



Health Department

Dear Colleague

IMPORTANT INFORMATION FOR ALL PRACTITIONERS ENGAGED IN ENDOSCOPY AND DECONTAMINATION OF ENDOSCOPES

A detailed survey of current practice in decontamination of (primarily) flexible endoscopes within NHSScotland and independent hospitals was commissioned by my predecessor, following a decontamination failure incident in Northern Ireland in June 2004. A [Hazard Notice \(HAZ\(SC\)04/05\)](#) was issued at that time, instructing an immediate review by NHS Boards and assessment of all endoscope reprocessing facilities and equipment. Based on preliminary information from the survey, I issued [CMO Letter CMO\(2005\)11](#) in December 2005, which reinforced the need for ensuring compliance with the Hazard Notice.

I have now received the final report on the survey, which will be published on Monday 6 March on the SEHD website <http://www.show.scot.nhs.uk/sehd/publications.asp>: a press statement will be issued at that point. While some examples of good practice were identified, a number of potential deficits in equipment and practice were also reported. The main findings in the report include:

- Less than half the endoscopes appeared to be cleaned and disinfected following typical manufacturer's instructions and current guidance;
- In around a quarter of endoscopes, one or more channels were not reported by respondents (based on reported model numbers, verified using data provided by endoscope manufacturers). There is a risk therefore that these may not be recognised or consistently cleaned/disinfected in everyday use.
- More than 10% of flexible endoscope 'model numbers' reported by respondents were not recognised by manufacturers. Knowing the model number is important for (e.g.) taking action on alerts from manufacturers; similarly, the serial number is required in tracing use of a particular endoscope in the event of an incident;

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For action

Chief Executives, NHS Boards

For information

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State Hospitals Board for Scotland
Directors of Public Health
CPHMs (CD&EH)
Care Commission
Scottish Healthcare Supplies
Clinical Director, HPS
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- The facilities for manual washing were often not to the required standard – for example, less than half of units reported a dedicated sink for manual washing of endoscopes. Many respondents reported inadequate working space, and more than 10% lacked a formal written procedure for endoscope decontamination;
- Many of the endoscope washer-disinfectors (EWDs) in use were technically inadequate by current standards.
- Most EWDs had not been suitably validated and tested to the standards described in current best practice guidance. Where validation studies had been undertaken, these usually did not include cleaning efficacy tests, which are an essential element of validation.

The key recommendations of the report include:

- The need to ensure compliance with HAZ(SC)04/05 (which should already have been actioned via CMO(2005)11);
- A review of priority areas for action; and
- Establishment of a group to advise the Department on the necessary actions arising from the report.

The report has resulted in the immediate formation of the Endoscope Decontamination Working Group, a subgroup of the Sterile Services Provision Review Group (the ‘Glennie Group’). The Working Group met on 24 January, and has already identified a number of short, medium and long term initiatives. The current Letter identifies the issues requiring immediate assessment and intervention as appropriate: this list is in the form of priority areas for action, appended as Annex A.

Annex B contains a listing of sources of further advice, key documents and web resources: included in this list is a link to the recently updated advice from the Advisory Group on Dangerous Pathogens (ACDP) regarding endoscopes and patients with, or at risk of, vCJD and other prion associated diseases.

Preliminary details of the Working Group’s proposed strategy are given in Annex C.

One of the medium term objectives is the completion and issue of Scottish Health Planning Note No. 13 on design of premises for medical device decontamination. Pending this guidance, a number of exemplar layouts for reprocessing facilities are attached as Annex D.

It is well established that endoscopy carries a very low (but possibly underestimated) risk of infection. In virtually all cases, the diagnostic and therapeutic benefits of endoscopy will far outweigh the risk of infection. **However, the requirement to ensure adequate and safe decontamination of re-usable instruments is a professional and legal obligation on all practitioners, and as such is not confined to NHS work.**

The issues listed in Annex A should be addressed at all sites as soon as is practicable. **I am asking each NHS Board to submit a short report on issues actioned, and a plan of action with timescales for those outstanding, by the end of May 2006.** Please email these reports to Mr Ian Roxburgh at Ian.Roxburgh@scotland.gsi.gov.uk

I would ask that Chief Executives distribute this letter and its attachments to:

- All medical and nursing practitioners engaging in use or decontamination of flexible endoscopes
- Infection Control Managers responsible for decontamination
- Sterile Services Managers
- Risk Management Committees
- Clinical Governance Committees
- Directors, Estates
- Infection Control Doctors
- Infection Control Nurses

I am grateful for your co-operation and assistance in managing this important issue.

