessories, which may require specific service user consultation follow up, in the event of a reprocessing failure or exposure to potential infection risk. The HSE has implemented a National Endoscope Track and Trace software system, "scope track" for the recording of the decontamination process and storage of flexible endoscopes and their accessories within the EDU. The objective of the National Scope Track system is to ensure that there is effective audit trail in place which can track the endoscopes and their accessories through their decontamination process and link them to the patient on whom they have been used and to ensure:*

- *Identification, mitigation and management of risk across the EDU services;*
- *Management information is available across the service*
- *Standard decontamination function across the health service*
- *Use of Unique Device Identification (UDI) and Standardised Coding (GS1) in compliance with the Medical Device Regulation 2017/745 which states that "Devices that are reusable shall bear a UDI carrier on the device itself. The UDI carrier for reusable devices that require cleaning, disinfection, sterilisation or refurbishing between patient uses shall be permanent and readable after each process*

performed to make the device ready for the subsequent use throughout the intended lift time of the device.

The UDI carrier shall be readable during normal use and throughout the intended life time of the device; business continuity and tracking of loaned and borrowed endoscopes".

(Note: We are awaiting to install this in the Endoscopy Department in CHI at Crumlin)

"The supporting documentation relating to the Endoscopes must be in a form that can accompany the set throughout the decontamination cycle.
Each Endoscope must be entered into the relevant tracking system to ensure that should an adverse incident occur, full traceability can be achieved.

The borrowed Endoscope must have the correct connection sets to allow it to be connected to the EWD and Endoscope Storage Cabinet.

Correct size brushes must be available. The Endoscope must be set up on the EWD and CESC system to allow for full traceability and correct decontamination and storage of the Endoscope.

Endoscope valves may be reusable or single use where deemed necessary.

All borrowed Endoscopes must be accompanied by a decontamination certificate and be checked on receipt for completeness and functionality and signed off accordingly."

2.0 Definition of Terms

Validation Printout. Printout issued by the Wassenburg Washer Disinfector at the end of each processing cycle and if applicable the validation printout issued by the Endoscopy Extended Storage Cabinet and the Surestore vac pack storage system

Wassenburg Washer Disinfector. Automated endoscope reprocessing machine used for all endoscope decontamination following manual precleaning.

Extended Storage Cabinet. A dedicated cabinet for endoscope storage for up to 2 weeks (336 hours)

***Surestore Endoscope Vacuum Pack Storage System*: A validated storage and transportation system for flexible endoscopes non channeled 35 days and 100 days for channeled endoscopes**

3.0 Responsibility

All nurses in the Operating Theatre and Outpatients Department are responsible for recording accurate details of each scope used for each patient.

Each individual must use their unique User Barcode issued to him / her when processing scopes.

4.0 Guideline

All endoscopes used **must have** a current validation printout, which is issued by the Wassenburg Washer Disinfector at the end of each disinfection cycle. In addition, if a scope is stored in the Extended Storage Cabinet, on removal there must be a printout to accompany this relevant scope from the extended cabinet plus the Wassenburg validation printout. On removing the endoscope from the Vac pack system, there must be a validation printout from the Wassenberg processor and the Vac pack storage system to accompany each scope.

Patient details and validation printout/s from the Wassenburg washer/disinfector and if applicable, the endoscope extended storage cabinet or Surestore vac pack system must be entered into relevant flexible endoscope log.

The second validation printout/s must be entered into the patient's medical notes. Ensure this printout is readable. Check that the printout remains readable over 30 year time span.

5.0 Procedure

- Ensure endoscope to be used is correctly decontaminated prior to use andused within 3 hours post disinfection time.
- Ensure number on validation printout/s corresponds to unique Barcode and Serial number of the endoscope.
- Place validation printout/s and patient details into the flexible endoscope log i.e Gastroscope / Colonoscope traceability log or Bronchoscope Traceability log
- The second validation printout/s is/are placed in the patient's healthcare record intraoperative nursing sheet for both GI and Bronchoscopy patients.
- A patient addressograph label is placed in the manual wash record book beside the Wassenburg Washer with unique barcode of scope used for patient written on the addressograph. This is to ensure the correct scope is barcoded into the washer / disinfector and linked to the correct patient on the Wassenburg computerized process manager

- A record of the model and serial number of each endoscope (including loan scopes) is maintained in the Wassenburg Washer / Disinfector Process Manager, the endoscope extended storage cabinet and the Surestore endoscope Vac pack storage system. A track and trace system enables timely identification of reprocessed endoscopes and their accessories to facilitate recall / withdrawal of potential faulty or contaminated endoscopes or accessories from use.

6.0 References

HSE Standards and Recommended Practices for Operational Management of Endoscope Decontamination Facilities June 2019 V.1 (QPSD-D-082-1)