INFO FILE
HYGIENE.

INSTRUMENT REPROCESSING IN THE DENTAL PRACTICE
AN INTRODUCTION TO INSTRUMENT DECONTAMINATION.

Hygiene requirements in a dental practice raise questions about practice organization, device configuration and the possibility of documenting instrument reprocessing. This info file answers the most important questions on infection prevention and instrument decontamination. Enjoy every day. With Sirona.

CONTENTS

An introduction to instrument decontamination 02
Instrument reprocessing: RKI guidelines 03
Instrument reprocessing methods 04
Reprocessing after every patient 05
Decontamination of instruments - an overview 06
Market overview of care and hygiene devices 07
DAC UNIVERSAL advantages 08
Fully automated reprocessing 09
Information on validation of the DAC UNIVERSAL 10
Batch inspection and release 11
Process documentation 12
Electronic documentation 13
Water supply 14
NitraDem Direct Connect – connections 15
NitraDem Direct Connect and SIRODEM 16
Market overview of water treatment systems 17
Requirements and information on installation 18
Instrument reprocessing in the hygiene area 19

HTM01-05 GUIDELINES FOR INSTRUMENT DECONTAMINATION

Patients deserve to be treated in a safe and clean environment with consistent standards of care every time they receive treatment. It is essential that the risk of person-to-person transmission of infections be minimised as much as possible.

In this respect, the decontamination of dental instruments has always represented a major challenge for even careful and well educated clinic staff. Especially the internal cleaning of dental instruments requires great care due to their complex internal structure. Additional difficulties arise from the fact that the instruments are typically contaminated with oil residue, blood, saliva, other body fluids, tissue and metallic abrasion caused by the friction of metal parts.

Fully automated reprocessing of the instruments in devices designed specifically for the decontamination of rotating dental handpieces, ultrasonic instruments and/or solid instruments increases the reliability of the decontamination process. At the same time, the use of automated reprocessing devices decreases the risk of cross contamination both for the patients and for the clinic staff, as it minimises the possibility of human errors.

DEFINITION OF DECONTAMINATION ACCORDING TO HTM01-05:
“Decontamination is the process by which reusable items are rendered safe for further use and for staff to handle. Decontamination is required to minimize the risk of cross-infection between patients and between patients and staff.”

A large number of tiny parts are compressed into modern dental handpieces, turning their internal lumen into a maze of small caves making the internal cleaning a severe challenge (picture showing a T1 CLASSIC instrument from Sirona).
INSTRUMENT REPROCESSING METHODS.

CLEANING AND DISINFECTION

Automated cleaning and disinfection – the safe way to decontaminate instruments
During an automated process, all the decontamination steps that are involved in cleaning and disinfection are performed by a hygiene device. Cleaning is carried out with water and, where necessary, cleaning agents are added. Disinfection is mostly thermal without the addition of chemicals. According to HTM01-05, whenever possible, cleaning should be carried out using an automated and validated device. Automated cleaning and disinfection devices must comply with the requirements set out in the international standard EN ISO 15883. They include a process evaluation system and can thus be validated (e.g., DAC UNIVERSAL, cleaning and disinfection devices).

Manual cleaning and disinfection
In principle, manual cleaning is the simplest method to set up. However, it is hard to validate because it is difficult to ensure that it is carried out effectively each time. The manual method is very time and labour intensive compared to most automated systems. Furthermore, compared to other cleaning methods, manual cleaning presents a greater risk of inoculation injury to staff. For dental procedures that are carried out according to the best practice requirements outlined in HTM01-05, manual cleaning should only be used for equipment that cannot be cleaned by automated methods.

Semi-manual cleaning and disinfection
Numerous care and hygiene devices offer partially automated decontamination processes. The steps not covered by these devices must be performed manually or by other devices (see page 6: “Market overview of care and hygiene devices”).

STERILIZER CLASSIFICATION
The standard for small sterilizers EN 13060 distinguishes between three classes of sterilization programs: B, S and N.

CLASS B – THE UNIVERSAL STERILIZATION TYPE
- With a Class B sterilization program, all wrapped and unwrapped, solid, hollow and porous devices can be sterilized – with a fractionated pre- and post-vacuum. Devices with such programs are referred to as Class B sterilizers (e.g., DAC PROFESSIONAL).

