

# COMPARISON OF DIFFERENT LOW TEMPERATURE STERILIZATION METHODS USER'S PERSPECTIVE

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**November 1st. 2018**

# PREAMBLE

I declare that I have no conflict of interest in this presentation.

The quantified data transmitted corresponds to daily practice, as part of a feedback experience.

They may be open to discussion based on contractual supplier customer commitments for each participant at that conference, and in each country represented.

**Thanks to :**

**Alberto Moura, Getinge**

**Bradley J. Catalone, TSO<sub>3</sub>**

**Lara Besseghini, its-jnj**

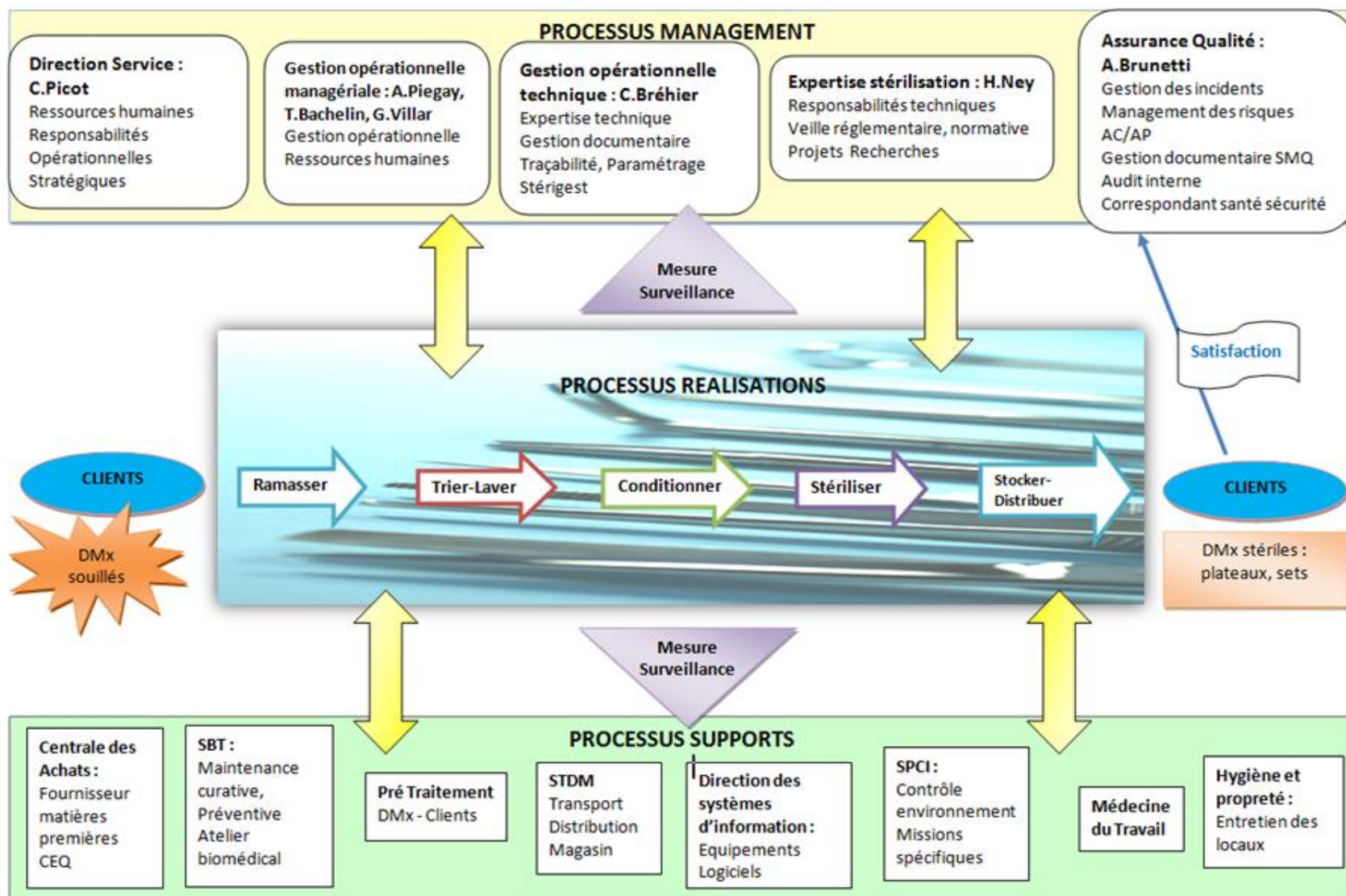
**José De Sousa Pinto, Laboratoires Anios**

