

Electronic
Bowie & Dick
Test

WI SCAN®
System



Sterlab

WI SCAN[®]

System

Data archiving software

Electronic result Reader



Electronic Bowie & Dick Test

SUMMARY

HOW DOES IT WORK?	page 2
INSTRUCTIONS FOR USE	page 4
QUESTIONS/ANSWERS	page 6
SIGNIFICANT INNOVATIVE FEATURES	page 7
TECHNICAL DATA / PRECAUTIONS FOR USE	page 8
WI SCAN® SYSTEM REFERENCES	page 9

ELECTRONIC BOWIE & DICK TEST



Has been awarded the most innovative sterilisation device in France for the year 2010

HOW DOES IT WORK ?

The WI SCAN® Electronic Bowie & Dick Test is made of a cylindrical detection chamber (1) closed at one end and two temperature sensors. The internal temperature sensor is located in the rear part of the detection chamber (2) and the external temperature sensor (3) on the surface.

During the sterilization cycle, after air extraction, the mixture of steam and air or NCG (Non-Condensable Gases) progresses along the SAS (Steam Air Separator) chamber. Inside the SAS chamber steam condensates and the proportion of air or NCG increases reaching the maximum level at the rear of the chamber.

The combination of several innovative features allows the WI SCAN® Electronic Bowie & Dick to reach the highest standards in detection, precision and result REPRODUCIBILITY

Innovation Horizontality of the detection chamber

At the same temperature, the density of air or other NCGs is superior to the density of the saturated steam. The horizontal detection chamber facilitates steam penetration and its detection.

The feature allows to control the steam penetration in all autoclave types and all types of sterilization cycles (as defined by **ISO 11140-4** and **ISO 11140-5**):

- sub-atmospheric cycle pulses
- trans-atmospheric cycle pulses
- super-atmospheric cycle pulses.

Innovation Air or other NCG separation from Steam through the SAS® (Steam Air Separator)

In the detection chamber, the SAS® device (4) acts as a porous load enabling steam condensation. The liquid condensation is eliminated by gravity outside the device, allowing air or other NCG to penetrate to the rear of the detection chamber (internal temperature sensor). The possible presence of air or NCG is amplified, increasing the detection capacity.