Yours sincerely

DR HARRY BURNS

Decontamination of flexible endoscopes: priorities for immediate action

- 1. Clear identification of responsibility.** A named person should be responsible for maintaining an overview of endoscope decontamination for the NHS Board area, including Primary Care procedures. This responsibility should include creation and maintenance of a complete inventory of flexible endoscopes and automatic endoscope reprocessors (see point 2 below), ensuring that standard decontamination protocols are developed, disseminated and applied, and ensuring a planned preventative maintenance programme is in place. This is an overall responsibility for the Infection Control Manager, but could be delegated to an Endoscope Decontamination Manager or other suitable named individual.
- 2. Assembling a detailed inventory of endoscopes, automatic endoscope reprocessors (AERs) and sites** where decontamination is carried out within each NHS Board area, including primary care sites. As signalled in CMO(2005)11, this should include for each endoscope a record of the manufacturer, model number, serial number and of all channels present. The feasibility of a Scottish on-line resource to assist with this is under consideration.
- 3. Channel identification.** Check and record clearly the number of channels in each endoscope and ensure that they can all be connected to the endoscope washer disinfector using the correct adaptor/connection sets provided by the manufacturer. If one or more channels is omitted by the adaptor, these must be manually cleaned and disinfected. The decontamination process must include all channels even if they have not been used during the procedure
- 4. Training.** All staff undertaking decontamination of endoscopes must be trained in the techniques and skills relevant to decontamination and the procedures they will be undertaking. They should be trained specifically on the endoscope(s) and AER(s) that they are using. Commercial training programmes are available, and this is an issue which will be considered further by the Endoscope Decontamination Working Group.
- 5. Procurement and compatibility.** It is important to ensure compatibility between the endoscope, the AER, and the detergent/disinfectant chemicals used. This applies at the point of purchase, and for existing stock, by consulting the manufacturers and/or the instruction manuals.
- 6. Detergents and disinfectants.** Deciding on the correct detergent and disinfectant for use with a specific endoscope and any one model of washer-disinfector can be complex. However, operators should be sure that they recognise which is which, what formulation and concentrations should be used (per manufacturers' instructions), and to cease use of inappropriate agents (e.g. chlorhexidine hand scrub, plain water, and alcohol pre-injection swabs). A simple way of ensuring the correct concentration of detergent is used for manual cleaning is to use a metered pump dispenser and a sink with a marking at the appropriate water fill level. **Ensure endoscopes and re-usable accessories are always manually cleaned prior to processing in an endoscope washer disinfector.**

- 7. Health Protection Scotland guidance on endoscope reprocessing.** All persons involved in endoscope decontamination should have access to, and review practice against, this document. The final draft version is currently available: the final version is not expected to be materially different, and will be posted on the HPS website shortly (weblink in Annex B below). Further advice can be found in SHTM 2030 (Washer Disinfectors) and MHRA Device Bulletin DB2002(05) – weblinks in Annex B.
- 8. Procedures for decontamination processes.** Formal Operational Procedures, clearly describing each step of the process from transport, manual cleaning, and automated processing to storage and pre-use management, should be produced for, and available at, each site. These should take account of the endoscope(s) and reprocessor(s) in use at that site, and must include the requirements for collating and storing local documentation. Procedures should be developed in collaboration with Infection Control Teams and others with expertise in endoscope decontamination.
- 9. Maintenance and testing.** Washer disinfectors should be serviced and tested according to manufacturers instructions and SHTM 2030 (with yearly revalidation), carried out by a suitably qualified person. An Authorised Person (Sterilizers), Test Person (Washer Disinfectors), Maintenance Person (Washer Disinfectors) and Microbiologist (Sterilizers) should all be identified and deployed per the HPS guidance [*Endoscope Reprocessing: Guidance on the Requirements for Decontamination Equipment, Facilities and Management*] and SHTM 2030. Documentation of periodic testing (daily, weekly, quarterly, and annual), maintenance and data logs for each decontamination cycle should be maintained at each site within a document portfolio prescribed by the Operational Protocol.
- 10. Premises should be fit for purpose.** New or refurbished facilities should be physically fit for purpose, but existing premises may require modifications to work patterns or layout to mitigate shortcomings. There should be dedicated sinks for manual cleaning, ideally one for washing and one for rinsing, and a separate wash hand basin. There should be separate working areas for setting down dirty, cleaned and rinsed devices, and for final inspection. Exemplar layouts are given in Annex D.