**Bernadette Almagro, Steris**

**Brisia Lòpes Ortega, Steris**

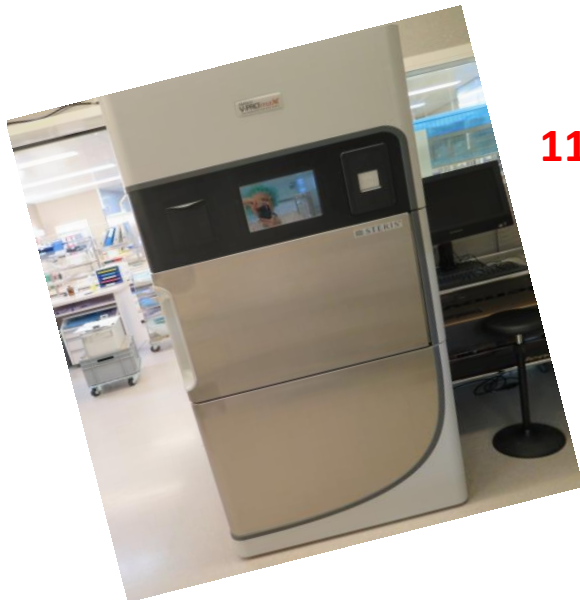
# THE CSSD TO THE HUG

- ▶ 70 employees // 24/7
- ▶ 4 washer-disinfectors tunnels
- ▶ 2 washer-disinfectors
- ▶ 2 washing tunnels for transport trolley
- ▶ 1 for reusable medical devices
- ▶ 5 moist heat autoclaves : 70 sterilization units
- ▶ 2 EO sterilizers
- ▶ 1 sterrad™ 100NX : sterilization with H<sub>2</sub>O<sub>2</sub> and phase plasma
- ▶ 1 VPRO Max : sterilization with H<sub>2</sub>O<sub>2</sub>
- 30 m<sup>3</sup> sterilized per day (saturated steam 95%)
- 1.4 million packets produced per year
- Specific activity for operating theatres : all surgical specialties
- ▶ SN EN ISO 13485 since 2005



# AGENDA

- ▶ User reviews
- ▶ Technical point of vue
- ▶ Parametric release
- ▶ Biological Indicators
- ▶ Cost Analysis
- ▶ Prospect



11/2016-?



2000-2010



1995-2015



2015 - ?



08/2010-2019



# USER REVIEWS

| Criterion                                     | Sterrad 100 NX (2010) | VPro Max (2016) |
|---|-----------------------|-----------------|
| Easy to use                                   | -                     | +               |
| Intuitive screen                              | +/-                   | +               |
| Reminder messages before starting a cycle     | +                     | +               |
| Vizualisation of the level of sterilant agent | -                     | +               |
| Size of the load                              | -                     | +               |
| Easy interpretation of cyle parameters        | -                     | +/-             |
| Reliability - breakdowns                      | -                     | +               |

# TECHNICAL POINT OF VUE

| Critère   | Sterrad 100 NX (2010) | VPro Max (2016) |
|---|-----------------------|-----------------|
| Parametric release  | +                     | +/-             |
| H <sub>2</sub> O <sub>2</sub> reduction at the end of the cycle | +/-                   | +               |
| Effectiveness to inactivate the prion (< french PSP 2018)       | +                     | +/-             |
| Failures  | -                     | +               |
| Ability to use SBS from different brands                        | -                     | +               |
| Experience  | +                     | +/-             |
| Corporate strategy in Switzerland                               | -                     | -               |



