



GIMA

PROFESSIONAL MEDICAL PRODUCTS

TEST HELIX DI BOWIE DICK (BDHT) **BOWIE DICK HELIX TEST (BDHT)** **TEST HELIX BOWIE DICK HELIX (BDHT)** **PRUEBA HELIX BOWIE DICK (BDHT)**

- Manuale d'uso e manutenzione
- Use and maintenance book
- Instructions de fonctionnement et entretien
- Manual de uso y mantenimiento

ATTENZIONE: Gli operatori devono leggere e capire completamente questo manuale prima di utilizzare il prodotto.

ATTENTION: The operators must carefully read and completely understand the present manual before using the product.

AVIS: Les opérateurs doivent lire et bien comprendre ce manuel avant d'utiliser le produit.

ATENCIÓN: Los operadores tienen que leer y entender completamente este manual antes de utilizar el producto.

GIMA 35951



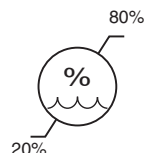
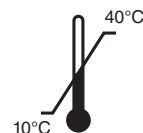
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ENGLISH

Direction for use (DFU BDHT 01-2023 version E)

This direction for use is applicable for the following Sterintech products (Stated Value: 134°C-3,5min/121°C-15min):

- 101.201.0100 Bowie Dick Helix Test with 100 indicators
- 101.201.0250 Bowie Dick Helix Test with 250 indicators

Bowie Dick Helix Test (BDHT)

Note: upon receipt of goods please check whether the package was undamaged and ensure you about the expiry date of the chemical indicators.

Introduction:

The BDHT and its indicator strips are used for Bowie Dick Tests in pre-vacuum Hospital steam sterilizers and Class B Bench Top Steam Sterilizers. The Bowie Dick Test delivers the proof of proper functioning of the steam sterilizer.

During steam sterilization a number of problems can occur. These can be a.o. presence of air in steam feed-in, Inert gases in generated steam or leakage of door seals but also low temperature or short holding times.

The print out parameters or chart of the recorded parameters by the steam sterilizers control is not sufficient to guarantee that sterilization conditions have been met in the complete chamber. Some of the above-mentioned disturbances cannot be detected by pressure and temperature sensors.

The BDHT is able to detect:

- Sterilization temperature too low
- Sterilization holding time too short
- Insufficient vacuum in depth and in number of vacuum pulses.
- Insufficient air removal from hollow A devices
- Insufficient steam penetration in hollow A devices
- Leakage of piping / valves / door seals
- Detection of presence of small volume inert gases
- Detection of excessive amounts of condensate

The indicator fields of the indicator strip are covered by a lacquer and therefore no ink or any substance from the ink can migrate on your instrumentation. The indicator ink is not containing any dangerous or toxic components and

can be discarded as normal waste.

How to use the BDHT

I. Take one of the indicator strips out of the plastic bag and close the bag in order that the indicators strips are protected against humidity. Bend the indicator strip in the middle in order that the indicator fields are pointing inwards.

II. Take the Helix and unscrew the cap.

III. Place the indicator strip into the cap in such a way that bended end is going into the cap as first.

IV. Close the Helix by screwing the cap incl. the indicator strip on the holder.

V. Place the Helix into the cotton bag and place it in an instrument tray near to the bottom of the steam sterilizer. Never place the Helix on the bottom of the sterilizer.

VI. Run the Bowie Dick sterilization cycle

VII. After completion of the sterilization cycle and cooling off during a few minutes take the Helix and remove it from the cotton bag. Condensate may drip out of the Helix.

VIII. Unscrew the cap and take the indicator strip from the cap (eventually use a plier)

IX. Judge the color change of the indicator. When all 4 indicator fields are completely pink the sterilization cycle has been successfully. You may use the color reference label for the end color judgement.

X. Dependent on the color change the staff may release the sterilizer to be used for the day.

XI. Remove the indicator strip double adhesive strip from the back and glue it into the daily documentation sheet.

XII. Add the sterilizer number, cycle number, date and release data on the sheet.

XIII. In case the Helix or its tube has been wetted by condensate, blow some compressed air through the Helix and let it dry in open condition.

Warnings






The indicator strips and Helix system are designed according to ISO 11140 and may not be used in combination with other indicator strips or other Helix systems as this may lead to malfunction and misinterpretations of the test results.

The plastic Helix device may not be dismantled or show any external damage before use. These defective, dismantled, damaged Helix devices should be replaced by a new Helix device in order to have right interpretations of test results.









Storage conditions.





It is important to store the indicator strips in accordance with the storage conditions as displayed on the box label. This Direction for use may be changed in the future. Check on our website regularly for updated Directions for use.

Reference of color change of BD Helix test

1		Position 1: Untreated indicator strip (original chemical indicator color)
2		Position 2: Low temperature / short holding time or absence of steam
3		Position 3: Typical for vacuum or leakage problem
4		Position 4: Typical for inert gas problem
5		Position 5: Complete successful color change

Symbols:

	Date of manufacture		Keep in a cool, dry place
	Manufacturer		Keep away from sunlight
	Product code		Temperature limit
	Lot number		Humidity limit

	Expiration date		Caution: read instructions (warnings) carefully
	Imported by		Consult instructions for use

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies