



STERILITY ASSURANCE PRODUCTS

20 YEARS NEW JOURNEY ...
NEW CHALLENGE

Autoclave Tape

- Conforms to ISO 11140-1 Type 1.
- CE marked.
- Easy to interpret.
- Cost effective.
- Individual rolls marked with lot.
- Number and expiry date.
- Non-toxic.
- Lead free.

Autoclave Tape

Autoclave tape for steam sterilisation enables the user to see at a glance that an item has been processed.

The easy to interpret black stripes prove that the pack has been exposed to the steam sterilisation process.

The tape securely sticks to non woven, paper, board, metal, plastic and glass and is manufactured from treated crepe paper and coated with high performance cross linked heat sensitive adhesive.



Order Details

PS1510

19 mm Autoclave tape Cartons of 48 rolls

PS1520

25 mm Autoclave tape Cartons of 36 rolls

Technical specifications

Name:	Autoclave tape for steam Sterilisation
Classification:	EN-ISO 11140-1 (Type 1)
Operating temp:	121°C - 134°C
Time:	As per specific sterilisation cycles minimum
Storage conditions:	134°C 3.5 minutes or equivalent
RH:	10°C - 30°C
Lot no.	30 - 70%
Prod date:	yes, on the core
Exp date:	yes, on the outer carton
Correct symbols:	yes, on the core in accordance with the standard
Indicator:	yes
Expiry Date:	2 years
Extra information:	Medical crepe paper yes
Substrate	Information can be written on the tape with a ParaSure PIP
Coated	Colour change from white to brown
Recordable Information:	25mm width tape = cartoon of 36 rolls 19mm
Packaging:	width tape = cartoon of 48 rolls

Parametric Assurance Systems

Product Name Steam Autoclave Tape

Product Description Parasure Steam Autoclave Tape is a self-adhesive tape printed along its length with diagonal strips of chemical indicator ink.

The indicator ink is sensitive to the process parameters of steam sterilization.

Steam Tape is used to seal steam sterilization packages that use non-woven packs or textile packs.

This product is designed for use in common steam sterilization processes at 121°C, 132°C or 134°C.

After the sterilization cycle, the indicator ink on the tape will change from the initial color (cream) to the reference color (dark brown / black).

Each roll of steam tape is 50 m long and 12mm, 19 mm or 25 mm wide.

LOT and expiry date information can be found on the product label.

The shelf life of our product is 2 years.

Instructions for use

- Pack the medical device to be sterilized with the appropriate size and type of dressing.
- Correct packing method will increase product performance.
- Secure the packages with Steam Autoclave Tape.
- Observe the Steam Band after sterilization.
- Make sure the autoclave tape indicator ink has returned to the reference color specified in the table.
- If the indicator ink has not changed, exposure to the sterilization process may not have occurred due to an equipment malfunction or procedural error in the sterilization process.
- In this case, repeat the sterilization process.

Precautions

- The medical device is for single use only, do not reuse.
- Check the product before using it. Do not use the product that is deformed or has a color change in the indicator color.
- Do not use expired products.

Storage, Storing and Disposal Information

- Do not expose to direct sunlight and keep dry.
- Between 0°C and 40°C and Max.
- Store at 70% RH humidity.
- Store in its original packaging.
- Dispose of as general waste.

Product and packaging information

Product Code	Product Description	Package Contents	Inner Box Quantity
PS 1575	Steam Autoclave Tape 12 mm X 50 m	1 Pc	64 pcs
PS 1510	Steam Autoclave Tape 18 mm X 50 m	1 Pc	48 pcs
PS1520	Steam Autoclave Tape 25 mm X 50 m	1 Pc	36 pcs

Bowie & Dick Test Sheet

- Clear pink to black colour change.
- Diagnostic technology.
- Conforms to EN ISO 11140-1 Class 2.
- Test results can be recorded directly on to sheet.
- Sterilization cycle of 134oC for 3.5 minutes.
- Non-toxic.
- Cost effective.

The ParaSure Bowie & Dick A4 Test Sheet

Are supplied in boxes of 50 sheets and are for use with huck-a-back towels.

A Bowie & Dick test should be carried out daily for each sterilizer in order to monitor performance effectively.

A successful cycle at 134oC for 3.5 minutes will ensure that the blue pattern on the test sheet changes completely to black but the diagnostic technology also helps to detect problems with time, steam quality or temperature.

Detailed instructions for use are included in each box of 50 sheets to ensure the correct application.

Each test sheet has fields into which the cycle details can be recorded, giving an easily accessible record for inclusion in the sterilization file.

For the daily monitoring of pre-vacuum steam sterilizers

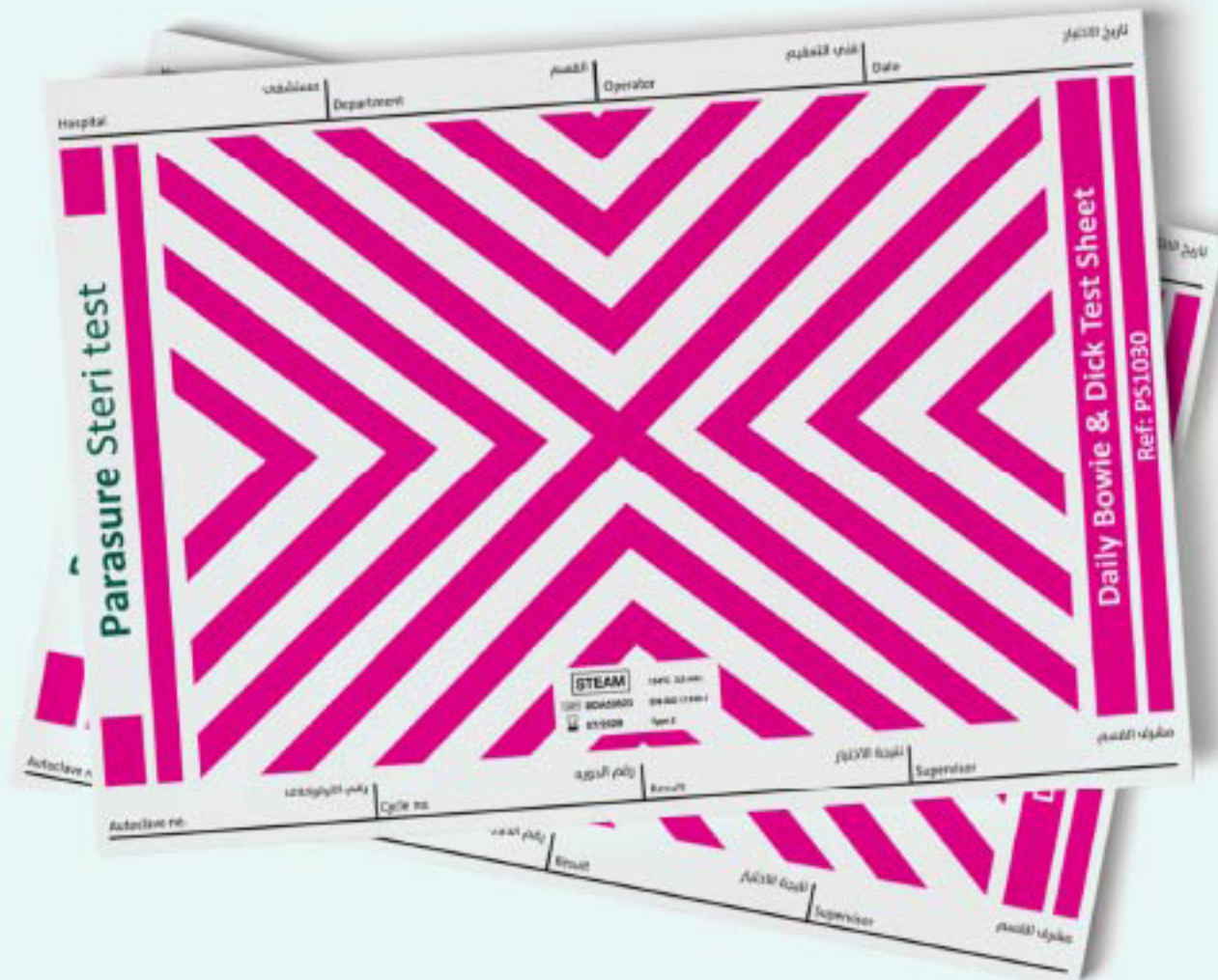


**Order
Details**

PS1030

Bowie & Dick A4 Test Sheet
Box of 50 sheets

Daily Bowie & Dick Test Sheets (Pink to Black)



Unprocessed test sheet



Successfully processed test sheet



FAIL: insufficient air removal



FAIL: superheated steam



FAIL: wet steam

Instructions for use

Steam Autoclave tape PS 1510, 1520 and PS 1575

The A4 test sheet is to be used in a standard textile pack which according to the ISO 11140-1 standards shall be composed of plain cotton sheets, each bleached to a good white and having an approximate size of 900mm x 1200mm.

The number of threads per centimetre in the warp shall be 30 (+/- 6) and the number of threads in the weft 27 (+/- 5). The weight shall be 185 (+/- 5) g/m² and the edges shall not be hemmed (EN 285).

The sheets will need to be aired for at least one hour under room conditions before the pack may be used again.

When soiled, the sheets shall be washed without the use of a conditioner.

After airing, the sheets must be folded to approx. 220mm x 300mm and stacked to a height of approx. 250mm after compressing by hand.

The pack must be wrapped in a similar fabric and secured with autoclave tape not exceeding 25mm in width.

The total weight of the pack shall be 7.0 kg +/- 10 %.

When the weight of the pack to form a stack of 25 cm exceeds 7.7 kg the sheets should be discarded.

Note: other textiles can be used provided equivalence is demonstrated.

A Bowie & Dick test shall be carried out at the beginning of each day the sterilizer is to be used (EN 554-6.3.4).