CUVÉ VIDE

CYCLE  
RAPIDE  
EXPRESS

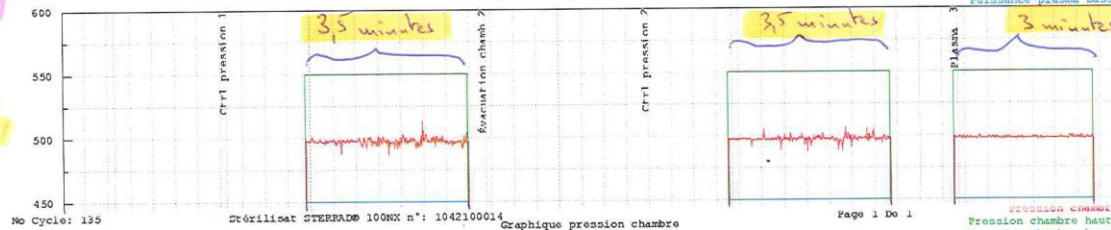
No Cycle: 135

Stérilisateur STERIPAD 100NX n°: 1042100014

Graphique de puissance du plasma

Page 1 De 1

Puissance plasma haute  
Puissance plasma basse



Puissance Plasma  
Maxi 550 Watts  
Mini 450 Watts  
Cible 500 Watts

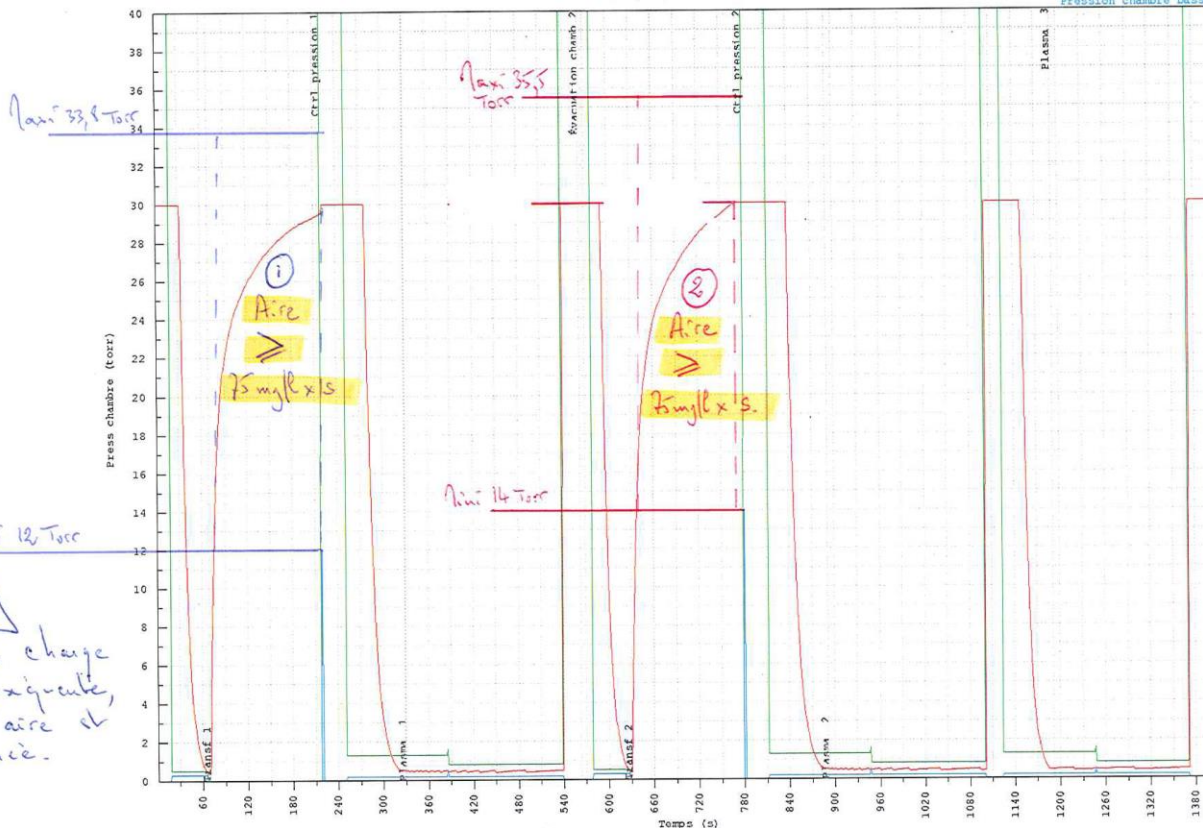
No Cycle: 135

Stérilisateur STERIPAD 100NX n°: 1042100014

Graphique pression chambre

Page 1 De 1

Pression chambre haute  
Pression chambre basse



Maxi 33.5 Torr

Maxi 33.5 Torr

Mini 14 Torr

Mini 12 Torr

Plus la charge  
est conséquente,  
plus l'aire est  
diminuée.

