Hygiene and quality management

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Certainty creates trust and ensures the lead
Certainty creates trust and ensures the lead

Quality management in practice

HygCheck®

used for activity recording in reprocessing with the cooperation of users and operators

based on cleverly arranged splitting of tasks and responsibilities between experts in accredited laboratories and the knowledge about the specific processes in implementation

an overall concept which is based on long-term considerations for optimum quality and economic efficiency at the same time!
Hygienic quality management with the way to safe reprocessing

WHY - HygCheck®

- Every washer disinfector must be validated.
- To achieve this validated status every 3 to 6 month revalidation (also performance tests) of the processes has to occur.
- If medical devices are reprocessed, machines and processes used for reprocessing fall in the medical device directive (MPG) respectively the medical device operator ordinance.
- Type tested machines have to be used for these reprocessing processes.

Besides the legally required validation the quality in reprocessing should be ensured by continuous performance tests of the used processes.

At this point HygCheck system joins in with the goal to ensure:
  Both performance capability
  and also continuous reproducibility of
  the used processes with comprehension of users and operators.

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WHY - HygCheck®

The **HygCheck** – system assists you to precisely **quantify** the effect of your **reprocessing**, to **analyze** it and to **document** it.

Only with this **combination** of

- standardized
- validated quantitative indicator systems
- intensive training and support service for application
- as well as the evaluation of the results by a therefore accredited test laboratory

a unique **symbiosis** between **test quality** and **economic efficiency** can be achieved.

As a side effect the **knowledge** of your **staff** concerning the used **processes** increases considerably which leads to a further **increase** of **quality** and **efficiency** in your **company**.

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How does it work - HygCheck® in practice

- Experts from accredited test laboratories take the main responsibility for validation and test methods.
- Users or other service staff chosen by the operator are involved in the continuous performance tests. All with the goal of an economic and sustained success for your company and advantages by exclusive knowledge of your on site staff to the customer. This authorization requires basic and continuous training and allows for the user according to specific procedures from experts the actual performance of measurements, tests and documentation by the use of test sets especially aligned to the specific requirements.
- For the testing itself the user respectively the service staff of the manufacturer takes responsibility.
- The evaluation of the specific tests from the test sets and the data gathered on site is carried out in reporting of an accredited test laboratory.

In summary this means:

1. Accredited test laboratory - Planning, organisation (including providing of standardized test sets)
2. User respectively service staff - Performance of the tests according to the specifications
3. Accredited test laboratory - Analysis and report generation

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HygCheck® system

- USERS AND SERVICE PERSONNEL
  - TRAINING by experts

- SERVICES
  - support, advice

- MEASUREMENTS
  - sampling provided with HygCheck® test sets
  - Detergent and Disinfectant ....
  - washing machines, instruments, flexible endoscopes

- HYGCHECK® TEST SETS

- ACCREDITED LABORATORY

- INDICATORS & SAMPLE ANALYSES accredited laboratory

- TEST REPORT accredited laboratory

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**Implementation - HYGCheck®**

1. **Basic principle:** Standardized test and validation processes
2. **The Tools:** Test sets with quantitative indicator systems
3. **The Qualification:** Full training on the processes and application of test sets
4. **The Documentation:** Test report of the accredited test laboratory aligned with the test protocol of the user
5. **Modul for Quality Management / „Calibration“**

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Implementation - HygCheck®

Test sets with indicator systems

HygCheck system provides the operator with a test set aligned to the specific process in order to conduct the performance tests including the required operating procedures (SOP) by express mail service.

The required test sets are ordered from the operator according to the provided order forms of the accredited test laboratory.

The enclosed indicators and other test control devices are exposed to the process according to the operating procedure and afterwards are being sent back by express mail service to the accredited laboratory which carries out the quantitative analysis.

Shortly after the operator receives a certificate from which merges test protocols from the test cycles with the test report of the accredited laboratory.
Implementation - HygCheck®

Full training on the processes and application of test sets

Qualification of staff members is an essential resource for every company as well as for hospitals. The trainings to conduct performance tests and routine controls gives staff members a broader detailed knowledge about the processes in their machines which also proves useful in day-to-day operations.

Within HygCheck system the operator performs self-dependent and on his own responsibility based on the trainings the tests with indicators from the sets provided. The evaluation of the results however is being carried out by experts in the field from accredited test laboratories.

Due to this comparison of the data a qualified evaluation of the stability of performance capability of the processes even after years is possible.
Implementation - HygCheck®

Test report of the accredited test laboratory according to the test protocols of the user

*Basis* of documentation is the *merging* of the *documents* for *tests* by the user or service provider with the *test report* of an accredited laboratory in order to establish a complete *test documentation* respectively *validation report*.

„Calibration“

In order to constantly verify the information's from the *performance controls / routine controls* according to their comparability a *revalidation* of the processes is performed in HygCheck system in a *three years cycle* by the *accredited test laboratory* itself.

Therefore a *continuous alignment* of the procedures and *data* is being provided.
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TEST SETS - HygCheck®

1. We provide you with standardized reaction carriers

2. You expose the reaction carriers according to the procedures trained from us and document the important process parameters

3. We process and analyze the carriers and issue a report with a certificate to you

4. The performance tests with one HygCheck-package each per programme is recommended at least twice a year

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TEST SETS - HygCheck® - TEXTILE

The components
Test sets according to the latest state of the art and technology with qualified indicator systems

Test set for performance qualification

Consisting of:
- disinfection efficacy
- cleaning efficacy
- control of environment

Order No: [Order number]
Article number set
Serial number set: [yyyy-mm-dd]
Compiled for:
Name
Street
City

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TEST SETS - HygCheck® - TEXTILE

The components

The tool: test sets with indicator systems

- Rodac plates for environmental investigations
- Top covered tubes for water samples
- Washing pouches for bactericidal efficacy tests
- Washing pouches for virucidal efficacy tests
- Washing pouches for cleaning efficacy blood
- Washing pouches for cleaning efficacy protein-fat homogenate
- Transport bags for the return
- Additional materials such as gloves, label for returns and sampling protocol

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TEST SETS - HygCheck® - TEXTILE

Performance testing of a washing process consists of testing on the:

- Cleaning efficacy of the processes
- Bactericidal and virucidal efficacy of the processes (disinfection efficacy)
- Microbial burden of the environment
- Microbial burden of the used water in the processes
- If applicable toxicology

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TEST SETS - HygCheck® - WD’s

Test set for performance qualification

- disinfection efficacy
- cleaning efficacy
- control of environment

Order No: Order number
HS: Article number set
SN: Serial number set
yyymm-dd: Compiled for
Name
Street
City

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TEST SETS - HygCheck® performance qualification of processes in WD‘s

- The tests carried out each WD and program ever used.

- This 3 test pieces are always placed at the same position in the WD (eg top left, middle, bottom right).

  After completing the process, the test pieces are taken – into individually labeled cups (for example WD No., TP 1-3) and with the completed documents from test sets - in the original package sent using the enclosed return labels to the HygCen GmbH.

- HygCen as an accredited test institut analyses the residual protein content of test pieces.

- Create a test report including certificate for conducted performance qualification of your reprocessing.

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TEST SETS - HygCheck® - WD’s

The test piece is clamped to the clean area in the terminal. This is placed in the basket of the WD. After the process, the terminal is removed and the test piece transferred to the sample cup.

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CERTAINITY creates trust and ensures the lead

TEST SETS - HygCheck® - STERILIZER’s
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CERTAINTY creates trust and ensures the lead

TEST SETS - HygCheck® - STERILIZER's

The components

- test sets with indicator systems
- Systems are specifically tailored to the respective treatment process.
- Indicators are produced under standardized conditions and controls on their performance skills

- Test pieces PTFE tubes (Inside diameter 2 mm / wall thickness 0.5 mm)
- 50 ml screw cap
- 20 ml splash
- 3 cannulas
- Transport bag for returning
- Additional materials such as gloves, cable ties, label for returns and sampling protocols

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0,03 % albumine solution treated with Bacillus atrophaeus (cfu 10⁹ /ml).

This corresponds to the clean conditions, especially before exposure in the system, a purification is required.
Hygienic quality management with HYGCHECK® the way to safe reprocessing

TEST METHOD - HygCheck® - STERILIZER’s

Performance qualification:
- Thermoelectric verification using loggers
- Examination of the sterilization efficiency by means of dummy
- Microbiological examination of liquids

Documentation for each batch:
- Inlet temperature
- Filling time by minutes
- Reaction time of minutes
- Concentration
- Temperature
- Number of cycles

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KNOWLEDGE CREATES SUCCESS
INNOVATIONS CHANGE STRUCTURES
STRUCTURES CREATE NEXT GENERATIONS

Ensure yourself quality on the highest level to your customers!

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