

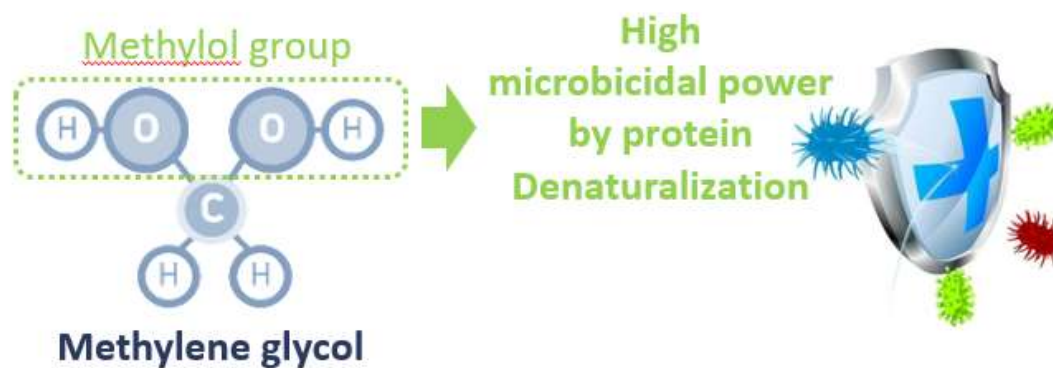
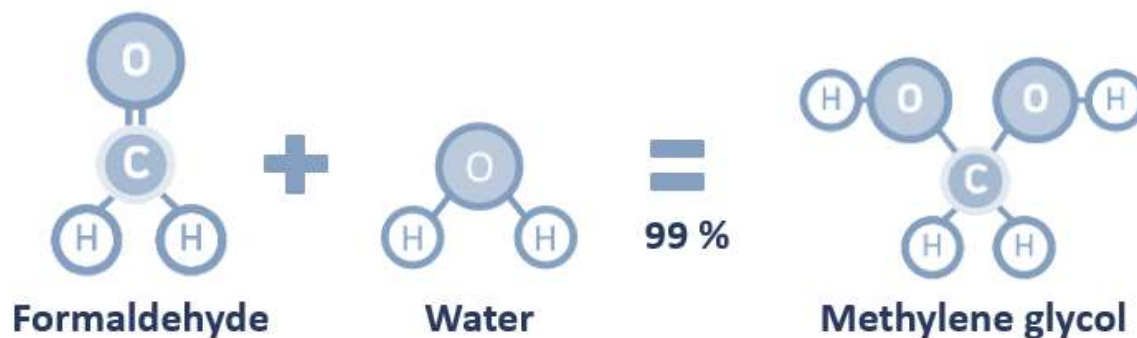


