Annual WFHSS and JSMI Conference 2012
13th World Sterilization Congress

Problems on Hydrogen Peroxide Sterilisation
― New Proposal for Safety and Effective Use ―

Rika Yoshida, Hiroyoshi Kobayashi

Division of Infection Prevention and Control,
Tokyo Healthcare University Postgraduate School

23 Nov,2012

Background

- Some central service employees of a tertiary university hospital engaged in hydrogen peroxide (HP) sterilisation had experienced the irritations to eyes and throats, and one of them had acute flare and swelling around eyes.
- It was supposed as the adverse event of HP sterilisation as reported to Food and Drug Administration (FDA) in the United States, though all of them were not evaluated as the actual adverse event by HP.
- Some of the employees also experienced the colour changes of chemical indicators (CIs) in the sterilising bags（Pouch) before sterilisation, as look like the one after sterilisation.

Ethylene oxide Exposure Limits:

NIOSH REL(2008): 8-hour TWA <0.1 ppm (0.18 mg/m^3)
5 ppm (9 mg/m^3) [10-min/day]

OSHA PEL(2002): 8-hour TWA 1 ppm
5 ppm [15-minute Excursion]

Formaldehyde Exposure Limits:

NIOSH REL(2011): TWA 0.016 ppm, 0.1 ppm [15-min]

OSHA PEL(2012): 8-hour TWA 0.5 ppm, 2 ppm [15-min]

Hydrogen peroxide Exposure Limits:

NIOSH REL(1992): 10-hour TWA 1 ppm (1.4 mg/m^3)

OSHA PEL(1996): 8-hour TWA 1 ppm (1.4 mg/m^3)

IDLH（Immediately Dangerous to Life and Health）: 75ppm

REL: Recommended exposure limit PEL: Permissible exposure limit
TWA: Time-weighted average

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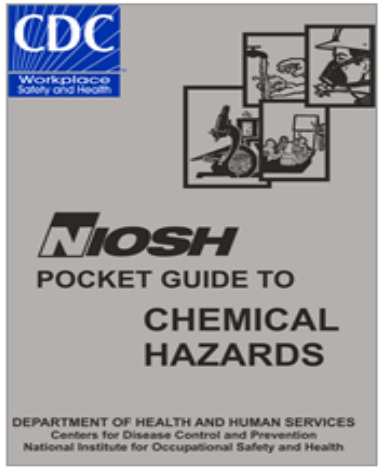
DHHS (NISOH) Publication Number 2005-149 September 2007

NIOSH Pocket Guide to Chemical Hazards

The NIOSH Pocket Guide to Chemical Hazards (NPG) is intended as a source of general industrial hygiene information on several hundred chemicals/classes for workers, employers, and occupational health professionals. The NPG does not contain an analysis of all pertinent data, rather it presents key information and data in abbreviated or tabular form for chemicals or substance groupings (e.g. cyanides, fluorides, manganese compounds) that are found in the work environment. The information found in the NPG should help users recognize and control occupational chemical hazards.



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Hydrogen peroxide	**Formula:** H_2O_2	**CAS#:** 7722-84-1	**RTECS#:** MX0900000	**IDLH:** 75 ppm
Conversion: 1 ppm = 1.39 mg/m^3	**DOT:** 2984 140 (8-20% solution); 2014 140 (20-60% solution); 2015 143 (>60% solution)			

Synonyms/Trade Names: High-strength hydrogen peroxide, Hydrogen dioxide, Hydrogen peroxide (aqueous), Hydroperoxide, Peroxide

Exposure Limits:
NIOSH REL: TWA 1 ppm (1.4 mg/m^3)
OSHA PEL: TWA 1 ppm (1.4 mg/m^3)

Measurement Methods (see Table 1):
OSHA ID126SG

Physical Description: Colorless liquid with a slightly sharp odor.
[**Note:** The pure compound is a crystalline solid below 12°F. Often used in an aqueous solution.]

Chemical & Physical Properties:
MW: 34.0
BP: 286°F
Sol: Miscible
Fl.P: NA
IP: 10.54 eV
Sp.Gr: 1.39
VP(86°F): 5 mmHg
FRZ: 12°F
UEL: NA
LEL: NA
Noncombustible Liquid, but a powerful oxidizer.

Personal Protection/Sanitation (see Table 2):
Skin: Prevent skin contact
Eyes: Prevent eye contact
Wash skin: When contam
Remove: When wet or contam
Change: N.R.
Provide: Eyewash
Quick drench

Respirator Recommendations (see Tables 3 and 4):
NIOSH/OSHA
10 ppm: Sa*
25 ppm: Sa:Cf*
50 ppm: ScbaF/SaF
75 ppm: SaF:Pd,Pp
§: ScbaF:Pd,Pp/SaF:Pd,Pp:AScba
Escape: GmFS/ScbaE

Sa : Supplied-air respirator
F : Full facepiece
Pd,Pp : Pressure-demand or other positive-pressure mode

Incompatibilities and Reactivities: Oxidizable materials, iron, copper, brass, bronze, chromium, zinc, lead, silver, manganese [**Note:** Contact with combustible material may result in SPONTANEOUS combustion.]

Exposure Routes, Symptoms, Target Organs (see Table 5):
ER: Inh, Ing, Con
SY: Irrit eyes, nose, throat; corn ulcer; eryt, vesic skin; bleaching hair
TO: Eyes, skin, resp sys

First Aid (see Table 6):
Eye: Irr immed
Skin: Water flush immed
Breath: Resp support
Swallow: Medical attention immed

No regulation for the environmental concentrations of hydrogen peroxide in Japan

A safe argument has not been held enough in Japan

Method 1

- The concentrations of hydrogen peroxide vapour (HPV) in the proximity of HP sterilisers（low-temperature hydrogen peroxide gas plasma steriliser：STERRAD ® NX™ , STRRAD® 100S, and STERRAD®200, Johnson &Johnson, and low-temperature vaporized hydrogen peroxide steriliser：Amsco V-PRO1®, Sakura Seiki）were measured by electrochemical detector（Polytron 7000®, Dräger, sensitivity: 0-300ppm）.

Method 2

- The HPV concentration on the plastic medical devices, experimental plastic panels (100 × 100 × 6mm), and the dummy of flexible fiberscope especially made were measured by the electrochemical detectors, sealing in the stainless steel containers.

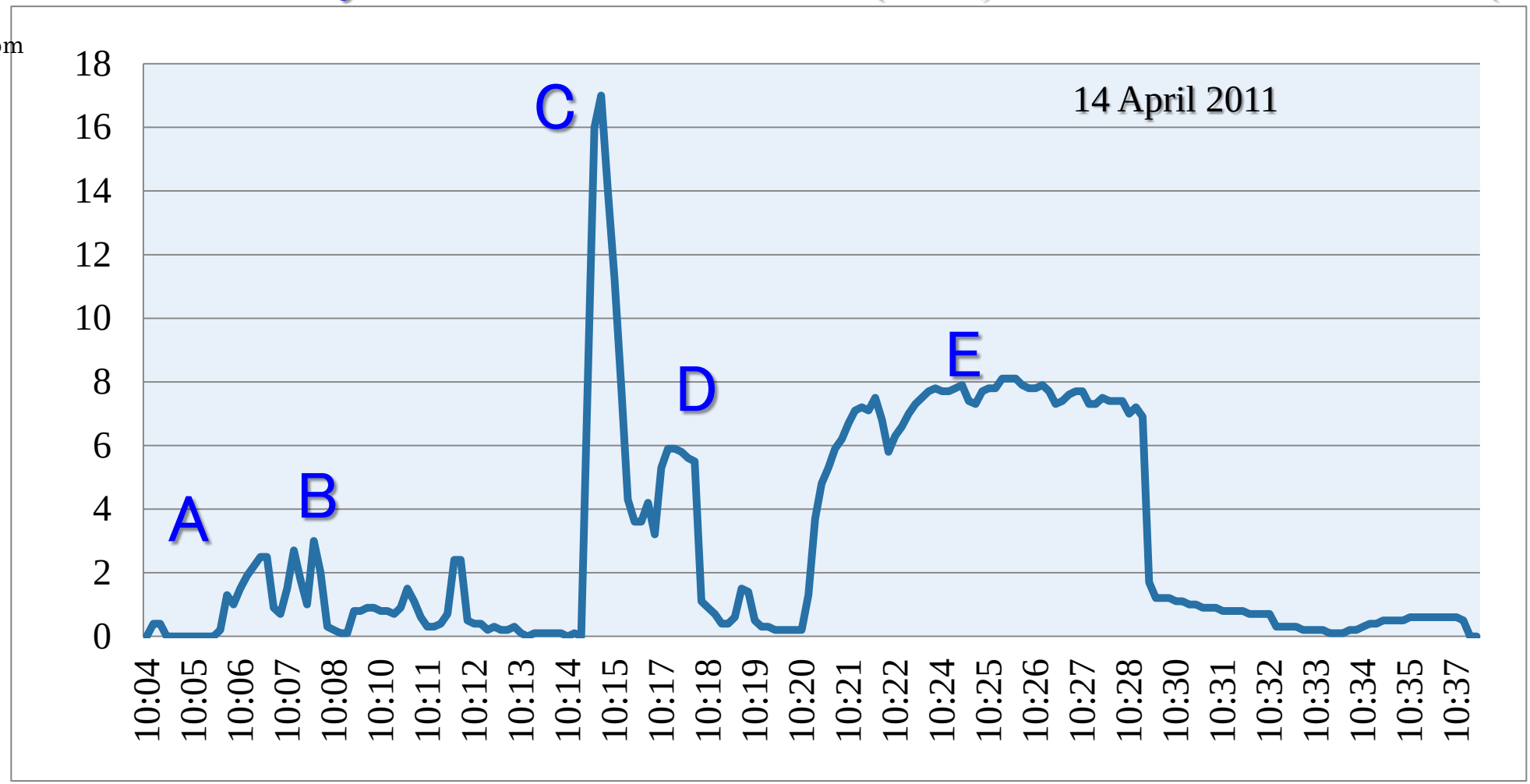
- The colours of three kinds of CIs(Johnson & Johnson, 3M, and Steris) sealed with plastic devices sterilised by HPV were observed before re-sterilisation.

Detector

- Polytron 7000® Draeger
- Principle of measurement: Electrochemical
- Sensitivity: 0～300ppm
- Accuracy: ±15%
- Electric source: DC24V 4～20mA

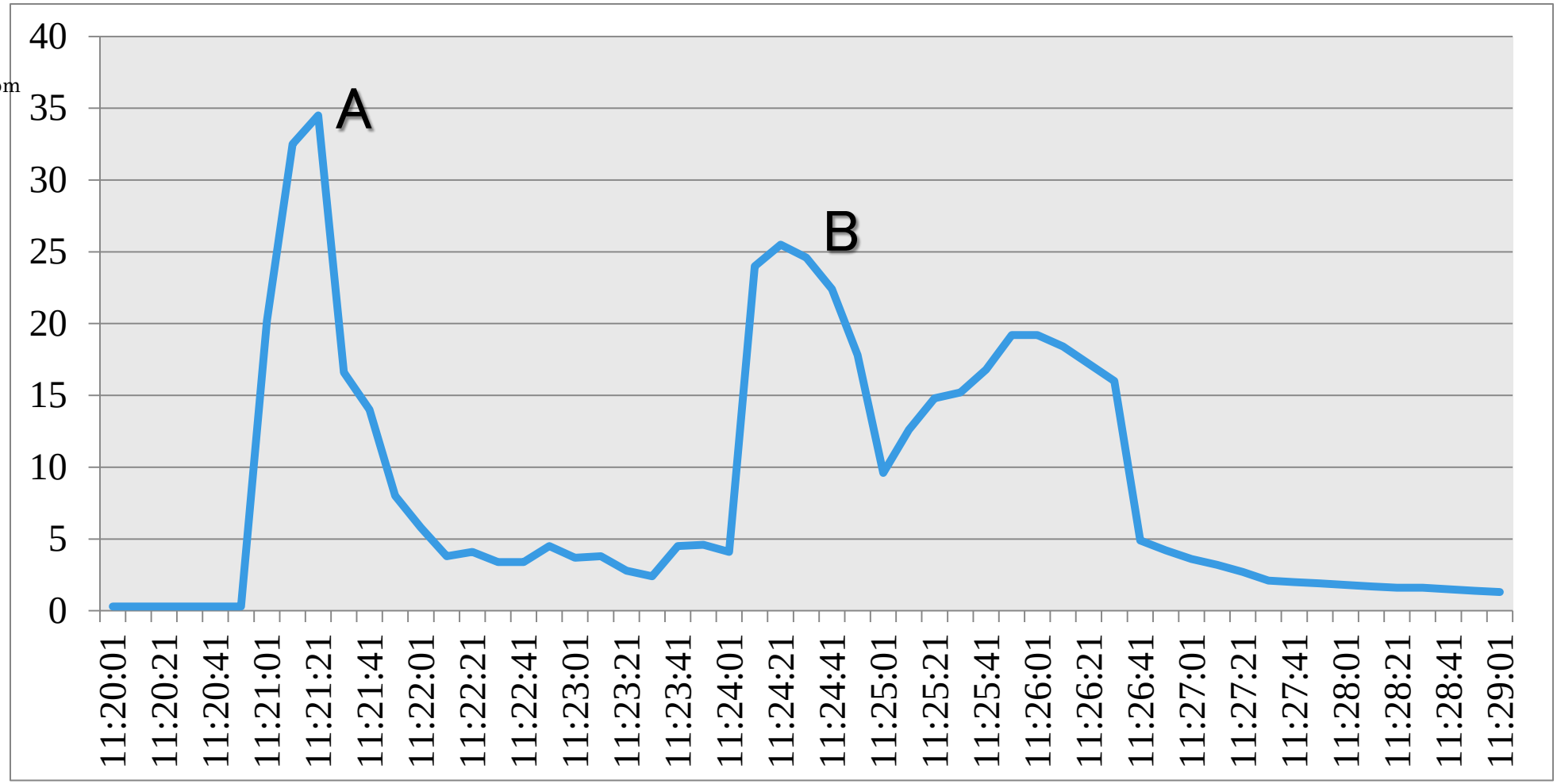
Problems on the Hydrogen Peroxide Steriliser

Concentration of Hydrogen Peroxide Vapour in the Proximity of STERRAD®NX™ (A-D) and STERRAD® 200 (E)



A: Inside the sterilising chamber , B: In front of steriliser door just after opened
C: Inside the outer bag opened, D: At the height of mouth over the bags on the cart
E: On the surface of outer bag which removed from the another sterilising chamber 14hr.

