Monitoring the Performance of your Automated Endoscope Reprocessor

Validation
Contents:

1. History of validation in the Haga Hospital
2. Guidelines
3. Annual technical validation
4. Quarterly performance tests
5. Results
6. Discussion / questions
History:

• Technical support in the hospital deals with maintenance and errors.
• The expert substantiates the requirements of SFERD and the experiences reported by validation technicians.
• Support for annual technical validation
• Program of requirements
• Managers of departments were informed of the costs, required time and investments
## Monitoring of AERs according to ISO 15883-4

### Annually
- Verification of system specifications (technical)

### Quarterly tests
- Cleaning performance
- Disconnection alarm
- Blockage alarm
- Microbiology

<table>
<thead>
<tr>
<th>Measure</th>
<th>At purchase</th>
<th>Monthly</th>
<th>Quarterly</th>
<th>Annually</th>
<th>Biennially</th>
<th>At incidents</th>
<th>After process-influencing interferences</th>
<th>After maintenance</th>
<th>Optional</th>
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</thead>
<tbody>
<tr>
<td>Technical validation</td>
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<td>Verification of system specifications of drying cabinet</td>
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<tr>
<td>Inspection endoscopes</td>
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<td>Check if new and loan endoscopes can be loaded in AER and drying cabinet (compatibility)</td>
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<td>Process controls</td>
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<td>Channel monitoring test with dummy scope</td>
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<td>Check the channel separators</td>
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<td>Check the connectors</td>
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<td>Process control test with dummy endoscope</td>
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<td>Check the cleanliness of the exterior of the endoscopes</td>
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</table>
Program of requirements (1):

- Verification that specifications of the AER are met
- Verification that reprocessing programs are still the same (process)
- Assessment of proper doses of cleaning and disinfection chemistry
- Efficacy of the cleaning and disinfection must be proven. Applied chemistry must be used at the proper concentration and at the proper temperature.
Program of requirements (2):

• Results of temperature tests at the front and the back of the endoscope, and at several locations in the AER

• Controls of standard safety specifications, depending on the type or brand of the AER
  – interruption of the process
  – documentation of the efficacy
  – multiple technical specifications
  – inspection of damage
Demands on the validation technician(1):

Assume that:

• Procedures will be well thought out and will be carried out safely:
  – No modifications to the hardware of AERs shall be made while carrying out measurements, tests or inspections. Sensors, wiring, piping or other permanent or temporary connections shall not be damaged or changed.
Demands on the validation technician(2):

- Technician performing measurements, tests and inspections must be demonstrably competent and specially trained. The individual must be familiar with the design, construction, use and maintenance of the specific type of AER. The starting points of the validation are always specified by the manufacturer.

- Taking into account current legislation, standards, guidelines etc., the authorities demand that procedures will be carried out demonstrably safe.
Assignment to the validation technician:

Programs that are validated:

• Reprocessing process “Normal Program”
• Thermal self-disinfection program

• Temperature measurement in the chamber and at safe, accessible locations of the water supply port and the water drain location using the surrogate endoscope with temperature probes at several locations in the AER.
• Technical report of results must be provided digitally and as hard copy.
Test for validation

- Technical validation by a company
- Quarterly performance tests by the disinfection departments
  - Cleaning performance
  - Disconnection alarm
  - Blockage alarm
  - Microbiology
Technical validation:

• Technical performance: measurements, tests and inspections
  – Temperature tests using a surrogate endoscope
  – Assessment of the timing and adequate chemistry decline during the process
  – Assessment of the normal and the self-disinfection programs
The validation report: Technical validation

Validation of AERs  November 8, 2013
Performance tests; quarterly
Process control by members of departments

<table>
<thead>
<tr>
<th>Disconnection alarm</th>
<th>Blockage alarm</th>
<th>Cleaning performance</th>
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<tbody>
<tr>
<td><img src="image" alt="Disconnection test" /></td>
<td><img src="image" alt="Blockage test" /></td>
<td><img src="image" alt="Cleaning performance" /></td>
</tr>
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</table>

Before After

Test soil from Brown according to ISO 15883-5

Validation of AERs November 8, 2013
Registration of all results in a report:
- disconnection alarms
- blockage alarms
- visual results of cleaning performance
- registration of the tested channel
- effect of the test (interruption of the program)
- alarm time
- the message given by the AER
Microbiological Validation

• Quarterly samples taken from the final rinse water
• Performance of growth tests by the hospital microbiology laboratory
• Support by experts on infection prevention
• Documentation of the results of all tests
Experiences on validation of AERs

- According to ISO 15883 part 4 the procedure must be carried out
- The technical validation and the process controls are very time consuming
- Problems caused by the surrogate endoscope may interfere with the test
- 1 out of 5 AERs shows problems during the validation procedures
- The validation procedure as a whole can be considered as a useful activity.
Questions and Discussion