Scottish Executive Health Department

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Further Information on Decontamination

1. Sources of Support and Advice

- Scottish Healthcare Supplies – Authorised Person/s (Sterilizers) – (name dependent upon NHS Board area): Gyle Square, 1 South Gyle Crescent, Edinburgh, EH12 9EB, Tel. 0131 275 6390, email sterap@shs.csa.scot.nhs.uk
- Local ‘Responsible Person’ (Decontamination Equipment) - e.g. Principal Engineer, or other designated person/s responsible for Decontamination equipment.
- Sterile Service Managers – via NHS Board Head Offices, particularly for sterilising accessories and ethylene oxide.
- Public Health Infection Control Nurse or Infection Control Nurse (as appropriate) – via NHS Board Head Offices
- Decontamination technical enquiry service at Health Protection Scotland, 1 Cadogan Square, Cadogan Street, Glasgow G2 7HF, Tel 0141 300 1945, email decon_team@hps.scot.nhs.uk

2. Useful documents and web resources

HPS Endoscope Reprocessing: *Guidance on the Requirements for Decontamination Equipment, Facilities and Management* (final draft, post-consultation version imminent but will not be materially different)

http://www.show.scot.nhs.uk/scieh/infectious/hai/decontamination/documents/301204_LIVE_Endoscopy%20Guidance.pdf

HPS Model Infection Control Policies (including Standard Infection Control Precautions)

<http://www.infectioncontrol.hps.scot.nhs.uk/>

HPS Decontamination web page

<http://www.show.scot.nhs.uk/scieh/infectious/hai/decontamination/haidecon.htm>

Scottish Health Technical Memorandum SHTM 2030 *Washer Disinfectors*

<http://www.show.scot.nhs.uk/pef/guest/decontamination/CDVer2/Contents1.pdf>

MHRA Device Bulletin DB 2002(05) *Decontamination of Endoscopes*

http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&useSecondary=true&ssDocName=CON007329&ssTargetNodeId=572

British Society for Gastroenterology *Guidelines on Decontamination of Equipment for Gastrointestinal Endoscopy 2006*

<http://www.bsg.org.uk/bsgdisp1.php?id=5ab3755137d1050e76b8&h=1&sh=1&i=1&b=1&m=00023>

Advisory Committee on Dangerous Pathogens (ACDP) and Spongiform Encephalopathy Advisory Committee (SEAC): *Transmissible spongiform encephalopathy agents: safe working and the prevention of infection*

Home page:

<http://www.advisorybodies.doh.gov.uk/acdp/tseguidance/Index.htm>

Annex F: *Decontamination of endoscopes*

http://www.advisorybodies.doh.gov.uk/acdp/tseguidance/annexf_amended.pdf

Consensus statement from the British Society of Gastroenterology (Decontamination Working Group) and the ACDP TSE Working Group (Endoscopy and vCJD Sub-Group) *Endoscopy and individuals at risk of v CJD for public health purposes*

<http://www.advisorybodies.doh.gov.uk/acdp/tseguidance/endoscopy-consensus.pdf>

The Global Rating Scale (GRS) will be introduced in Scotland during 2006 as part of the Diagnostics Collaborative Programme, which is launching in April 2006. GRS is a self assessment tool that has been developed in England to promote a patient-centred view of an endoscopy unit and provides a framework for service and quality improvement. The issue of decontamination is highlighted in the section on patient safety. All endoscopy units should ensure that they are encouraged to participate in the bi-annual self assessment for the GRS to help identify progress in this area. If you would like more information about GRS contact Dr Perminder Phull (National Clinical Lead for GRS) P.Phull@arh.grampian.scot.nhs.uk . See *Diagnostics Collaborative: Endoscopy* homepage at http://www.cci.scot.nhs.uk/cci/cci_display_np.jsp?pContentID=2951&p_applic=CCC&p_service=Content.show&

3. Decontamination Equipment Failures

In the event of decontamination equipment failure, and where an NHS maintenance contract is in place, contact the 'Responsible Person' (Decontamination Equipment), or other designated person/s as above. Dependant upon the contract agreement, the faulty equipment should either be replaced or repaired as soon as is reasonably practicable. Where maintenance/service is provided by an independent source, contact should be as per the contract agreement. Otherwise contact should be directed to the Manufacturer. Where there are concerns that improperly decontaminated instruments have been used on patients, the local NHS Board Public Health team should be alerted, who in turn should alert HPS, IRIC at Scottish Healthcare Supplies and the NHS Board Risk Management team.