LOW TEMPERATURE STEAM FORMALDEHYDE STERILIZATION

Nathan Ronsse

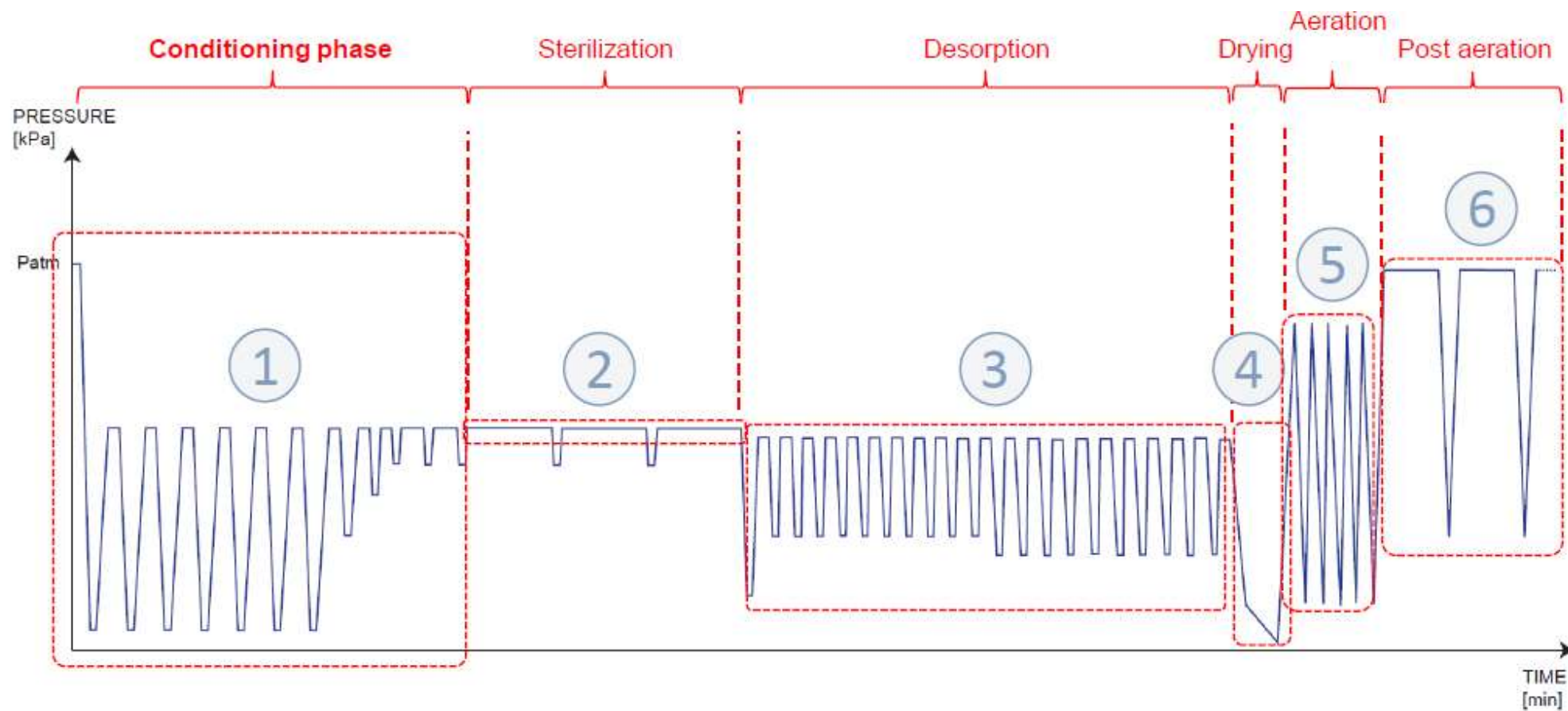
- Introduction: the technology explained
- Guidelines & quality control
- Comparison with hydrogen peroxide sterilization
- Case study in Belgium
 - Cycle times & cycle cost
 - Performance
 - Satisfaction survey
- Conclusion

LTSF TECHNOLOGY



Source: Matachana

LTSF TECHNOLOGY



Source: Matachana

GUIDELINES & QUALITY CONTROL

Safety

DIRECTIVE (EU) 2019/983 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 5 June 2019
amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to
carcinogens or mutagens at work

User safety

Patient safety

DIN EN 14180

Sterilizers for medical purposes - Low temperature steam and
formaldehyde sterilizers - Requirements and testing

GUIDELINES & QUALITY CONTROL / COMPARISON WITH H₂O₂

TECHNOLOGY	STEAM STERILIZATION (AUTOCLAVE)	LOW TEMPERATURE STEAM FORMALDEHYDE	HYDROGEN PEROXIDE
Sterilizer requirements	EN 285	EN 14180	PrEN 17180
Validation & monitoring	ISO 17665	ISO 25424	Future ISO 22441


Parametric release

BI's for release

ISO 14937

COMPARISON WITH H₂O₂ STERILIZATION


Lumen claims (penetrability)

Technology	LTSF		H ₂ O ₂ (average values)
Plastic lumens	Diameter: min. 0,5mm Length: max. 3000mm	Diameter: min. 1mm Length: max. 4000mm	Diameter: min. 1mm Length: max. 990mm
Steel lumens	Diameter: min. 0,5mm Length: max. 500mm	Diameter: min. 0,7mm Length: max. 2000mm	Diameter: min. 0,7mm Length: max. 500mm



COMPARISON WITH H₂O₂ STERILIZATION

Other differences

- Cycle time
 - Cycle cost
 - ...
- 
- Part of the case study
- Installation: an LTSF device needs a water connection and a drain
 - *Built-in water softener for osmosis water?*
 - *0,2µm bacterial filter present*
 - Sterilization technology:
 - Sulfur bridges in DNA ⇔ disruptive on M.O. Membranes
 - ...