10247102A1

HUG Genève

Sterilisation

9

1042100014

135

3

Sans objet

Néant

Néant

Rapide

09/08/2011

14:22:13

09/08/2011

14:45:46

00:23:33

① 1648.3 mg-s/l

② 1506.7 mg-s/l

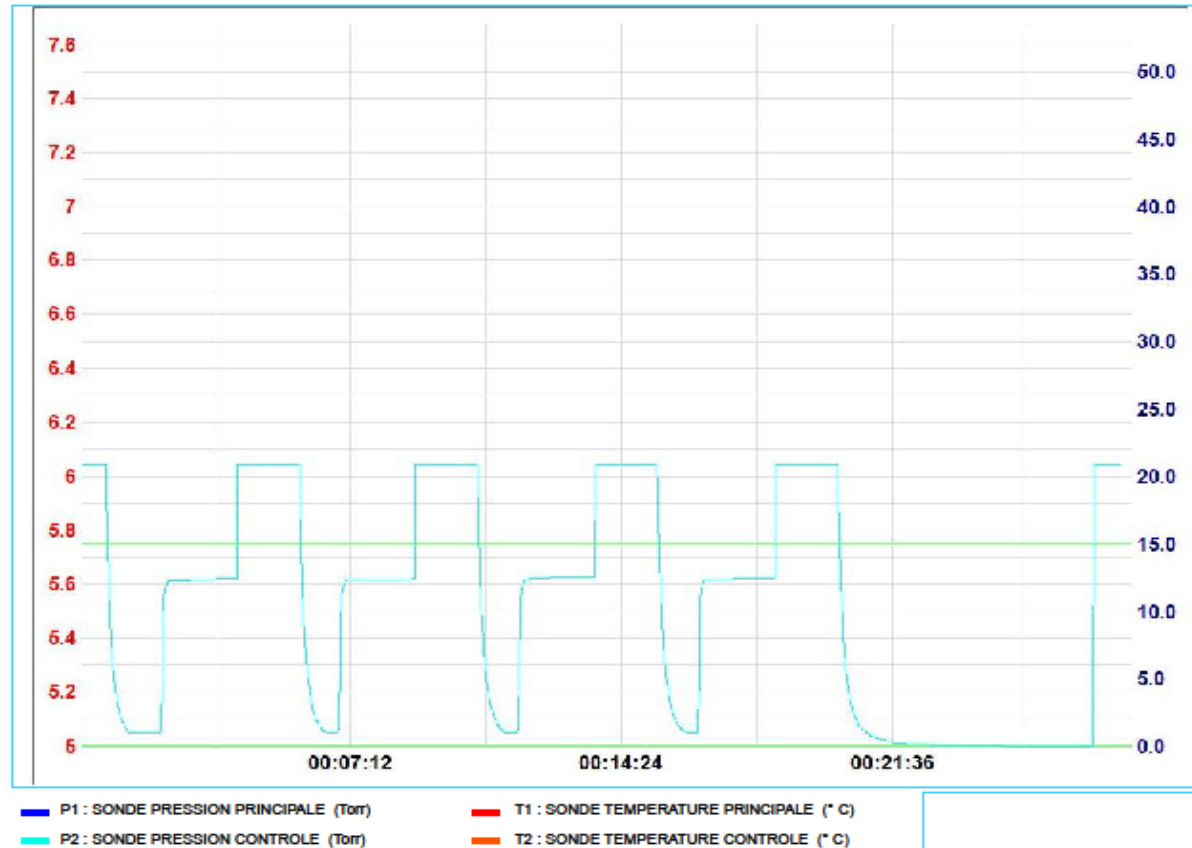
Réussi

30.08.2011

H. J. J.  
Hervé Jey  
Responsable  
Ster. centrale - HUG  
Tél. 022 372 76 61



Hôpitaux  
Universitaires  
Genève



|                        |                       |
|------------------------|-----------------------|
| Appareil               | VPRMAXX               |
| Type cycle             | SANS LUMIERE          |
| N° cycle               | 45                    |
| Début                  | 07/01/2015 à 13:32:56 |
| Tps de conditionnement | 00:01:51              |
| Tps de stérilisation   | 00:18:00              |
| Phase aération         | 00:06:43              |
| TOTAL                  | 00:27:34              |
| Fin                    | 07/01/2015 à 14:00:37 |
| Durée                  | 00:27:41              |

|            | T°         | Pres | T°          | Pres |
|------------|------------|------|-------------|------|
| Injections | pre Injec. |      | post Injec. |      |
| 1          | 50.3       | 1.0  | 49.7        | 12.5 |
| 2          | 50.6       | 1.0  | 50.3        | 12.5 |
| 3          | 49.7       | 1.0  | 50.8        | 12.6 |
| 4          | 50.7       | 1.0  | 49.8        | 12.5 |

|                   |          |
|-------------------|----------|
| Temp. réf. Min    | 48.50 °C |
| Temp. réf. Max    | 51.50 °C |
| Pression réf. Min | 0        |
| Pression réf. Max | 15       |

|                  |            |
|------------------|------------|
| Cartouche lot N° | HC1844W8   |
| Date péremption  | 03/07/2015 |

|            |                       |
|------------|-----------------------|
| Conformité | CONFORME              |
| Validation | VALIDE                |
| Date       | 07/01/2015 à 16:22:34 |
| Opérateur  | CBR                   |

# PARAMETRIC RELEASE

- ▶ SN EN ISO 14937 (Half cycle method)
- ▶ Pr EN 17180 (12/2017)
- ▶ Qualification of the machine AND the Independent Monitoring System

## Prévention de la maladie de Creutzfeldt Jakob et retraitement des dispositifs médicaux: état des connaissances scientifiques actuelles et recommandations pour la Suisse