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Outline of proposed short, medium and long term strategy for endoscope decontamination in Scotland.

Endoscope Decontamination Working Group, January 2006

Safe and effective decontamination of endoscopes is a highly technical and complex task for the operator, and this is made more difficult by the wide variety of endoscope and washer disinfectant design and accessories, lack of clarity from manufacturers of endoscopes or of washer disinfectants over which detergents and disinfectants should be used with the other's equipment, and lack of a standardised or coherent education and training programme (including competencies and review).

The EDWG has examined the results from the HPS review of endoscope decontamination, and is proposing a programme of immediate, medium and longer term measures aimed at dealing with the potential deficits and at improving standards of practice across the country (as has been achieved by the Glennie Group since 2001 for central decontamination units).

- Immediate steps
 - These relate primarily to relatively simple changes to working practices, formal documentation of equipment and activities, ensuring validation, periodic testing and maintenance of equipment, and clear identification of responsibilities.
 - The immediate steps are outlined in more detail in Annex A of this document.
- Medium-term interventions
 - Endoscope reprocessor gap analysis and identification of remedial manual procedures.
 - Education and training are of prime importance, but it is recognised that it will take some time to develop and validate an educational framework or programme, develop competencies, and to examine the possibility of mandatory accreditation for all staff engaging in endoscope decontamination.
 - Developing a quality management/assurance approach for NHS Boards.
 - Improving the information available to customers for the procurement process, including dialogue with manufacturers.
 - Clarification of testing issues, especially microbiological testing
 - Development of access to authoritative advice
 - Consideration of an endoscopy decontamination forum for sharing of best practice
- Long term issues
 - Many washer disinfectors are not, and cannot be engineered to be, compliant with best practice (i.e. compliance with the appropriate standards, regulations and guidance). A major programme of replacement with fully compliant equipment is required, but will take several years owing to constraints on

supply volumes and availability of suitable qualified personnel to install and validate these machines. It is likely that this will take around five years to address.

- Many of the premises where decontamination is carried out are physically unfit for purpose, either in terms of size, layout or facilities. Rectifying this will again be a long term issue, and is likely to be dealt with in the process of commissioning new build hospitals or in extensive refurbishment. The revised Scottish Health Planning Note 13 should help address the design issues which require to be considered, and will be published shortly. Meantime, Annex D gives interim guidance on what is currently regarded as best practice (Fig 3), which would be suitable for newbuild projects. Where unavoidable constraints remain, e.g. in refurbishment of existing premises, acceptable (if less ideal) arrangements are shown in Figure 4 (two rooms without ante-rooms) and Figure 5 (a single room for all operations).