CASE STUDY IN BELGIUM

Part 1: UZ Gent (1049 beds)

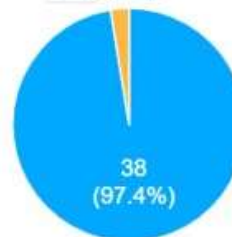
- April 2022 – May 2022
- Extensive validation by German company
- 13 test users
- 72 test cycles
- Focus on testing with Da Vinci medical devices



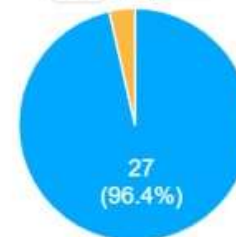
VT (2) VACUUM...



60°C (69) 60°C



78°C (79) 78°C



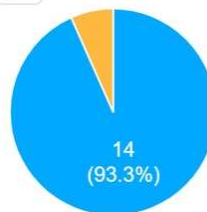
CASE STUDY IN BELGIUM



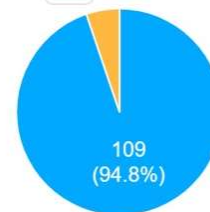
Part 2: UZ Leuven (1950 beds)

- July 2022 – October 2022
- Validation by Belgian company
- 11 test users
- 184 test cycles
- Focus on testing endoscopes

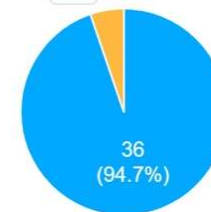
VT (2) VACUUM TEST



60°C (69) 60°C

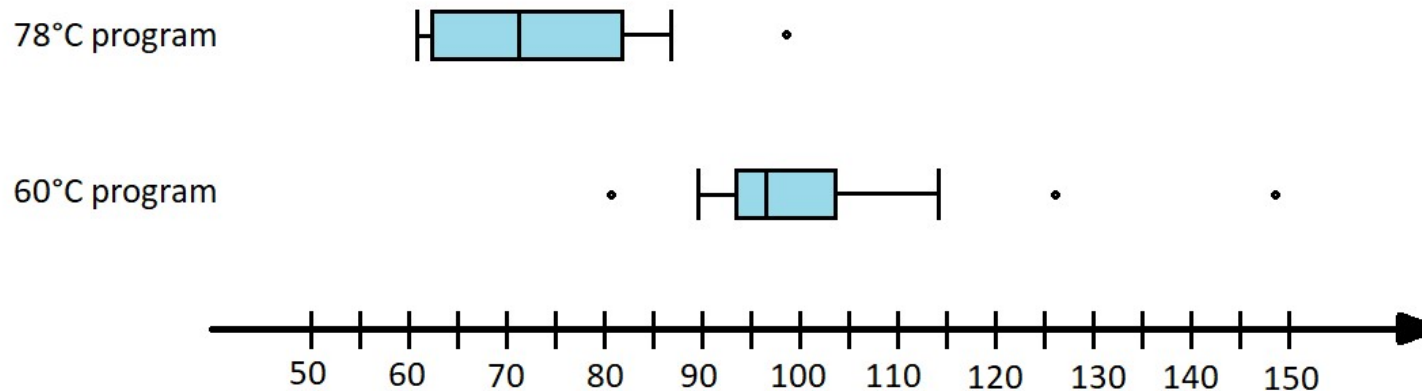


78°C (79) 78°C



CASE STUDY IN BELGIUM: RESULTS

Cycle time



H2O2 technology:

- Lumen cycle ($\approx 78^{\circ}\text{C}$): av. 55 minutes
- Flexible cycle ($\approx 60^{\circ}\text{C}$): av. 35 minutes

→ Other lumens...