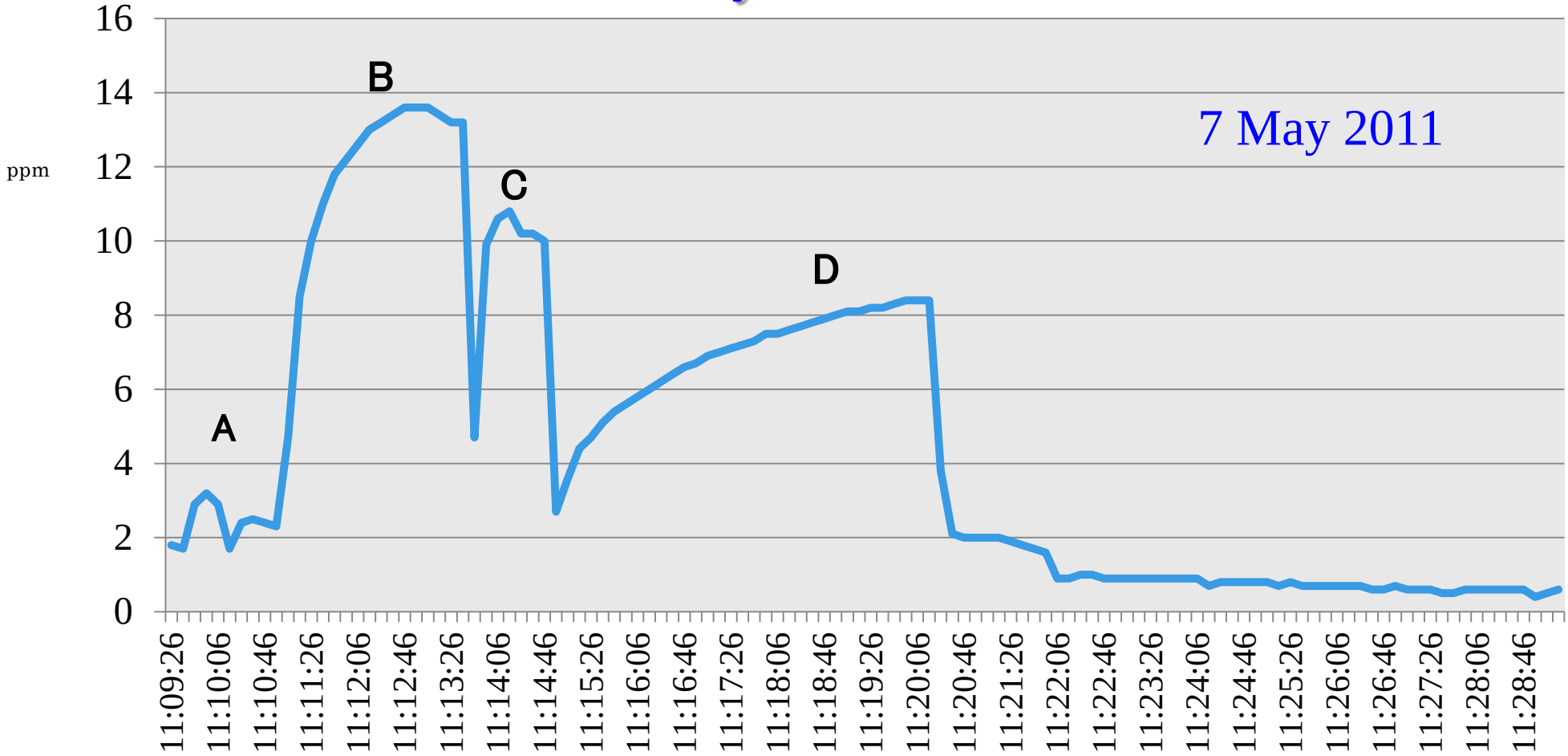
Concentration of Hydrogen Peroxide Vapour in the Proximity of STERRAD®100S



A:Inside the sterilising chamber just after sterilisation process.

B:Surface of non-woven fabric side of sterilising bag

Concentration of Hydrogen Peroxide Vapour in the Proximity of Amsco V-PRO1®



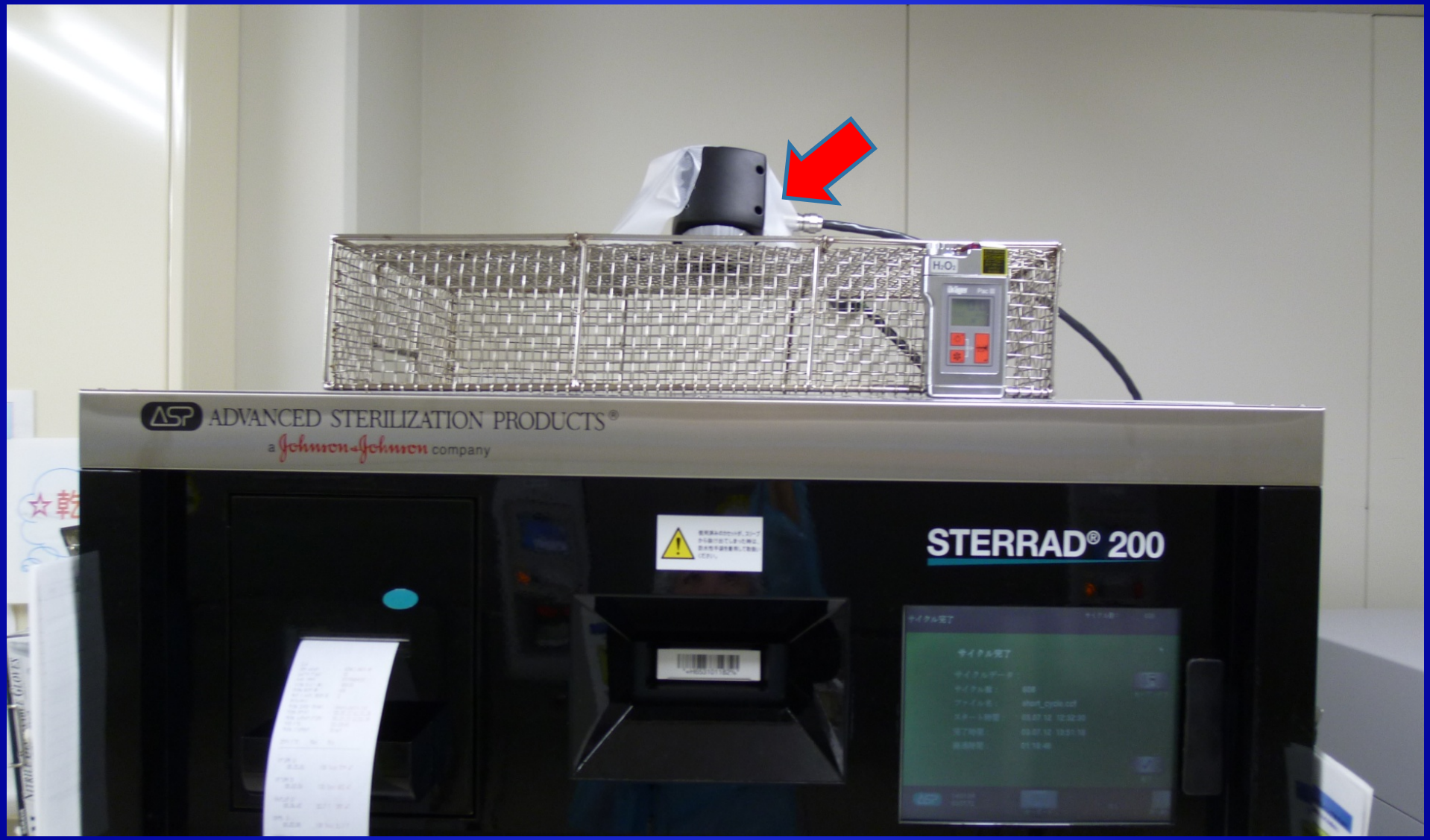
No HPV had been detected at the exhausted air passed through catalytic convertor which is installed below the sterilising chamber.

A: At the height of mouth in front of the steriliser door just opened .B: Inside of chamber C:The surface of the sterilising bag. D: Inside the sterilising bag just after opened.

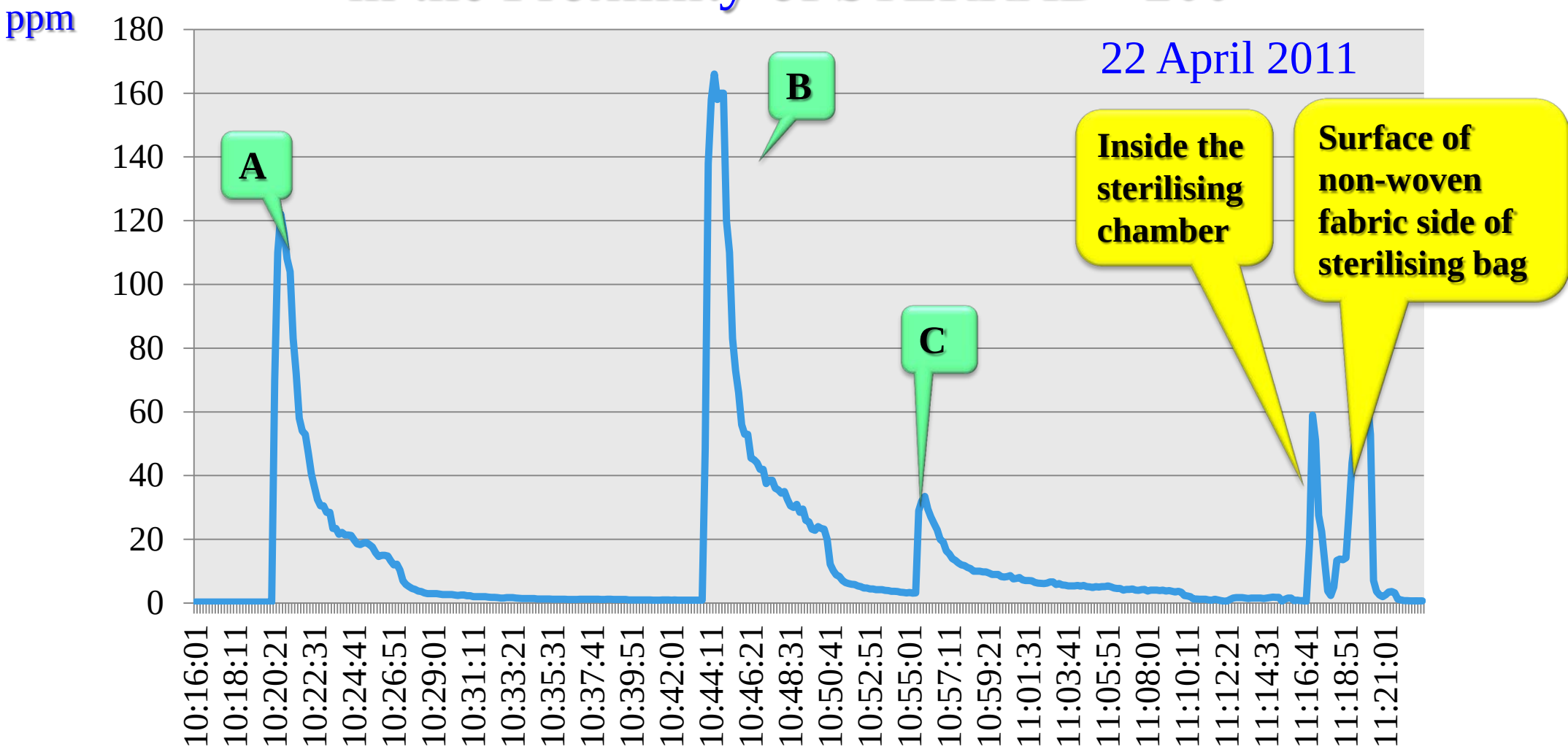
Concentration of Hydrogen Peroxide Vapour in the Proximity of STERRAD® 200