Decontamination of flexible endoscopes: exemplars of room layout and facilities

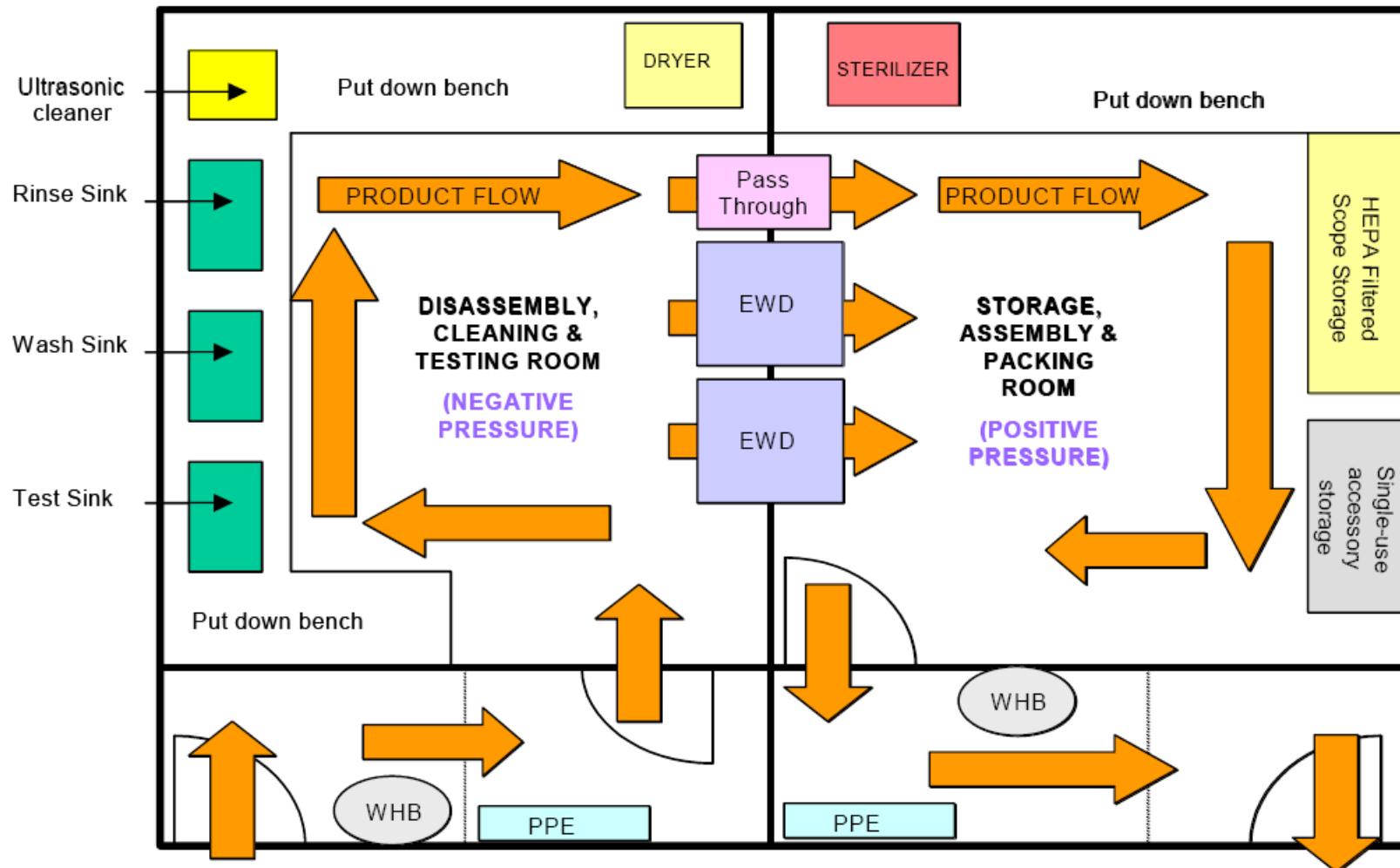
These diagrams are abstracted from the Health Protection Scotland document *Endoscope Reprocessing: Guidance on the Requirements for Decontamination Equipment, Facilities and Management* (Figs 3-5 in the final draft, post-consultation version imminent but will not be materially different) -

http://www.show.scot.nhs.uk/scieh/infectious/hai/decontamination/documents/301204_LIVE_Endoscopy%20Guidance.pdf

Further advice on facilities within the HPS guidance includes:

- Design the unit so that it is physically separated from all other work areas.
- Ensure that there is a planned work flow from the 'dirty' (receipt of contaminated endoscopes to transfer into the EWD) to 'clean' (inspection, drying and storage of the decontaminated endoscope).
- Segregate the 'dirty' and 'clean' activities wherever possible.
- Provide ventilation to ensure a pressure differential between the dirty reprocessing area and linked areas (clean reprocessing, patient treatment, hospital corridor).
- Ensure that the decontamination room in the unit is equipped with:-
 - dedicated sink/s for pre-cleaning;
 - compressed airline;
 - work surfaces;
 - Endoscope washer disinfectors (EWD/s) and associated services;
 - extract ventilation linked to the EWD (if required);
 - task lighting;
 - hand wash sink;
 - storage facilities.
- Ensure that finishes on walls and other surfaces are smooth, water resistant and able to withstand frequent cleaning.
- Ensure that the junctions between walls, floors and ceilings are coved and flush.
- Ensure that floors are covered in a washable non-slip sheet material which is adequately sealed.
- Ensure that there is adequate lighting to permit good working practice eg visual inspection of devices and the results of process residue tests.