CASE STUDY IN BELGIUM: RESULTS

Cycle cost (prices in Belgium – jan. 2022)

Technology	LTSF	H ₂ O ₂	Autoclave
Electricity	Av. € 0,25	Av. € 0,25	Av. € 1,50
Water	Av. € 0,90	€ 0,00	Av. € 1,00
Sterilant	Av. € 4,50	Av. € 12,00	€ 0,00
Total	Av. € 5,65	Av. € 12,25	Av. € 2,50

Other influences:

- Monitoring: biological indicators?
- Tyveck ⇔ Polypropylene

CASE STUDY IN BELGIUM: RESULTS

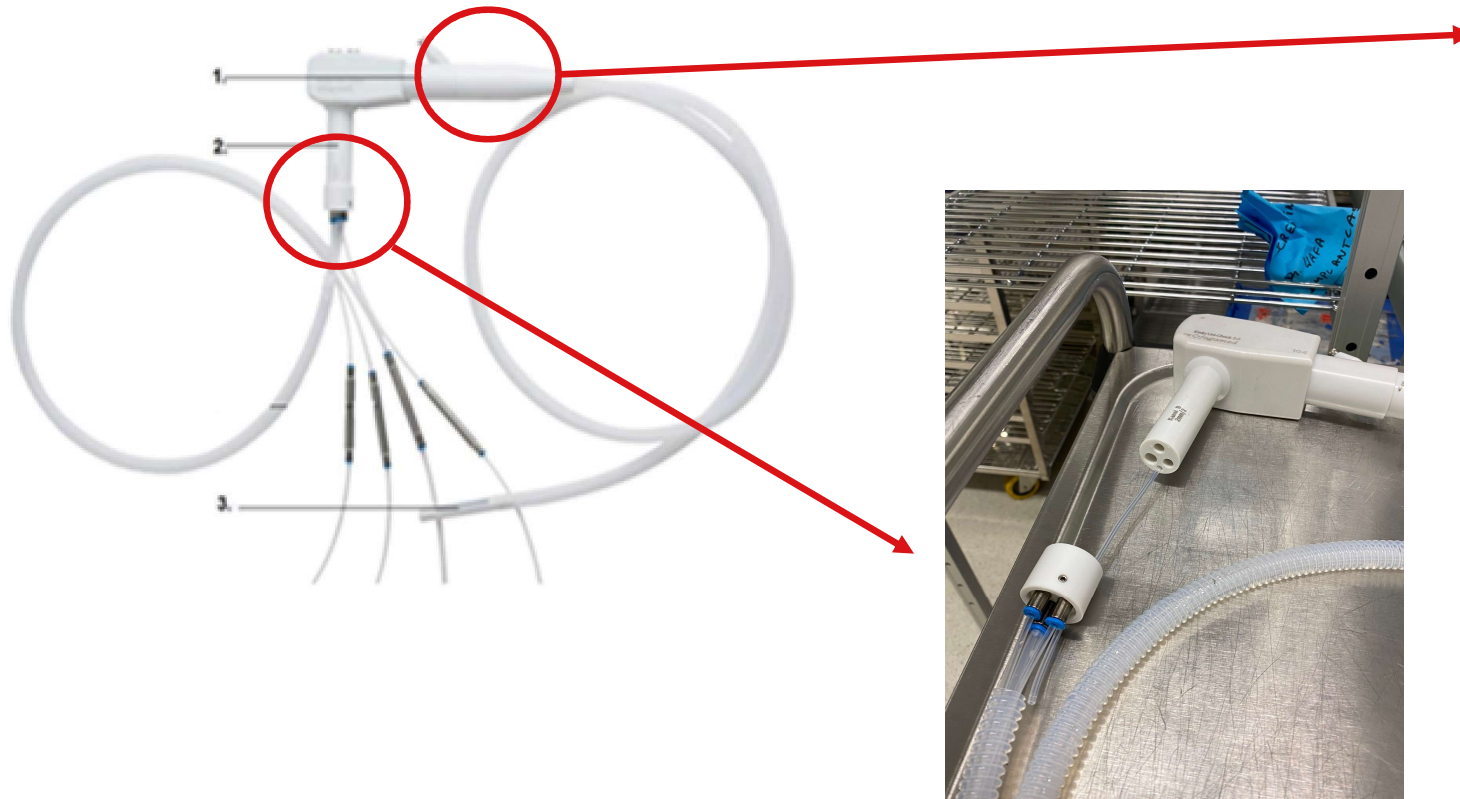
Biological testing of a worst-case lumen