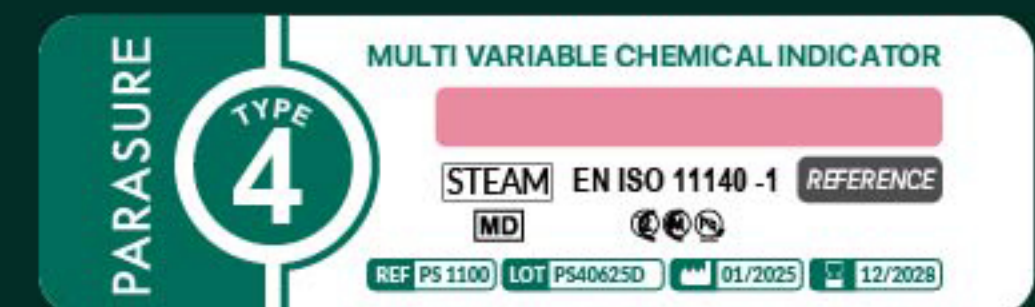
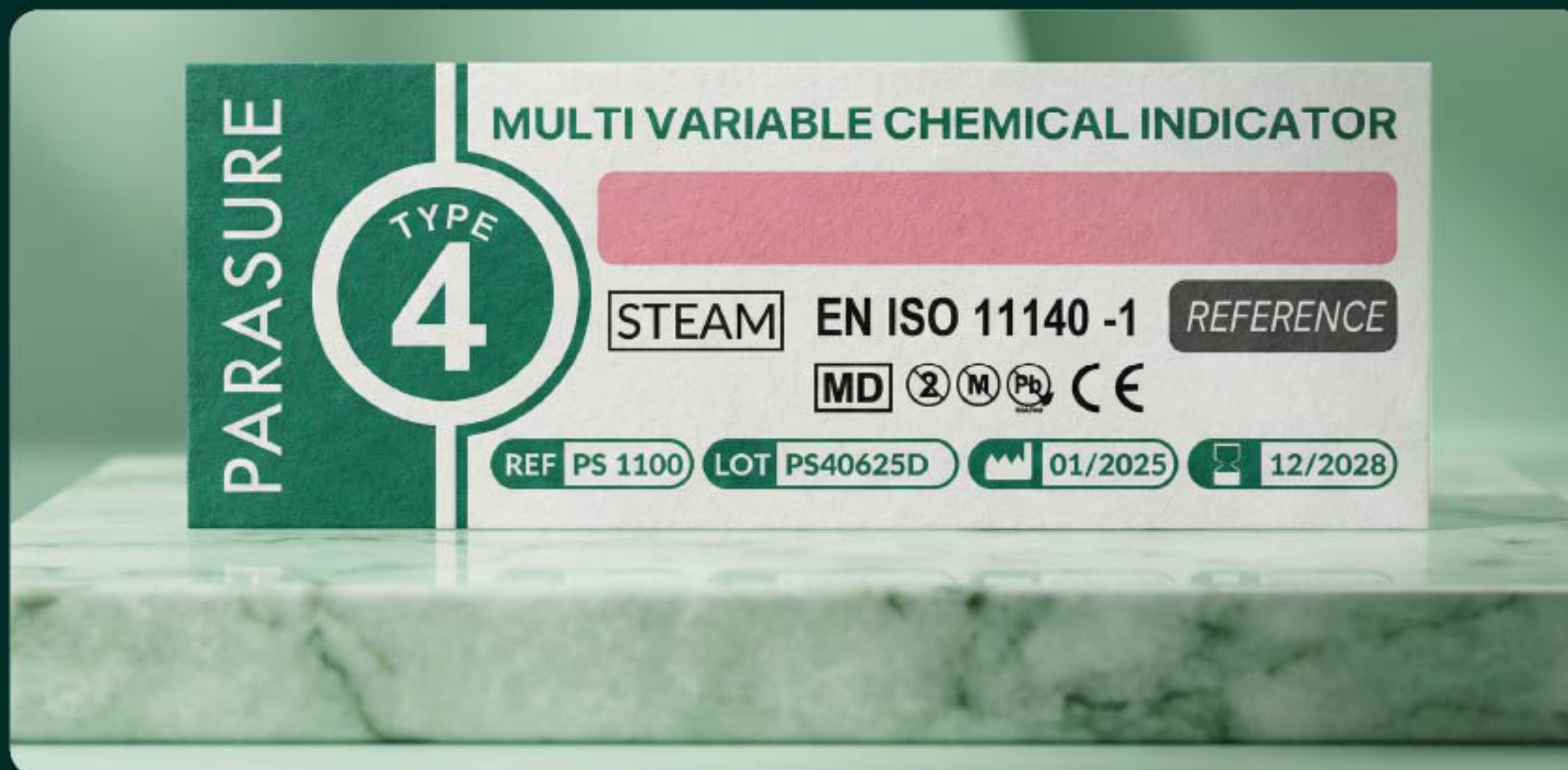
1. Before conducting the Bowie and Dick test first run a warm up cycle to ensure that the sterilizer is in operating condition.
 2. Open the test pack.
 3. Place the Bowie & Dick A4 Test sheet in the middle of the test pack and re-wrap the pack.
 4. Place the pack in the centre of the sterilizer chamber, using the normal sterilizer chamber furniture.
 5. Make sure the pack is at least 10 cm away from the chamber walls, floor, ceiling and doors.
 6. Run a 3.5 minutes 134°C sterilization cycle, which uses the same air removal steam penetration phase as the routine production cycle does.
 7. Do not exceed a post sterilization drying time.
 8. Take the pack from the sterilizer, leave it to accommodate for approx. 5 minutes.
 9. Open the pack and interpret the results.
 10. The test sheet must have changed from blue to black.
 11. Record the results on the test sheet with other relevant data.
- In case of failure the sterilizer is not functioning properly and needs maintenance, adjustment and / or subsequent validation.
12. The test sheet should be included in the sterilization file.

Type 4 Multivariable Chemical Indicator

- CE Marked.
- Patented Design.
- UDI Numbered.
- Each strip can monitor all Steam sterilization cycles ranging from 121°C to 134°C.
- Conforms to ISO 11040 Part 1 Type 4.
- Clear accurate colour change.
- Laminated.
- For use in every tray or item.

The ParaSure Type 4 Dual Multi Parameter indicators offer an economical yet effective way of monitoring your steam sterilisation processes.

- With one accurate calibration world wide it is a secure and safe monitoring system yet simple and easy to use.
- Unlike most other Type 4 indicators available today the ParaSure indicator is non toxic.
- Another sign of its advanced technology.



Order Details

PS 1100 200/400 tests

Type 4 Multi-Parameter Indicators

Successfully
processed indicator



All lines shows evidence of black.

PASS

*Items in
tray/pack can
be safely used*

Unsuccessfully
processed indicator



One or more lines shows evidence of pink.

FAIL

*Do NOT use
items in
tray/pack*

Unsuccessfully
processed indicator



One or more lines shows evidence of pink.

FAIL

*Do NOT use
items in
tray/pack*

Unsuccessfully
processed indicator



One or more lines shows evidence of pink.

FAIL

*Do NOT use
items in
tray/pack*

Type 4 Multi-Parameter Indicators

PS1110

Type 4 laminated Indicator Systems PS 1100

Instructions for use

ParaSure Type 4 Indicators are designed for use in steam sterilizers and are specifically calibrated to operate at temperatures from 121°C to 134°C in steam sterilization cycles when used as directed, the type 4 indicator gives visual confirmation that sterilization conditions were met at the location in the sterilizer chamber.

Colour change

During steam sterilization, the 3 indicators must all change from pink to black . Any pink remaining reflects a fail.

Instructions for use

1. Place a ParaSure Type 4 Indicator into each pack, peel-pouch or tray to be processed.
2. Process the loads according to the sterilizer manufacturer's instructions.
3. Following the arrival of the item / pack or tray at the point of use the user should visually inspect that all indicator lines have changed to black.
4. If the indicator lines have not changed colour, it suggests inadequate sterilization conditions and the items must be re-sterilized with new indicator monitors.

Safety precautions

- If there is any doubt about sterility of item, it must be considered NOT sterile.
- Do not use any strips whose indicator box is not blue in colour prior to exposure.
- Not recommended for use in a "flash" sterilization cycle.

Storage

ParaSure Type 4 Indicators should be stored between (50°F - 100°F / 10°C - 38°C) in the re-sealable bag provided.

No special storage conditions are necessary after exposure to steam sterilization conditions.

Lot number

A unique identification code, LOT printed on each indicator strip and packaging labelling.

Calibration

PS 1100 – steam sterilization cycles operating from 121°C to 134°C.

Expiry date

Expiry date is printed on the product and packaging.

Integrating Chemical indicator

Moving Line
Type 5

- Conforms to requirements of ISO 11140 Part 1 Type 5.
- CE Marked.
- UDI numbered.
- Patented Design.
- It is easy to read and interpret.
- Non-toxic.



Order
Details

PS1830
500 pieces per box

Integrating chemical indicator moving line

Integrating chemical indicator moving line - Type 5.

The ParaSure type 5 indicator mirrors the performance of biological indicators used in steam sterilisation processes at 134 or 121 degrees celcius.

When exposed to the correct parameters the pellet melts and travels through the wicking paper to the accept area.

If the correct parameters are not achieved the bar will remain in the reject / fail area.



Type 5 Chemical Indicator

PS1830

Successfully
processed indicator

The bar has gone beyond the accept line.

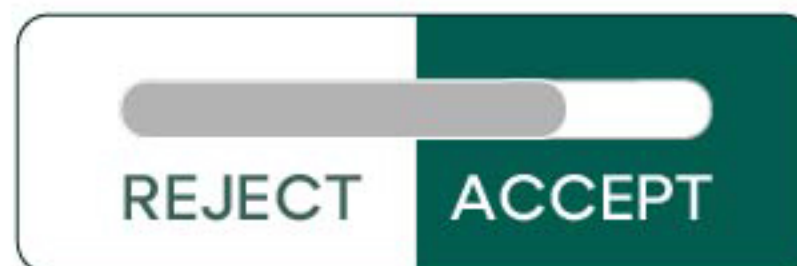


PASS

*Items in
tray/pack can
be safely used*

Unsuccessfully
processed indicator

The bar has gone beyond the accept line.



PASS

*Items in
tray/pack can
be safely used*

Unsuccessfully
processed indicator

The bar has not reached beyond the accept line.