Upper Vent of the Steriliser

Location of Detecting Sensor

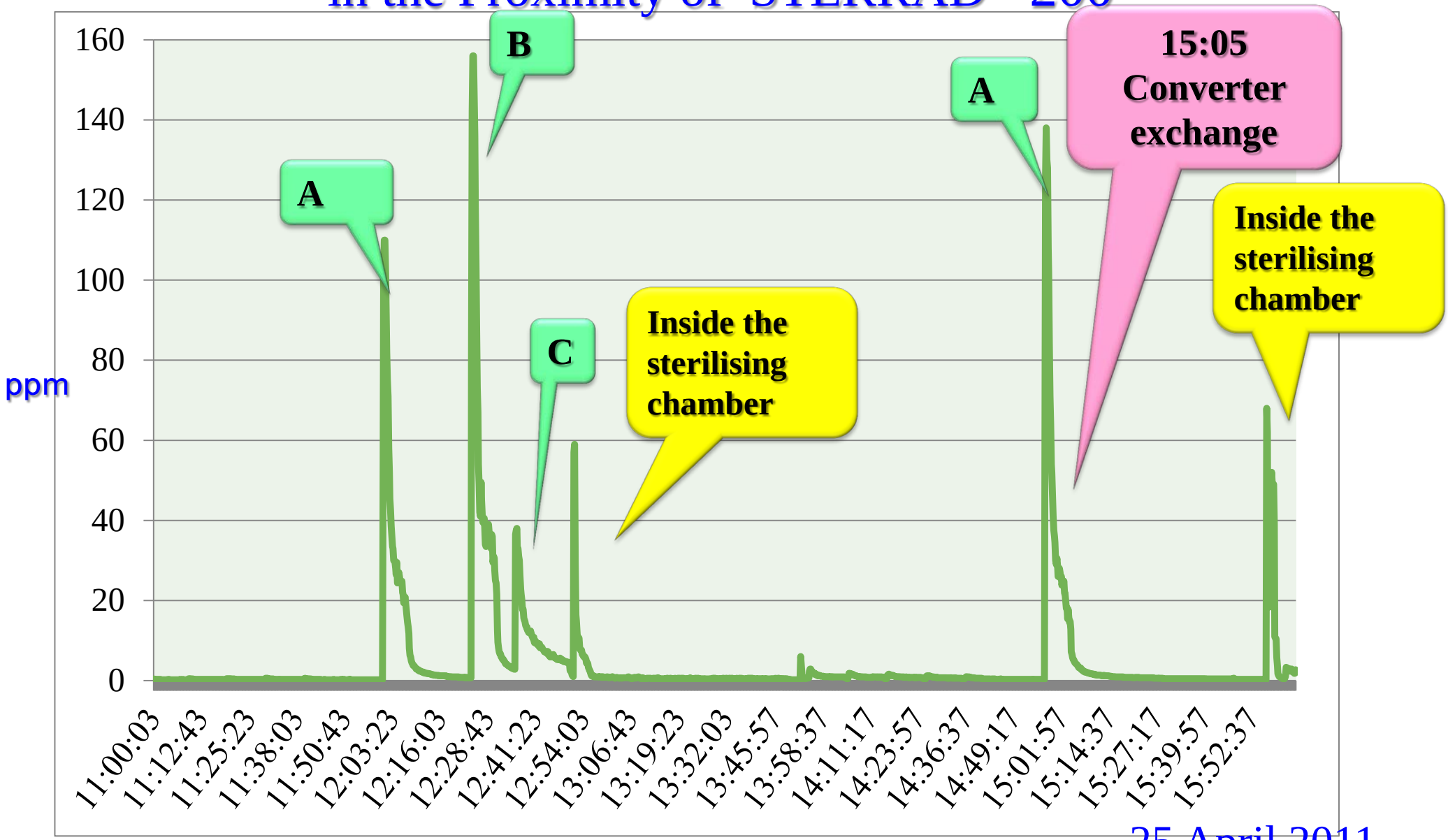


Concentration of Hydrogen Peroxide Vapour in the Proximity of STERRAD® 200



A ,B and C: At the exhaust port on the top panel just after hydrogen peroxide infusion and decompression into the sterilising chamber.

Concentration of h Hydrogen Peroxide Vapour in the Proximity of STERRAD® 200

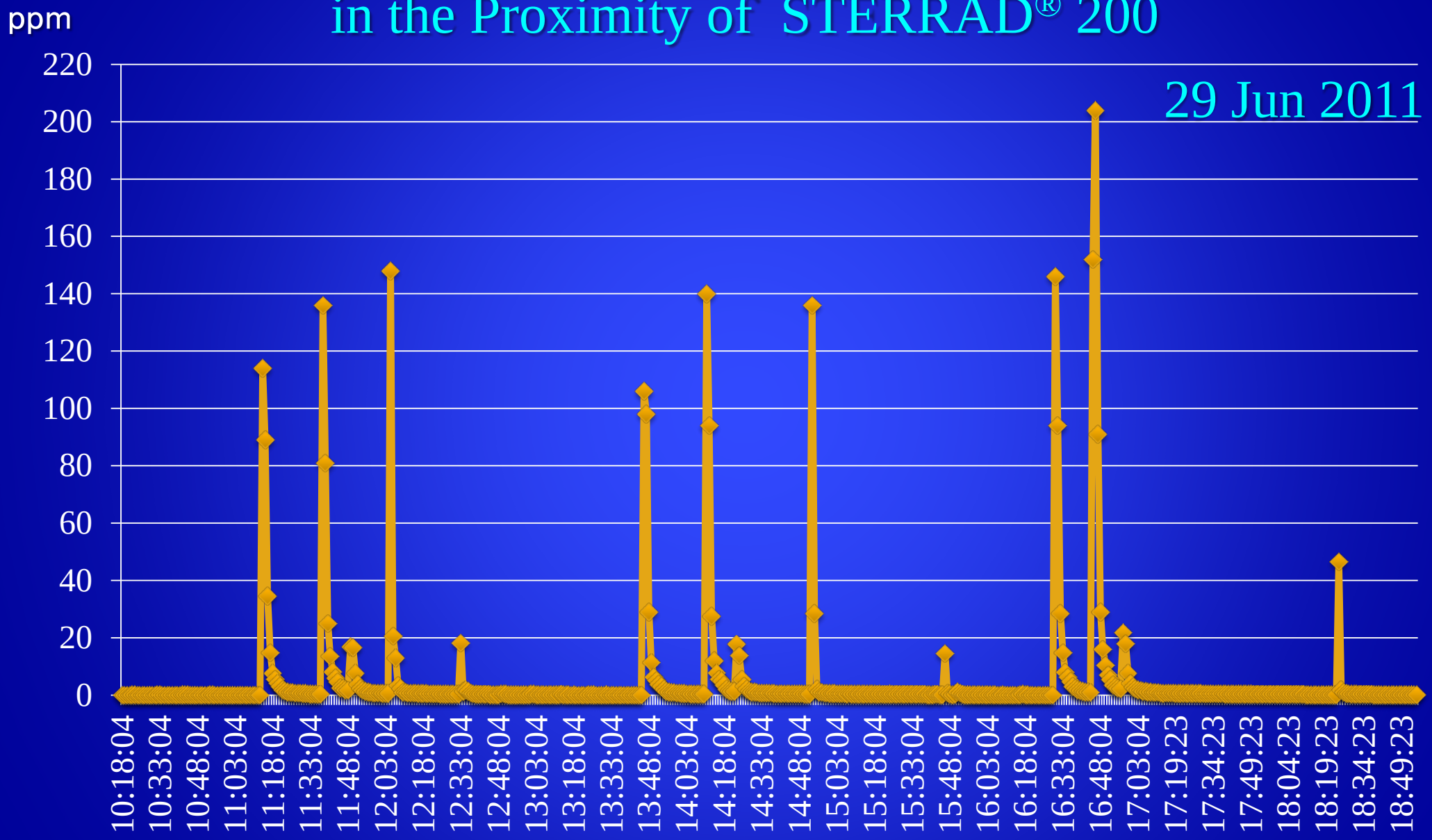


25 April 2011

When the convertor was exchanged,

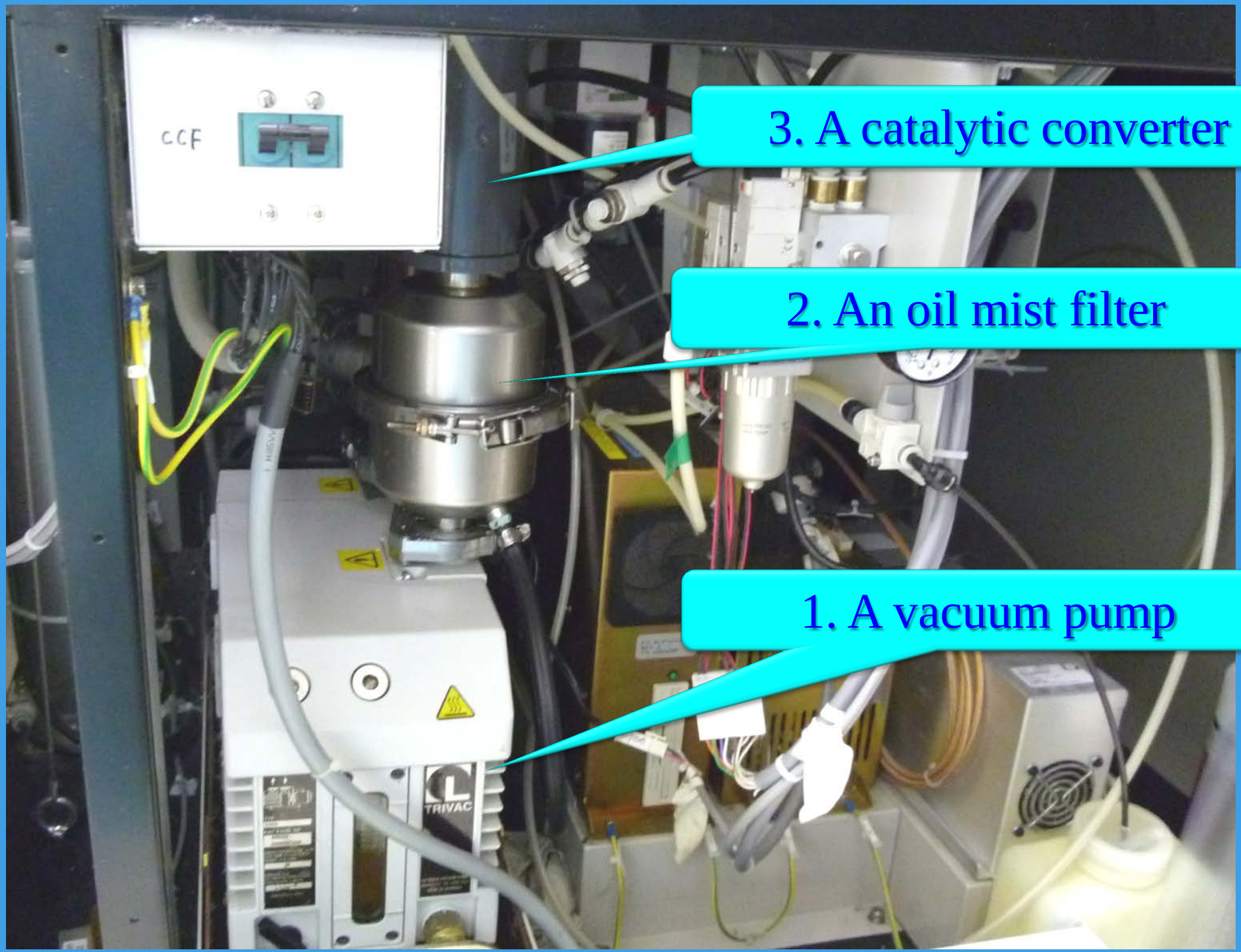
improvement was shown once, but ...