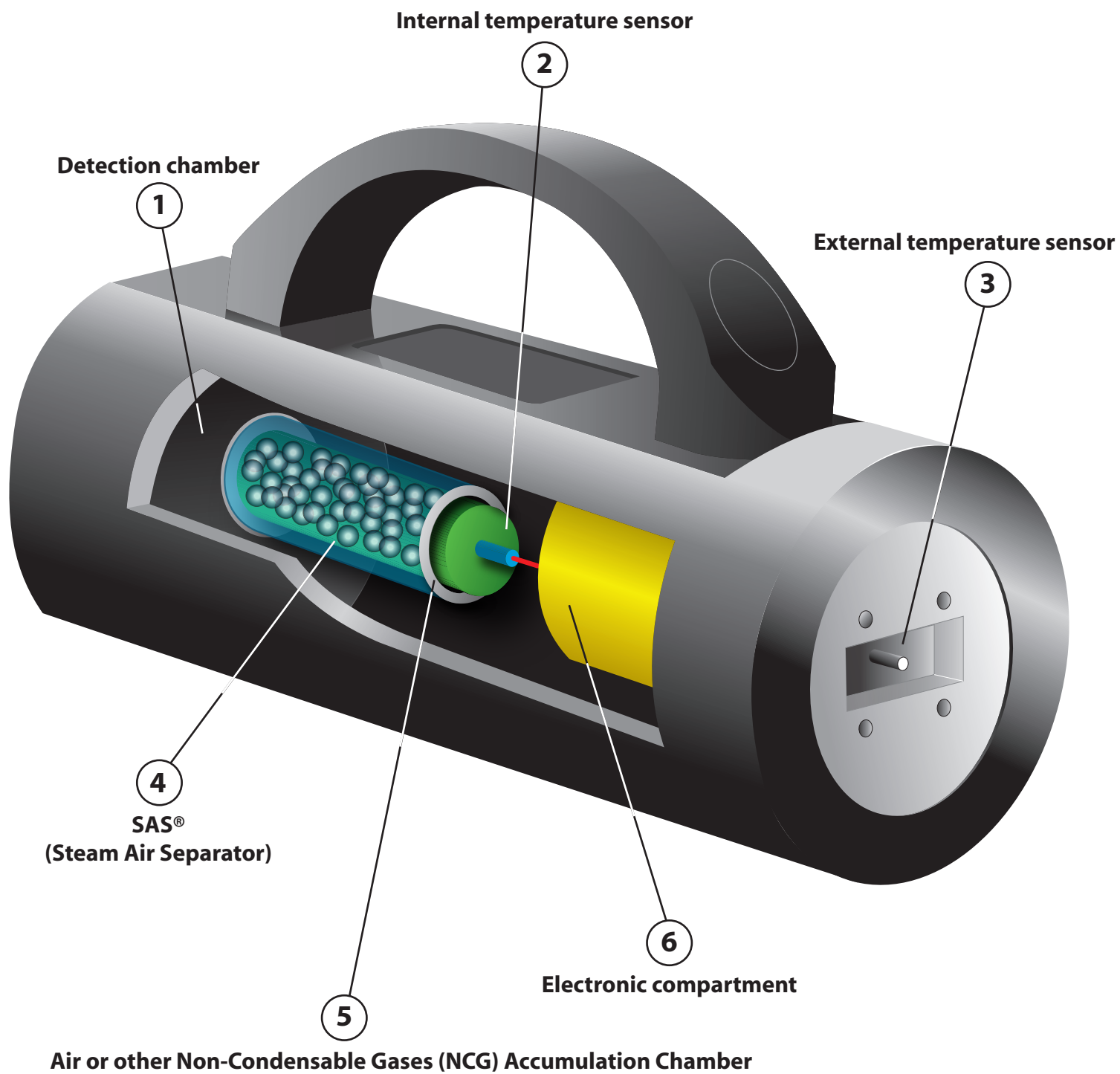
Innovation Air mass or NCG conservation

The SAS® also prevents recombination of air or NCG with steam until the end of the sterilization plateau at 134°C (5).

The presence of air or NCG is therefore amplified allowing more accurate temperature measurements and results reproducibility ever obtained from a Bowie & Dick tests.

Innovation Air extraction and steam penetration algorithm

In the electronic compartment (6), an algorithm, developed by STERLAB, measures the temperature difference between the two probes (external and internal) during various stages of the Bowie & Dick sterilization cycle. This algorithm gives the "Pass/Fail" result and indicates the "security margin" (see page 7).



INSTRUCTIONS FOR USE

- 1 To switch on, place the device vertically with the white side on the top for a few seconds.
The flashing green LED confirms that the device is switched on and ready to be placed in the autoclave chamber.

The Bowie & Dick cycle is to be launched within the 10 following minutes (after 10 minutes the device will automatically start to blink red if it does not detect any steam). The device will blink red for approximately 10 minutes then will become inactive (no blinking at all). To switch it on again, one need to place the device vertically once more for a few seconds until a green blinking appears again.

The action can be repeated several times if necessary.

- 2 Place the Electronic Bowie & Dick Test horizontally, handle on the top, in the middle of the autoclave chamber like a regular Bowie & Dick test pack.

- 3 When the sterilisation cycle is over and the autoclave opened the flashing LED indicates automatically the results.

The flashing green LED indicates a "Pass" result allowing the preparation of the first sterilisation cycle of the day.

The flashing red LED indicates a "Fail" result.

- 4 Accelerated flashing LED indicates that the wireless data transmission to the WI SCAN® Reader is activated. At this point switch on the Reader and follow the instructions. The data transmission is possible up to 8m. The WI SCAN® Bowie & Dick switches off automatically after the data transfer is finished.

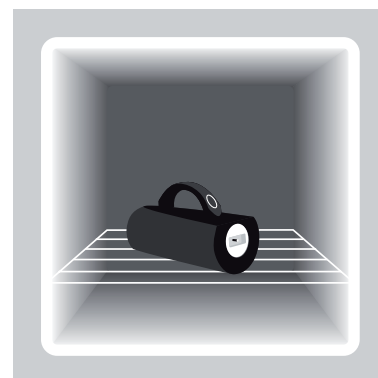
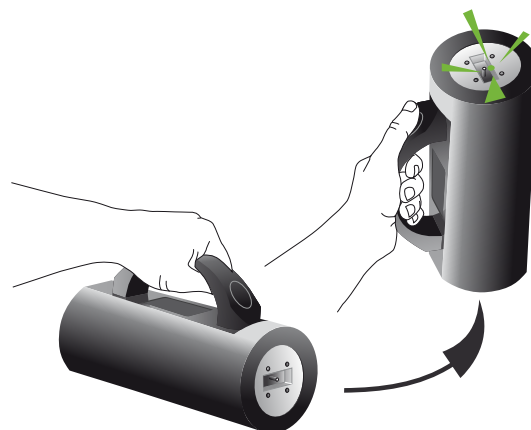
The Reader keeps the data until it is transferred to the computer.

