

Instructions For Use



EN INSTRUCTIONS FOR USE

REF	BM33002030 - CP Helix Test System 3.5 min (100)	STEAM
REF	BM33002031 - CP Helix Test System 3.5 min (400)	STEAM
REF	BM33002032 - CP Helix Test System 5.3 min	STEAM
REF	BM33002034 - CP Helix Test System 7 min	STEAM

Intended use

The Helix Test System is intended to be used as an independent control product to check both the steam penetration performance and the sterilization values of your sterilization process.

Instruction for use of the product

- Open the Helix Test System tube, fold the indicator strip with the indicator on the inside, place the indicator strip in the top of the Helix Test System tube with the fold first and finally close the Helix Test System tube. (See the below images for an illustration.)



- The Helix Test System is placed into the autoclave chamber or sterilization basket (not inside the package/container/pouch), there where the sterilization agent penetration is most difficult.
- Run the sterilization cycle.
- After the sterilization cycle, remove the indicator from the autoclave chamber and evaluate the result of the test by checking the indicator of the product.
- Use the "Product result references" from this Instruction For Use to see if a Pass or Fail can be evaluated.

If a Pass, then the cycle/test was successful.

If a Fail, then the cycle/test was unsuccessful. The content of the sterilization cycle should not be used! The sterilization system should be checked / maintained on its performance!

Intended users

- For professional use only!
- Central Sterile Services Department (CSSD) employees assigned for handling sterilization control products and ancillary products.
- Other professionals assigned for handling sterilization control products and ancillary products.

Indications and contra-indications

Use the product conform the information on the label. Do not use for any other purposes than indicated on the label or as specified under "Intended use".

User specifications

Handle, process and dispose in compliance with your facility/department policy and validated processes for sterilization. Use in compliance with the indicated standards which apply for this product (see Declaration of Conformity).

Standard process values

BM33002030: STEAM 134°C – 3,5 min. / 121°C – 15 min.

BM33002031: STEAM 134°C – 3,5 min. / 121°C – 15 min.

BM33002032: STEAM 134°C – 5,3 min. / 121°C – 15 min.

BM33002034: STEAM 134°C – 7 min. / 121°C – 20 min.

Disposal information

Dispose in compliance with your facility/department policy for disposal of all sterilization packaging.

Residual risks

The Helix Test System tube will be hot when the cycle is finished.

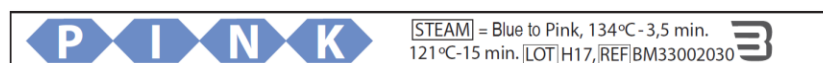
Risks if reused could be an incorrect representation of the tested cycle.

Do not use if any unexpected abnormalities appear in or on the product, such as, but not limited to inequalities in structure and/or color.

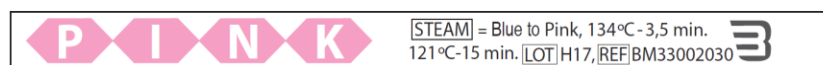
Avoid handling that could cause damage to the product or its properties.

Product result references

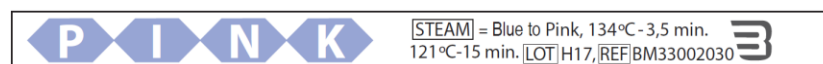
Do not use the below images as reference color! Only a clear pink and complete present pink pattern is a Pass. The showed Fail results are indications only. The extent of the presence of blue and pink in the Fail results can deviate from the patterns below but will still indicate a Fail.



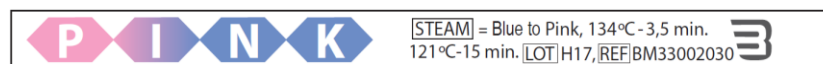
Not processed



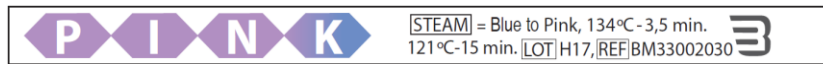
Pass



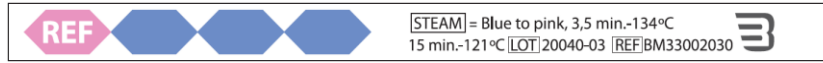
Fail! Possible cause: only temperature exists, no or insufficient steam penetration / air removal.



Fail! Possible cause: insufficient steam penetration / air removal.



Fail! Possible cause: steam penetration and inert gas exist at the same time.



Not processed



Pass



Fail! Possible cause: only temperature exists, no or insufficient steam penetration / air removal.

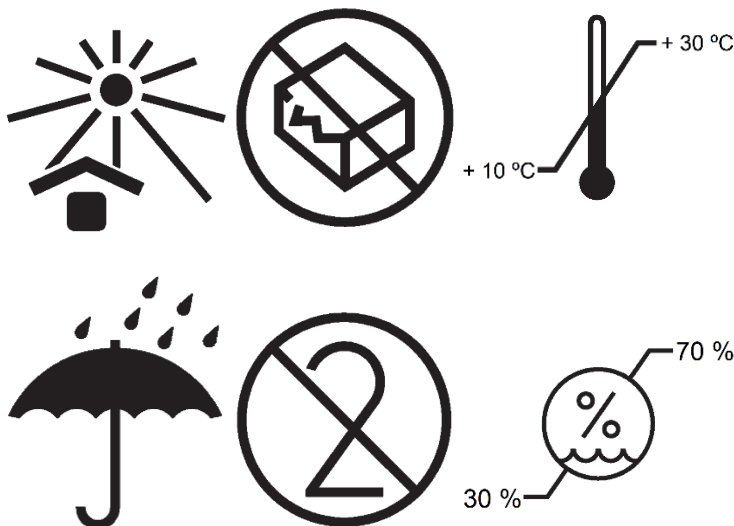


Fail! Possible cause: insufficient steam penetration / air removal.



Fail! Possible cause: steam penetration and inert gas exist at the same time.

Notice: any serious incident that has occurred in relation to this product should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.





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This Instructions for use is issued under the sole responsibility of Blue Medical B.V.. We hereby declare that the Instructions for use specified above meets the indicated standards. All supporting documentation is retained at the premises of the manufacturer.

Signature:



Mr. Alex Welleweerd
Sales Director

Place, date (dd.mm.yyyy) of issue and version:

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