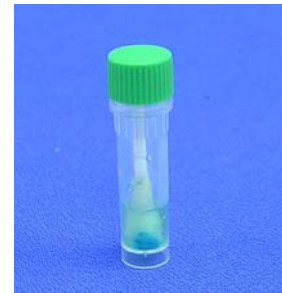
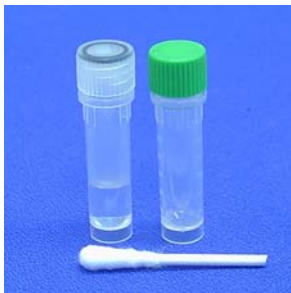




# The clean monitoring user guide

## HemoCheck-S



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## 1.1 Introduction

Beside problems with cleaning efficacy, blood residue can also be found on surgical instruments after a cleaning process due to inadequate handling or special cleaning problems. In case of visual residue, it is important to find out the cause as blood residue present poses a serious hygiene risk to patients and staff. Next to controlling the cleaning process with indicators the chemical test for blood residue (HemoCheck-S) is necessary for quality assurance and safety. HemoCheck-S is a test-kit for detection of blood residue on surfaces and instruments down to 0.1µg. The test is based on the sensitive peroxidase reaction and its application is applied by a swabbing technique for an immediate result.

## 1.2 Description of use

1. For swabbing of dry surfaces or instruments, the swab is moistened with one drop of clean (non-chlorinated) water.
2. Swab the surface or item to be checked. Care must be taken to apply sufficient pressure in order to remove denatured residue.
3. Check the swab for visual residue and note the result (visible residue like rust will not give a colour change but should also be noted for the trouble-shooting process)
4. Activate the HemoCheck-S test.
5. Drop the swab into the activated liquid.
6. Record the result and information regarding the tested device and cleaning process for quality assurance.

## 1.3 Testing of different instruments

Testing of general Instruments:

General instruments are swabbed after the visual check for difficult to clean areas and or discolouration. Special care must also be taken for the joint areas, crevices and other difficult to clean parts.

Testing of cannulated instruments:

The external surface of the cannulated instrument is swabbed as described for the general instrument, however for penetrating the internal surface, a long swab with the right diameter must be used.

## 1.4 Cleaning Validation

**Purpose:** Manual cleaning processes cannot be validated by cleaning indicators. Cleaning validation must be performed by direct control of the cleanliness of the washed items with HemoCheck-S. In addition, automated cleaning of special instruments, where standardised test objects are not available can yet be validated with HemoCheck-S combined with a blood-test soil according to EN ISO 15883.

**Description:** A representative number of cleaned items are checked for blood residue with HemoCheck-S, the validation process needs to be repeated and documented. In case of a failure, the process needs to be optimised and the validation process repeated. Validation must be conducted on a yearly basis, after any major

change of the cleaning process (e.g.: new cleaning parameters or detergent and after maintenance).

## **2.1 Routine Test**

**Purpose:** Even a validated process needs to be monitored on a routine base according to EN ISO 15883. This is due to the fact that cleaning parameters can easily change during routine use. Routine tests will ensure that the cleaning process is still up to the validated specifications.

**Description:** In comparison to validation, a reduced but still representative number of instruments are checked for blood residue. Instruments are chosen according to the outcome of the validation, e.g: difficult to clean instruments. The result of the routine test must be recorded for quality assurance purpose.

## **2.2 Diagnostic Test**

**Purpose:** While visual check for cleanliness can detect very small amount of residue, however one cannot always distinguish between blood and other sources of residue like corrosion or water spots. Without knowing the result, trouble-shooting and optimisation will be difficult. In order to distinguish between blood residues from other substances, HemoCheck-S is used as a diagnostic tool.

**Description:** The unknown spot is sampled with the swab and tested with HemoCheck-S. To help trouble shoot future problems, the outcome of the diagnostic test should be recorded.

## **2.3 Blind control**

**Purpose:** Thin layers of blood residue can contaminate Instruments by one of the following:

- a) Adsorption of blood proteins on surfaces in combination with a low efficient cleaning process.
- b) Blood residue carried over by the washer.

