J-F. Rey[1]
K. B. Spencer[2]
P. Jurkowski[3]
H-W. Albrecht[4]

ESGE Guidelines for Quality Control in Servicing and Repairing Endoscopes

In issuing guidelines on repairing endoscopes, the aim of the European Society of Gastrointestinal Endoscopy (ESGE) Guidelines Committee is to draw the attention of those who manage endoscopy units to the quality control requirements involved in having endoscopes repaired. Information on endoscope repair is important not only for medical doctors, nurses and assistants, but also for medical engineers and – even more so – for hospital administrators.

The aim of these ESGE guidelines is to draw the attention of endoscope users to both the technical and the legal implications relating to endoscope repair. The sources of spare parts and the exact repair procedures used should be clearly stated in the repair contract. If second-hand spare parts are used, traceability and hygiene issues should be taken into consideration.

For the ESGE, it is clear that repair services can be provided both by endoscope manufacturers and by other repair service providers (known as "third parties"), as long as they follow the same quality control processes and guarantees as those followed in endoscopy units.

The intention in these guidelines is to provide users of medical endoscopes with information about the appropriate selection of service providers, including information on how to reduce user liability relative to compliance with the Medical Device Directive (MDD) during the lifespan of endoscopic equipment and devices.

The Medical Device Directive (MDD) regulates the requirements for the design, manufacture and sale of new medical devices and equipment very precisely. A clear sign for the user that the equipment or device complies with MDD regulations is the CE mark. A reference to the original manufacturer is also provided by the identification label on each product. The basic aim of these measures is to ensure the safety of users, patients, and others, as well as to ensure compliance with technological standards. Before the first use of any new endoscope, the MDD requires proof that these requirements have been met, based on both clinical and nonclinical testing procedures. The original manufacturer maintains a master configuration file, which documents the design configuration, manufacturing configuration, and test results. This ensures seamless configuration control.

After the product has been sold, the liability and responsibility for ensuring safe usage of the product is transferred to the user. The degree of user liability is likely to depend on the contract between the user's organization and the selected service provider. The transfer of liability, and all associated risk, depends on the person or organization undertaking the service and on the way in which maintenance and repair work is carried out. If a failure in use occurs after maintenance or repair and this failure leads to serious injury to a patient or user, there is a greater likelihood that the user and service provider may be held legally responsible for any injuries caused, if the endoscope was not repaired in accordance with the manufacturer's instructions and operating standards.

Institution
[1] Arnault Tzanck Institute, Saint-Laurent du Var, France
[2] Olympus Europe, Ltd., Hamburg, Germany
[3] Fujinon Europe, Ltd., Willich, Germany
[4] Pentax Europe, Ltd., Hamburg, Germany

Corresponding Author
J-F. Rey, M.D. · Institut Arnault Tzanck · Avenue du Dr Maurice Donat · F-06700 Saint-Laurent du Var · France · Fax: +33-493075158 · E-mail: jean-francois.rey@wandadoo.fr

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Users need to ensure that they follow an appropriate strategy for maintaining and repairing the equipment. Options for maintenance and repair services include choosing either:
- The original manufacturer of the endoscope
- An in-house biomedical engineering department
- An independent service provider
- A managed service provider.

Usually, the original manufacturer is the primary source for maintenance and repair services. However, not all manufacturers carry out repair and maintenance of their devices. Whoever is carrying out the maintenance and repair activity, the written service documentation provided by the manufacturer should always be used. If any organization other than the original manufacturer undertakes repair or maintenance work, the organization concerned should ensure that the work and inspection is carried out in accordance with the latest manufacturer's instructions and specifications, and according to defined standards.

The most important issues to be considered as selection criteria for any service provider are in the four core areas:
- General competence
- Workmanship
- Parts and materials
- Verification, inspection, and risk management.

However, in addition, the following criteria are important elements that should also be taken into account when choosing a service provider:
- A clear analysis and understanding of the relationship between apparent financial savings and increased liability risks, and calculation of total ownership costs relative to repair frequency
- The frequency with which maintenance and repairs are likely to be needed and the time required to respond to endoscope malfunction
- Uptime requirements
- Requirements for loan equipment
- Requirements for a mobile service.

It is advisable for the owner of the endoscopic equipment to always make a clear contractual agreement with the chosen service provider. This agreement should clearly describe the level of service to be provided to the owner organization, and it is recommended that it should include:
- Reference to the original manufacturer's written instructions
- Information on availability, source, and traceability of spare parts
- Notification of any changes in parts, procedures, tests performed, etc., including the use of parts and methods other than those specified by and originating from the original manufacturer
- Details of the training and qualifications of the technicians and inspectors
- Details on the way in which requirements for adequate record-keeping regarding traceability are ensured
- Regulations on the use of subcontractors employed by the service provider.

A repair organization that complies with both the comprehensive legal and quality aspects as well as with specific customer requirements will be able to respond positively to the following questions.