BIOLOGICAL INDICATOR						
Format: SCBI, Strip, Disc, Self-contained						
Manufacturer	GKE	LOT NUMBER	EXPIRY DATE	POPULATION	D _{60°C} value	F _{Bio60°C} value
Art. Number	223-998	508 2047	01-2023	1,7 x 10 ⁶ cfu/carrier	12,6 min.	78,5 min.
Matachana code	85027					



CASE STUDY IN BELGIUM: RESULTS

Biological testing of a worst-case lumen



CASE STUDY IN BELGIUM: RESULTS

Biological testing of a worst-case lumen



CASE STUDY IN BELGIUM: RESULTS

Biological testing of a worst-case lumen

RESULTS	
Controls	Results
Positive control 1 (batch 508 2047)	Positive growth
Positive control 2 (batch 508 2047)	Positive growth
Negative control	Negative growth

Program	Bioindicator	
T1 Cycle 170	Bioindicator P1	Negative growth
	Bioindicator P2	Negative growth
	Bioindicator P3	Negative growth
	Bioindicator P4	Negative growth
	Bioindicator P5	Negative growth
	Bioindicator P6	Negative growth

Program	Bioindicator	
T2 Cycle 171	Bioindicator P1	Negative growth
	Bioindicator P2	Negative growth
	Bioindicator P3	Negative growth
	Bioindicator P4	Negative growth
	Bioindicator P5	Negative growth
	Bioindicator P6	Negative growth

Program	Bioindicator	
T3 Cycle 172	Bioindicator P1	Negative growth
	Bioindicator P2	Negative growth
	Bioindicator P3	Negative growth
	Bioindicator P4	Negative growth
	Bioindicator P5	Negative growth
	Bioindicator P6	Negative growth

CASE STUDY IN BELGIUM: RESULTS

Other tests

- Biological indicators
- Helix test: PCD with T2 chemical indicators
- Heavy load tests
- Worst-case desorption testing
- ...

Auswertung

Indikator-Nr.	1	2	3	4	5	6	7	8	9	10	11
Befund	-	-	-	-	-	-	-	-	-	-	

Indikator-Nr.	12	13	14	15	16	17	18	19	20	Kontrolle
Befund										+

- kein Wachstum des Testkeims/steril

+ Wachstum des Testkeims/unsteril

Ergebnisse:

Nr.	Probe	Parameter	Prüfverfahren	Einheit	Messwert	Bem.
473	Blind	Formaldehyd	EBL-UL01 2012-03	µg	<1	
475	Probe 2	Formaldehyd	EBL-UL01 2012-03	µg	147	
478	Probe 5	Formaldehyd	EBL-UL01 2012-03	µg	250	

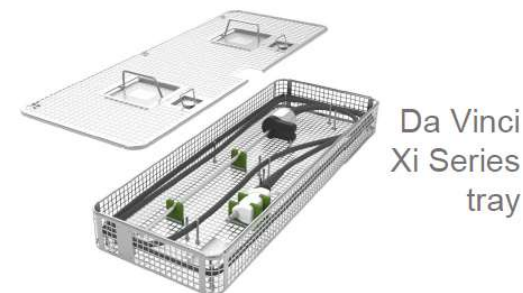
CASE STUDY IN BELGIUM: RESULTS

Satisfaction survey

EASE OF USE (scale 0-5)