Concentration of Hydrogen Peroxide Vapour in the Proximity of STERRAD® 200



Results

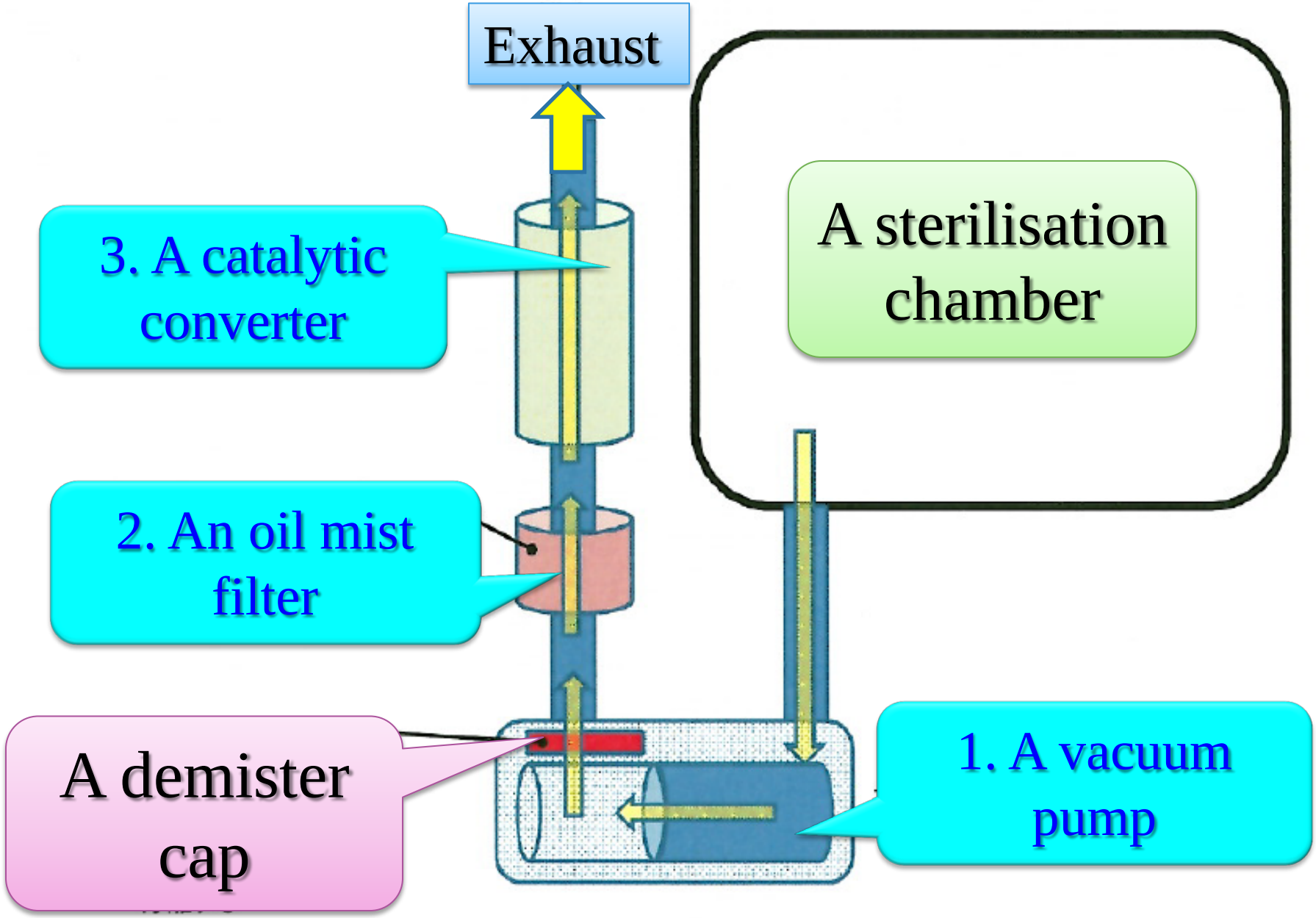
- The concentrations of HPV in the proximities of sterilisers were much higher than expected.
- In the exhaust air of one steriliser filtered through the catalytic convertor between inner sterilizing chamber and outer surrounding panels, the concentration was more than 100ppm, though the catalytic convertor was still in the available period.


3. A catalytic converter
2. An oil mist filter
1. A vacuum pump
CCF
TRIVAC

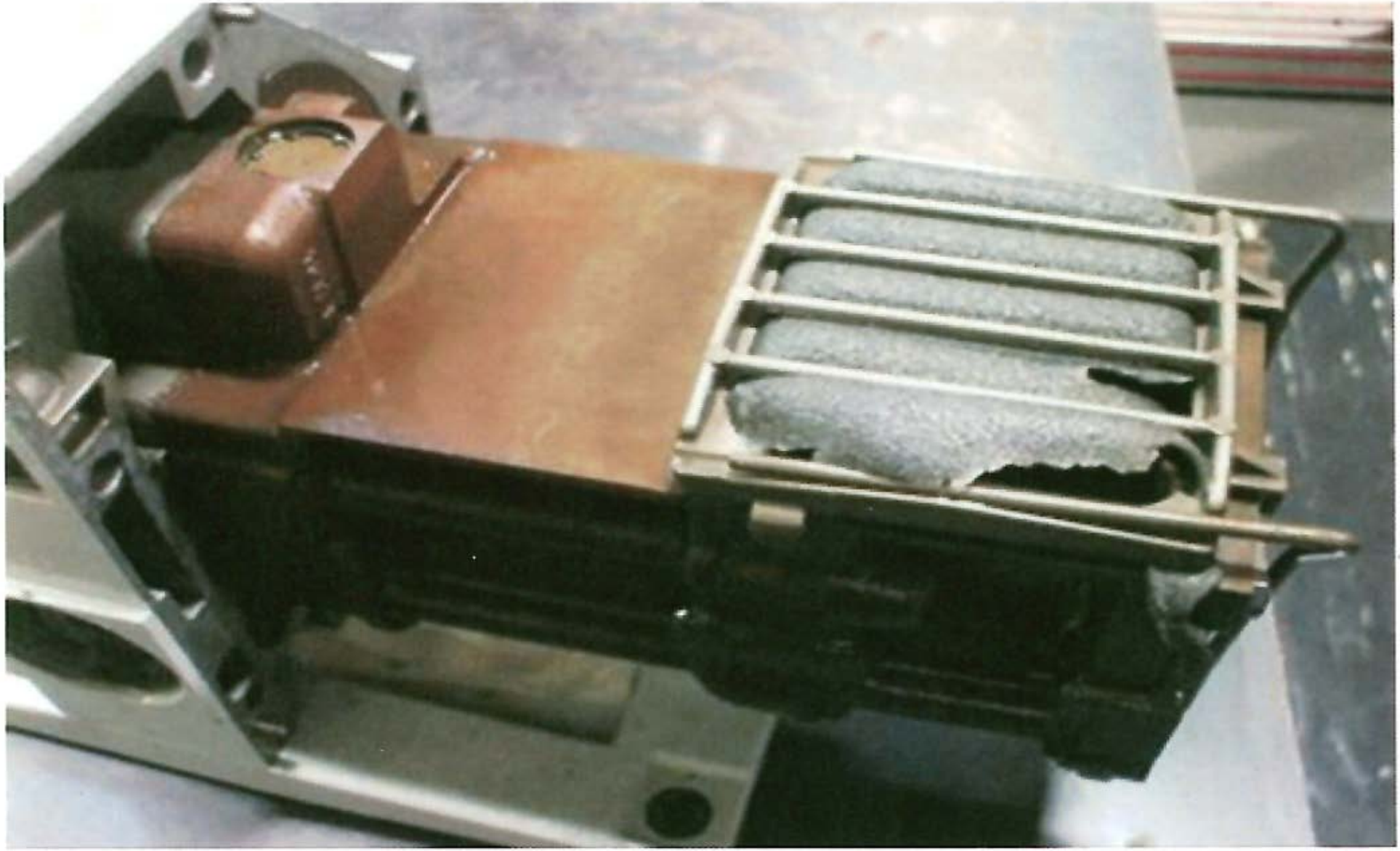
Voluntary repair of STERRAD® 200

- Approximately one year had passed until a problem was found out, and it was examined.
- This STERRAD® 200 had been sent to the laboratory in US and the details of the pieces had been studied.
- The cause was found to be the break of the inside filter (a demister cap) of the vacuum pump.
- The routine periodic inspection could not check the filter.
- The result of this analysis was officially announced by Phamaceuticals and Medical Devices Agency (PMDA) in Japan. (22Mar,2012）

An exhaust system schematic

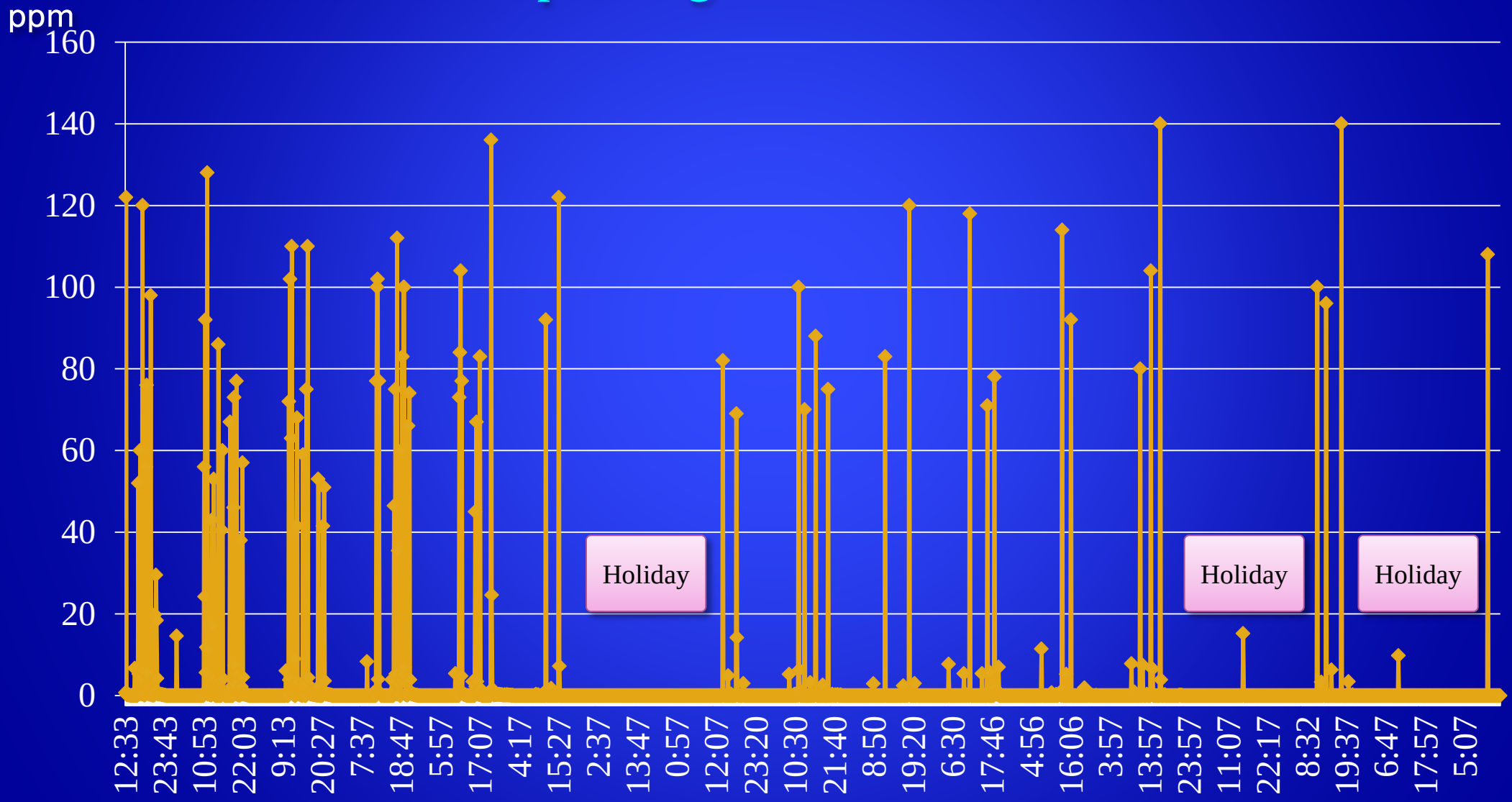


Break of a Demister Cap



New STERRAD® 200
Beginning to use on 7 Oct, 2011

Concentrations of Hydrogen Peroxide in the Proximity of STERRAD® 200 Operating between 5 Mar to 21 March 2012



About Hydrogen Peroxide Sterilization

- Four models of hydrogen peroxide gas sterilisers on the market were investigated.
- The existence of hydrogen peroxide in the proximity of each model was detected, although the concentration was different respectively.
- After exchanging the catalytic convertor to new one, the exhaust air showed a lower concentration of hydrogen peroxide less than 1ppm, but the concentration in the chamber just after opening the door at the end of sterilization process was shown to be approximately 80ppm.