Further guidance will be available in due course within Scottish Health Planning Note 13 (Property and Environment Forum) which will deal with design of premises for local decontamination.



**Figure 3: IDEALISED SCHEMATIC FOR ENDOSCOPY REPROCESSING UNIT
(2 - room with ante rooms)**

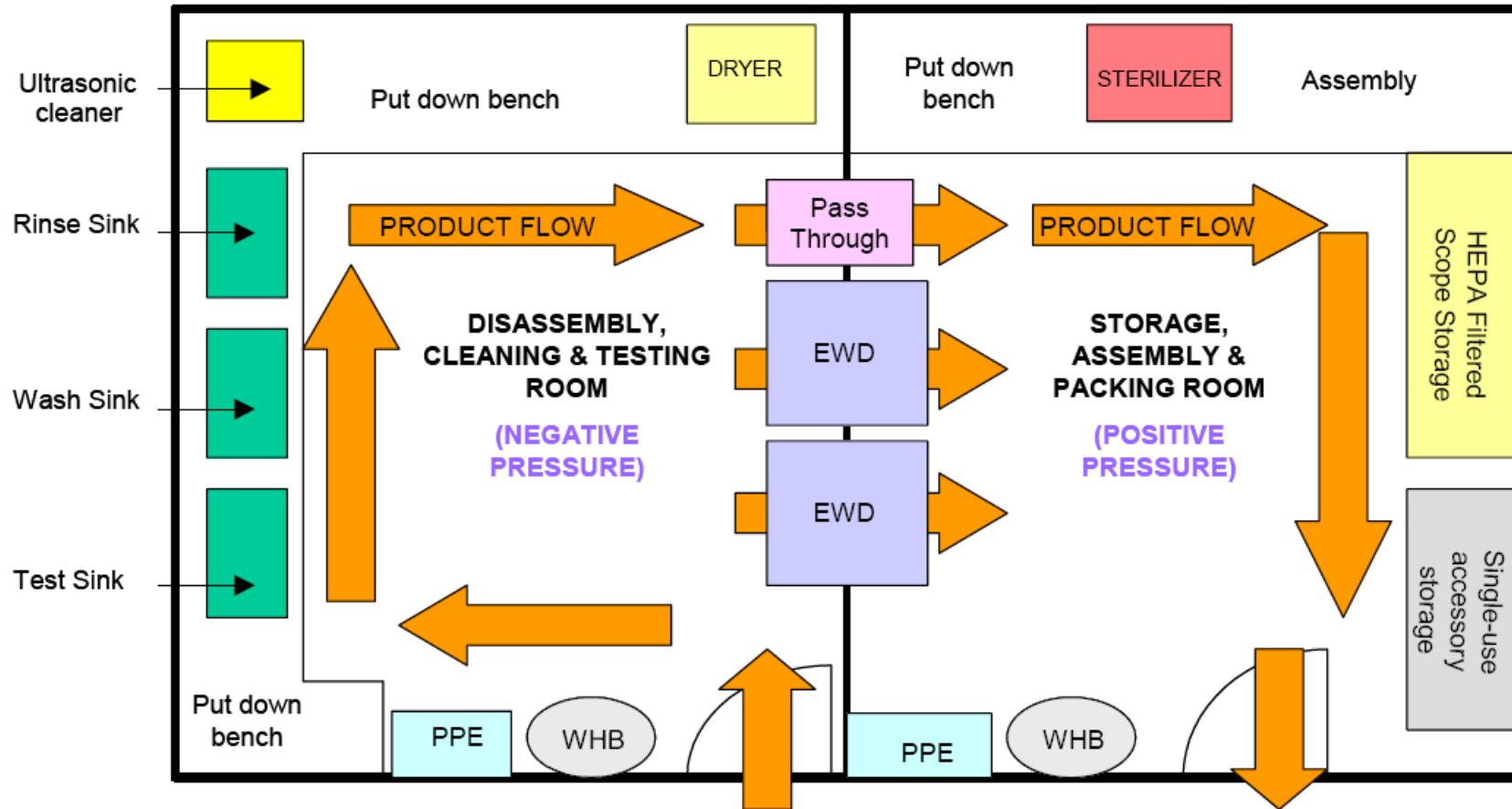


Figure 4: IDEALISED SCHEMATIC FOR AN ENDOSCOPY REPROCESSING UNIT
(2- room without ante rooms)

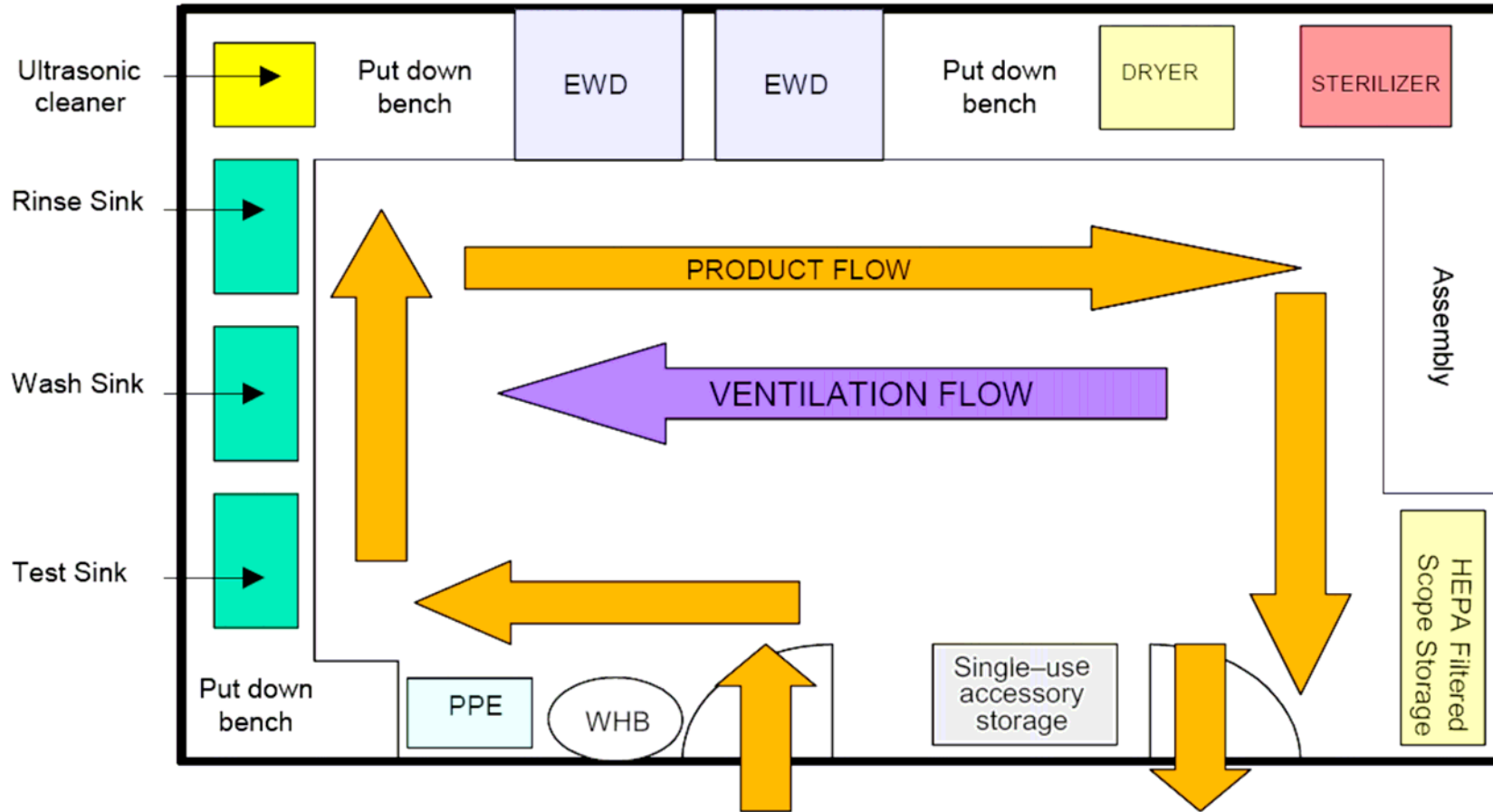


Figure 5: IDEALISED SCHEMATIC FOR AN ENDOSCOPY REPROCESSING UNIT (Single-room)