2017 / 01

Frédéric Cavin\*, Centre Hospitalier Universitaire Vaudois; Hervé Ney, Hôpitaux Universitaires de Genève

|  |        |   |
|--|--------|---|
| PROLYSTICA 100<br>PID Prion<br>Inactivating<br>Detergent | STERIS | Immersion (bain thermostaté), laveur-<br>désinfecteur, tunnel de lavage / 0,8% /<br>43°C / 7,5 min                                |
| PROLYSTICA 2X<br>+ cycle non lumen<br>du VPRO 1          | STERIS | <ul style="list-style-type: none"> <li>PROLYSTICA 2X: immersion / 0,4% / 65°C / 5 min</li> <li>VPRO 1: cycle non lumen</li> </ul> |

Swissnoso Bulletin, 2017 / 01

Prévention de la maladie de Creutzfeldt Jakob et retraitement des dispositifs médicaux

3/4

|                 |                                       |  |
|-----------------|---------------------------------------|--|
| STERRAD® NX™    | Advanced Sterilization Products (ASP) | <ul style="list-style-type: none"> <li>Cycle avancé</li> </ul>                       |
| STERRAD® 100NX™ | Advanced Sterilization Products (ASP) | <ul style="list-style-type: none"> <li>Cycle Standard</li> <li>Cycle Flex</li> </ul> |

[http://ansm.sante.fr/var/ansm\\_site/storage/original/application/e44cbf8dd10218ea221e0a6607729dc1.pdf](http://ansm.sante.fr/var/ansm_site/storage/original/application/e44cbf8dd10218ea221e0a6607729dc1.pdf)



# COST ANALYSIS (AMOUNTS IN CHF)

| Item?   | Sterrad 100 NX (2010)<br>Per Year / Per cycle (700) | Vpro Max (2016)<br>Per Year / Per cycle (700) |
|---|---|---|
| Economic depreciation<br>over 10 years:<br>Double door sterilizer<br>software +<br>IQ/OQ validation by<br>external body | <b>21 000 / 30</b>                                  | <b>13 500 / 19.30</b>                         |
| PQ  | Included in package maintenance<br>+ 1 PQ           | 4 000 / 5.70                                  |
| Maintenance<br>(2 x per year)   | 18 000 / 25.70                                      | 5 000 / 7.15                                  |
| Sterilant   | 18 900 / 27   | 9750 / 13.95                                  |
| Biological Indicator  | 4 000 / 5.70  | 3750 / 5.40                                   |
| Total   | 61 900 / <b>88.40</b>                               | 36 000 / <b>51.50</b>                         |

# COST ANALYSIS

- ▶ Negotiated prices
- ▶ Important impact of the investment
- ▶ Increasing the number of cycles will decrease the cost per cycle
- ▶ Without surprise, the annual costs of maintenance and validations are higher than the costs for steam sterilizers
- ▶ Low reprocessing cost must be compared to the price of some specific devices (Da Vinci Robotic)

# STERIZONE VP 4

2011 Optreoz company 3M

2012 Presentation of Optreoz JNSS by 3M

2012-2015 ... .Nothing moves ...

2015 Sterizone VP 4 AFS - WFHSS Lille

2016 Technical data following the WFHSS congress  
Brisbane

2017 Formal contacts for loan in 2018

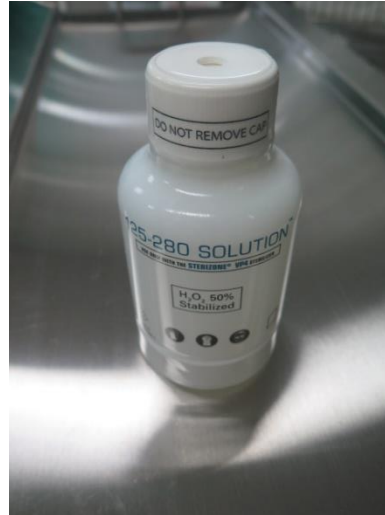
2017 Presentation of the concept to Prof. Pittet in  
Geneva

