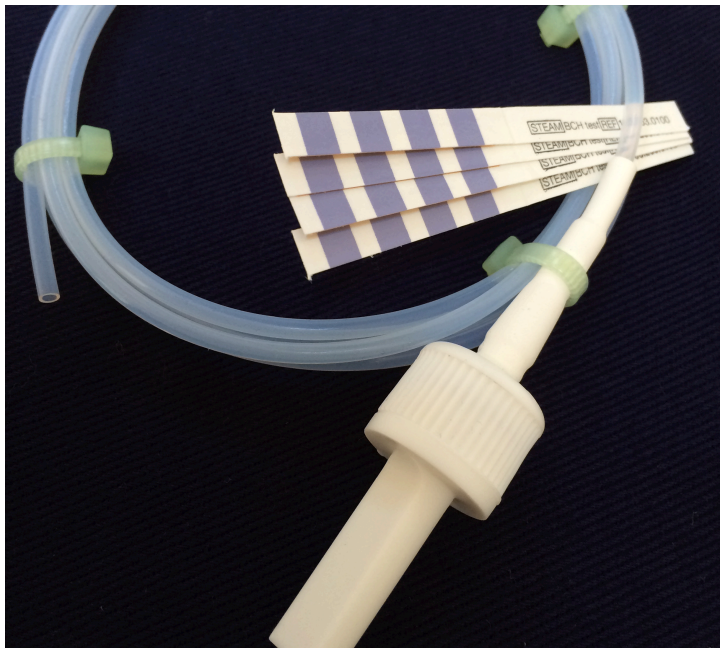


Technical Data Sheet

Product name:

Batch Control Helix Test



Product reference:

- 103.203.0100 STEAM 134°C - 3,5 min
/121°C - 15 min
- 103.203.0250 STEAM 134°C - 3,5 min
/121°C - 15 min
- 103.203.0500 STEAM 134°C - 3,5 min
/121°C - 15 min

Applicable standards:

- EN 867 - 5 : 2001
- ISO 11140 : 2014
- EN 285 + A2 2009
- EN 980
- ISO 13485

Content:

- 1 Introduction
- 2 Description
- 3 Confirmation to standards
- 4 Raw Materials
- 5 Quality assurance
- 6 Packaging
- 7 Storage conditions
- 8 Explanation of Symbols
- 9 Manufacturer's declaration

Attachment(s):

- A Certificate of conformity
- B Dimensional and Material Data Helix Device

1 Introduction

The Batch Control Helix Test (or BCHT in short) is a test which is recommended by the Dutch RIVM, German Robert Koch Institute and specified in the EN 285 Amendment A;2009 as a Steam sterilization performance test. Both the RIVM and Robert Koch Institute are recommending to use Helix based tests in every cycle of the steam sterilizer. SP Medikal is offering a wide range of BCHT including different chemical indicators for the different temperature / time combinations.

2 Description

The BCHT is based upon the EN 285 Amendment A2;2009 standard description of a Process Challenging Device and consists out of a Chemical Indicator Holder connected to a 1,5 mtr long tube. When used in every cycle the BCHT is early detecting failures during the steam sterilization cycles. Failure which are picked-up by the BCHT are:

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

The capabilities of Helix devices of detecting failures at an early stage of their appearance is THE reason for many end-users at CSSD's to use these at a daily basis with every cycle and for the Dutch RIVM (part of MOH) and German Robert Koch Institute to make their recommendations.

The BCHT is a Helix based test system designed to be the most difficult to sterilize object and to have one uniform reference for monitoring all your steam sterilization processes.

As such it can be used in every cycle regardless whether the cycle is carrying various loads or load types (f.i. gum, plastic, MIC, hollow, plain instruments etc). As the loads can vary from containers, instrument trays and baskets, to linen packs or other typical CSSD items and the content of your sterilization cycle varies all the time, the Helix is designed in such a way that it forms one of the best monitoring system for the various loads and cycles.

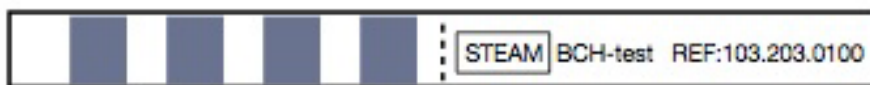
The bottom line is that you are detecting the vacuum and steam penetration capabilities of your steam sterilizer in a uniform way while loads and cycle parameters are varying.

The BCHT is consisting out of the following items:

- 1 piece of Helix device
- 100 (250/500) pieces of Chemical indicator strips ISO 11140 - Type 2 with adhesive on the back
- 1 piece of Cotton bag
- 1 piece of Direction For Use (DFU) with color change images
- 1 piece of Carton

Each chemical indicator strip is 6 mm wide and 76 mm long. For lay-out of both front and back of the chemical indicator strip pls refer to the next page.

Lay-out:



3 Confirmation to standards

The Sterintech™ BCHT are compliant to the following standards:

Helix: EN 285 :2005 + Amendment A2 : 2009
EN 867 part 5 : 2001

Hollow Load Process Challenge
Device EN 857/5 Steam

Chemical Indicator: ISO 11140 part 1 : 2014 - Type 2

Pls refer to the attached Certificate of Conformity.

