COMPARISON OF DIFFERENT LOW TEMPERATURE STERILIZATION METHODS
USER’S PERSPECTIVE

Hervé NEY
Expert en stérilisation
Hôpitaux Universitaires de Genève

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

Lara Besseghini, its-jnj
José De Sousa Pinto, Laboratoires Anios

Bernadette Almagro, Steris
Brisia Lopes Ortega, Steris
THE CSSD TO THE HUG

- 70 employees // 24/7
- 4 washer-disinfektors tunnels
- 2 washer-disinfektors
- 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 $\text{H}_2\text{O}_2$ and phase plasma
- 1 VPRO Max: sterilization with $\text{H}_2\text{O}_2$

- 30 m$^3$ 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
## USER REVIEWS

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Sterrad 100 NX (2010)</th>
<th>VPro Max (2016)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Easy to use</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>Intuitive screen</td>
<td>+/-</td>
<td>+</td>
</tr>
<tr>
<td>Reminder messages before starting a cycle</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Vizualisation of the level of sterilant agent</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>Size of the load</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>Easy interpretation of cycle parameters</td>
<td>-</td>
<td>+/-</td>
</tr>
<tr>
<td>Reliability - breakdowns</td>
<td>-</td>
<td>+</td>
</tr>
</tbody>
</table>

# TECHNICAL POINT OF VIEW

<table>
<thead>
<tr>
<th>Critère</th>
<th>Sterrad 100 NX (2010)</th>
<th>VPro Max (2016)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parametric release</td>
<td>+</td>
<td>+/-</td>
</tr>
<tr>
<td>$\text{H}_2\text{O}_2$ reduction at the end of the cycle</td>
<td>+/-</td>
<td>+</td>
</tr>
<tr>
<td>Effectiveness to inactivate the prion ($&lt;\text{french PSP 2018}$)</td>
<td>+</td>
<td>+/-</td>
</tr>
<tr>
<td>Failures</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>Ability to use SBS from different brands</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>Experience</td>
<td>+</td>
<td>+/-</td>
</tr>
<tr>
<td>Corporate strategy in Switzerland</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>
PARAMETRIC RELEASE

- SN EN ISO 14937 (Half cycle method)
- Pr EN 17180 (12/2017)
- Qualification of the machine **AND** the Independant Monitoring System
Prévention de la maladie de Creutzfeldt Jakob et retraitement des dispositifs médicaux: état des connaissances scientifiques actuelles et recommandations pour la Suisse

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

Prion inactivation using a new gaseous hydrogen peroxide sterilisation process

Guillaume Fichet a,*, K. Antleca a, E. Comoy b, J.P. Deslys b, G. McDonnell a

a STERIS/CEA/DSV/INMET/SEPA, Fontenay-aux-Roses, France
b CEA/DSV/INMET/SEPA, Fontenay-aux-Roses, France

Received 19 January 2007, accepted 21 August 2007
Available online 22 October 2007

http://ansm.sante.fr/var/ansm_site/storage/original/application/e44cbf8dd10218ea221e0a6607729dc1.pdf
## COST ANALYSIS (AMOUNTS IN CHF)

<table>
<thead>
<tr>
<th>Item?</th>
<th>Sterrad 100 NX (2010) Per Year / Per cycle (700)</th>
<th>Vpro Max (2016) Per Year / Per cycle (700)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Economic depreciation over 10 years: Double door sterilizer software + IQ/OQ validation by external body</td>
<td>21 000 / 30</td>
<td>13 500 / 19.30</td>
</tr>
<tr>
<td>PQ</td>
<td>Included in package maintenance + 1 PQ</td>
<td>4 000 / 5.70</td>
</tr>
<tr>
<td>Maintenance (2 x per year)</td>
<td>18 000 / 25.70</td>
<td>5 000 / 7.15</td>
</tr>
<tr>
<td>Sterilant</td>
<td>18 900 / 27</td>
<td>9750 / 13.95</td>
</tr>
<tr>
<td>Biological Indicator</td>
<td>4 000 / 5.70</td>
<td>3750 / 5.40</td>
</tr>
<tr>
<td>Total</td>
<td>61 900 / <strong>88.40</strong></td>
<td>36 000 / <strong>51.50</strong></td>
</tr>
</tbody>
</table>
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® V144 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

<table>
<thead>
<tr>
<th>STEP</th>
<th>PHASE</th>
<th>PARAMETER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-conditioning</td>
<td></td>
<td>Pressure: 00001 Torr</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Duration: 00:05:41 hms</td>
</tr>
<tr>
<td>Dynamic H2O2</td>
<td>1</td>
<td>Pressure: 0020 Torr</td>
</tr>
<tr>
<td>Exposure</td>
<td></td>
<td>Duration: 00:03:23 hms</td>
</tr>
<tr>
<td>H2O2 reduction</td>
<td>1</td>
<td>Dose: 02.0 mg/L</td>
</tr>
<tr>
<td>-03 injection</td>
<td></td>
<td>Pressure: 0030 Torr</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Duration: 00:00:56 hms</td>
</tr>
<tr>
<td>H2O2 reduction</td>
<td>1</td>
<td>Duration: 00:05:02 hms</td>
</tr>
<tr>
<td>-03 dwell</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Evacuation</td>
<td></td>
<td>Pressure: 00001 Torr</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Duration: 00:14:04 hms</td>
</tr>
<tr>
<td>Dynamic H2O2</td>
<td>2</td>
<td>Pressure: 0020 Torr</td>
</tr>
<tr>
<td>Exposure</td>
<td></td>
<td>Duration: 00:03:01 hms</td>
</tr>
<tr>
<td>H2O2 reduction</td>
<td>2</td>
<td>Dose: 02.0 mg/L</td>
</tr>
<tr>
<td>-03 injection</td>
<td></td>
<td>Pressure: 0030 Torr</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Duration: 00:00:56 hms</td>
</tr>
<tr>
<td>H2O2 reduction</td>
<td>2</td>
<td>Duration: 00:05:02 hms</td>
</tr>
<tr>
<td>-03 dwell</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Duration: 00:20:44 hms</td>
</tr>
</tbody>
</table>

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

OPERATOR I.D.: 0000

Name: [Signature]

CYCLE COMPLETED: 09:18:02 hms
Cycle ID: 1
Cycle Number: 000027
## COST ANALYSIS (AMOUNTS IN CHF)

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

*Electrical consumption, $o_3$ and small accessories considered as negligible compared to other costs*

*PQ and maintenance should increase the cost of a cycle > of 100.00 CHF*
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, 2016

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 76.7 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 0843
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
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**
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

CLOSED ENVIRONMENT

Oxygen → UV radiation of 185nm → Ozone → UV radiation of 254nm → Oxygen

rises hydroxyl radicals in presence of water

STERILIZATION
Thank you for the attention