Cause: insufficient steam penetration

FAIL

*Do NOT use
items in
tray/pack*

Unsuccessfully
processed indicator

The bar has not reached beyond the accept line.



Cause: non-condensable gases present

FAIL

*Do NOT use
items in
tray/pack*



Moving Line Type 5

500 pieces
per box

Type 5 Integrating Moving line indicator

Instructions for use

ParaSure Type 5 moving line indicators are designed for use in steam sterilizers and are specifically calibrated to operate at temperatures from 121 C to 134 C in steam sterilization cycles when used as directed, the type 5 indicator gives visual confirmation that sterilization conditions were met at the location in the sterilizer chamber.

Accept / Fail

During steam sterilization process the wick line moves along the window moving from reject to accept during a successful sterilization process

Instructions for use

1. Place a ParaSure Type 5 Moving line Indicator into each pack, peel-pouch or tray to be processed.
2. Process the loads according to the sterilizer manufacturer's instructions.
3. At the point of use the indicator is inspected to determine the pass / fail result.
4. If the accept / pass line has not been reached, it suggests inadequate sterilization conditions and the items must be re-sterilized with new indicator monitors.

Safety precautions

- If there is any doubt about sterility of item, it must be considered NOT sterile
- Do not use any strips whose indicator window has progressed in any way prior to exposure.
- Not recommended for use in a "flash" sterilization cycle.

Lot number

A unique device identification code and lot number are printed on each indicator strip and packaging labelling.

Expiry date

Expiry date is printed on the product packaging.

Storage

ParaSure Type 5 moving line Indicators should be stored between 50°F-100°F 10°C-38°C) in the re- sealable bag provided.

No special storage conditions are necessary after exposure to steam sterilization conditions.

Calibration

PS 1830 and PS1830 L – all steam sterilization cycles operating from 121°C to 134°C.

PS 1830 and PS 1830 L

Type 5 Integrator Steam

PS 1840



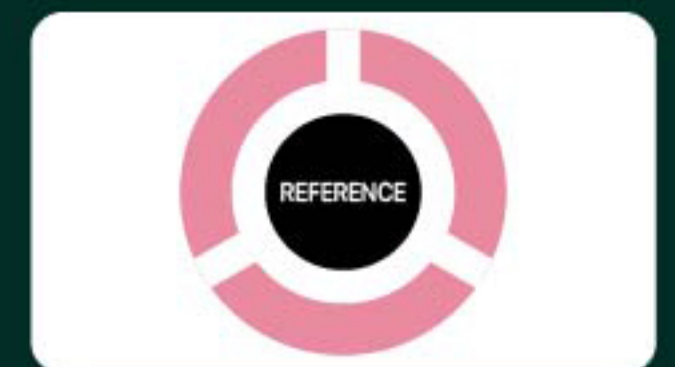
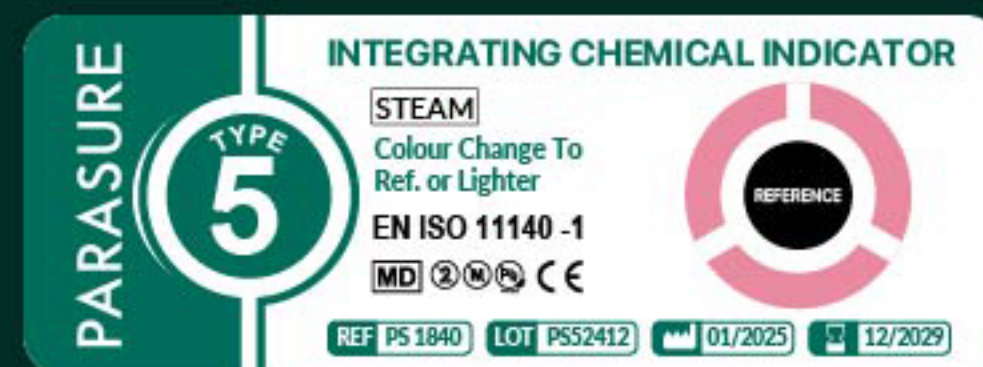
- Conforms to EN ISO 11140-1.
- Type 5.
- Type 5 Integrating indicator.
- Monitors critical parameters Time, Temperature, Steam.
- For use in every tray or item.
- Clear and abrupt colour change.
- Easy to interpret - easy to record.
- Non-toxic / Lead free.

The ParaSure Type 5 Integrator Steam offers the highest level of proof of the achievement of Sterility Assurance levels in your trays and items.

The type 5 integrator follows the death curve of the relevant Biological spore.

Order
Details

PS 1840
Type 5 Integrator Steam
Bag of 250 indicators

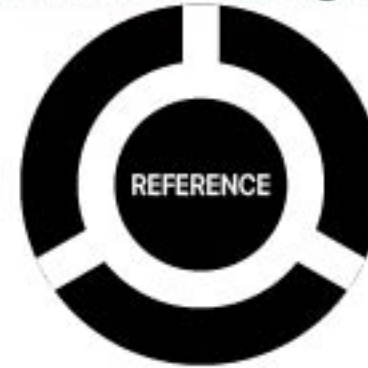


Type 5 Chemical Indicator

PS 1840

Successfully
processed indicator

All three additional triangles are now black.



PASS

*Items in
tray/pack can
be safely used*

Unsuccessfully
processed indicator

Only partial colour change to bottom triangle.



Cause: only temperature present

FAIL

*Do NOT use
items in
tray/pack*

Unsuccessfully
processed indicator

Only partial colour change to top and middle triangle.



Cause: insufficient steam penetration

FAIL

*Do NOT use
items in
tray/pack*

Unsuccessfully
processed indicator

Only partial colour change to middle and bottom triangle.



Cause: non-condensable gases present

FAIL

*Do NOT use
items in
tray/pack*

Type 5 Integrator Steam



PARASURE

Bag of 250
indicators

Type 4 laminated Indicator Systems PS 1100

Instructions for use

ParaSure Type 5 Indicators are designed for use in steam sterilizers and are specifically calibrated to the individual cycles listed below. When used as directed, the Indicator gives visual confirmation that sterilization conditions were met at the location in the sterilizer chamber.

Colour change

During steam sterilization, the indicator changes from pink to dark brown / black .

Instructions for use

1. Place a ParaSure Type 5 Indicator into each pack, peel-pouch or tray to be processed.
2. Process the loads according to the sterilizer manufacturer's instructions.
3. Following the sterilization cycle, visually verify that the indicator spot has changed colour from pink to black.
4. If the indicator spot has not changed colour, it suggests inadequate sterilization conditions and the items must be re-sterilized with new indicator monitors.

Safety precautions

- If there is any doubt about sterility of item, it must be considered NOT sterile.
- Do not use any strips whose indicator box is not pink in colour prior to exposure.
- Not recommended for use in a "flash" sterilization cycle.

Lot number

A unique identification code, LOT printed on each indicator strip and packaging labelling.

Expiry date

Expiry date is printed on the product packaging.

Storage

ParaSureType 6 Indicators should be stored between (50°F-100°F 10°C-38°C) in the re-sealable bag provided.

No special storage conditions are necessary after exposure to steam sterilization conditions.

Calibration

All steam sterilization cycles operating between (121 °C & 134°C).

Type 6 Emulating Indicator

PS 1840

3.5 minutes at 134°C | 15 minutes at 121°C

- Conforms to EN ISO 11140-1 Type 6.
- Type 6 emulating indicator.
- Specifically calibrated to 3.5 minutes at 134°C and 15 minutes at 121°C.
- Monitors critical parameters Time, Temperature, Steam.
- For use in every tray or item.
- Clear and abrupt colour change.
- Easy to interpret - easy to record.
- Non-toxic / Lead free.

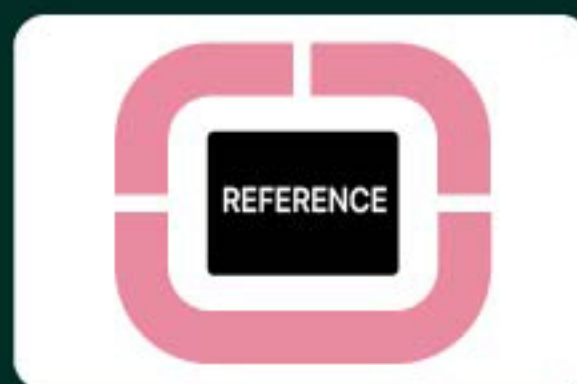


PARASURE



The ParaSure Type 6 chemical indicators offer the highest level of proof of the achievement of Sterility Assurance levels in your trays and items.

- These indicators are calibrated specifically to your cycle requirements.
- ParaSure Type 6 indicators offer validated security that every tray or item has been effectively processed, thereby providing a direct link between the sterility of the items and the patient.



Order
Details

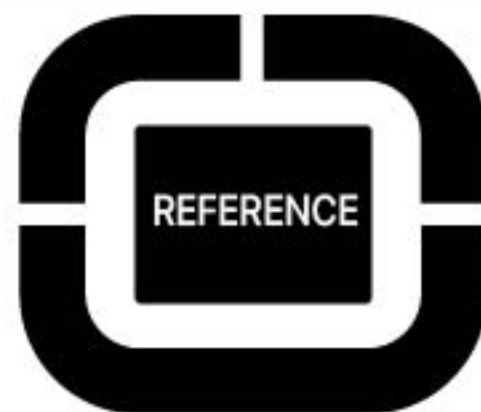
PS1110

Type 6 emulating indicator,
Box of 200 indicator

Type 5 Chemical Indicator

PS 1840

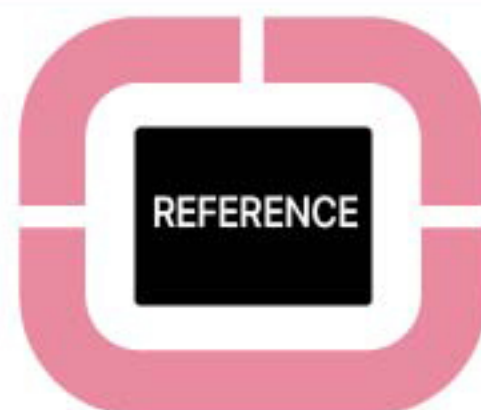
Successfully
processed indicator



PASS

*Items in
tray/pack can
be safely used*

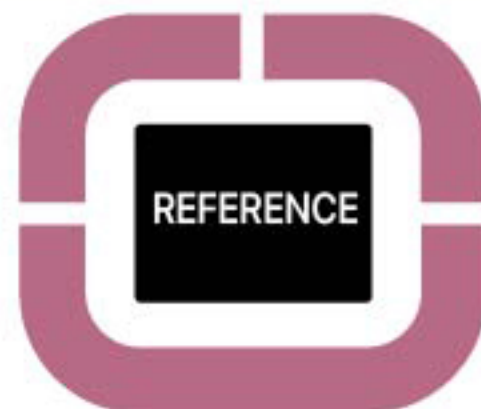
Unsuccessfully
processed indicator



FAIL

*Do NOT use
items in
tray/pack*

Unsuccessfully
processed indicator



FAIL

*Do NOT use
items in
tray/pack*

Unsuccessfully
processed indicator



FAIL

*Do NOT use
items in
tray/pack*

PS

PS 1110

3.5 minutes at 134°C.

PS 1130

5.3 minutes at 134°C.

PS 1140

4.0 minutes at 134°C.

PS 1160

7.0 minutes at 134°C.

Type 6 Indicator

PS 1110

Instructions for use

ParaSure Type 6 Indicators are designed for use in steam sterilizers and are specifically calibrated to the individual cycles listed below. When used as directed, the Indicator gives visual confirmation that sterilization conditions were met at the location in the sterilizer chamber.

Colour change

During steam sterilization, the indicator changes from pink to dark brown / black .

Instructions for use

1. Place a ParaSure Type 6 Indicator into each pack, peel-pouch or tray to be processed.
2. Process the loads according to the sterilizer manufacturer's instructions.
3. Following the sterilization cycle, visually verify that the indicator spot has changed colour from pink to black.
4. If the indicator spot has not changed colour, it suggests inadequate sterilization conditions and the items must be re-sterilized with new indicator monitors.

Safety precautions

- If there is any doubt about sterility of item, it must be considered NOT sterile
- Do not use any strips whose indicator box is not pink in colour prior to exposure.
- Not recommended for use in a " flash " sterilization cycle.

Lot number

A unique identification code, LOT printed on each indicator strip and packaging labelling.

Expiry date

Expiry date is printed on the product packaging.

Storage

ParaSureType 6 Indicators should be stored between (50°F-100°F 10°C-38°C) in the resealable bag provided.

No special storage conditions are necessary after exposure to steam sterilization conditions.

Calibration

PS 1110 3.5 minutes at 134°C.
PS 1130 5.3 minutes at 134°C.
PS 1140 4.0 minutes at 134°C.
PS 1160 7.0 minutes at 134°C.

Type 4 chemical indicator

FOR VHP / H2O2 Sterilisation processes

- Conforms to requirements of ISO 11140 - Part 1 Type 4
- CE Marked - Non-toxic - UDI Numbered
- Tyvek substrate
- Patented Design
- It is easy to read and interpret.

The Type 4 chemical indicator

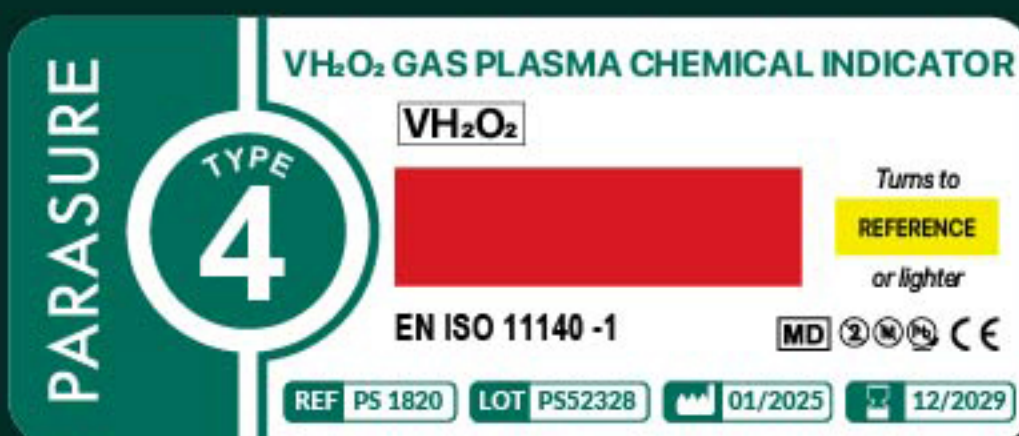
The ParaSure Type 4 chemical indicator for all calibrations of VHP, H2O2 and plasma sterilisation processes.

Color Conversion Chart

Before Sterilization



After Sterilization



Order
Details

PS1820

200 pieces per box



VHP / Plasma type 4 indicator

PS 1820

Description:

Product Name: Chemical Indicator Plasma Type 4

Product Description:

Parasure VHP Chemical Indicator Strips for Hydrogen Peroxide Plasma sterilizers are designed for use with individual units (e.g. packs, containers) to indicate that the unit has been directly subjected two or more of the parameters a VH₂O₂ / Plasma process. After a successful sterilization cycle, the indicator color changes to the reference color.

LOT and expiry date information can be found on the product label.

The shelf life of our products is 3 years from date of manufacture.

Our product meets the performance specifications of ISO 11140-1 "Sterilization of health care products - Chemical indicators - Part 1: General specifications" for type 4 Indicators.

Instructions for use

Product Name: Chemical Indicator Plasma Type 4

Place a Parasure chemical indicator strip in each pack, peel bag or tray for sterilization.

Always sterilize the load in a Hydrogen Peroxide (Plasma) sterilizer.

At the end of the sterilization cycle, verify that the indicator ink has returned to the reference color.

Packages, pouches and containers should only be opened during use as they are considered non-sterile items once opened.

Follow hospital policy for load release.

If the indicator has not changed to the reference color, this indicates inadequate sterilization conditions and the medical device must be reserialized (as per hospital policy) with new/unprocessed indicator strips.

Storage, Storing and Disposal Information

- Do not expose to direct sunlight and keep it dry.
- Between 0°C and 40°C and Max. Store at 70% RH humidity.
- Store in its original packaging.
- Dispose of as general waste.

Warnings and Precautions

- The medical device is for single use only, do not reuse.
- Check the product before using it.
- Do not use the product that is deformed or has a color change in the indicator color.
- Do not use expired products.

Duplex 3 Line Documentation Label & Gun

- Conforms to EN ISO 11140-1 Type 1.
- Duplex Label for effective sterilisation.
- Steam process indicator - easy to read.
- Records : process date, expiry date, operator number, steriliser number and cycle number.
- Easy to use with the ParaSure Label Gun.
- Non-toxic.
- Lead free.

Duplex 3 Line Documentation Label & Gun

This simple to use duplex documentation label for steam sterilisation processes creates a direct link between the process and the patient.

Copatile with all manual traceability systems, it is suitable for use in hospital, clinic, GP and dental environs in both large and table top sterilisers.

Used in conjunction with the ParaSure label gun, the relevant information including process date, expiry date, operator number, steriliser number and cycle number is printed using the gun during the preparation process.

After sterilisation, the label is peeled off and reapplied to either patient or departmental records as evidence of an effective process.



Order Details

PS1500

Duplex 3 Line | Documentation Labels
30 rolls x 400 labels/carton

PS1530

3 Line Documentation
Label Gun | Single unit

PS1540

Ink Cartridge for Label Gun | Single Unit

Technical specifications

Name:	Duplex 3 Line Documentation Label & Gun.			
Classification:	EN ISO 1140-1 Type 1.			
Operating temp:	121°C-134°C Steam.			
Time:	3.5 mins at 134°C (Steam).			
Storage conditions:	10-30°C			
RH:	30% - 70%			
Lot no.	yes			
Prod date:	yes			
Exp date:	yes			
Correct Symbols	In accordance with EN ISO 11140-1 Type 1.			
Indicator:	clear colour change, pink to brown for steam.			
Disp/single use:	yes but can be used as part of a record system.			
Extra Information:	Non-toxic/Lead free	yes	Adhesive	yes
Recordable Information:	Process date	yes	Cycle number	yes
	Expiry date	yes	Operator	yes
	Autoclave number	yes	Colour change	yes
Recordable Information:	Sterilisation Label Gun Easy to use, the label gun prints the following onto the label for record purposes; process date expiry date operator number steriliser number cycle number.			

EN 867-5 Helix Device

- Universal application in all Type B sterilisers.
- Complete system (device and 250 indicators).
- Easy to interpret.
- Self-adhesive indicator.
- Conforms to EN 867-5.



3.5 minutes at 134°C



PS1400
EN 867-5 Helix Device
Device & 250 Indicator

**Order
Details**

EN 867-5 Helix Device

The ParaSure EN 867-5 Helix device is used for the daily testing of the mechanical function of small vacuum - assisted steam sterilisers as specified in EN ISO 13060 Type B.

It is a combination of an indicator placed into a hollow lumen challenge device of 1.5 metres in length with a 2 mm inner diameter.

Technical specifications

Name:	EN 867-5 Helix Device
Classification:	EN867 Part 5
Operating temp:	134°C/132°C
Time:	3.5 min / 4 min
Storage conditions:	10°C -30°C
RH:	30-70%
Lot no.	yes, on the indicator
Prod date:	yes, on the box
Indicator:	yes in accordance with EN-ISO 11140-1 (Type2)
Disp/single use:	250 cycles
Extra information:	
Coated	yes
Non-toxic/Lead free	yes
Lot no.	yes
Recordable Information:	
Pass/fail result:	yes
Colour change:	pink to black

Bowie and Dick Test

- Conforms to EN ISO 11140-4.
- CE Mark.
- GTIN numbered.
- Independently validated to mirror the performance of the original.
- Diagnostic capabilities:
 - air removal.
 - wet steam.
 - super heated steam or presence of non-condensable gases.
- Clear and accurate colour change.
- Easy to interpret – easy to record.
- Non-toxic, single use, disposable.
- Lead free.