The WI SCAN® Reader can receive up to 10 readings.

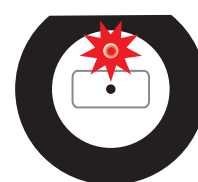
- 5 Transferred data is archived on a computer via the USB cable connection.

Once the data transfer is finalised, switch the Reader off. The user-friendly software has been designed as a comprehensive tool to be used by anyone without previous training.

The "Administrator" Mode allows the person in charge to access and analyse recordings, enter data (register devices, operators, autoclaves etc), visualise process variability (Security Margin), print data: graphics, multiple charts.



PASS



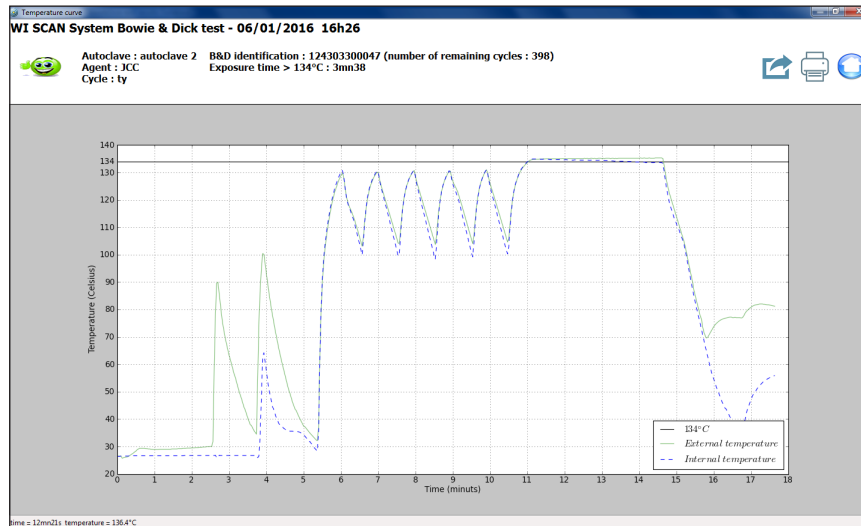
FAIL



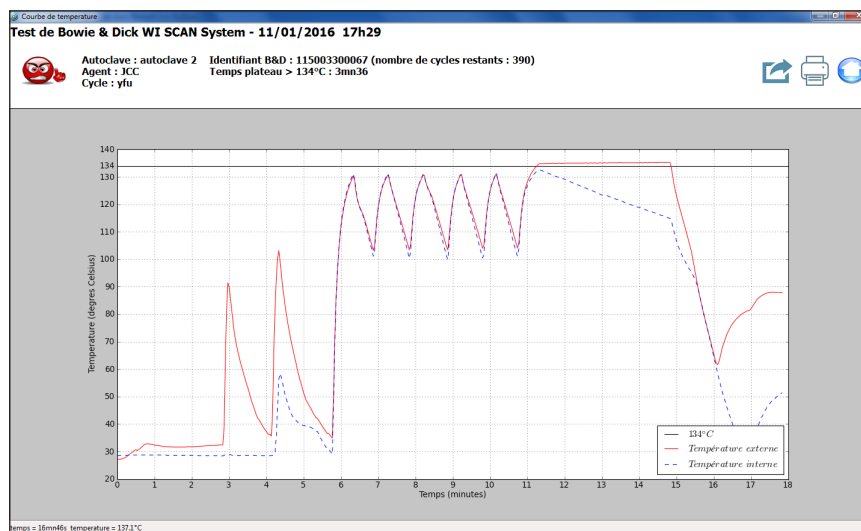
Mode Administrateur									
N°	Identifiant utilisateur	Identifiant matériel	Date d'expiration	Identifiant code	Attribution	Utilisateur d'activation	Etat	Commentaires & signatur	
Autoclave 2	ASIMO	344	64002015 2704	1510-0330-0040	Autoclave 2				
Autoclave 1	EBURGLU	376	64002015 0514	1510-0330-0040	Autoclave 1				
Autoclave 2	NOU-IR	376	64002015 0502	1510-0330-0040	Autoclave 2				
Autoclave 4	EBURGLU	376	64002015 0502	1510-0330-0020	Autoclave 4				
Autoclave 1	EBURGLU	377	64002015 0502	1510-0330-0027	Autoclave 1 et Autoclave 4 et Autoclave 2				
Autoclave 2	EBURGLU	347	64002015 0503	1510-0330-0075	Autoclave 2				
Autoclave 4	NOUWTEGRO	364	65002015 0503	1510-0330-0020	Autoclave 4				
Autoclave 2	NOUWTEGRO	361	65002015 0503	1510-0330-0040	Autoclave 2				
Autoclave 1	NOUWTEGRO	362	65002015 0503	1510-0330-0040	Autoclave 1				
Autoclave 3	NOUWTEGRO	362	65002015 0503	1510-0330-0086	Autoclave 3				
Autoclave 1	AYTOUR	368	66002015 0502	1510-0330-0040	Autoclave 1				
Autoclave 3	AYTOUR	368	66002015 0502	1510-0330-0086	Autoclave 3				
Autoclave 4	AYTOUR	368	66002015 0502	1510-0330-0020	Autoclave 4				
Autoclave 2	AYTOUR	368	66002015 0503	1510-0330-0040	Autoclave 2				
Autoclave 1	AYTOUR	368	66002015	6600-0330-0006	Autoclave 1				