About hydrogen peroxide sterilization

- Safety analyzer for hydrogen peroxide concentration in the proximity of each steriliser is not installed.
- And it is almost impossible to detect the concentration every time practically. So, any alarm apparatus as same as for ethylene oxide sterilisation is required for safety.

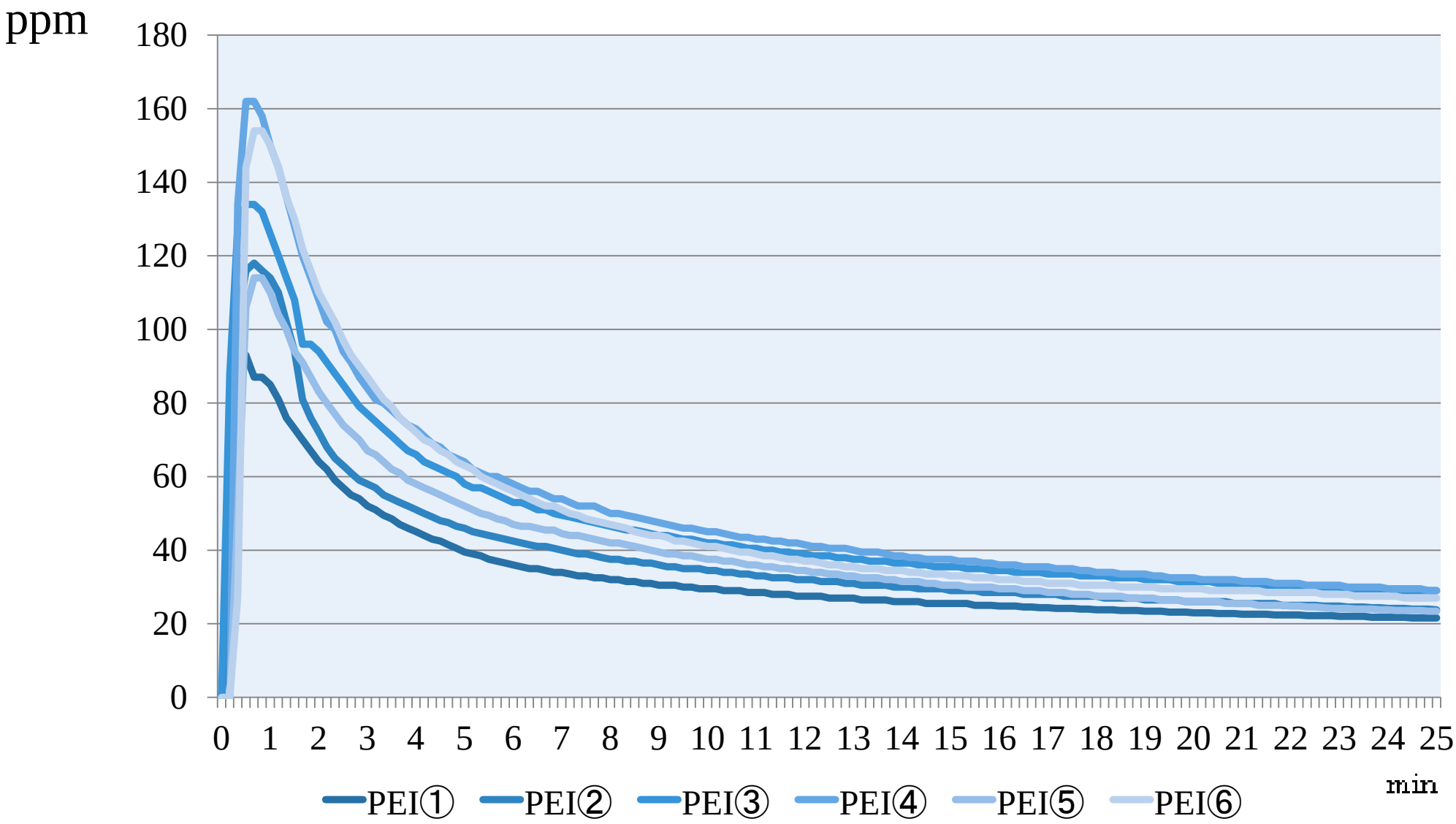
Hydrogen Peroxide Vapour from Plastic Test Panels after Low Temperature Hydrogen Peroxide Gas Plasma (LTHPGP) sterilisation (STERRAD® J&J)

Eleven kinds of Plastic Test Panels

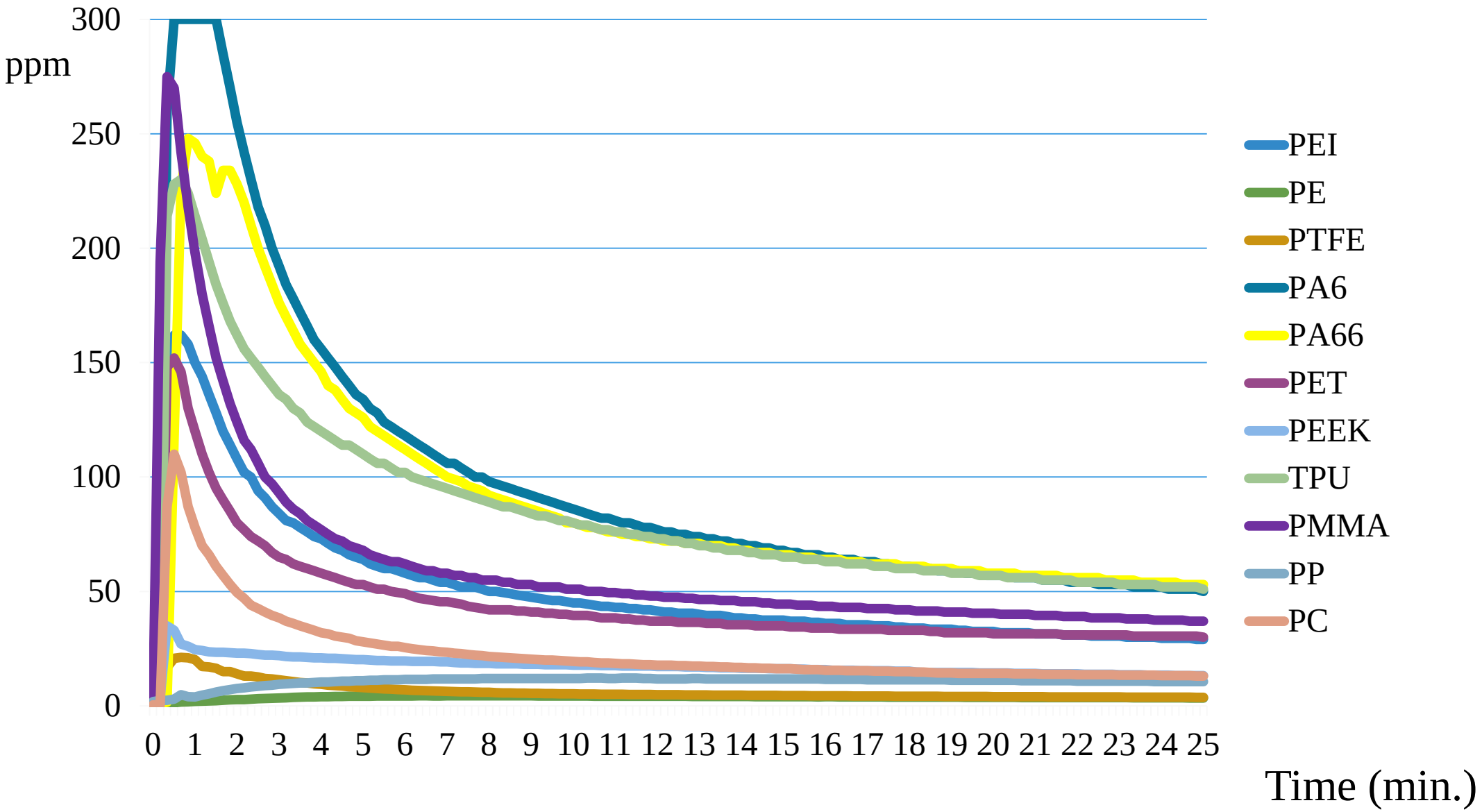
Eleven Kinds of Plastic Test Panels100mm × 100mm × 6mm
Detection 1 × /10sec. for 25min.

- polyetherimide (PEI)
- polyethylene (PE)
- polytetrafluoroethylene (PTFE)
- polyamide 6 (PA6)
- polyamide 66 (PA66)
- polyethylene terephthalate (PET)
- polyetheretherketone (PEEK)
- thermoplastic polyurethane (TPU)
- polymethyl methacrylate (PMMA)
- polypropylene (PP)
- polycarbonate (PC)

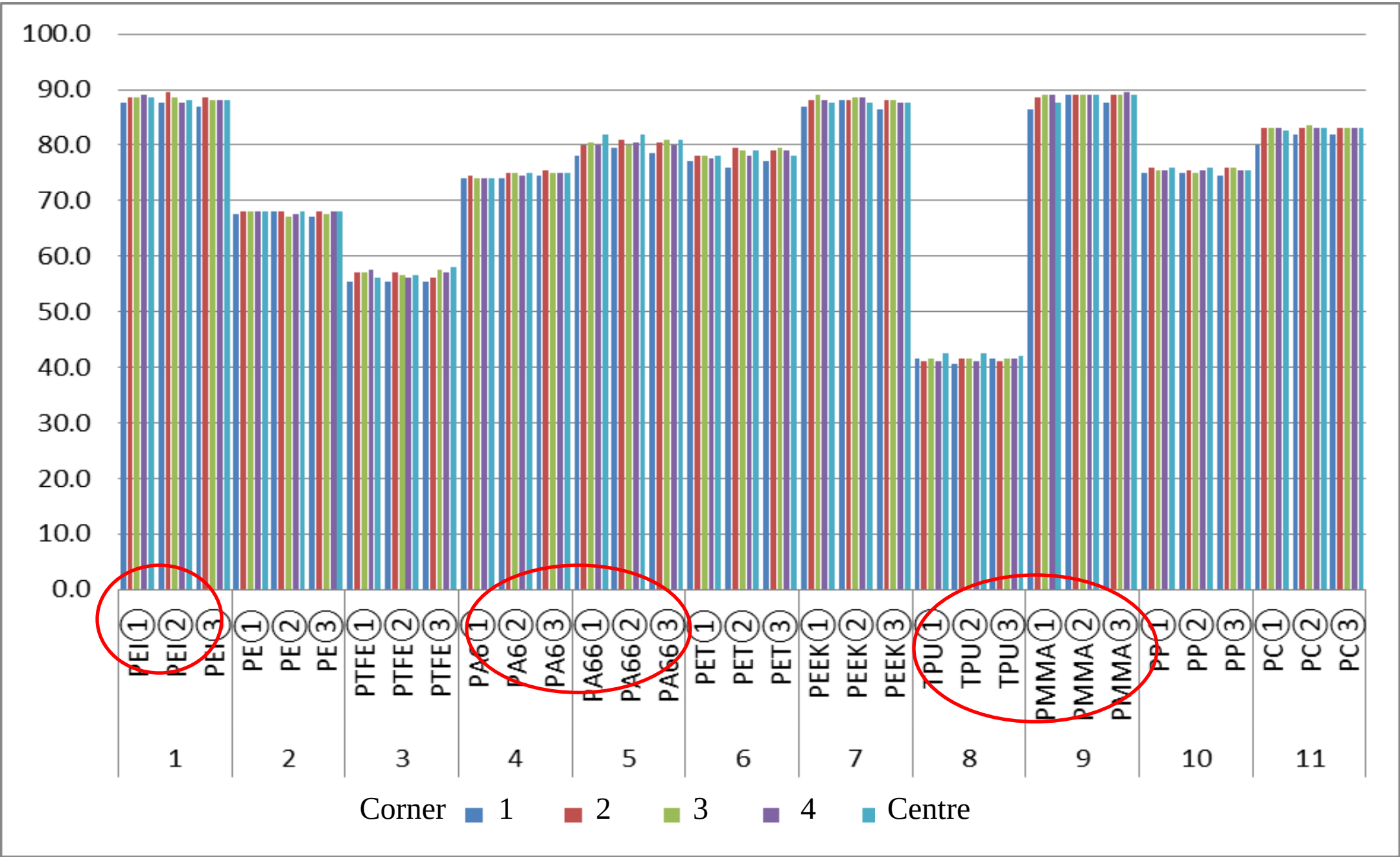
Hydrogen Peroxide Vapour from PEI Panel (100D × 100W × 6 T mm)
Each Sealed in A Stainless Steel Container After Sterilization by STERRAD NX®