CLASS S – FOR STERILIZATION OF MEDICAL DEVICES
- This program sterilizes unwrapped and wrapped (single or double) devices as per the manufacturer’s specifications (see proof of origin). Devices with such programs are referred to as Class S sterilizers (e.g., DAC UNIVERSAL).

The sterilization result meets the same quality requirements as Class B sterilizers.

CLASS N – FOR THERMAL DISINFECTION
- The sterilization program as per Class N is used for unwrapped, solid devices. It can be used for turbines and straight and contra-angle handpieces for final thermal disinfection (risk class “Semi-critical B”).

FOR FURTHER READING
- HTM01-05. 2013.
- A Clean Matter. Test of the cleaning efficiency of the DAC UNIVERSAL at Charite Medical University in Berlin, Germany. ZWP Special, 2009.
- Evaluation of the cleaning efficacy of instruments for processing of handpieces. Test of the cleaning efficacy of the DAC UNIVERSAL and other hygiene devices at the Medical University of Vienna, Austria. Hygiene & Medizin, 2008.
- Medical Devices Regulations 2002. SI 2002 No. 618. HMSO.
- BS EN 13060. Small steam sterilisers.
- BS EN ISO 15883-1. Washer-disinfectors. General requirements, terms and definitions and tests.
DECONTAMINATION OF INSTRUMENTS – AN OVERVIEW.

MARKET OVERVIEW OF CARE AND HYGIENE DEVICES.

For the reprocessing of turbines and straight and contra-angle handpieces

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>DAC UNIVERSAL</th>
<th>Assistina 3X3</th>
<th>QUATTROcare CLEAN</th>
<th>iCare+</th>
<th>Lubrina</th>
<th>X-Cid</th>
<th>STATMATIC PLUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cycle time</td>
<td>approx. 16 min.</td>
<td>approx. 6 min.</td>
<td>approx. 12 min.</td>
<td>approx. 12 min.</td>
<td>approx. 2 min.</td>
<td>approx. 30 min.</td>
<td>approx. 10 min.</td>
</tr>
<tr>
<td>Capacity [instr.]</td>
<td>6</td>
<td>3</td>
<td>4</td>
<td>4</td>
<td>3</td>
<td>3</td>
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</tr>
<tr>
<td>Weight [kg]</td>
<td>23</td>
<td>75</td>
<td>18.5</td>
<td>14</td>
<td>10</td>
<td>8</td>
<td>7.6</td>
</tr>
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<td>Water connection</td>
<td>✔</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>✔</td>
<td>No</td>
</tr>
<tr>
<td>Waste water connection</td>
<td>✔</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>✔</td>
<td>No</td>
</tr>
<tr>
<td>Compressed air connection</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>External cleaning</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Internal cleaning</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Disinfection</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Sterilization</td>
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<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Electronic documentation</td>
<td>optional</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Instruments can be directly used for semi-critical B</td>
<td>✔</td>
<td>No (additional sterilization)</td>
<td>No (additional manual external cleaning and sterilization)</td>
<td>No (additional manual external cleaning and sterilization)</td>
<td>No (additional sterilization)</td>
<td>No (additional manual external cleaning and sterilization)</td>
<td></td>
</tr>
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<td>Ultrasonic tips</td>
<td>✔</td>
<td>No</td>
<td>✔</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Ultrasonic handpieces</td>
<td>✔</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Attachments for multifunctional syringes</td>
<td>✔</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

*Pre-disinfection
**Device is not a disinfector/sterilizer


Information based on manufacturers’ details (April 2013)
The DAC UNIVERSAL cleans, lubricates and disinfects/sterilizes up to 6 straight and contra-angle handpieces, as well as turbines in a fully automated process. You can now also reprocess ultrasonic tips and handpieces, attachments for multifunctional syringes and solid instruments with maximum hygienic safety in the DAC UNIVERSAL.