Marketed by:
Majac Medical Products Pty Ltd
Tel: 1300 138 578 * Int: +617 3265 6355
Email: sales@majacmedical.com.au
www.majacmedical.com.au



FS 540017

Also available from:

4 Raw Materials

The Sterintech™ BCHT are consisting out of the following materials:

Helix: See enclosed Attachment B

Cotton bag: Natural cotton, Blue

Indicator strip: Paper Blanc wood free offset satinated paper
Indicator Ink, Waterbased, non solvent, non-toxic, non-heavy metals
Lacquer: Waterbased, non solvent, non-toxic

Plastic bag: PE - fully recyclable

Box: Carton, dim.: 170 x 120 x 55 mm (LxWxH)

Box Label: Vellum and acrylic glue, no natural latex

Manual: 90 gr/m2 paper

5 Quality assurance

The Sterintech™ BCHT are produced in accordance with our ISO 13485 based procedures. All working instructions and checking methods are laid-down in our Quality Assurance system which is audited twice a year internally and once year by external auditors.

All products produced by SP Medikal are traceable by lot numbers. Production files are recorded and kept for 10 years and by these every product can be traced and linked to raw materials used for the production of the product.

Re-call procedures are in forming a part of our quality manual.

6 Packaging

The Sterintech™ BCHT packed in a standard carton box as specified under 4) Raw Materials with the following dimensions: 170 x 120 x 55 mm (L x W x H)

7 Storage conditions

On each box the storage conditions are mentioned which guarantees the product specifications within the expiry time. Claims of non-performance of the product are subject to registered storage conditions. SP Medikal is guaranteeing the performance of the products within the specified Expiry time unless the packaging was opened or damaged.

8 Explanation of Symbols

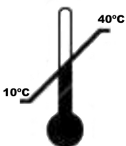
The following storage conditions symbols (EN 980) are used on the box:



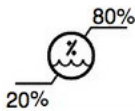
Keep dry and away from fluids



Protect against UV light



Store at specified temperatures



Store at specified relative humidity

9 Manufacturer's declaration

Interfering substances or conditions and release of toxic substances.

On this date there are no known interfering substances or conditions that are affecting the performance of the indicators as long as they are stored as per required storage conditions.

To the best of our knowledge there are no bleeding / staining effects or releases of toxic substances in the quantities which can cause a health hazard or hazard to the goods during sterilization.

The BCHT are produced in a climate controlled production room which has been designed based upon the GMP guidelines at the following location by:

SP Medikal San Ltd. Sti.
Rami Kışla Cad. 63, Altındağ İş Merkezi D1-2
Rami / Eyüp İstanbul
Turkey

Certificate of Conformity

We, SP Medikal San Ltd Sti., represented by undersigned, herewith declare that the

Batch Control Helix Tests (BCHT) with:

- REF.: 103.203.0100 STEAM 134°C - 3,5 min / 121°C - 15 min
- REF.: 103.203.0250 STEAM 134°C - 3,5 min / 121°C - 15 min
- REF.: 103.203.0500 STEAM 134°C - 3,5 min / 121°C - 15 min

have been tested in a CIER-Vessel at an independent Laboratory based upon the requirements as per ISO 11140 part 1.

We herewith confirm that the BCHT's are designed and compliant to the following standard:

Helix:

EN 285, 2005 + A2, 2009:

'Sterilization Steam Sterilizers, Large Sterilizers'

EN 867 - part 5, 2001 :

'Non-biological systems for use in sterilizers. Specification for indicator systems and process challenge devices for use in performance testing for small sterilizers Type B and Type S'

Chemical Indicator:


ISO 11140 - part 1, 2014:

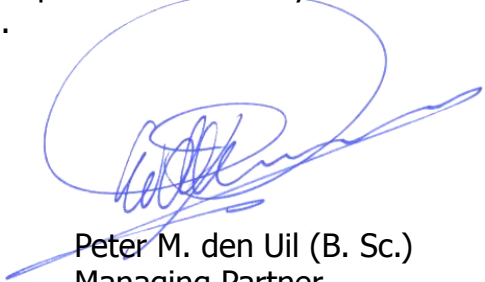
'Sterilization of health care products

Chemical indicators -- Part 1: General requirements'

Based upon these tests the chemical indicator in combination with the Helix device they are classified as Type 2. Processed Chemical Indicator can be kept for minimum 5 years under recorded environment parameters without end-color being effected.

1 June 2016


Seda Küçükylmaz
Quality Department


Peter M. den Uil (B. Sc.)
Managing Partner

B Dimensional data Helix Device



Helix Indicator holder:	Polypropylene, white (melting point > 175°C) Dimensions: Company Confidential
Tube:	100% PTFE Virgin, Natural color, ASTM D3295 compliant Length: 1.5 mtr, ID: 2 mm, OD: 3 mm.
Sealing ring:	Silicon FDA rot (-60 - +220°C) 8 mm – internal diameter
Shrink Sleeve:	PTFE, (-55°C - + 195°C) 6 mm Internal diameter. – 40 mm length
Cable Binders:	High Temperature Resistant > 150°C for 5.000 hours Color: Natural, Material: Polyamid 4.6 Dimensions: 100 x 2,5 mm