Hydrogen Peroxide Vapour from Eleven Plastic Panels (100D × 100W × 6 T mm) Each Sealed in A Stainless Steel Container After Sterilization by STERRAD NX®

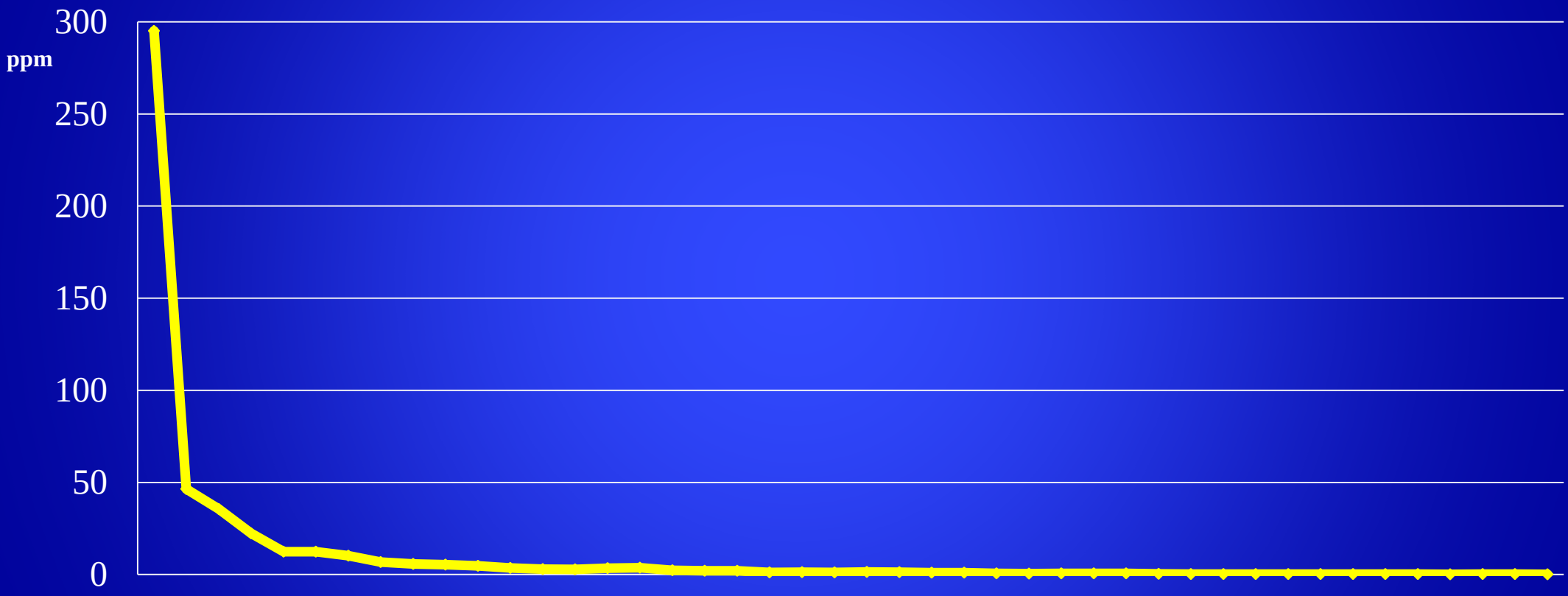


Durometer ASTM



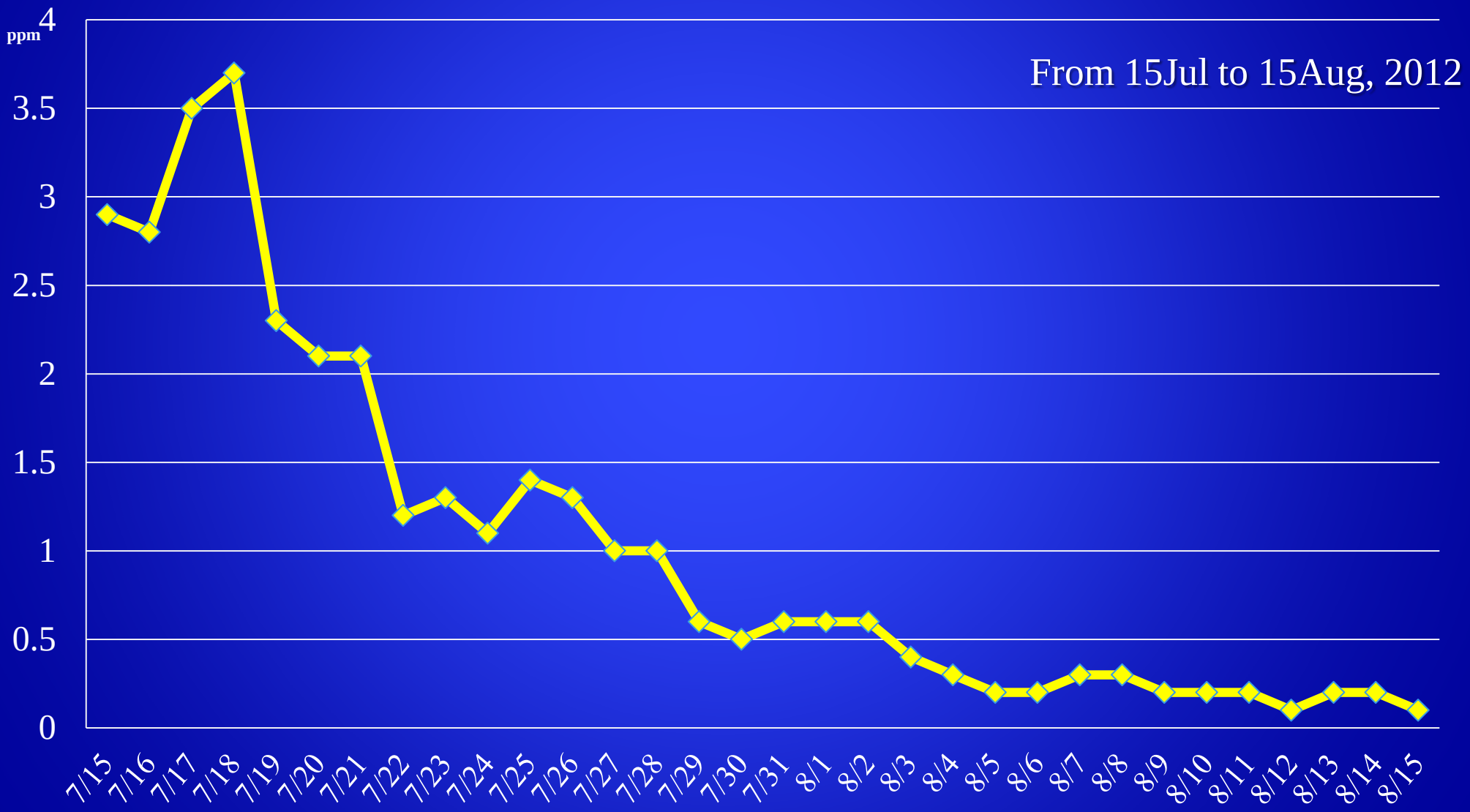
Residual Concentrations of Hydrogen Peroxide Vapour on the Stapler (PEI) after the Sterilization by STERRAD® NX