**Description:** In order to check out for adsorbed protein, choose a blood contaminated surface that is very easy to clean (e.g kidney dish) or prepare an appropriate test object contaminated with blood. After the cleaning process visually check the object for cleanliness then test the visibly clean area with HemoCheck-S. To find out if the washer is carrying over blood residue from one cleaning step to the next, check a surface that has not been contaminated with blood (e.g. the chamber wall) for any blood residue with HemoCheck-S.

### 3.1 Procedure on failure of a test (positive result for blood)

A correct cleaning process should have no difficulty to comply with both the validation tests and the routine tests described. Blood residue left on instruments poses a health risk such as blood transmitted diseases and compromises the sterilisation process. Moreover it bears the risk of toxic, allergic and pyrogenic reactions to patients. Blood residue left on instruments indicates that the cleaning process was inefficient. In case of a failure of the cleaning process (verified blood residue), the processed load needs to be rejected and reprocessed after trouble-shooting and optimisation have been performed. Bare in mind that protein residue, denaturated during the disinfection process, will be much harder to clean than fresh blood! A cleaning process with strong protein dissolving efficacy will be necessary for this purpose.

### 3.2 HemoCheck-S trouble shooting guide

Visual detection of residue is a very efficient test method and therefore should also be used after swabbing. Often residue on the swab can easily be detected and can give additional information about possible residue. The following table describes the different possibilities of test results:

<b>Visual check of swab</b>	<b>HemoCheck-S result</b>	<b>Explanation</b>	<b>INFO</b>
No discolouration	No colour change	Clean surface	-
No discolouration or red-brown discolouration	Blue colour change	Blood residue present!	Check and optimise the cleaning process
Discolouration	No colour change	Non blood residue e.g. rust	Investigate for other problems e.g. corrosion

### 3.3 Optimisation

Due to the high risk of inadequately cleaned instruments, optimising the inefficient process is mandatory and action should be taken as soon as possible depending on the nature of the problem. In most cases a lack of cleaning efficacy can be lead by incorrect process parameters; however, special cleaning problems can also be the cause.

#### 4.1 Check list for general cleaning problems

- Pre-rinse
  - Check if a cold pre-rinse is programmed
  - Check if the pre-rinse is at least 5 minutes and the temperatures is not above 45°C
- cleaning efficacy
  - Check if the right type of detergent is being used (alkaline/enzymatic) at the right temperature
  - Check if the cleaning time is long enough
  - Check if the dosage of detergent is according to the instruction and according to the water quality
  - Check the cleaning efficacy of the detergent. (Contact your local distributor for more information)
  - Check for blocked spray arms

#### 4.2 Check lists for special cleaning problems

- Pre-treatment or (contact to aldehyde or other chemicals)
  - Pre-disinfection prior to cleaning can cause blood denaturation on instruments.
  - Contact to chemicals or fumes such as disinfectants also denaturate blood.
  - A very long (e.g. over night) drying time can make cleaning more difficult.
- Care and handling of instruments
  - All jointed instruments need to be opened prior to cleaning.
  - Complicated instruments need to be dismantled beforehand.
  - Cannulated instruments need to be connected to the irrigation system.
  - Overloading of the instrument baskets need to be avoided.
  - Avoid covering instruments with metalwares as it reduces or stop the water jets.
- Mechanical cleaning problems
  - Water pressure can be lost at the water connection of the trolley.
  - The spray system might not reach the corners or the middle of the instrument trays.
  - Certain design of instrument basket can block the water jets and decrease the mechanical action.

**NOTE:** Insufficient cleaning prior to sterilisation, will allow blood residue to bake onto the instruments. In this case baked on blood residue will be very difficult to clean later on by the following cleaning cycle. That blood residue might be found even if the cleaning efficiency is sufficient to remove fresh blood and tested accordingly.

#### 4.3 Quality Assurance summary

The use of HemoCheck-S can only be part of an effective monitoring system when Quality Assurance is in place. It is important that during this process cleaning results and information are recorded for trouble shooting and optimisation purposes. **PEREG Trouble-shooting Parameters log books will guide you through the process.**