Bowie and Dick Daily Steriliser Test (B&D Test) The ParaSure B&D test pack fulfils the requirements of both EN 285 and EN ISO 17665

- The test is performed at the beginning of each working shift in every vacuum assisted steam steriliser.
- This non-toxic test is not a test of sterility but a test of the mechanical function of the steriliser to ensure rapid and even steam penetration into a small porous load.



Order Details

PS1020

Bowie and Dick Test pack | Box of 30

Technical specifications

Name: Duplex 3 Line Documentation Label & Gun.

Classification: EN ISO 1140-1 Type 1.

Operating temp: 121°C-134°C Steam.

Time: 3.5 mins at 134°C (Steam).

Storage conditions: 10-30°C

RH: 30% - 70%

Lot no. yes

Prod date: yes

Exp date: yes

Correct symbols: In accordance with EN ISO 11140-1 Type 1.

Indicator: clear colour change, pink to brown for steam.

Disp/single use: yes but can be used as part of a record system.

Information on pack:	cover	yes	Filtration medium	yes
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Extra information:	Sheet	yes	Non-toxic/Lead free	yes
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	Coated	yes	Lot no.	yes
--	--------	-----	---------	-----

Recordable Information:	Hospital	yes	Operator	yes
--------------------------------	----------	-----	----------	-----

	Department	yes	Supervisor	yes
--	------------	-----	------------	-----

	Autoclave no.	yes	Pass/fail result	yes
--	---------------	-----	------------------	-----

	Cycle no.	yes	Colour change	Pink to black
--	-----------	-----	---------------	---------------

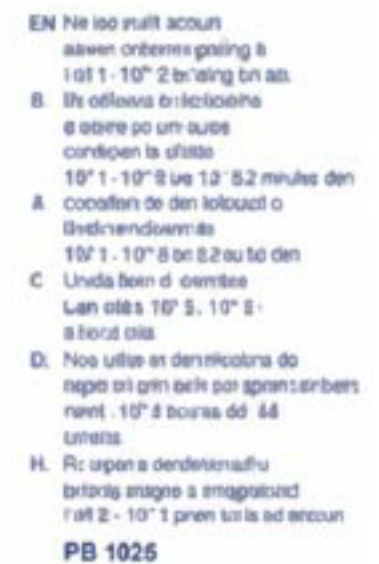
	Date	yes		
--	------	-----	--	--

Reverse of Indicator Sheet

Daily Bowie and Dick type test



Daily Bowie and Dick type test



Wrapper



SITE KRANNENHAUS OSPEDALE HOSPITAL	AUTOClave NO STERILISATOR NO AUTOCLAW NO N° ESTIERILUZDOR
DEPARTMENT ABTBILLIG REPARTO DEPARTAMENTO:	CYCLE NUMBER ZYKLUS NUMBER NUMERO DI CICLO N° CICLO
SUPERVISOR LEITER SUPERVISORE SUPERVISOR	OPERATOR AUSGEFÜHRT VON OPERATORE OPERARIO
DATE DATUM DATA FECHA	RESULTS ERGERINS RISULTATO RESULTADO

Biological Indicator for Steam Sterilization

- Conforms to EN ISO 11138.
- 24 hour results for steam sterilization.
- No laboratory required - Easy to culture.
- Dramatic colour change - Easy to interpret.
- Non-toxic.

ParaSure self-contained biological indicators monitor steam and sterilization. Each unit contains bacterial spores on a filter-paper carrier packaged within a small, thermoplastic culture tube.

Inside the thermoplastic culture tube is a sealed-glass ampoule of specially-formulated soybean casein digest culture medium containing a colour indicator which turns a dramatic yellow when spores grow.

ParaSure biological indicators are easy-to-use and produce visual results within 24 hours (steam) without laboratory transfers and are traceable to a recognized culture collection and certified for population, D-value, Z-value and performance.

The ParaSure incubator is an adjustable temperature unit offering 3 temperature settings, an integrated thermometer, an activation cavity and a 60°C temperature setting for inexpensive incubation of biological indicators for steam.



**Order
Details**



PS1900

Self-Contained Biological Indicators for
Steam Sterilization 10⁶ box of 100 units

Instructions for use

Self-Contained Biological Indicators for Steam PS 1900

For optimum control of hospital sterilized goods, we recommend that ParaSure biological indicators be used to monitor every sterilizer load. Monitoring use is the responsibility of each institution or end user.

CAUTION: After sterilization, the contents of the ParaSure biological indicator are hot and under pressure. Always allow to cool at least 10 minutes. Failure to cool at least 10 minutes may cause the glass ampoule to burst and may result in injury from hot liquid.

EXPOSURE

1. Remove an appropriate number of units from the box.
2. Identify the indicators by labeling pertinent process information.
3. It is recommended that at least two BI's be used per cycle.
4. Place the biological indicators in a horizontal position with representative materials to be sterilized. These materials should be located in the "worst case" (least lethal location) in the load.
5. Select the appropriate cycle and process the load.

NOTE: If a Flash cycle is selected the goods should be unwrapped. If the come up time is less than one minute, a three minute exposure cycle may have to be extended to four minutes to ensure that the BI is killed.

6. Remove from the sterilizer and allow to cool for at least 10 minutes.
7. Retrieve the biological indicators from the test load.
8. The chemical indicator on the label changes from blue to black when exposed to steam. This distinguishes exposed from unexposed units.

NOTE: a black colour does not indicate acceptable sterilization.

INCUBATION:

Any microbiological incubator that is adjusted for 55°C to 60°C will satisfy the incubation conditions for the ParaSure biological indicator. To activate the media, place the indicator in an upright position in a plastic crusher.

Gently squeeze the crusher to break the glass ampoule. Place the activated indicator in the incubator rack, and incubate immediately.

Instructions for use

Self-Contained Biological Indicators for Steam PS 1900

INTERPRETATION

1. Examine the indicator at regular intervals for any colour change (i.e. 8, 12, 18 and 24 hours). The appearance of a yellow colour indicates bacterial growth. No colour change indicates adequate sterilization.
2. Act on a positive test (a colour change of yellow) as soon as the colour change is noted. Notify appropriate hospital personnel (i.e. Infection Control). Always retest the sterilizer with several ParaSure biological indicators throughout the test load. ParaSure biological indicators can be subcultured if identification of positive growth is desired. Recommended subculturing procedure techniques are available upon request from ParaSure.
3. The incubation time is 24 hours (meets the US FDA/RIT protocol).
4. Record the results.
5. Dispose of all used ParaSure biological indicators in accordance with your institution's policy. Incinerate or autoclave any positive cultures at 121°C (250°F) for not less than 30 minutes.

USE OF CONTROLS

1. As a positive growth control, place an activated, un-sterilized ParaSure biological indicator in each incubator on a daily basis.
2. Examine the positive indicator at regular intervals (i.e. 4, 8, 12, 18 and 24 hours). The yellow colour is evidence of bacterial growth. Record the results. Remove all positive indicators as the yellow colour is noticed and dispose of as mentioned above.
3. If the positive control does not grow, do not use the units from this box. Contact ParaSure.

STORAGE

Store ParaSure biological indicators at room temperature. Do not desiccate. Do not store these indicators near sterilants or other chemicals. ParaSure biological indicators have a shelf life which is clearly designated on each box. Rotate your stock accordingly.

NOTE

Do not use after expiration date printed on package. Dispose of expired indicators by autoclaving at 121°C for not less than 30 minutes.

For Biological Indicators

Usage

Incubator for Biological Indicators at (37 ± 2) °C or (60 ± 2) °C.

Applicable regulation

Low Voltage Directive 2014/35/EU. Electromagnetic Compatibility Directive 2014/30/EU.

Characteristics

Dimensions: 8.8 cm length, 14.8 cm width, 5.5 cm high.

21 metal positions: (0.9 cm diameter, 3.3 cm deep) to incubate

PS1900 Voltage range : 100 – 240 V AC.

Power : 15 W.

Frequency : 50 – 60 Hz.

Average power : 8 W.

Environmental conditions during manufacture

T = 15-30 °C, RH = 35-85 %.

Storage conditions

T = 10-30 °C, RH = 30-80 % keep away from light.

Transport conditions

Storage conditions should be strictly followed.

Products should be transported in closed and reinforced boxes in order to avoid damages.

The transport of this product does not represent any risk for human health.

Self Life 5 years.

Packing 1 Unit per box.

Packing information: product code and description, storage conditions and manufacturer information.

Labelling

On the product and on product's box: product code and description, storage conditions, batch number, serial number, barcode and manufacturer information.

PARASURE PS1930 INCUBATOR



Precautions

Do not pour any liquid inside.

Do not immerse into any liquid.

Only for indoor use.

Disconnect the power cord before cleaning.

Do not use abrasive or corrosive cleaners or disinfectants.

Make sure that the incubator is connected to a properly rated power cord.

Not compatible with fluorescence readout Biological indicators.

Use only for extended incubation for an optional visual color change confirmation.

Superfast Biological Indicators



- Conforms to EN ISO 11138 – Parts 1 & 3.
- 20 min results for steam and VH2O2 sterilization.
- Incubation in the Parasure superfast reader.
- Each BI has a barcode to be read in the incubator.
- No laboratory required.
- Dramatic colour change.
- Easy to interpret
- Non-toxic

The Parasure superfast BI (PS and BI test pack range for Steam is designed for use to monitor 132°C, 134°C and 135°C pre-vacuum sterilization cycles and 121°C (20 min).

The self contained biological indicator contains *Geobacillus Stearothermophilus* spores on a cultivated spore strip , culture media and includes an external process indicator to indicator if the Biological indicator has been exposed to a process.

For Incubation the Parasure Superfast reader must be used as a closed system.

The Parasure VH2O2 biological indicators can be used in all VH202 sterilization cycles.

- For Steam (PS 1950).
- Vaporised Hydrogen Peroxide (VH2O2) (PS 1960).
- Sterilization processes and the Parasure superfast reader (PS 1940).