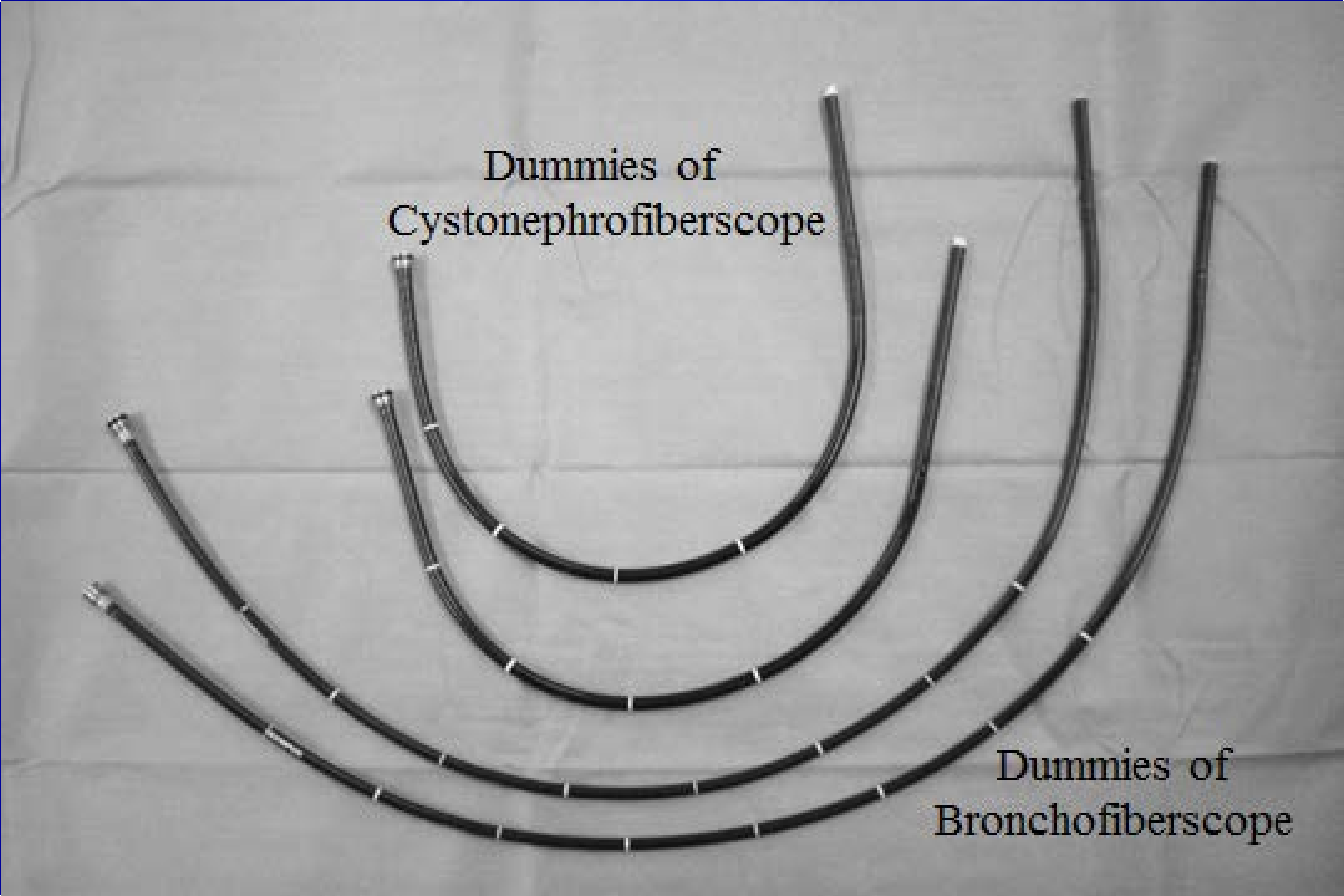
From 3Jul to 15Aug,2012



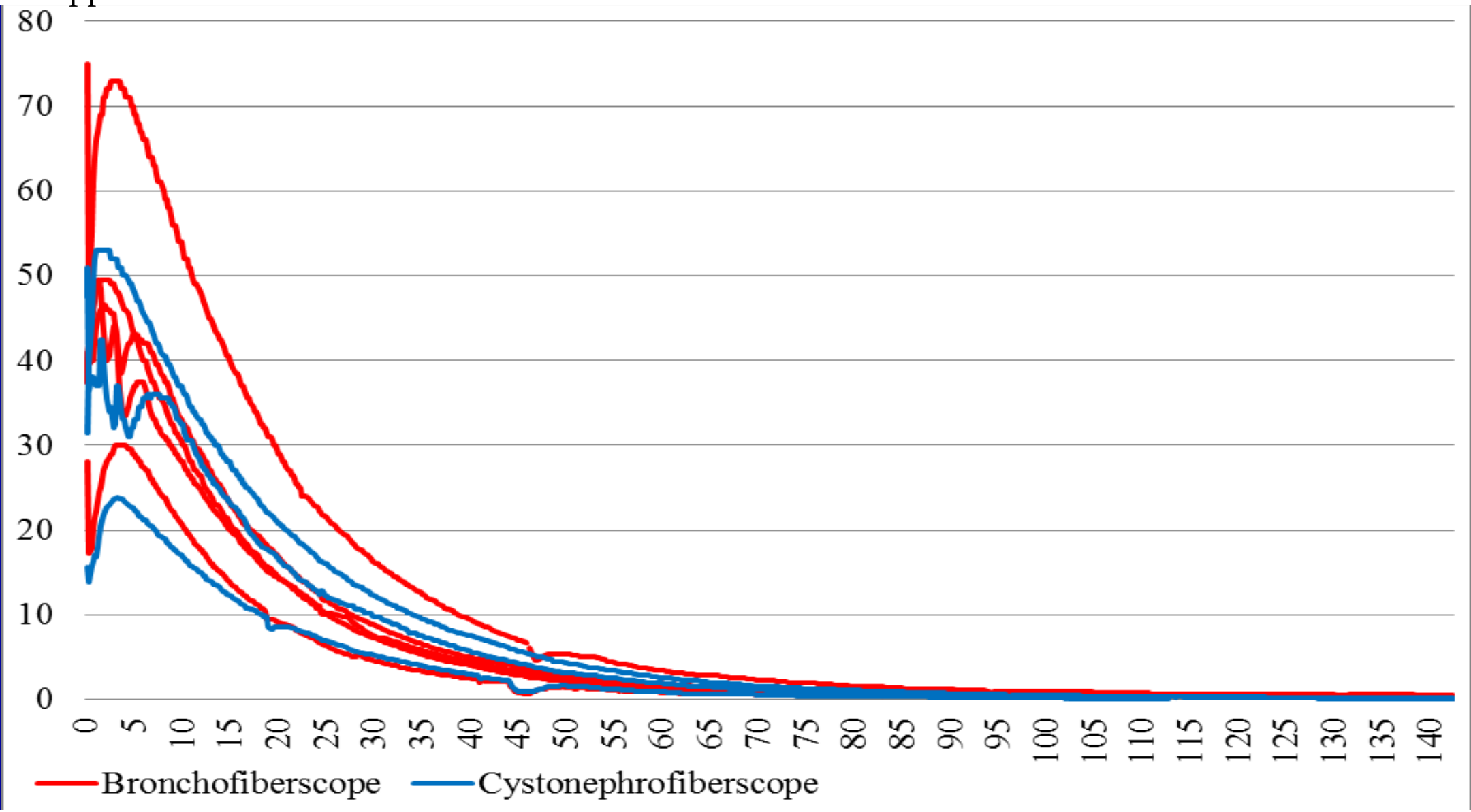
	7/3	7/4	7/5	7/6	7/7	7/8	7/9	7/10	7/11	7/12	7/13	7/14	7/15	7/16	7/17	7/18	7/19	7/20	7/21	7/22	7/23	7/24	7/25	7/26	7/27	7/28	7/29	7/30	7/31	8/1	8/2	8/3	8/4	8/5	8/6	8/7	8/8	8/9	8/10	8/11	8/12	8/13	8/14	8/15
最大値	295	47	36	22	12	12	10	6.8	5.8	5.4	4.7	3.6	2.9	2.8	3.5	3.7	2.3	2.1	2.1	1.2	1.3	1.1	1.4	1.3	1	1	0.6	0.5	0.6	0.6	0.6	0.4	0.3	0.2	0.2	0.3	0.3	0.2	0.2	0.2	0.1	0.2	0.2	0.1

Residual Concentrations of Hydrogen Peroxide Vapour on the Stapler (PEI) after the Sterilization by STERRAD® NX




Dummies of
Cystonephrofiberscope
Dummies of
Bronchofiberscope

Hydrogen Peroxide Vapour from Surfaces of Dummy Fiber Scopes (ppm) n=8



Kobayashi H, Yoshida R. JJMI 2012; in press.

Results

- In the results of experimental detections of residual HPV on test plastic panels, those on PEI, polyamide 6 and 66, thermoplastic polyurethane (TPU), and polyethylene terephthalate (PET), polycarbonate (PC) showed more than 100ppm just after sterilisations.
- Forty- four days are needed to become less than 0.1ppm on the surfaces.

Results

- The residual concentration on the dummy flexible fiberscopes showed also more than 10ppm for 18 to 40 hours after sterilisations.
- The adverse events affecting mucous membranes have not yet been proven, however, healthcare workers should carefully observe the occurrence of adverse events among patients in order to maintain safety.

STERRAD NX® × 3 times

STERRAD 200® × 25 times

U.S. Food and Drug Administration

Protecting and Promoting *Your* Health

The list of adverse events of HP exposures in the Manufacturer and User Facility Device Experience (MAUDE) database of the Food and Drug Administration (FDA)

MAUDE - Manufacturer and User Facility Device Experience

154 records meeting your search criteria returned - **Brand Name:** *sterrad* **Event Type:** *Injury* **Report Date From:** *06/01/1998* **Report Date To:** *06/04/2012*

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Manufacturer	Brand Name	Date Report Received
ADVANCED STERILIZATI	STERRAD 200 STERILIZ	03/26/2012
ADVANCED STERILIZATI	STERRAD 100NX STERIL	01/26/2012
ADVANCED STERILIZATI	STERRAD 100NX STERIL	01/26/2012
ADVANCED STERILIZATI	STERRAD NX STERILIZE	10/20/2011
ADVANCED STERILIZATI	STERRAD NX STERILIZE	06/08/2011
ADVANCED STERILIZATI	STERRAD 100S STERILI	12/30/2010
ADVANCED STERILIZATI	STERRAD 100S STERILI	11/22/2010
ADVANCED STERILIZATI	STERRAD NX STERILIZE	10/13/2010
ADVANCED STERILIZATI	STERRAD NX STERILIZE	10/12/2010
ADVANCED STERILIZATI	STERRAD NX STERILIZE	10/12/2010

Page Last Updated: 04/30/2012
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Adverse Event Report

ADVANCED STERILIZATION PRODUCTS STERRAD 100S STERILIZER Event Date 11/03/2010

Event Description

A healthcare worker (hcw) reported chronic sneezing, queasiness, coughing and chest tightness while working in the area where the sterrad 100s and the sterrad 200 are located. The hcw alleges that the symptoms went away while the employee was on vacation, but recurred when she returned to work. It was also reported that the hcw had symptoms of coughing and tightness in her chest for a duration of three months. The hcw experienced symptoms while in the room whether or not the units were running. The hcw did seek medical attention and was prescribed an inhaler, antibiotics, steroid pills and over the counter cough medicine. The healthcare worker has no known allergies and no relevant medical history. It is unknown which sterrad unit was causing the issue, if any additional information is provided a supplemental medwatch report will be submitted. An asp field service engineer (fse) was dispatched to assess the unit.

Source

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=1904782

Adverse Event Report

ADVANCED STERILIZATION PRODUCTS STERRAD NX STERILIZER Event Date 05/14/2011

Event Description

An international customer reported that between (b)(6), patients experienced eye inflammation twelve hours after cataract surgery. The doctor prescribed medication of cycloplegic and steroid drops. The inflammation was resolved one week post op. The number of patients is unknown at this time. It is reported that prior to (b)(6) and after (b)(6) the surgical instruments (cataract sets from (b)(4)) were processed by autoclave and there were no infections reported. During the period of (b)(6), the instrumentation was processed in eight cycles of the sterrad nx sterilizer. The doctor suspects the issue is related to processing in the sterrad nx sterilizer. The instruments are processed with enzymatic cleaner and then dried in a heating machine and then processed in the sterrad nx sterilizer. The instruments for cataract eye surgery are made up of **plastic and steel**.

Source

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=2117155

Adverse Event Report

ADVANCED STERILIZATION PRODUCTS STERRAD 100S STERILIZER Event Date 09/23/2011

Event Description

A healthcare worker (hcw) was transported via ambulance from the surgery center where she is employed to the hospital emergency room for symptoms of red swollen eyes, eye pressure, difficulty in breathing and lethargy. The hcw was administered oxygen and eyes were flushed with water before transporting. The hcw reported, she was in the sterile processing department (spd) 20 minutes when she began to experience the symptoms. The hcw was put on monitoring, given eye drops and blood work was done. The results of the blood work were within normal limit. The hcws eye swelling and redness subsided after eye drops were administered. There were no abnormalities detected during monitoring. She was discharged the same day. After turning on the sterrad nx and starting the cycle which was making an abnormal noise, the hcw said, the cycle completed and she then noticed her eyes swell up, and turn red. The reported smell was noted when the unit was running. The door was closed to the unit. A facility representative confirmed that the room smelled strongly of h202 or a chemical smell. The spd also houses an autoclave in the same room with the sterrad nx. It was reported there are no other chemicals. The facility had their autoclave checked and it is working normally. They also checked the air exchange in the room and found it to be normal. An asp field service engineer (fse) was dispatched to assess the unit. A preventive maintenance call was performed the day prior to this reported event.

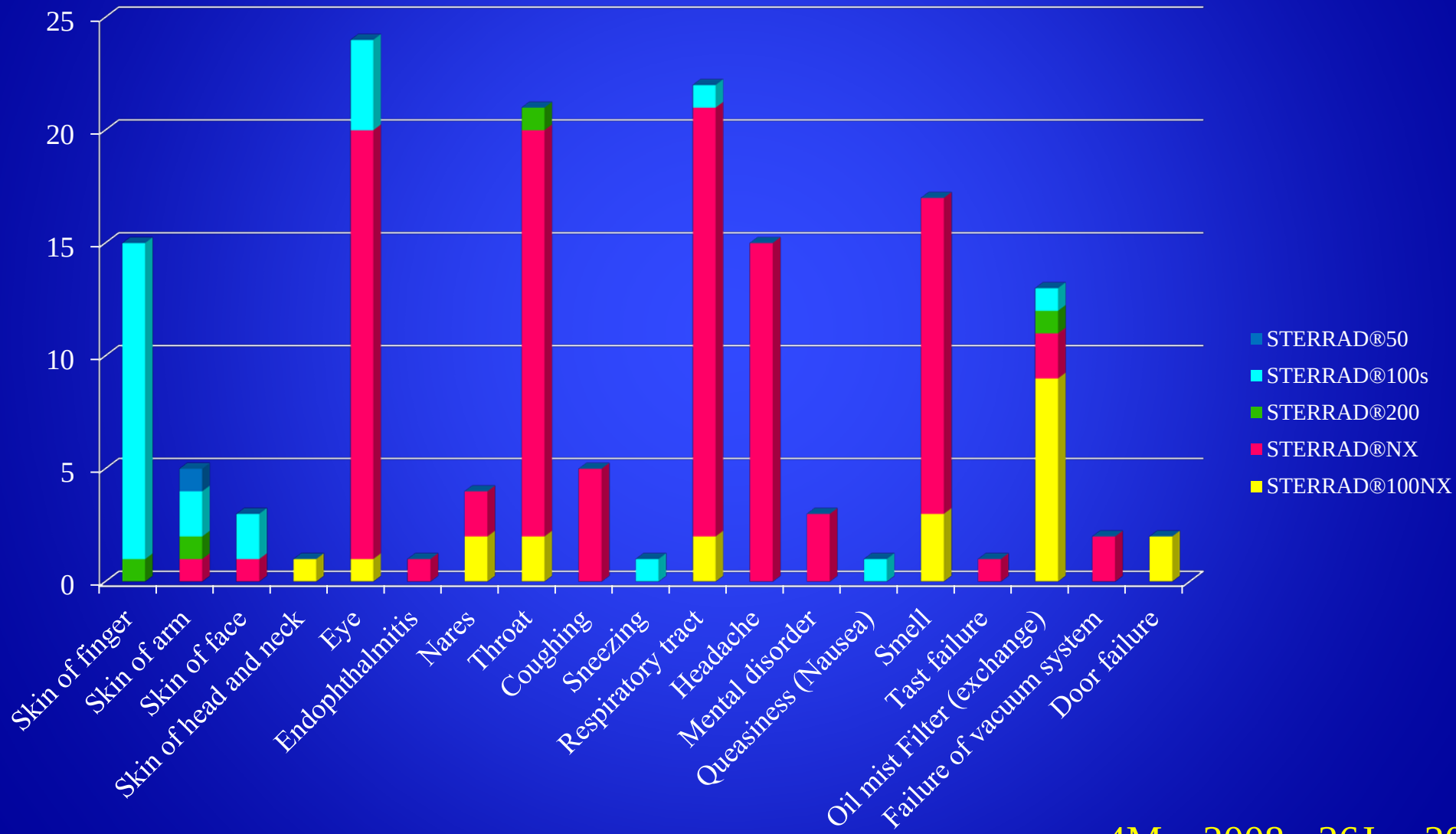
Manufacturer Narrative

On (b)(4) 2011, a preventive maintenance was performed in accordance with the service guide. The device met mfg specifications. The fse reassessed the unit and found no odors or mist emanating from the unit. The device met mfg specifications.

