

## ESGE Newsletter

### Definition of “endoscope families” as used in EN ISO 15883-4

European Society of Gastrointestinal Endoscopy



Welcome to the February issue of the Endoscopy newsletter. This month it is given over to a technical matter – the categorization of different endoscope models. You will be aware of the international standard EN ISO 15883-4 that sets out the requirements and tests for washer-disinfectors for heat-sensitive endoscopes. This standard groups endoscopes into different generic “families,” and this grouping will also be used in future standardization and guidelines. However the “endoscope families” are not defined and therefore ESGE and ESGENA (European Society of Gastroenterology and Endoscopy Nurses and Associates) are providing a definition here.

#### 1. Background

The performance of washer-disinfectors (WD) is specified in the international standard series EN ISO 15833 parts 1 and 4 [1,2], and the ESGE – ESGENA “Guideline for process validation and routine testing for endoscope reprocessing” emphasizes the need for validating the whole reprocessing cycle [3].

National authorities for hygiene and infection control are responsible for incorporating EN ISO 15883 into their national regulations, and in Germany, a multidisciplinary working group was established to develop a national guideline for implementation of EN ISO 15883. In the course of their task, the working group realized that the term “endoscope families” is used without definition in various chapters of EN ISO 15883-4, in relation to testing the efficacy of the cleaning and disinfection process for flexible endoscopes using endoscope washer-disinfectors (EWD). According to EN ISO 15883, “type testing” and “validation” can be carried out by selecting representatives for each specific endoscope family. (“Type testing” is defined as a test program to verify conformity of the WD type to the standard and to establish data for reference in subsequent tests. “Validation” is defined to be “a documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield products complying with predetermined specifications”; in this case the “products” are appropriately cleaned and disinfected endoscopes.)

It was necessary to define the term “endoscope families” as there was no universal,

manufacturer-independent definition that was available worldwide.

#### 2. Aim and method

A subgroup tasked with definition of the term “endoscope families” was set up within the German working group responsible for developing the national validation guideline for EWD [4]. The subgroup included representatives of the endoscope manufacturers and the national endoscopy nurses society (i.e., there were representatives from the German Society of Hospital Hygiene [DGKH], German Society of Gastroenterology [DGVS], German Society of Endoscopy Nurses and Associates [DEGEA], German Society of Sterile Supply [DGSV], Working Group Instrument Preparation [AKI] – Coordinator for manufacturers of flexible endoscopes, EWD, process chemicals).

The classification criteria for endoscope families were based on the significant characteristics of endoscopes, including the number, construction, and purpose of the different endoscope channels and their clinical applications.

The scope of the definition of “endoscope family” includes commercially available heat-sensitive endoscopes. Endoscopes which cannot be categorized into one of the families require an individual assessment.

### 3. Classification of endoscope families

Three different endoscope families have been identified.

#### 3.1. Group 1

This comprises endoscopes:

- ▶ with air/water channels
- ▶ with instrument/suction channel
- ▶ with/without additional instrument channel
- ▶ with/without waterjet channel

Endoscopes belonging to this group are typically intended for use in the gastrointestinal (GI) tract. Main representatives for this group are gastroscopes and colonoscopes. Duodenoscopes with an encapsulated elevator wire also belong to this group.

#### 3.2. Group 2

This comprises endoscopes:

- ▶ with air/water channels
- ▶ with instrument/suction channel
- ▶ with/without additional instrument channel
- ▶ with/without elevator wire channel
- ▶ with up to two control channels for balloon functions

Group 2 mainly comprises models intended for use in the GI tract. They are equipped with a so-called elevator wire channel and/or control channels, the latter designed to fill and deflate balloons as components of the endoscope. Examples for these endoscopes are duodenoscopes with open elevator channel, endoscopes for endoscopic ultrasound (EUS) and enteroscopes.

#### 3.3. Group 3

This comprises endoscopes:

- ▶ with up to two instrument channels, but without a channel system in the ‘umbilical cord’ (where the ‘umbilical cord’ refers to the connection between the light source and the head of the endoscope)
- ▶ or
- ▶ without any channel within the entire endoscope

Group 3 comprises models with only one channel system for biopsy, irrigation and suction or models without any channel. They are used in bronchoscopy, ear-nose-throat (ENT; otorhinolaryngology) applications, gynecology and urology.

#### 4. Conclusion

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The classification of endoscopes into “endoscope families” is an important contribution towards effective processing of different types of endoscopes in EWD. Close cooperation between the manufacturers of endoscopes and EWD is essential. Categorizing endoscopes into families supports the EWD manufacturer during type testing, as uniform recommendations allow comparability of data and more transparency for users. Such a categorization also supports the clinical service provider: users can classify their endoscopes according to the most significant characteristics. By selecting representatives for each specific endoscope family, validation and microbiological surveillance tests can provide comparable data; the workload will be reduced as endoscopes with similar channel construction can be clustered into one group. The new definitions will also be used in future international and national guidelines and standards. The definitions of endoscope families are currently incorporated into the updated version of the EN ISO 15883-4. The validity of the definitions will be proven by their implementation in daily use and by relevant studies.

**Competing interests:** None.

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