**PROFESSIONAL CARE**
- Cleaning, if necessary lubrication, disinfection and sterilization in just one cycle
- Internal and external cleaning of turbines and straight and contra-angle handpieces, ultrasonic tips & handpieces, syringe nozzles
- Optimum lubrication of drive channels
- Disinfection or sterilisation of instruments

**FULLY AUTOMATED DECONTAMINATION**
- Decontamination of 6 handpieces with minimum effort
- Reliable and reproducible instrument decontamination
- Easy to operate
- Interface for electronic documentation systems

**COST-EFFECTIVE REPROCESSING**
- Low operating and consumption costs – no use of cleaning and disinfection chemicals
- Significant time savings
- Proper maintenance helps extend the lifetime of your handpieces
- The fast turnover means that fewer handpieces are needed in the clinic

**DECONTAMINATION ACCORDING TO STANDARDS AND GUIDELINES**
- Decontamination process tested by an accredited laboratory
- Cleaning and sterilisation process in compliance with EN/ISO 15883 Part 5 and EN 13660 type S
- The cleaning and sterilisation processes can be validated according to HTM01-05
- Can be revalidated on-site in the practice according to HTM01-05

**LEGAL CERTAINTY**

**FULLY AUTOMATED REPROCESSING.**

**REPROCESSING OF ROTATING INSTRUMENTS IN JUST ONE CYCLE (STANDARD LID)**

1. **INTERNAL CLEANING**
   - Step 1 Leak test
   - Step 2 Internal cleaning: The internal channels are rinsed with water

2. **EXTERNAL CLEANING**
   - Step 4 External cleaning: The instruments are cleaned by means of a pulse wash procedure (multi-cyclical cleaning method)
   - Step 5 Warm external cleaning
   - Step 6 Heating up to 134°C
   - Step 7 Back-flush: Saturated steam is forced through the instruments

3. **LUBRICATION**
   - Step 3 Lubrication: The drive channels are lubricated*

4. **STERILIZATION**
   - Step 8 Sterilization: 3 minutes at 134°C
   - Step 9 Back-flush: Saturated steam is forced through the instruments
   - Step 10 Drying
   - Step 11 The lid opens slightly
   - Step 12 The lid opens fully when the “C” button is pressed

**REPROCESSING WITH THE FLEX LID**

1. **INTERNAL CLEANING**

2. **EXTERNAL CLEANING**
   - Internal cleaning with cold water
   - External cleaning with cold and hot water

3. **LUBRICATION**
   - Fully automatic lubrication

4. **STERILIZATION**
   - Sterilization and drying

* Only sufficient for the next treatment.
The revalidation must be carried out after two years or 3000 cycles. If complete technical-physical initial validation is demanded by the operator’s signature, the batch can be documented with a printer, connected to a PC (also via a network) or via a USB data-logger system. The results of this test cycle are documented in the installation report QR 22 and confirmed by the manufacturer by means of a hygiene appraisal report from an accredited hygiene laboratory. The proof of origin of the DAC UNIVERSAL confirms the effectiveness of cleaning and disinfection as per EN ISO 15883 Part 5 and the effectiveness of sterilization as per DIN EN 13060, Class S. In contrast to Class B devices with which the steam penetrates into the hollow spaces of sterilization as per DIN EN 13060, Class S. In contrast to Class B devices with which the steam penetrates into the hollow spaces via a vacuum, as a Class S device, the DAC UNIVERSAL is based on a circulating steam penetration process.

Maintenance as recommended by the manufacturer must, in addition to the repeated performance qualification, also be performed after two years or 3000 cycles. A spare parts set is available (REF. 60 80 480). Approx. 4 working hours must be allowed for the validation technician.

It is recommended to use Class 5 chemical indicators (REF. 58 92 059) with each cycle for ultrasonic handpieces, scaler tips, as well as nozzles for multifunctional syringes. It is recommended to use Class 5 chemical indicators for batch release. Indicator holder (REF. 65 42 489) with Class 5 chemical indicator (REF. 58 92 059).

For rotating dental handpieces, e.g. turbines and contra-angles, it is recommended to use Class 5 chemical indicators for batch release. Indicator holder (REF. 60 51 798) with Class 5 chemical indicator (REF. 58 92 059).

For critical applications, the use of Class 5 chemical indicators is recommended (REF. 58 92 059). After the standard program, 3 handpieces can be packaged in sterile form for transport, storage and Critical B applications.

If release is not possible due to an objection, the entire reprocessing process must be carried out again. Then, written release and batch documentation from the competent staff occurs.
The MP LOG Box is connected to the DAC UNIVERSAL serial port. The log files are saved on a USB flash drive and, for example, manually saved to your PC daily.