RAPID CHALLENGE STEAM TEST PACK

- Conforms to EN ISO 11138 – ISO 11140
- 20 minutes readout time.
- Incubation in the Parasure superfast reader.
- Each BI has a barcode to be read in the incubator.
- No laboratory required.
- Dramatic colour change.
- Easy to interpret.
- Non-toxic.

The Parasure RAPID CHALLENGE STEAM TEST PACK presents a resistant challenge to the steam sterilization process equivalent to the AAMI 16-towel PCD.

It is used to monitor 132°C, 134°C and 135°C pre-vacuum sterilization cycles and 121°C (20 min) .

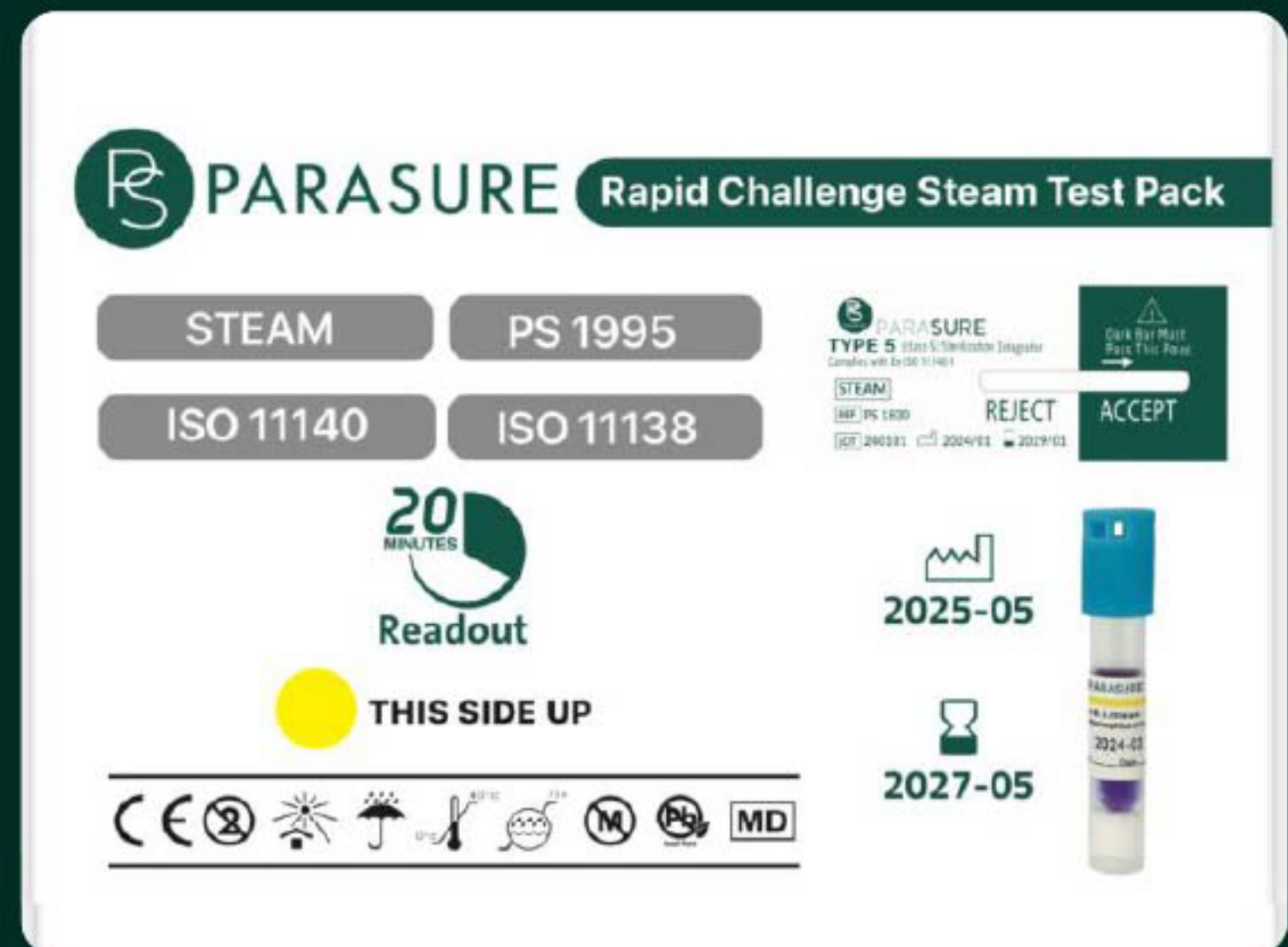
The self contained biological indicator contains *Geobacillus Stearothermophilus* spores on a cultivated spore strip , culture media and includes an external process indicator to indicator if the Biological indicator has been exposed to a process.

For Incubation the Parasure Superfast reader must be used as a closed system.

The integrator type-5 chemical indicator gives positive visual results when it passes to the accept zone of the line.



(PS 1995) contains a PARASURE 20 minutes readout steam biological indicator in addition to a PARASURE class-5 integrator chemical indicator



Mini Rapid Biological Reader

PS 1970

Mini rapid biological reader

- Is suitable for the sterilization effect of steam/VHP/ LTSF/ EO sterilizer.
- It can monitor the survival of *Bacillus stearothermophilus* spores in the rapid biological indicator.
- It should be used with the recommended special indicator.
- The reader is used to cooperate with 58°C / 37°C (the temperature can be adjusted according to different requirements of the indicator) constant temperature incubation indicators.
- The final negative / positive incubation results were automatically obtained by reading the fluorescence changes of the special indicator in VH2O2 20min / steam 20min / LTSF 60min / steam 60min / steam 180min / EO 240min.
- In the design of mini rapid bio reader, the application requirements of visual PH color interpretation are considered.
- The reader is allowed to continuously incubate the special indicator at 58°C / 37°C for 24-48 hours.
- The final negative / positive incubation results can be determined by visual interpretation of PH color change.
- Compared with the visual PH color change interpretation, the fluorescence intensity interpretation method has the advantages of high sensitivity, fast response and small error.



Mini Rapid Biological Reader

Performance

1. Rapid test

Positive readout at 20 minutes (models for steam and VH 2O 2 20mins), 1 hour (model for steam and LTSF 1 hour), 3hours (model for steam 3 hours), 4 hours (model for EO 4hours).

2. Data process and save

After the incubation, the reader automatically saves the incubation results, which can be easily viewed on the app; and can be exported through the USB interface or Ethernet interface on the machine body, so as to facilitate the user to query, edit and print the historical records on other devices, or to print the results in real time through the reader equipped with a printer.

3. Traceability

During the incubation process, the reader can be connected with computer through the Ethernet port, and the indicator and operator related information can be input by the reader related app.

The information can be included in the saved final incubation results, and can be queried, edited and printed through the previous "data processing and preservation".

Note: the incubation traceability information can only be entered after the indicator starts to incubation.

4. Visibility

Touch screen, user interface visual is available.



PARASURE CEI

Cleaning Efficacy Indicator

- For monitoring the cleaning efficiency of washer - disinfectors.
- Test soil simulation of human blood in accordance with ISO 1 5883.
- Diagnostic - Easy to use, Easy to read.
- Stainless steel - Non toxic.
- Routine monitor/validation tool.
- For use in Washer Disinfectors and Ultrasonic machines.

ParaSure CEI (Cleaning Efficacy Indicator) cleaning efficiency check is designed for the validation and the routine monitoring of the cleaning efficacy of cleaning processes in washer disinfectors for surgical instruments.

ParaSure CEI a special cleaning indicator made of stainless steel, which is contaminated with a quantitative measure of test soil (blood and additives), according to ISO 1 5883.

This product is easy to use, easy to read and can be disposed of with domestic waste.



**Order
Details**

PS1600
Cleaning Efficacy Indicators
Box of 50

PARASURE CEI

Cleaning Efficacy Indicator

Name: ParaSure CEI (Cleaning Efficacy Indicator)

Classification: ISO 15883

Low Storage conditions/RH: +18°C-RH 35%

High Storage conditions/RH: +25°C-RH 70%

Lot no: yes

Prod date: yes

Exp date: yes

Correct symbols: In accordance with ISO 15883

Indicator: Cleaning Efficacy Indicator







Disp/single use: yes

Extra information:

Non Toxic yes

Shelf Life 18 months



Result	Assessment	Action needed
	Reference indicator: Spot of test soil completely visible	
INSUFFICIENT CLEANING PROCESS :		
	Spot of test soil completely visible	Do not release batch! Check load, temperature, dosage and time. Repeat test. In case of repeated insufficient cleaning process: Call service technician
	Spot of test soil visible	
	Spot of test soil visible	
	Spot of test soil slightly visible	
SUCCESSFUL CLEANING PROCESS :		
	Spot of test soil completely removed	Release batch. No further action needed.

Standard Basket Process Challenge Device



- Stainless steel tray for testing of the ParaSure CEI.
- Conforms to ISO 15883.
- Easy to use –Easy to read.
- Non toxic.
- For use in Washer.
- Disinfectors and Ultrasonic machines.

Standard PCD (Washer/Disinfector Process Challenge Device)

- Container system for the ParaSure CEI (Cleaning Efficacy Indicator) creating a realistic and repeatable challenge.

Process Challenge Device (PCD) for standard/general non-lumen instrumentation.



PCD

**Order
Details**







PS1610
Standard Basket Process
Challenge Device (PCD)

PARASURE CEI

Cleaning Efficacy Indicator

Name:	Standard Basket Process Challenge Device
Classification:	(PCD)
Storage conditions:	ISO 15883
RH:	n/a
Lot no:	n/a
Prod date:	n/a
Exp date:	n/a
Correct symbols:	n/a
Indicator:	n/a
Disp/single use:	In conjunction with ParaSure CEI
Extra information:	reusable
Non toxic	yes



Result	Assessment	Action needed
	Reference indicator: Spot of test soil completely visible	
INSUFFICIENT CLEANING PROCESS :		
	Spot of test soil completely visible	Do not release batch! Check load, temperature, dosage and time. Repeat test. In case of repeated insufficient cleaning process: Call service technician
	Spot of test soil visible	
	Spot of test soil visible	
	Spot of test soil slightly visible	
SUCCESSFUL CLEANING PROCESS :		
	Spot of test soil completely removed	Release batch. No further action needed.