6 Results reading: by double clicking on the smiley 😊 😡 the graphic appears on the screen, examples:

PASS TEST



FAIL TEST



The graphs show the two temperature curves:

- the green curve or a red curve (depending on the results) correspond to the external temperature sensor (see page 3),
- the blue dotted curve corresponds to the internal temperature sensor (see page 3).

The measurement of the Bowie & Dick test is calculated through a difference of the external and internal temperatures.

In order to determine the test result, the WI SCAN® BD calculates the temperature difference between the two curves at the plateau (during the exposure time).

If the steam penetration is correct, the two curves will be either close to each other or will overlap at the plateau.

The result is therefore PASS and the curve of the external temperature sensor is green.

The more air and NCG are detected in the SAS chamber, the lower the value of the internal temperature sensor will be. And as consequence the bigger gap in-between two curves (internal and external temperature sensors).

The result becomes negative when this temperature difference reaches a threshold calculated by us according to the ISO 11140-4 or – 5 standards.

Once this threshold is exceeded, the test result is negative and the external sensor curve is red.

QUESTIONS / ANSWERS

The Reader has been accidentally switched off before data has been transferred to the computer.	The Reader keeps in memory all non transmitted data. Data will be transferred with the next connection to the computer.
Lack of brightness of the Readers 'screen.	Change or recharge the Reader's battery.
No display on the Reader's screen.	<ul style="list-style-type: none"> • Make sure the Reader is switched on. • Change or recharge the Reader's battery.
The WI SCAN® B&D test does not flash once the autoclave doors are opened (end of the sterilisation cycle).	<ul style="list-style-type: none"> • The B&D WI SCAN® test has not been switched on before being placed in the autoclave chamber. • The B&D WI SCAN® test has been flashing RED when placed in the autoclave chamber. • The B&D WI SCAN® test has already transmitted data on the Reader through the autoclave doors. • The B&D WI SCAN® test remained longer than 4 hours without being placed close to the Reader for data transmission.
The WI SCAN® B&D test flashes RED when is placed in a vertical position (switch on function).	The B&D WI SCAN® test did not cool down; it is too hot to be used. The delay of 3 hours between two cycles has not been respected.
Once switched on and blinking GREEN for 10 minutes , the WI SCAN® B&D test flashes RED during 10 following minutes.	The B&D WI SCAN® test stayed switched on for longer than 10 minutes without being used. Wait until the RED LED finishes to blink and switch on the B&D test again by putting it vertical until the GREEN light appears.
The WI SCAN® B&D test does not blink GREEN after being switched on by the vertical rotation.	It may be necessary to wait up to 15 seconds in the vertical position to switch the device on.
The WI SCAN® software flags that the user approaches 400 cycles limit of use.	Contact STERLAB or your local distributor to proceed with the recalibration of the device for the next 400 cycles.
Storage conditions of the WI SCAN® B&D test in between two uses.	Horizontal storage, the handle on the top in order to preserve the batteries.