FUNCTIONS IN DIOS MP STERIDAT

The process data from the DAC UNIVERSAL and other devices involved in the reprocessing process are transferred to your PC via direct or network cable. All logs are processed there with DIOS MP Steridat for documentation and archived after release by qualified staff in a tamper-proof encrypted PDF format. Process logs and staff-related documentation labels can also be created for patient records.

FUNCTIONS IN DIOS MP FULL VERSION

You can use the full version of DIOS MP to organize your entire medical device management system, incl. warehouse, supplier and manufacturer management, batch traceability, inventory control, management of staff training, activities and access rights, release options via smart card or digital signature, machine logs, cost-effectiveness analyses and much more. Easy upgrade options from MP LOG and MP Steridat to the full version of DIOS MP.

SEGOSOFT

EASY RETROFITTING, EASY INSTALLATION

The Segosoft Storage module of the USB solution is simply installed at the serial interface of your unit. It receives the available log data, checks the process parameters and stores the cleaning log on the USB flash drive. A signal is given to indicate that the cleaning and disinfecting process has been run correctly. This control mechanism is necessary to ensure security in the area of instrument reprocessing.

EASILY OPERATED, PAPERLESS, LONG-TERM FILING

With Segosoft documentation software, data stored on the USB flash drive is automatically transferred to the PC of your practice. You approve and release the cleaning logs on your PC, sign them digitally and file them long-term. Long-term filing occurs in PDF format, of course, which protects the documents against unauthorized changes.

Information based on manufacturers’ details (April 2013)
WATER SUPPLY.

High-quality treated water is required for the DAC UNIVERSAL. Most standard reprocessing systems cannot guarantee a constant flow which satisfies this need. In order to avoid cycle interruptions due to poor water quality, we recommend the NitraDem Direct Connect water treatment system.

NitraDem Direct Connect – CONNECTIONS.

NitraDem Direct Connect features 3 water outlets. Depending on the autoclave type, up to three autoclaves can be connected.
NitraDem Direct Connect
AND SIRODEM.

NitraDem Direct Connect

ADVANTAGES

- Direct water connection
  - EN 1717-compliant for direct connection
  - Fully automated demand-supply of all connected hygiene systems
  - Connection of up to 3 hygiene systems simultaneously
- Easy handling
  - Simple filter replacement
  - Universal application for DAC UNIVERSAL and all standard sterilizers
- Continuous control
  - Always the right water quality
  - No quality losses due to storage
  - Continuous control via conductivity meter

SIRODEM

ADVANTAGES

- Simple and cost-effective
  - The practical wall unit for fully desalinated water directly at the workstation
  - Simple installation
  - Unpressurized system for tank filling
- Reliable water quality
  - No quality losses due to storage
  - Inclusive control via conductivity meter
- Clean Instruments
  - High quality water protects the instruments from corrosion and spotting and protects the device

MARKET OVERVIEW OF WATER TREATMENT SYSTEMS.

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>NitraDem Direct Connect</th>
<th>SIRODEM</th>
<th>Destillo 2</th>
<th>MELadem 40</th>
<th>LisaDem 30</th>
</tr>
</thead>
<tbody>
<tr>
<td>Throughput [l/h]</td>
<td>40</td>
<td>50</td>
<td>50</td>
<td>250</td>
<td>38</td>
</tr>
<tr>
<td>Pure water quality [μS/cm]</td>
<td>0.1 – 12</td>
<td>0.1 – 20</td>
<td>0.1 – 20</td>
<td>1 – 5</td>
<td>0.1 – 20</td>
</tr>
<tr>
<td>Electrical connection</td>
<td>100V – 240 V 50-60 Hz</td>
<td>100V – 230 V 50-60 Hz</td>
<td>220 V</td>
<td>230 V 50-60 Hz</td>
<td>230 V 50-60 Hz</td>
</tr>
<tr>
<td>Dimensions [H x W x D] [cm]</td>
<td>26.5 x 30 x 12</td>
<td>8 x 600</td>
<td>5 x 11.5 x 11.5</td>
<td>10 x 30 x 15</td>
<td>30 x 30.5 x 19</td>
</tr>
<tr>
<td>Weight [kg]</td>
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<td>3</td>
<td>2.5</td>
<td>2.4</td>
<td>3</td>
</tr>
<tr>
<td>Capacity / 10° dH / [litre]</td>
<td>430</td>
<td>425</td>
<td>320</td>
<td>210</td>
<td>150</td>
</tr>
<tr>
<td>Conductivity test</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>Direct connection</td>
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<td>EN 1717-compliant for direct connection</td>
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<td>no</td>
<td>no</td>
</tr>
<tr>
<td>Electrical connection</td>
<td>yes</td>
<td>EN 1717-compliant for direct connection</td>
<td>no</td>
<td>no</td>
<td></td>
</tr>
</tbody>
</table>

