



SENDING A PENTAX™/ OLYMPUS / WOLF FLEXIBLE ENDOSCOPE FOR REPAIR


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Document Review History

Review Date	Reviewed By	Signature
December 2018		


Document Change History

Change to Document	Reason for Change
New HSE Standards	To bring in line with new standards
Update to: Responsibilities, Procedure, References, Appendices	

Children's Health Ireland at Crumlin		
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1.0 Purpose

To outline the correct procedure for sending a Pentax, Olympus, Machida or Wolf endoscope out for Repair.

2.0 Responsibility

It is the responsibility of all Endoscopy Clinical Nurse Manager (CNM I & II), Endoscopy Health Care Assistants (HCA), Clinical Engineering (ENT Bronchoscopes) and the trained nursing staff (decontamination) in the Operating Theatre Department and Outpatients Department using flexible endoscopes to follow the correct procedure when sending it for Service and / or repair

3.0 General Principles

All flexible endoscopes intended for repair must be decontaminated before dispatch unless the endoscope cannot be reprocessed without further damage occurring: i.e. leak in the endoscope and procedures are in agreement with the manufacturer / supplier for the endoscope.

In all circumstances, the flexible Endoscopes must be accompanied by a certificate stating the status of the Endoscope i.e. contaminated and also state if there is an **Infection Control Alert** or the method by which it was decontaminated.

4.0 Procedure

Returning a Flexible Endoscope for Repair


- If flexible endoscope cannot be manually washed or decontaminated due to a leak, proceed with the following:

Dry Leak Phase Stage


- Wipe down the scope externally with J-cloth and Wassenburg Endohigh Cleaner (1.25 mls Endohigh cleaner to 250 mls water).
- Use recommended cleaning brush to **dry brush only** all internal channels.

Wet Leak Phase Stage

- Empty the sink of water (this decreases the risk of further damage to the Endoscope), wipe down the scope externally with J-cloth and Wassenburg Endohigh Cleaner (1.25 mls Endohigh cleaner to 250 mls water).
- Use recommended cleaning brush to **dry brush only** all internal channels.


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- You will find the appropriate suitcases (as per manufacturer's requirements) downstairs in the bulk store room (store 120) for sending flexible Endoscope for repair. The key is hanging in the CNM Office in Theatre;
- Line suitcase with plastic to protect case (for all scopes non-infected & infected);
- Place flexible Endoscope in lined case, ensure it is positioned correctly so that it won't get pinched when closing the case and cover with plastic;
- Select and fill out correct form, i.e. Olympus, Pentax (Wolf; give to Clinical Engineer to send);
- Include CHI at Crumlin Decontamination Form (see Appendix 1), please state if the Endoscope was used on a patient with an Infection Control alert;
- Fill out "Endoscope Tracking Record" for all scopes and tick "Out for Repair" field;
- Place on top of plastic cover and lock suitcase. Place suitcase in plastic cover for Olympus endoscopes only, the rest of the endoscopes are not placed in a suitcase cover (as not requested to do so by Sword Medical);
- Phone relevant company to request collection, this is organized by the company and the courier will collect Endoscope from Theatre Reception;
- Fill out theatre repair book; leave both copies in book (for record keeping);
- Suitcase should then be locked and the packaging must be marked "USED MEDICAL DEVICE". Please retain the key as the relevant companies have Master Keys to open the case on arrival.
- Request the Theatre Secretary or Clinical Engineer to log the endoscope as "out of use" in the Wassenburg Process Manager on the Theatre computer System.
- On return of the endoscope following repair, place the technical report in the relevant service folder on shelf in Prep room 6.
- Request the Theatre secretary or Clinical Engineer to log the endoscope as "in use" on the Process manager.

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5.0 References

- HSE Standards and Recommended Practices for Operational Management of Endoscope Decontamination Facilities 2019
- Guidance on the Implementation of the Health and Safety Authority Competent Authority – Exemption 03/2016 on the Carriage of Uncleaned Reusable Invasive Medical Devices by Road, Revised May 2018
- Pentax User Manual
- Olympus User Manual
- Wolf User Manual

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6.0 Appendices

Appendix 1

PENTAX No.4057

Medical Service Form

Your official Order No: _____ Date: ____/____/____

Model No: _____ Serial No: _____

Hospital return address: _____

Postcode: _____

Contact name: _____ Telephone No: _____

Is this Endoscope under service contract? Yes No

If not, is it chargeable? Yes No

If no, please explain _____

Do you require an estimate if over €1000? Yes No

Please give a brief description of any problems you are experiencing with the equipment:

Is there a date by which the instrument must be returned to you? Date: ____/____/____

Do you require a loan endoscope? Yes No

Would you like a representative to call to demonstrate our latest equipment? Yes No

Would you like a Clinical Nurse Advisor to call to advise on cleaning techniques? Yes No

Cleaning and Decontamination Certificate

For damaged scopes failing a leakage test, please do not immerse in any fluid. Wipe down the outside of scope with cloth dampened with dilute enzymatic detergent and dry brush all channels.