Loading height	4,1
Placing trays / containers in the sterilizer	2,5
Removing trays / containers from the sterilizer	2,8
Determining the right program to use	3,8
Starting a cycle	3,6
Stopping a cycle	3,3
Placing the sterilizer in stand-by mode	3,2
Determining the sterilizer's operating status	4,9
Determining visually that the cycle has started	3,8
Determining visually that the cycle has ended	3,7
Determining audibly that the cycle has ended	3,6
Operating the sterilizer with the touchscreen	4,1
Replacing the bag with sterilization solution	2,2
Finding a cycle report in the internal memory	4,5

Differences with
H₂O₂ sterilization
chamber: depth



Sometimes bag
was rejected

CASE STUDY IN BELGIUM: RESULTS

Satisfaction survey

FUNCTIONING (scale 0-5)

The different sterilization program choices	3,9
The options how the sterilizer can be loaded with shelves and trays	3,2
Opening / closing of the door	3,8
Shelve life of e-bag	4,5

CAPACITY (scale 0-5)

The number of endoscopes that might be sterilized	3,5
The number of instruments that might be sterilized	4,1
The number of packs that might be sterilized	4,2

CASE STUDY IN BELGIUM: RESULTS

Satisfaction survey

ADDITIONAL COMMENTS:

- (+) Good ergonomic features if enough custom baskets are present
- (+) Monitoring with helix tests is easy and performant
- (+) Installation requirements made easier thanks to the addition of water softener and bacterial filter
- (+) Load is always dry after cycle (even 18kg)

- (0) Development of water saving options

- (-) Time needed when switching between programs

CONCLUSION

SWOT analysis

Strengths:

- Penetrability
- Cycle cost
- ...

Weakness:

- Cycle time

CSSD: combination of LTSP and H₂O₂
AER units: investments?

Opportunities:

- Sterilization of endoscopes (criticality of medical device?)
- Reduction of operational costs creates room for other investments

Threat:

- Less present in IFU's

On the rise...

#	Model name	Description	Sterilization efficacy	Material Compatibility	IFU that stating 130LF issued
1	ED-3490TK	Duodenoscope	Complete	Complete	Complete
2	ED34-i10T	Duodenoscope	Complete	Complete	Complete
3	ED34-i10T2	Duodenoscope	Complete	Complete	Complete
4	EG34-i10	Gastroscope	Complete	Complete	Complete
5	EC34-i10TL	Colonoscope	Complete	Complete	Complete
6	EC34-i10TF	Colonoscope	Complete	Complete	Complete
7	EC34-i10TM	Colonoscope	Complete	Complete	Complete
8	EG29-i10c	Gastroscope	Complete	Complete	Complete
9	EC34-i10cL	Colonoscope	Complete	Complete	Complete
10	EC34-i10cF	Colonoscope	Complete	Complete	Complete
11	EC34-i10cM	Colonoscope	Complete	Complete	Complete
12	EC38-i10cL	Colonoscope	Complete	Complete	Complete
13	EC38-i10cF	Colonoscope	Complete	Complete	Complete
14	EC38-i10cF2	Colonoscope	Complete	Complete	Complete
15	EC38-i10cM	Colonoscope	Complete	Complete	Complete
16	EG34-J10U	Ultrasound upper GI scope	Complete	Complete	Complete
17	EG36-J10UR	Ultrasound upper GI scope	Complete	Complete	Complete
18	EG36-J10UT	Ultrasound upper GI scope	Complete	Complete	Complete
19	EG17-J10	Upper GI scope	Complete	Complete	Complete
20	EE17-J10	Esophagoscope	Complete	Complete	Complete
21	EC34-i10NL	Colonoscope	Complete	Complete	Complete
22	EC34-i10NF	Colonoscope	Complete	Complete	Complete
23	ED32-i10	Duodenoscope	Complete	Complete	Complete

Instructions for use
**PENTAX Medical Video Duodenoscope
ED34-i10T2**

CONCLUSION

Just as everything else in a CSSD...

... use it in a smart way!