Information based on manufacturers' specifications [April 2013]
REQUIREMENTS AND INFORMATION ON INSTALLATION

REQUIREMENTS ON SITE
The DAC UNIVERSAL should be positioned in an open space, on a flat surface. Place the DAC UNIVERSAL in a well-ventilated place on a flat, heat-resistant surface near to a power source. A compressed air connection of 5 to 8 bar is required. Recommended minimum distance from the wall is 10 cm. Furthermore, there must be enough space to enable the sterilizer to be opened upward. The total height of the open DAC UNIVERSAL is 53 cm. The minimum height should be 70 cm in order to prevent possible injuries when opening the lid (risk of crushing).

INSTALLATION OF THE DAC UNIVERSAL

(A) Process documentation: Interface RS232 for printer, PC, USB data logger.

(B) AC input: 90–120 & 190–240 volt ~ 50-60 Hz – 1100 W

(C) Air input: Connect clean and dry air (tube size 6 mm). The air pressure must be between 5 and 8 bar [short-term air consumption approx. 60 Nl/min at 5 bar].

NOTE: You must fit an air filter up stream (included in the scope of supply) to prevent dirt particles from the hose and compressor entering the device!

This filter can be ordered [REF. 60 78 575].

(D) Drain: The drain hose must be made from heat-resistant material [PTFE hose] and have a diameter of 6 mm. The maximum length is 3 m. Please use the original drain tank [REF. 60 78 526] or the original syphon (REF. 61 26 341) for direct connection to the waste water system.

(E) Water connection: Water from a water treatment system can be connected to the water connector with the 6 mm hose. We recommend NitraDem Direct Connect [REF. 62 59 852] as the direct connection. Water can also be filled manually into the water container. Note: The water quality must not be above 3 μS/cm. Note: The maximum water pressure is 6 bar.

INSTUCTION REPROCESSING IN THE HYGIENE AREA.

According to HTM01-05, there is a clear need to maximise the separation of decontamination work from clinical activity within the constraints of space and room availability. Regardless of the choice of location used for the reprocessing facilities, a dirty-to-clean workflow should be maintained so that used instruments are at a lower risk of coming into contact with decontaminated instruments.*

The DAC UNIVERSAL must be positioned in the dirty zone, directly on the border to the clean zone.

* HTM01-05, section 5.1.5.8
ALWAYS AT THE FOREFRONT OF INNOVATION!

As global innovation leader for dental equipment, we continuously invest in research and thus in the future of modern dentistry. By networking digital technologies with integrated solutions and optimizing the treatment workflow, we create improved treatment results, more comfort and safety for the patient as well as time and cost savings in everyday work. The combination of constant innovative power and globally growing sales and service structures makes Sirona the global market leader trusted by thousands of practices and labs around the world.

Enjoy every day. With Sirona.

CAD/CAM systems
From pioneer to new standard. For 30 years we have been developing digital dentistry and creating new possibilities for the future practice and lab.

Imaging systems
Best image quality with the lowest dose. More than 100 years of developing x-rays for the dental practice make us the number 1 innovation partner.

Treatment centers
The business card of modern practices. We are striving to create the ideal ergonomic and innovative center. Individually tailored to the well-being and demands of the patient and dentist.

Instruments
Advantages that speak for themselves. We make sure that we provide the right balance of proven quality, individual ergonomics and innovative technology for user-friendly work.

Hygiene systems
Competence that gives you safety. When it comes to hygiene in the practice, we do not take any shortcuts.