STANDARD LUMEN PCD



- Unique simulation of cannulated instruments
- Conforms to recommendations in EN
- ISO/TS 1 5883-5
- Realistically challenges the process
- Easy to interpret results
- Polypropylene head
- Cost effective

The ParaSure Standard Lumen Process Challenge Device (PCD) simulates the cannulated devices used in Minimally Invasive Surgery (MIS), to effectively test the machine's cleaning performance.

The polypropylene head houses the indicator and is connected to a 30 centimeter length of PTFE tubing which terminates in a luer lock.

Manufactured in accordance with EN ISO/TS 15883-5:2005, the Standard Lumen PCD challenges the machine to ensure effective soil removal by simulating the conditions found within cannulated instruments.

The Standard Lumen PCD is designed to be used with the ParaSure Cleaning Efficacy Indicators (CEI), PS1600.



**Order
Details**

PS1620P
Standard Lumen







PCD
each

Technical specifications

Product name:	Standard Lumen PCD
Unit of measure:	Each
Conforms to:	EN ISO/TS 15883-5:2005
Materials:	Polypropylene and PTFE
Frequency of use:	Every cycle
Number of uses:	Reusable
Indicator:	ParaSure Cleaning Efficacy Indicators (PS1600)
Supplied with:	Instructions for Use & Assessment Aid

Assessment Aid



Result	Assessment	Action needed
	Reference indicator: Spot of test soil completely visible	
INSUFFICIENT CLEANING PROCESS :		
	Spot of test soil completely visible	Do not release batch! Check load, temperature, dosage and time. Repeat test. In case of repeated insufficient cleaning process: Call service technician.
	Spot of test soil visible	
	Spot of test soil visible	
	Spot of test soil slightly visible	
SUCCESSFUL CLEANING PROCESS :		
	Spot of test soil completely removed	Release batch. No further action needed.

MULTI LUMEN CHANNEL CONTROL



- Unique simulation of endoscope
- Conforms to recommendations in EN ISO/TS 15883-5
- Realistically challenges the process
- Easy to interpret results
- Polypropylene heads
- Cost effective

Order Details

PS1650P

Multi Lumen Channel Control
each



The ParaSure Multi Lumen Channel Control (MLCC) simulates an endoscope with 3 channels (1 x 1 mm diameter and 2 x 2mm diameter), providing a unique solution to realistically test the effectiveness of the washer-disinfector.

The MLCC combines 3 polypropylene head indicator holders, each of which is connected to a 1.5 metre length of PTFE tubing that terminates in a luer lock.







Manufactured in accordance with EN ISO/TS 15883-5:2005 (Annex R6 Test Pieces UK), the MLCC challenges the machine to ensure effective soil removal by simulating the conditions found within the endoscope.

The MLCC is designed to be used with the ParaSure Cleaning Efficacy Indicators (CEI), PS1600.

Technical specifications

Product name:	Multi Lumen Channel Control
Unit of measure:	Each
Conforms to:	EN ISO/TS 15883-5:2005 (Annex R6 Test Pieces UK)
Materials:	Polypropylene and PTFE
Frequency of use:	Every cycle
Number of uses:	Reusable
Indicator:	ParaSure Cleaning Efficacy Indicators (PS1600)
Supplied with:	Instructions for Use & Assessment Aid



Result	Assessment	Action needed
	Reference indicator: Spot of test soil completely visible	
INSUFFICIENT CLEANING PROCESS :		
	Spot of test soil completely visible	Do not release batch! Check load, temperature, dosage and time. Repeat test. In case of repeated insufficient cleaning process: Call service technician.
	Spot of test soil visible	
	Spot of test soil visible	
	Spot of test soil slightly visible	
SUCCESSFUL CLEANING PROCESS :		
	Spot of test soil completely removed	Release batch. No further action needed.



PARASURE

Order
Details

PS1650P

Multi Lumen Channel Control
each

Protein Test Kit

For the rapid detection of protein residues



- Conforms to recommendations in EN ISO 15883.
- Results within 10 seconds.
- Easy to use - no incubation required.
- Clear colour change.
- Use on surfaces to detect protein residue.
- For endoscopes, use the ParaScope Protein Test Kit.

**Order
Details**

PS1400

ParaSure Protein Test Kit

The ParaSure Protein Test Kit allows the quick and reliable detection of residual proteins left behind on the surfaces of washer disinfectors, ultrasonic cleaners, endoscopes and surgical instruments.

The short swab provided with each test is simply rubbed on the designated surface and then swirled for 10 seconds in the liquid, to provide a clear and almost instantaneous result.

Based on a dye-binding solution used in clinical chemistry, this test is sensitive enough to detect protein residues to within 1µg. The protein test liquid will change to various shades of blue depending on the amount of protein detected, as can be seen on the colour guide overleaf.

Any shade of blue indicates that protein has been detected.

For testing the internal surfaces of endoscopes, the Parasure ParaScope Protein Test Kits should be used, which come 2.5 metre swabs with a range of different head sizes.

Protein Test

Technical specifications

Product name:	Protein Test Kit
Unit of measure:	box of 25 tests with 25 short swabs and 2 positive controls
Conforms to:	EN ISO 15883
Storage conditions:	if refrigerated, shelf life is extended from 6 months to 2 years
Frequency of use	as required
Number of uses:	single use
Supplied with:	instructions for use and record labels

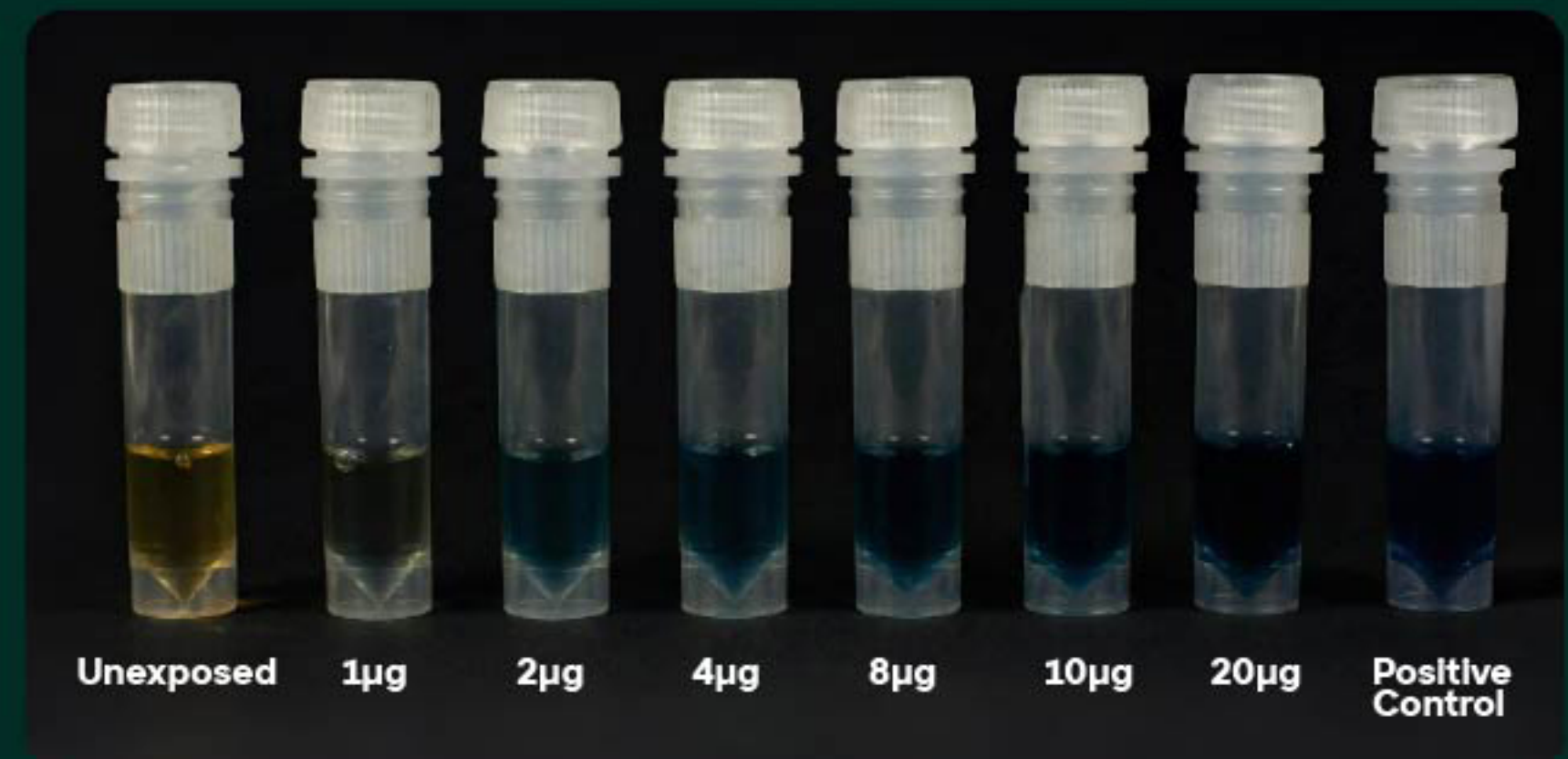
Instructions for Use

1. If the object to be tested is already wet, vigorously swab the object, focusing in hinges or crevices which may be contaminated. If the object of interest is dry, simply wet the swab with tap water before vigorously swabbing.

2. Unscrew the cap and swirl the swab in the brown reagent for about 10 seconds, then discard the swab and screw the cap back on the reagent vial.

3. Visually inspect the reagent for colour change. If the reagent has turned blue, protein residue is present. The darker the blue colour the more protein has been detected. If the reagent remains brown, protein residue has not been detected.

Two test strips have been supplied for use as a positive control. To use them, simply wet the swab, and vigorously rub it on the red test soil on the aluminium strip. Unscrew the cap and swirl the swab in the reagent. Discard the swab and screw the cap back on the reagent vial. The result will be bright blue, and provides a reference colour for a highly positive reaction to protein.