Competence

- What is the experience and customer reputation that the service provider has in repairing and maintaining the specific type of endoscopic or electronic equipment? (List of customers)
- Is a quality assurance system in place? (ISO 9001 – 2000 as a minimum; preferably ISO EN13488 to show compliance with MDD)
- How are the requirements for adequate record keeping and traceability ensured?
- Is the availability of loan equipment adequate to meet customer demand, and is the loan equipment chargeable or not?
- What is the response time and what are the regular service hours?
- Is a mobile service offered, and where is it located?
- Is the service organization sufficiently flexible to adapt to customers' uptime requirements?
- Is a risk management strategy in place?
- Does the service provider have reliable access to the original manufacturer's information (manuals, safety information, and device specifications) and spare parts?

Workmanship

- Are the original manufacturer's repair procedures in place and regularly updated, (preferably by the original manufacturer) and what is the source for the relevant documentation?
- How does the update procedure work, and how is it documented?
- Is a written agreement with the original manufacturer available?
- Is the level of documentation appropriate to the level of repair?
- Are the technicians regularly trained on the basis of the original manufacturer's manufacturing and service standards (preferably by the original manufacturer's approved trainers)?
- What certificates and records are available for repair and inspection training with regard to the specific equipment type and the extent of repair training that has been performed?
- What are the training intervals for technicians?
- What regular reviewing of the training level is done, and is it done at appropriate intervals?
- Are the tools that are being used in accordance with the original manufacturer's jigs and special tools specifications, or are they originally provided by the manufacturer?
- Are specific repair and inspection procedures in place, regularly updated, and followed (preferably by the origin manufacturer)?
- If repair and inspection procedures other than the original manufacturer's are being used:

- Are the methods and procedures documented and regularly updated and appropriately detailed on the basis of the required level of maintenance and repair?
- Is a system in place to inform the user organization of any alternative methods used?
- What certificates and records are available for inspection?
- Have the risks been identified and documented?
- Is a risk management strategy for this documentation in place?

Parts and Materials

- Are the criteria for the definition of part defects documented and verified as being in accordance with the original manufacturer's criteria and with MDD requirements?
- Are all the parts and materials used for repairs the certified original manufacturer's parts, and are they purchased from the original manufacturer or any authorized agency?
- If no original parts and materials (e.g., adhesives) are used, is the service provider willing to certify the origin of the parts and materials used for repairs?
- Is a risk management strategy for these parts and materials in place and the appropriate documentation available?
- Have the risks been identified and documented?
- Are certificates of biocompatibility available?
- Do the parts and materials comply with the original manufacturer's specifications of compatibility with reprocessing agents?
- Is the sourcing of these parts covered by a contract (to ensure continuity of supply?

Verification, Inspection and Risk Management

- Have criteria for functionality and safety testing been defined, and are they available and verified as being in accordance with MDD requirements and the original manufacturing standards?
- Have the methods and equipment used for quality assurance inspection been defined and are they appropriate for verifying the quality of the repaired endoscope according to the origin manufacturer's standards? Is a quality assurance tracking report available?
- Will the repair contractor provide a statement of conformity with the original manufacturer's functional, safety, and quality standards after an endoscope has been repaired?
- Is the repair process documented and traceable?
  - Process steps
  - Technicians involved
  - Parts used
- How long will the necessary documentation be kept available?
- What notification and approval procedures are in place to ensure that the user organization is aware of any changes in spare parts and methods other than those covered by the contract?
- With regard to the whole repair process, is a risk management system in place and who is the person responsible for it?
- Is a procedure in place for reporting conditions to the user organization that have a potential to cause a device failure or otherwise compromise the intended use of the endoscope?

Note

To carry out any repairs, it is necessary to disassemble an endoscope either partly or wholly. During this procedure, the functionality and condition of subcomponents or parts inside the endoscope can be inspected in addition to verifying the originally detected problem. Reassembling the parts, including internal adjustments of subcomponents, also requires specialized understanding and expertise in the manufacturer's procedures. Performing the repairs in accordance with the manufacturer's standards ensures the continuing functionality and safety of the endoscope.

If any changes are made during a repair procedure with regard to the materials, spare parts used, or characteristics of the medical endoscope, this may invalidate the related CE marking. In case of doubt, a new CE marking procedure carried out by a registered medical device manufacturer for the endoscope concerned will be required.

Responsibility for the safety of the device lies primarily with the owner or his or her delegated person, regardless of who carries out any repairs.

Effectively, this means that in the event of endoscopic equipment being subjected to any work, processing, etc., that is not in accordance with the original manufacturer's specifications and/or quality standards, the equipment may have performance standards that deviate from (i.e., are inferior to) those for which the original CE approval by a notified body and its registration was issued.

This would therefore completely invalidate any continuing liability on the part of the original manufacturer even for equipment that might still normally be within the manufacturer's warranty period. Any liability for claims arising from subsequent malfunctioning or harm to patients and/or users would therefore pass to the owners of the equipment.

Disclaimer

This ESGE Guidelines Committee publication is intended to provide general support and guidance to ESGE members. It is recommended that specific aspects regarding liability issues and contractual structures should be checked and adjusted according to local practices, with the help of user organizations' in-house lawyers or other professional advisors.

(N.B. The information contained in this document is not intended for use to support any legal claim or possible court action and should not be used for such purposes.)