HART

HOLLOW AIR REMOVAL TEST

ROUTINE & DAILY PCD

INSTRUCTIONS FOR USE

PRODUCT DESCRIPTION

STS Professional's Hollow Air Removal Test or 'HART' test (**9S-HART**) is manufactured to **ISO 11140-6:2022** in the 'helix' style to demonstrate the air removal and steam penetration efficiency for hollow items in small steam sterilisers. A declaration of conformity from the manufacturer is available on request.

The HART test is made up of Type 2 chemical indicator strips (250 pieces to ISO 11140-1:2014) and the PCD device.

The HART test is used to demonstrate that a small steam steriliser is efficiently removing all air from inside its chamber, and therefore the air inside a hollow item within that chamber. The PCD is manufactured to emulate a narrow lumen instrument, with 1.5M of tube.

To demonstrate its efficiency, steam will only be able to travel the 1.5M to the end of the PCD, where it will reach and saturate the indicator strip, if the air was sufficiently removed.

The indicator strip also emulates the following sterilisation parameters and will only change colour when the following conditions are met:

- Air has been sufficiently removed
- Steam has penetrated and saturated the strip and has held for:
  - 134°C for 3.5 mins or
  - 121°C for 15 mins

The HART test may be used for daily and/or routine batch monitoring in every cycle for hollow air removal and steam penetration testing to AS5369:2023.

USE & SAFTEY PRECAUTIONS

The HART test is designed for small steam sterilisers, less than 60L, with fractionated vacuum pulses. It is not suitable for gravity or single vacuum sterilisers or cycles.

This test is used to demonstrate a basic minimum level of steam penetration and is not intended to provide assurance that any particular item or load is satisfactorily sterilised by the process and the use of the HART test daily and/or for routine batch monitoring is not a replacement for steriliser validation.

The PCD device is tested and rated for up to 250 uses in the following cycles:

- Daily Testing
- 134°C Universal
- 121°C Universal

The HART test is suitable for use in delayed start daily testing cycles. In these circumstances, follow the test procedure below, leave PCD on a tray in the empty chamber and set delay.

The PCD must not be placed up against the chamber walls, where temperatures can, at times, exceed the softening point. Ensure it is placed on a tray. The softening point of the PCD is 170°C, do not exceed 170°C as the PCD may damage the steriliser.

When removing the PCD, take care as the device, rack and chamber may still be hot. Allow to cool before touching, ensure heat resistant gloves are worn to avoid burns.

STORAGE & DISPOSAL

To ensure correct performance of the product, the chemical indicator strips must be kept inside an airtight zip lock bag and away from moisture, heat, light and vapour sources.

Once all strips have been used, the PCD should be disposed of in the general waste along with any used and/or expired strips.

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TEST PROCEDURE

1. Open the PCD device by unscrewing the black cap.
2. Take a chemical indicator strip, fold in half, with the colour and text **inside**.
3. Insert into the cap, **fold end out**.
4. Screw close the cap, ensuring a firm airtight fit.
5. PCD device is now ready to be placed inside the chamber, on a tray, ready to complete a daily test cycle or to be included in a load for routine batch monitoring of hollow instruments.
6. Ensure PCD is not up against chamber wall.
7. At the end of the cycle, taking care that it may still be hot, unscrew the cap, remove strip, open and interpret the results.

RESULTS INTERPRETATION

If all of the air inside the device was effectively removed, and the steriliser was therefore able to inject steam to reach the strip, and also held for the following sterilisation parameters:

- 134°C for 3.5 mins or
- 121°C for 15 mins

the colour on the strip will change from **yellow to grey/black**, confirming that the parameters have been achieved.

A PASSED TEST

Please see examples of passed test strips below.

A FAILED TEST

If the indicator strip does not completely change to grey/black, the test should be considered a fail. Please see examples of failed test strips below.

If your test fails, first check the expiry of the indicators, the storage conditions, the integrity of the seal inside the cap, that the small hole inside the PCD housing, and the clear tube tail are free and clear, and are not blocked, as that may interfere with the testing process.

If an issue has been identified and can be remedied, retest with a new strip.

However, if no potential issue has been identified and/or the test fails again:

- Place the steriliser out of use.
- Fail the cycle/s and do not release any instruments or load.
- Contact your authorised steriliser technician.
- Follow internal documented procedures on how to proceed.

IMPORTANT: a steriliser may indicate that the test or cycle was a 'pass' on screen, however, a failed strip means the cycle must be recorded as a 'fail', and any instruments or load in that cycle must be considered unprocessed and must not be released. Follow internal documented procedures on how to proceed.

REORDERING

It is recommended to order a replacement HART test well before running out of strips to allow for shipping and handling time.

Please visit **www.stspro.com.au** or your usual distributor to reorder.

REORDER CODE:
9S-HART

STEAM
REF 9S-HART
ARTG 460985

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