

# g-Type Statistical Quality Control Charts for Monitoring and Evaluating Reprocessing of Flexible Endoscopes

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## Objectives

In our Quality control (QC) program and in the international literature, infection has been related to high-risk flexible endoscopes (FE) with proliferation of micro organisms in the channels.

A Number-Between g-Type Statistical Control Chart and associated statistical methods had been used to evaluate and monitoring Cold-chemical (CCR) and Thermo-chemical (TCR) reprocessing of FE with the purpose of identifying High-risk FE.

### Definitions for the Quality Control Program Bacteria from flush water from the water channel of flexible endoscopes

Clean FE	Critical FE	High-risk FE
0-4 CFU per 0.2 ml	5-50 CFU per 0.2 ml	>50 CFU per 0.2 ml

## Methods

**Recommendations:** Sterile FE bottles with sterile water- Manual cleaning of FE with an enzymatic detergent — Brushing - Alcohol flushing before storage.

### CCR: Fibro Cleaner Washer-disinfectors (WD)

2% glutaraldehyde (GA) for 10 min in rum temperature, filtered rinse water, self disinfection with hydrogen peroxide. (Lancer, France)

### TCR: ETD and ETD 2(+)- WD

Thermal disinfection with a mixture of heat and a detergent. Chemical disinfection with 0,24% GA or a GA free disinfectant between 59 and 60 °C. (Olympus, Europe)

**QC sampling:** Microbial counts from flush water from the water channel of FE obtained immediately before an endoscopy are used as checkpoint.

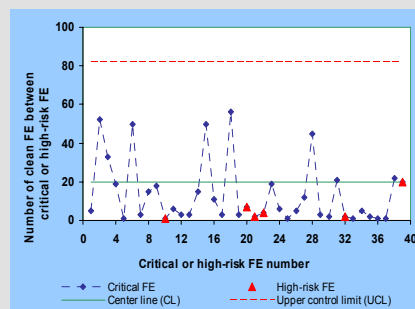
### g-Control Charts

- X-axis** represents the consecutive number of identified critical or high-risk FE.
- Y-axis** represents the number of clean FE between critical or high-risk FE.
- CL** (the centre line) illustrates the central tendency of the y-axis values.
- UCL** (the upper control limit) is  $CL + 3 \times \text{standard deviation}$ . (the lower control limit is zero).

### Criteria for lack of statistical control

- Control values outside the UCL.
- Eight consecutive values on the same side of the CL.
- Any 12 of 14 consecutive control values on the same side of the CL.
- Eight consecutive values exhibiting either an increasing or decreasing trend.

(Infect Control Hosp Epidemiol 1998;19: 265-283)



**Figure 1: g-Control Chart.** 529 QC samples from the water channel of FE. The control chart shows a statistical out of control cold-chemical reprocessing of FE with high-risk FE.

**Table 1:** Evaluating of and 7458 QC samples from the water channel of FE after different reprocessing procedures. **CL** is the centerline in a g-Control Chart (Figure 1). **GA**=Glutaraldehyde.

Procedure	CL	High-risk FE	Infections
<b>Manual cleaning</b> (No proliferation of micro organisms in FE)	20		
<b>Olympus EW10</b> (CCR - Data from 1985)	2	+	+
<b>Fibro cleaner</b> (CCR)	12	+	+
<b>Fibro cleaner</b> (Procedure optimized)	20	-	-
<b>ETD 2+</b> TCR - Original products	46	-	-
<b>ETD</b> GA + Detergent 2	12	+	+
<b>ETD</b> GA + Detergent 3	>46	-	-
<b>ETD 2+</b> GA-free + Detergent 4	>140	-	-

## Results

2181 CCR and 5277 TCR Qc-samples were evaluated. Table 1 presents a summary of the results and figure 1 shows QC samples from a CCR of FE out of control.

### General

- High-risk FE were only detected in FE reprocessing out of control using the g-Control Chart for manual cleaning (Figure 1).
- High-risk FE were related to proliferation of micro organisms over night in FE channels and insufficient manual cleaning.
- Alcohol flush of FE channels prevented proliferation of gram negative rods but not of Staphylococci.

### Cold chemical reprocessing

- CL in the g-Control Chart for the manual cleaning (table 1) seemed to be the upper limit for CL in CCR.
- Outliers above UCL were correlated to FE with residuals of GA.

### Thermo chemical reprocessing

- The combination of heat and detergent killed thermo sensitive micro organisms
  - ⇒ After proliferation of micro organisms in FE channels.
  - ⇒ After insufficient manual cleaning.
- Temperatures below 59 °C and chose of detergent were critically.

[www.clean-endoscope.com](http://www.clean-endoscope.com)

## Conclusion

- Only reprocessing of FE with thermo-chemical disinfection with a process temperature between 59 and 60 °C with a suitable detergent could prevent high-risk FE.
- The g-Control Chart was found to be a valuable statistical tool to identify out of control procedures for reprocessing FE with occurrence of high-risk FE.