SIGNIFICANT INNOVATIVE FEATURES

Autoclave diagnostic tool: SECURITY MARGIN

In a case of a PASS result and through the "Administrator mode" you can visualise the Security Margin data.

The outstanding precision of measurement through the SAS® allows the definition of the Security Margin of the autoclave:

- if no air or NCG are detected, the Security Margin is set at 100%,
- if the quantity of air or NCG reaches the ISO 11140-4 failure criteria, the Security Margin **does not exist**.

Each PASS result will be therefore accompanied by its Security Margin, set between 5% and 100%, allowing an early autoclave malfunction detection (early warning) or confirming the adequate autoclave performance.

Continuous re-use

The WI SCAN® Electronic Bowie & Dick Test gives reproductive results for 400 cycles or 1000 cycles. When approaching the calibration limit, an early warning indicates on the table of results the number of remaining cycles.

The Manufacturer-Sterlab, provides probe recalibration and battery renewal allowing the device to be reused continuously year after year.

This non-disposable policy induces the reduction of various costs (procurement cost, storage, shipping, recycling cost) in line with Sterlab's environmental friendly policy.



TECHNICAL DATA

- Scanning rate: 2 seconds.
- Data memory: 1 hour of data acquisition.
- Autonomy: 400 cycles or 1000 cycles.
- Recalibration frequency: - 400 cycles Bowie & Dick Test: 400 cycles,
- 1000 cycles Bowie & Dick Test: 1000 cycles.
- The WI SCAN® Electronic Bowie & Dick Test is tested according to methods described in **ISO 11140-4 and ISO 11140-5**.
- Complies with sub-atmospheric, trans-atmospheric and super-atmospheric cycle pulses.
- Requires the WI SCAN® Reader WISCAN01 and the WI SCAN® software WISOFT01.
- Cooling time between two uses: 3 hours minimum.
- Automatic switch-on by vertical rotation of the device.
- Instant switch-off after data transfer to the WI SCAN® Reader.
- Data transfer to the WI SCAN® Reader via RF 2,4 Ghz.
- WI SCAN® software compatible with PC under Windows 10 or later version.
- "Help" function included in the software.
- Dimensions and weight:
 - WI SCAN® BD: 240 mm x 100 mm x 140 mm - 2.4kg.
 - WI SCAN® READER: 147 mm x 89 mm x 25 mm - 0.3kg.

PRECAUTIONS FOR USE

Storage conditions:

- Temperature: between 0°C and 50°C.
- Relative humidity: between 30% and 70%.
- Store horizontally, handle upward.
- Do not use with other cycles than standard Bowie & Dick tests (134° C - 3.5 min).
- Put thermo-isolating gloves (ex. EN 407 standard) before taking out the device from the autoclave (risk of burns).
- In case of a suspicious smell while opening the door of the autoclave (at the end of the cycle), move away from the autoclave and call Sterlab.



Year of application 2010

STEAM 134°C-3.5min


The CE marking of this product certifies its compliance with the requirements of the Medical Devices Regulation 2017/745/EU, as well as the requirements of the ROHS 2011/65/EU and Electromagnetic Compatibility 2014/30/EU Directives.

WI SCAN® SYSTEM REFERENCES

STERLAB references	Description
WISCAN01	USB / Wireless result reader.
WIBODI01	Bowie & Dick probe 400 cycles.
WIBODI04	Bowie & Dick probe 1000 cycles.
WISOFT01	WI SCAN® Software.
WICALBD1	400 cycles Bowie & Dick probe recalibration.
WICALBD4	1000 cycles Bowie & Dick probe recalibration.
WISCANPACK	Complete WI SCAN® pack 400 cycles Bowie & Dick probe and reader.
WISCANPACK4	Complete WI SCAN® pack 1000 cycles Bowie & Dick probe and reader.

[illegible]



 **Sterlab** - 2720 Chemin Saint-Bernard - 06220 Vallauris - FRANCE
TEL : +33 (0)4 97 24 58 58 - FAX : +33 (0)4 97 24 58 59 - WEB : www.sterlab.com

Last revised March 2023