Search Alerts/Recalls

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=2302493

The List of Adverse Events of HP Exposures in the MAUDE Database of the FDA.



4Mar,2008 - 26Jan,2012

Adverse Events by Low temperature Hydrogen Peroxide Gas Plasma Sterilisation Reported by Certified Sterilisation Service Technicians (CSST) and Certified Sterilisation Specialists(CSS) in Japan

Method

- A questionnaire was sent to the total of 2,888 CSST and CCS by e-mails or letters.
- As a result, 515 CSST, 95 CSS, 119 others and 59 without replying their types of certifications had responded.
- A multiple response was excluded from the data.
- A total of 774 replies were included in the analysis.

Replies to Items in the Questionnaire

Item	Total	Yes (%)	No (%)	No reply (%)
Outsourcing of the Personnel Engaged in Central Service (外部委託)	774	324(41.9%)	386(49.9%)	64(8.3%)
Installation of LTHPGP Steriliser	774	472(61.0%)	251(32.4%)	51(6.6%)
Experience of Adverse Event(有害事象の経験)	472	136(28.8%)	302(64.0%)	34(7.2%)
Experience of the Influence on Sterilised Devices (デバイス影響の経験)	472	150(31.8%)	302(64.0%)	20(4.2%)
Contract for Regular Service(定期点検)	472	329(69.7%)	112(23.7%)	31(6.6%)
Sterilisation of Fiberscope by LTHPGP(内視鏡滅菌)	472	203(43.0%)	247(52.3%)	22(4.7%)
Adverse Event Caused by Fiberscope Sterilised by LTHPGP(内視鏡への影響)	203	6(3.0%)	194(95.6%)	3(1.5%)

Facilities Responded for the Number of Each Adverse Event Observed

Adverse event observed	Responded facilities*	Maximum N** /facility	Minimum N** /facility	Mean**
Skin of hand	57	10	1	1.9
Skin of arm	9	13	1	3.4
Skin of face	3	60	1	20.7
Skin of head	0			
Eye	2	60	1	30.5
Eyelid	1	1	1	1.0
Smell	13	20	1	5.8
Nasal cavity	6	60	1	11.0
Taste failure	0			
Tongue numbness	0			
Pharyngeal disorder	4	10	1	3.3
Coughing	2	2	1	1.5
Sneezing	3	2	1	1.3
Tracheal disorder	1	2	2	2.0
Headache	2	3	1	2.0
Nervous system disorder	0			
Nausea	4	2	1	1.3
Others	1	1	1	1.0

* : Number of facilities

Type of the Mask Employed

Mask	N*	%
Ordinary mask	21	6.7%
Surgical mask	289	92.6%
N95 mask	1	0.3%
Respirator	1	0.3%
Others	0	0.0%

* : Number of facilities

Nothing 22.8%

Results

- One hundred and thirty-six of 472 (28.8%) facilities have experienced adverse events caused by LTHPGP sterilisation.
- Experience of the influence on sterilised devices was reported from 150 out of 472 facilities, i.e., 31.8% of the all facilities .
- Among these facilities lesion of hand skin is the highest in number and followed by abnormal smell and lesion of arm as illustrated .
- However, routine use of respirator was adhered in only one facility.

Chemical Indicator
for Hydrogen Peroxide Sterilisation

Chemical Indicator（CI）

- CI is not intended to guarantee the sterility of medical equipment after the sterilisation.
- Class 1 process indicator is used for HP sterilisation.
- It is recommended that CI should be inserted into and put on the surface of each sterilising pouch with device or instrument, and that the colour change of CI should be confirmed after sterilisation process.


2011.8.21
10:37
inserted


2011.8.21
10:37
inserted
TANITA
Leukoclip SD
CI: 35min after insertion

TANITA

TIME ▲ ALM SNZ MAX MIN LIGHT

Control

STERRAD® Chemical Indicator Strip

3M Comply™ 1248 Gas Plasma Chemical Indicator Strip

VERIFY VAPORIZED VH2O2 Process Indicator

STERIS

2011.8.21
10:37
inserted

Leukoclip SD

CE

STERRAD® Chemical Indicator Strip

CI: 54min
after insertion


CI: 134min after insertion
1
2
Precise Vista Skin Stapler
TANITA
Cl insertion at 06:29
Control

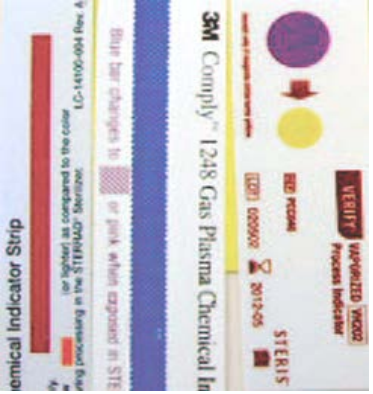

Staplers made
by polyetherimide
CI: 30min
after insertion
Leukoclip SD
Leukoclip SD

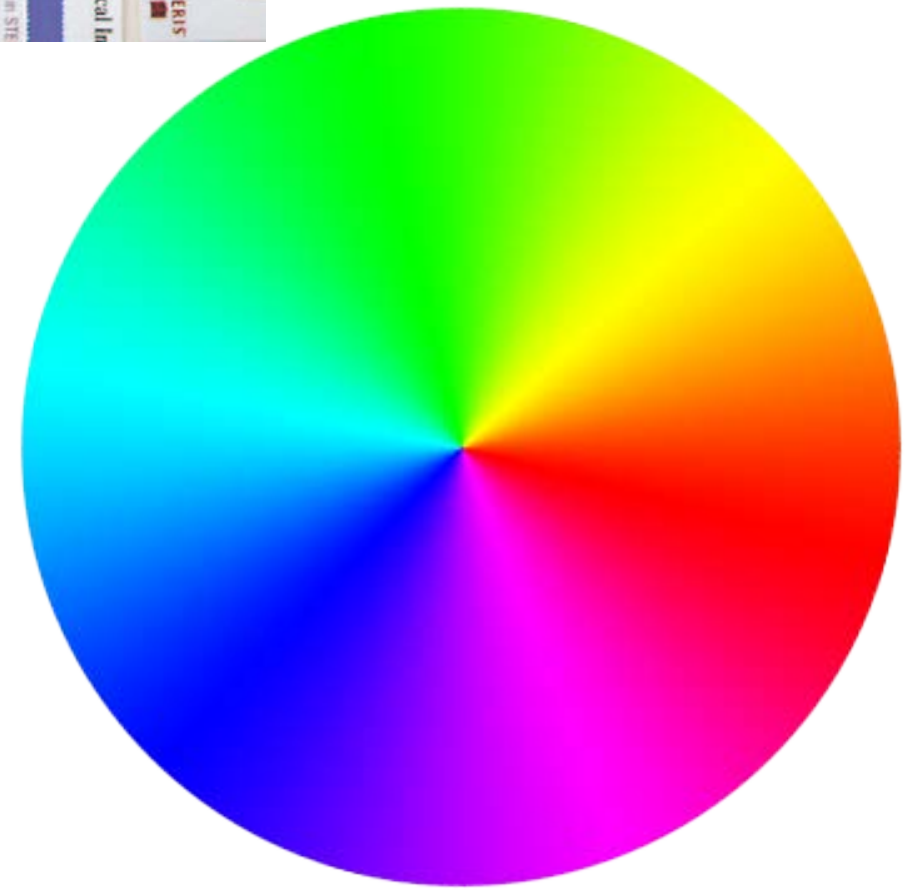

Staplers made
by polyetherimide
9:21
2011. 8. 21
CI: 60min
after insertion
STERRAD Chemical Indicator Strip
TAMITA
25.1 °C
51 %
10:21 45

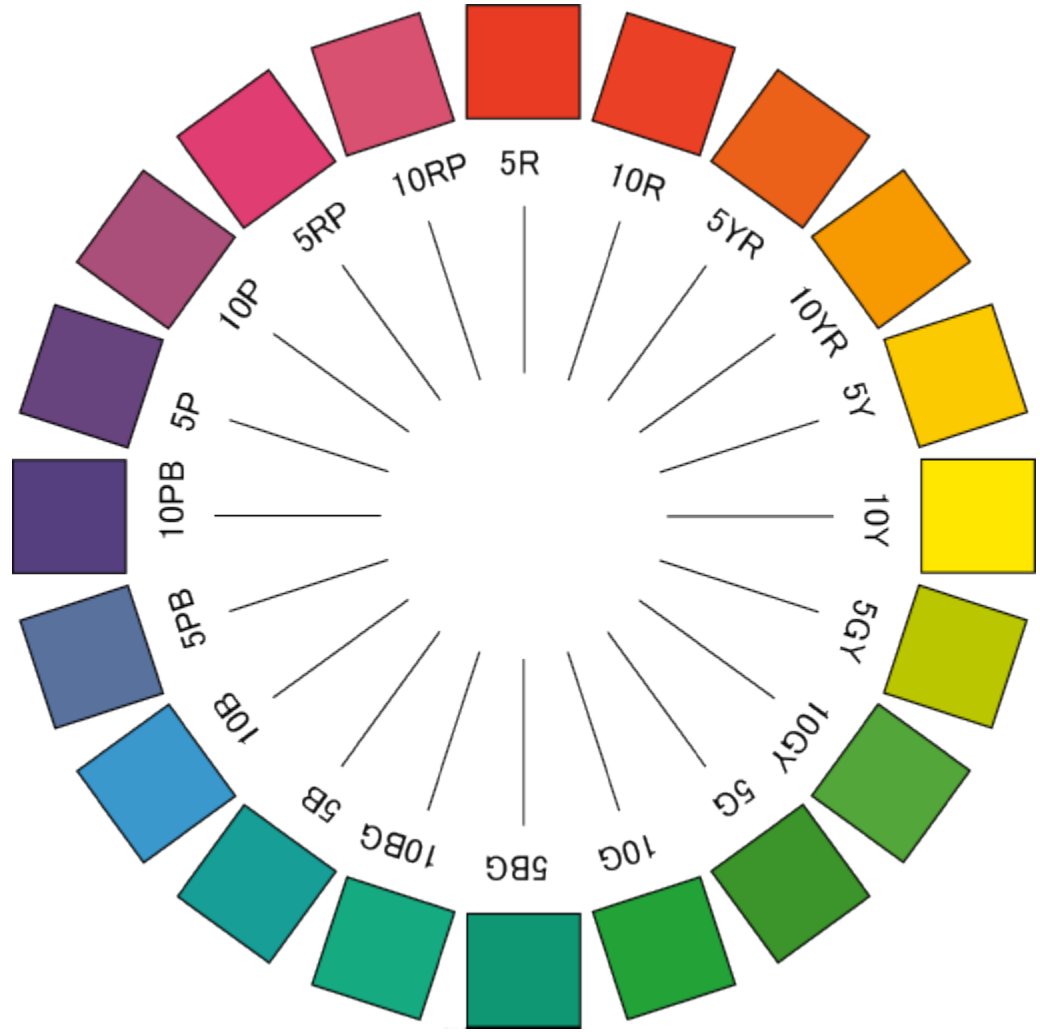
Results

- Before sterilisation, the colours of all three kinds of CIs contacted with reusable plastic devices sterlised by HPV and sealed in the sterilising bags or in the stainless steel containers were changed completely or incompletely.
- The colour change of CI endpoint is confirmed macroscopically.
- The macroscopic confirmation is easy method, however that is depending on the personal sense
- In three kind of CIs tested this time, both colour before and changed one after sterilisation belong to similar colour groups which means to may result in the misjudge of colour change.

Hue Circle


Indicator Strip
3M Comply™ 1248 Gas Plasma Chemical
Blue bar changes to
or pink when exposed in
STERIS




5R
10R
5YR
10YR
5Y
10Y
5GY
10GY
5G
10G
5BG
10BG
5B
10B
5PB
10PB
5P
10P
5RP
10RP

- Colour of CI should be investigated just before sterilising process, as occasionally the colour changes before sterilisation.

CI colour investigation should be

just before putting into pouch

just before sterilising process

just after sterilising process

- Three times investigation should be required for the sterility assurance.

Conclusion

- HPV sterilisation is the most useful procedure for the sterilisation of heat-labile medical devices at present. However, Safe and effective use of HPV steriliser should be re-evaluated.
- When HPV steriliser is employed, adequate air conditioning, donning gloves for bag handling, use of supplied-air respirator for door opening, adequate maintenance and other measures for the security of healthcare personnel should be seriously reevaluated.
- The CIs in the pouches with reusable items must be carefully checked before sterilization. It should be better to pack the devices with CIs just before sterilisation.
- For the safety of patients and hospital personnel, we must be careful for handling the medical devices sterilised by HPV and for the adverse events.

Thank you very much
for your kind attention