2018 Presentation during a training day SSSH french  
part speaking 2018 Getinge Exchange Forum

2018 Device ready for testing (April to July)



# STERIZONE VP 4

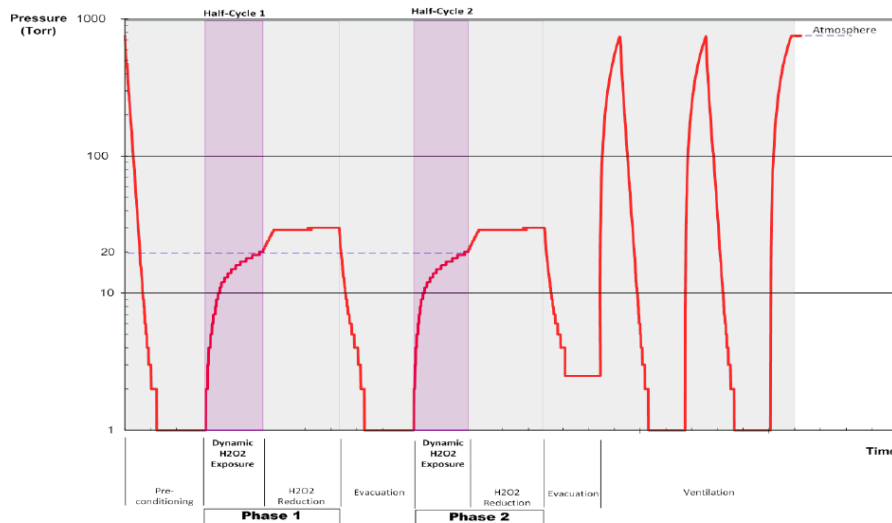


**STERIZONE® VP4  
RVP40217002**

**EMPTY CYCLE  
STERILIZATION NOT ACHIEVED**

DATE: 2018/04/23  
CYCLE NUMBER: 000027  
LOAD ID: 000000

CYCLE ID: 1  
CYCLE START: 08:19:05 hms



| STEP                         | PHASE | PARAMETER  |
|------------------------------|-------|--|
| Pre-conditioning             |       | Pressure: 0001 Torr<br>Duration: 00:05:41 hms                    |
| Dynamic H2O2 Exposure        | 1     | Pressure: 0020 Torr<br>Duration: 00:03:23 hms                    |
| H2O2 reduction -03 injection | 1     | Dose: 02.0 mg/L<br>Pressure: 0030 Torr<br>Duration: 00:00:56 hms |
| H2O2 reduction -03 dwell     | 1     | Duration: 00:05:02 hms   |
| Evacuation                   |       | Pressure: 0001 Torr<br>Duration: 00:14:04 hms                    |
| Dynamic H2O2 Exposure        | 2     | Pressure: 0020 Torr<br>Duration: 00:03:01 hms                    |
| H2O2 reduction -03 injection | 2     | Dose: 02.0 mg/L<br>Pressure: 0030 Torr<br>Duration: 00:00:56 hms |
| H2O2 reduction -03 dwell     | 2     | Duration: 00:05:02 hms   |
| Evacuation and Ventilation   |       | Duration: 00:20:44 hms   |

Door unlocked at: 09:18:02 hms  
Total cycle duration: 00:58:57 hms

OPERATOR I.D.: 0000

Name: \_\_\_\_\_

**CYCLE COMPLETED:** 09:18:02 hms

Cycle ID: 1

Cycle Number: 000027



# COST ANALYSIS (AMOUNTS IN CHF)

| What?  | Quantities per year | Quantities per cycle? <sup>(700)</sup> |
|--|---------------------|--|
| Economic depreciation over 10 years:<br>Double door sterilizer software +<br>QI/QO validation by external body | 18 000              | 25.70                                  |
| Performance Qualification  | ?                   | ?                                      |
| Maintenance  | ?                   | ?                                      |
| Sterilant  | 28 000              | 40.00                                  |
| Biological Indicator (+ PCD)   | 11 400              | 9.20 (16.20)                           |
| Total  | 57 400              | 74.90 (81.90)*                         |

*Electrical consumption,  $\text{o}_3$  and small accessories considered as negligible compared to other costs*

*PQ and maintenance should increase the cost of a cycle > of 100.00 CHF*

# STERIZONE VP 4 – USER REVIEWS

12/06/2018

- ▶ Easy to use +
  - ▶ Intuitive screen +/-
  - ▶ Reminder messages before starting a cycle ++
  - ▶ Visualization of the level of sterilant agent -
  - ▶ Size of the load ++
  - ▶ Easy interpretation of cycle parameters +
  - ▶ Reliability – breakdowns **not evaluated at this step**
- 
- ▶ If VP 4 is off : 1.5 hours before first cycle -

# NOT IN EUROPE ....AUGUST 1, 2018



## Press release

### Getinge and TSO3 ends exclusive distribution agreement on low temperature sterilization

Gothenburg, Sweden  
August 1, 2018

Getinge and TSO3 have mutually decided not to renew the exclusive distribution agreement between the two companies, which was initiated in 2015. The agreement ends on August 1, 2018. The impact on the income statement for 2018 is expected to be – 126,4 MSEK mainly related to write-off, and this will be reported as IAC (Items Affecting Comparability). The cash flow for the period will be positively impacted by 70,7 MSEK due to sell-back of inventory to TSO3.