ParaScope Protein Test Kit

For the rapid detection
of protein residues



- Conforms to recommendations in EN ISO 15883.
- Results within 10 seconds.
- Easy to use - no incubation required.
- Clear colour change.
- Detects protein residue inside endoscope channels.
- 2.5 metre long swabs available with 3 different.
- head sizes: 1.9mm, 2.8mm and 3.7mm.

The ParaScope Protein Test Kit has been designed to allow the quick and reliable detection of residual proteins left behind inside endoscope channels. The long swabs provided are simply pushed down the length of the channel, removed and then swirled for 10 seconds in the liquid, to provide a clear and almost instantaneous result.

Based on a dye-binding solution used in clinical chemistry, this test is sensitive enough to detect protein residues to within 1µg. The protein test liquid will change to various shades of blue depending on the amount of protein detected, as can be seen on the colour guide overleaf. Any shade of blue indicates that protein has been detected.

For testing the surfaces of washer disinfectors or surgical instruments, use the ParaSure Protein Test, PS1700.

Order Details

PS1710

ParaScope 1.9mm Protein Test Kit
box of 25 tests with 25 2.5 metre
long swabs with 1.9mm head

PS1720

ParaScope 2.8mm Protein Test Kit
box of 25 tests with 25 2.5 metre
long swabs with 2.8mm head

PS1720

ParaScope 3.7mm Protein Test Kit
box of 25 tests with 25 2.5 metre
long swabs with 3.7mm head

Protein Test

Technical specifications

Product name:	Protein Test Kit
Unit of measure:	box of 25 tests with 25 short swabs and 2 positive controls
Conforms to:	EN ISO 15883
Storage conditions:	if refrigerated, shelf life is extended from 6 months to 2 years
Frequency of use	as required
Number of uses:	single use
Supplied with:	instructions for use and record labels

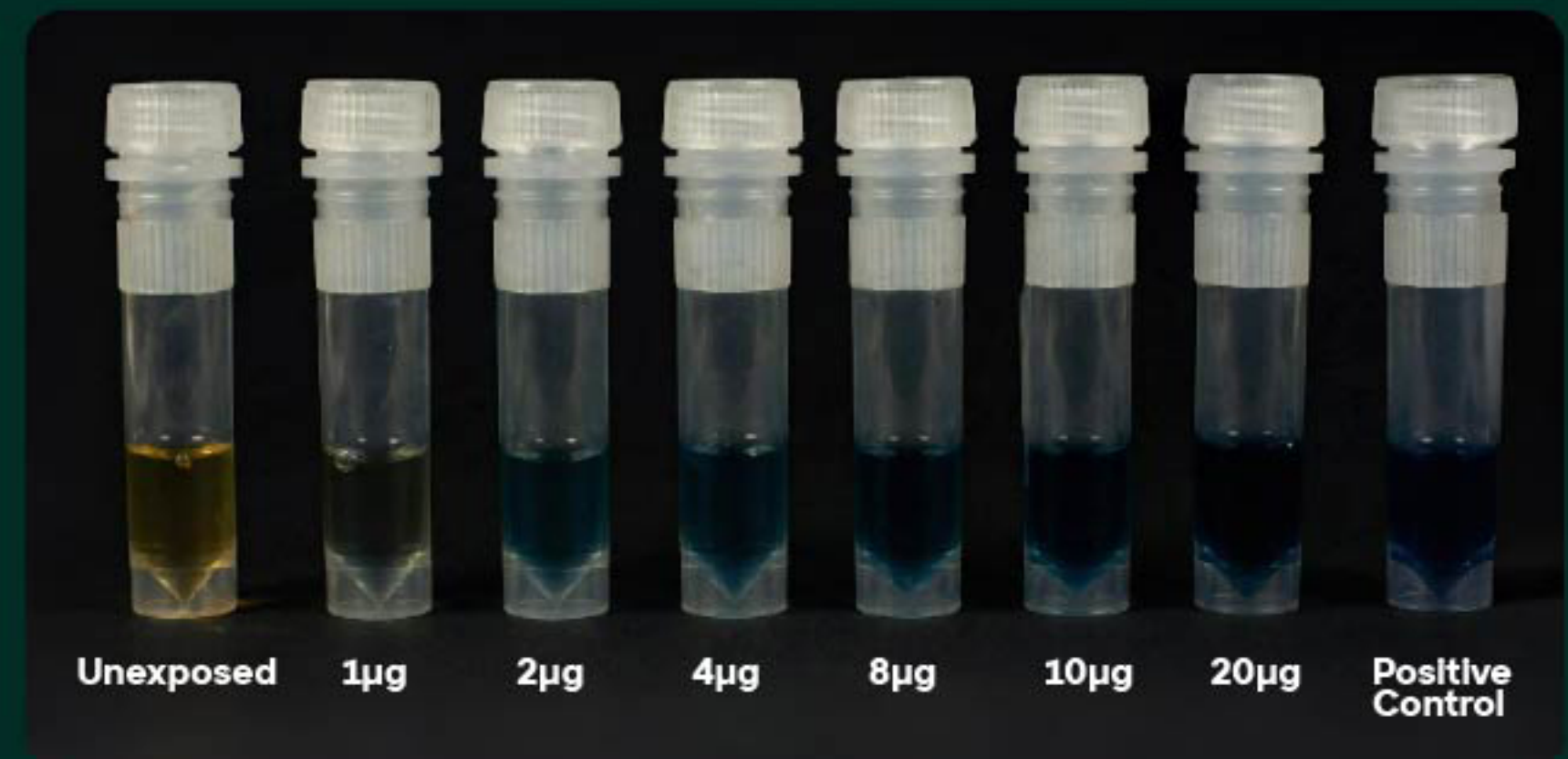
Instructions for Use

1. If the object to be tested is already wet, vigorously swab the object, focusing in hinges or crevices which may be contaminated. If the object of interest is dry, simply wet the swab with tap water before vigorously swabbing.

2. Unscrew the cap and swirl the swab in the brown reagent for about 10 seconds, then discard the swab and screw the cap back on the reagent vial.

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Two test strips have been supplied for use as a positive control. To use them, simply wet the swab, and vigorously rub it on the red test soil on the aluminium strip. Unscrew the cap and swirl the swab in the reagent. Discard the swab and screw the cap back on the reagent vial. The result will be bright blue, and provides a reference colour for a highly positive reaction to protein.



Ultrasonic Foil Test



- Conforms to requirements of HTM01 -05
- Product size 1 00 x 67.5mm
- Non-toxic / Lead free
- It is easy to read and interpret.
- Suitable for archiving.
- Compatible with 15883-5.
- Patented Design

Ultrasonic foil tests consist of foil-based material.

If the appliance operates correctly, the cavitation energy emitted from sources will dismember the foil inside the frame.

The wash test should be used daily and the results should be recorded.

There are areas on the product that can be filled in so that the results can be recorded.

**Order
Details**

PS2220
50 pieces per box

To be used with PS 2022

PARASURE

REF PS-2220 LOT 2105190

2021-05 2026-05

ULTRASONIC FOIL TEST

Date : _____ Washer No : _____

Person ID : _____ Set Name : _____

Result: PASS ☐ FAIL ☐



Ultrasonic Foil Test

To be used in conjunction
with PS 2022

Technical specifications

Physical Parameters

Process

Ultrasonic Washer

Packaging

50 PCS. / BOX

Speciality

Initial Situation: Full Foil

Signal Situation: Fragmented Foil

Fail

PARASURE

REF PS-2022 LOT 2105190

50-5102 50-1305

ULTRASONIC FOIL TEST

Date : _____ Washer No : _____

Person ID : _____ Set Name : _____

Result: PASS ☐ FAIL ☒

Pass

PARASURE

REF PS-2022 LOT 2105190

50-5102 50-1305

ULTRASONIC FOIL TEST

Date : _____ Washer No : _____

Person ID : _____ Set Name : _____

CSU : R ILPASS ☒ FAIL ☐

ULTRASONIC FOIL TEST

Date : _____ Washer No : _____

Person ID : _____ Set Name : _____

Result: PASS ☐ FAIL ☐



ULTRASONIC CAVICHECK

ULTRASONIC WASHER TEST

- Routine monitoring and validation in accordance to EN ISO 15883.
- Detects sufficient energy for cavitation.
- A pre-prepared test showing immediate results.
- Colour changes from blue to yellow indicate the presence of cavitation energy.
- Suitable for archiving.
- Easy interpretation.
- Easy to use.

Monitoring the energy of ultrasonic bath for cleaning of surgical instrument.

As the temperature rises, the conversion time may extend.

Important reminders;

-The performance after a corrective action needs to be tested again with a new PARASURE.

- The average time needed for a colour change is 6 min @27KHz. However a slower change will indicate a weak spot.



Order Details

PS2221

Contents: •30 PCS Tests •30 PCS Archived Labels •1 PCS IFU

ULTRASONIC CAVICHECK

ULTRASONIC WASHER TEST

The average time needed for a colour change is 6 min @27KHz.
However a slower change will indicate a weak spot.

Technical specifications



Negative Result
Insufficient energy



TO



Positive Result
Record according to
your quality policy

PARAMETERS	POSSIBLE REASONS	CORRECTIVE ACTION
Lowenergy (cycle time, trays & load)	<ul style="list-style-type: none">• Cycle time is too short.• The ultrasonic basket or the load may absorb too much energy.	<ul style="list-style-type: none">• Test a longer cycle.• Test cycle without load (functional test) and avoid wire mesh trays.• Wire mesh trays absorb ultrasonic energy. Solid bottom trays are recommended.
Water level	<ul style="list-style-type: none">• Reflection of ultrasonic energy on the surface may change energy distribution.	<ul style="list-style-type: none">• Refer to the instruction manual of instruments for correct water level.
Degassing	<ul style="list-style-type: none">• Dissolved gases in the water may absorb ultrasonic energy.	<ul style="list-style-type: none">• Refer to instruction manual for a proper degassing.
Transducers	<ul style="list-style-type: none">• The efficiency of the transducers may decreases with age or individual transducers may be out of order	<ul style="list-style-type: none">• Re do the functional test and check the individual transducers

FROM DETECTION TO PREVENTION



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