This equipment/item has been used in an invasive procedure or in contact with blood or body fluids. Yes No

This equipment/item has been cleaned in preparation for inspection, servicing or repair. Yes No

This equipment has been cleaned and decontaminated. The solution and method employed for decontamination was:

The equipment could not be decontaminated because:

The safety precautions to be taken due to endoscope not having been decontaminated are:

Signed _____ Date: ____/____/____

Position: _____ Tel. No: _____ Ext: _____

Official address: _____



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Appendix 2

Service Solutions 



ISO 9001 Registered
Certificate No. FM 20968

OLYMPUS

OLYMPUS SERVICE
KeyMed House, Block Road, Southcoast-on-Sea, Essex SS2 9QH, UK
Telephone: +44 (0)1702 616333, Facsimile: +44 (0)1702 644235
e-mail: service@olympus.co.uk website: www.olympus.co.uk

Issue 7

A Testimony to Quality and Service

KI 5048199/0416

KMAF 07/13

OLYMPUS

HELP US TO SPEED THE RETURN OF YOUR FLEXIBLE ENDOSCOPE

Please ensure that all sections below are completed and return form with the instrument that requires repair.

SECTION ONE - CUSTOMER CONTACT INFORMATION

Name (Print):

Title:

Department:

Tel No: Fax No:

E-mail:

Hospital Name / Address:

Contact Name & Delivery Address (if different from above):

SECTION TWO - INSTRUMENT DETAILS

Model: Serial No:

Official Order No:

Repair covered by:

A) Warranty B) Service Contract C) Neither or Unknown

If not A or B above, name of person who will approve repair cost:

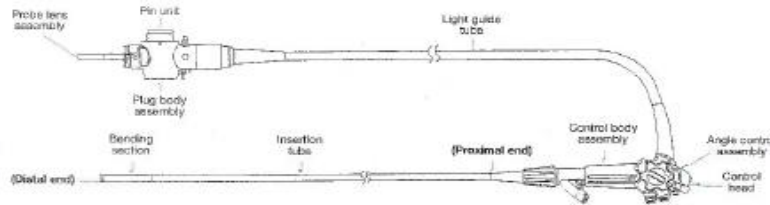
Telephone No: Ext:

Note: If not covered by Warranty or Service Contract, we cannot proceed with any repair work until we have an official order number.

Service Solutions 

SECTION THREE - RETURN DETAILS

Please highlight the area of concern and tick the relevant box detailing the reason for return, supplying as much information as possible with respect to the defect.



General Service	Fault in angulation system		
Leak in bending section	Scope immersed without waterproof cap		
Leak in control head	Light output deteriorated		
Leak in channel system	Insertion tube covering damaged	Light guide tube covering damaged	
Restriction in channel system	Image fault	Misty/foggy	Interference/lines
Air/water channel blocked		No image	Broken fibres (Optical)

Other (please specify)

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SECTION FOUR - vCJD STATEMENT FOR GI FLEXIBLE ENDOSCOPES

All endoscopes must be managed in accordance with the guidance provided by the Advisory Committee on Dangerous Pathogens TSE working group and must be quarantined or destroyed as appropriate.

Olympus KeyMed has agreed to accept some models of GI endoscopes (CF, PCF, JF, TJF and GIF) for refurbishment only, following use on a patient whom is classified as 'At Risk' from vCJD. This does not include endoscopes which have been used on a patient falling within the defined vCJD categories of 'Definite', 'Possible' or 'Probable'.

Is this instrument being returned for Refurbishment following use in an invasive/therapeutic procedure on a patient classified as 'At Risk'? Yes No

Signing this form indicates confirmation that this endoscope has been managed in accordance with guidance from the Advisory Committee on Dangerous Pathogens TSE working group (Annex F) www.advisorybodies.doh.gov.uk/acdp/tseguidance/index.htm

SECTION FIVE - DECLARATION OF CONTAMINATION STATUS

Tick box A if applicable. Otherwise complete all parts of B, providing further information as requested or appropriate.

A) IS THE ITEM CONTAMINATED? Yes* No Unknown

*State type of contamination: blood, body fluids, respired gases, pathological samples, chemicals (including cytotoxic drugs), radioactive material or any other hazard?

.....

B) HAS THE ITEM BEEN DECONTAMINATED? Yes* No* Unknown

NOTE: For leaking instruments, superficial social clean only

◆ What method of decontamination has been used? Please provide details:

Cleaning

Disinfection

Sterilisation

Reprocessing Equipment

◆ Please explain why the item has not been decontaminated?

.....

UNLESS AGREED WITH OLYMPUS PRIOR TO THEIR RETURN, CONTAMINATED ITEMS WILL NOT BE ACCEPTED AND WILL BE RETURNED AT THE SENDERS COST.

This item has been prepared to ensure safe handling and transportation and has been managed in accordance with the guidance provided by the Department of Health (SEAG annex F).

Name: Position:

Signed: Date:

IMPORTANT

- When returning instruments always lock the carrying case before you place it in the carrying case transport bag, ensuring that the necessary paperwork is enclosed.
- No claims for missing items from unlocked cases will be accepted. Please retain your key as we have master keys at Olympus KeyMed to open your case on arrival.
- Simply telephone the Olympus Service Help Desk to arrange collection of the instrument - courier charges will be forwarded to Olympus KeyMed and included on your repair invoice, unless covered by warranty or service contract, when transportation is free of charge. Please do not use this service for small items and accessories that can be sent by post.

If you have any queries relating to the completion of this form, please contact Olympus Service Help Desk on 01702 616333.