Getinge and TSO3 entered into an agreement in 2015, where Getinge acquired exclusive global distribution rights to the STERIZONE VP4 Sterilizer. Due to an overall slower market development than expected both companies have jointly decided it would be equally beneficial not to continue with the current distribution set-up.

Getinge continues to believe in the future of low temperature sterilization technology and will primarily focus on the development of the company's own product, Stericool, offering a wide portfolio of sterilizers and a complete range of consumables for markets outside North America.

The Stericool sterilizers are Getinge's technologically advanced and affordable solution for low temperature sterilization. Stericool sterilizers employ patented technologies to deliver rapid and safe sterilization for delicate, heat-sensitive, and moisture-sensitive instruments.

Getinge and TSO3 will continue to maintain a collaborative working relationship in North America, which will enable Getinge to offer the Sterizone VP4 when low temperature sterilization is requested by a customer as part of total infection control solution.

#### Media contact:

Lars Mattsson, Head of Investor Relations  
Phone: +46 (0)10 335 0043  
E-mail: lars.mattsson@getinge.com

- ▶ Stop of tests
- ▶ Disappointment
- ▶ Europe will have to wait again
- ▶ Open market for the other two "historic" companies in Switzerland : ASP and Steris

# READY TO CHANGE ??



Montesquieu

- ▶ *It's the competition that puts a fair price on the goods and establishes the true relationship between them*

Prof Jean Pierre Claveranne IFROSS Lyon

- ▶ *The magic of numbers is the most elaborate form of lying*





# WHAT'S NEW COMPARED TO PREVIOUS VERSIONS ?

## **Sterrad 100 NX ALLclear**

Larger screen 31.75 cm x 25.4 cm +

Modified Cassette Management System ++

An optional conditioning cycle (5 min), which can detect moisture, dry and control residual moisture before the start of the cycle. (more cycle cancellations due to humidity, less sterilant used) +

A new Software (user interface) +

A modified spectrometer ***No opinion without testing***

ASP® compatible ACCESS™ and STERRAD® VELOCITY™ +/-

Captive system Studies on the french PSP 2018: **Work will begin**

# WHAT'S NEW COMPARED TO PREVIOUS VERSIONS ?

## VPRO MAX II

4 cycles (a fourth rapid cycle without light of 16 minutes). ½ dose so more cycles +

Opening the "hands-free" door with a pedal, while maintaining the possibility to open the door manually +/-

RFID reading of VAPROX sterilant cartridges (before QR code) for expiry date and number of cycles remaining +/-

New connectivity system compatible with the main traceability systems on the market +

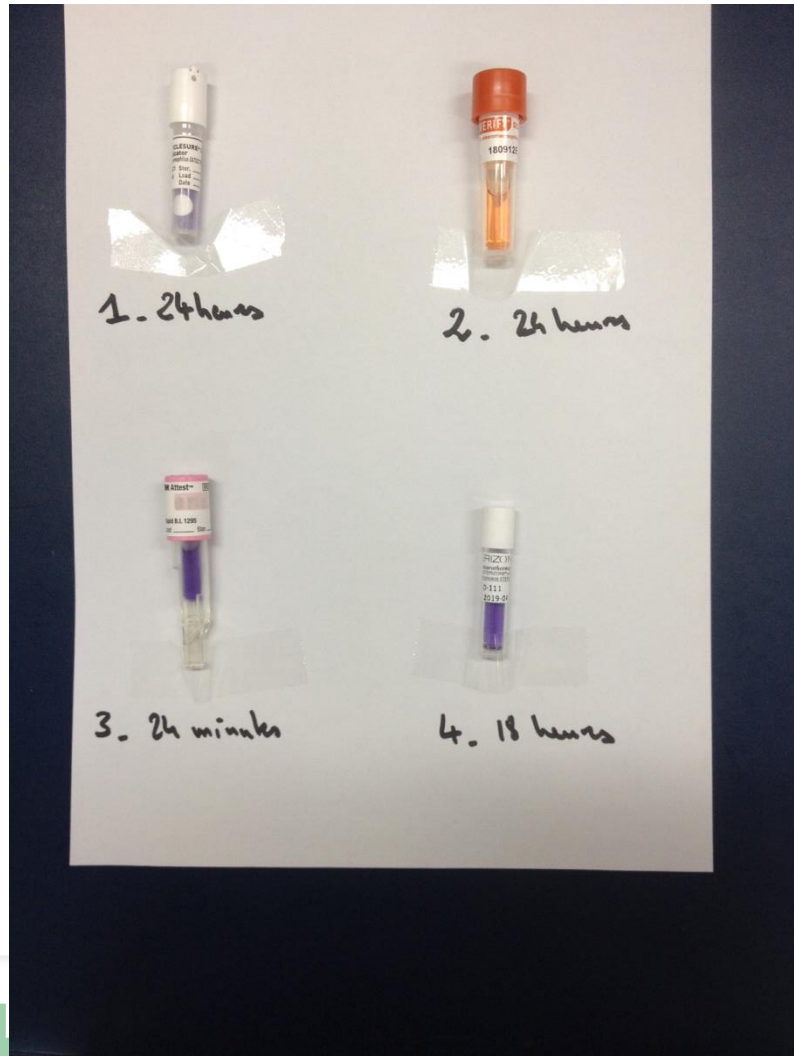
More user-friendly user interface with pictograms –

Studies on french PSP 2018: **Results in 2020**



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# BIOLOGICAL INDICATOR



- ▶ 1 = exclusive for 1 method
- ▶ 2 = for 2 methods
- ▶ 3 = for 2 methods and tested with Sterizone VP 4
- ▶ 4 = for 1 method ?

# THE ISSUE OF BIOLOGICAL INDICATORS

What meaning if used once a week?

Why not ?...only if it is rapid test

Reading time is not a determining factor: 20 or 30 minutes of incubation do not change anything "in real life"

To consider with a Process Test Device

Has an impact on the cost price of the cycle

To be used in addition to the parametric release, depending on the load



# I HAD A DREAM...

- ▶ Complies with pr EN 17180
- ▶ One cycle for all types of loads
- ▶ Easy to use
- ▶ Biological indicator with rapid reading
- ▶ Parametric release
- ▶ Sufficient room size
- ▶ Compatible with different SBS manufacturers
- ▶ Inactivating the infectious nature of the prion protein
- ▶ A reasonable purchase price
- ▶ Value-Added Marketing of the product, not systematic comparison with the competition
- ▶ A comprehensible business policy for customers: loyalty, continuity
- ▶ The formalization of a user club
- ▶ **Research and development for the sterilization of multi-channel flexible endoscopes : The Main Point**

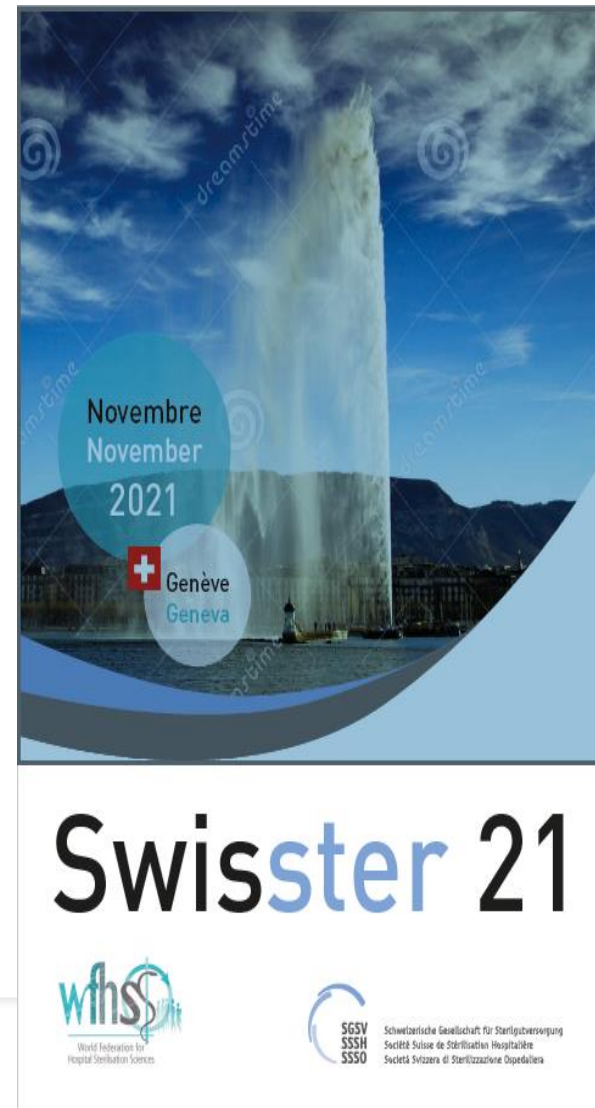
# AND I WOKE UP..



Cycle parameters Ok, BI Ok, Same conditions, load as PQ ....



- ▶ The choice will be difficult (especially as the selling price of Sterrad 100 NX ALLclear seems to have been divided by more than 2 times in 8 years ....)
- ▶ It will be necessary to live with the frustration of H2O2 + Ozone technology ...
- ▶ Benefit from both technologies allows to "play a little"
- ▶ We must remain open to surprises



# STERILUX....STAY OPEN MINDED

