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Guideline for

Hygienic cleaning processes of

Respiratory Home Care Devices

Recommendations for patients, operators, users, home care providers and manufacturers

by

EUROM VI

Medical Technology

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Introduction

This document is based on the recommendations for “Hygienic preparation of respiratory aids for home therapy” which have been developed by the Respiratory Home Therapy Group within the German association) SPECTARIS ^{med}, with the support of competent and qualified expert groups. We would like to express our gratitude for the valuable support, the extensive discussions and all the helpful comments and advice received in the process of creating this document, which helped considerably to complete this project successfully. Our special thanks go to:

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These recommendations on “Hygienic Reprocessing of Respiratory Home Care devices” are intended to be reviewed on a regular bases. They are a concretion of the recommendation of the Commission for Hospital Hygiene and Prevention of Infection at the Robert-Koch-Institute, Berlin Germany (RKI) and the German Federal Institution for Medicinal Products and Medical Devices (BfArM) for “Hygiene Requirements for the Reprocessing of Medical Devices” in respiratory home therapy. Review and updating will especially become necessary if the recommendations of the RKI and BfArM are continued or if the practical application of these recommendations suggests that changes are necessary.

Cologne, March 2005

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Hygienic Reprocessing of Respiratory Home Care Devices

Recommendations for patients, operators, users, home care providers and manufacturers

Foreword

These **recommendations are primarily aimed at the manufacturers** of devices for respiratory home therapy. Depending on individual cases, e.g. with products to be reused, these manufacturers have to provide instructions on suitable reprocessing procedures and possible numeric limitations on reuse of the product.

These **recommendations include important information for users operators and any other person** responsible for the reprocessing of medical products.

Often operators authorise other people, businesses or institutions to carry out the hygienic reprocessing of these devices. These **recommendations will help** those third parties to **put the guidelines into practice**.

Additionally, these recommendations include information for the operators and the people authorised with reprocessing on **how to handle used devices**. As is often the case in practice, many medical devices that have been in use for a long time lack such information on hygienic reprocessing in their instructions. These recommendations are designed to provide this missing information.

The **tables in the appendix** provide very **detailed recommendations** on reprocessing the listed medical devices and their accessories in different situations or conditions of use. Also, empiric values that have been collected in the use of these products in the last few years are supplied for guidance. These tables also contain details on the recommended reprocessing frequencies and the expected average life of these medical devices. They also provide a risk evaluation and a classification of the listed medical devices and their accessories.

1. Preamble

Medical devices shall not be operated or used if they show deficiencies which could compromise patients, employees or third parties.

Amongst others, this means that medical devices must not be operated or used if they are a potential danger of infection. In order to prevent this regional or national hygiene requirements for the reprocessing of medical devices must be met.

In the following recommendations provide special hygiene requirements for the reprocessing of medical devices used in respiratory home care applications.

Medical devices used in respiratory home care applications are generally to be used semi-sterile very rarely sterile. The term ‘sterile’ is defined sufficiently in scientific literature and standardisation, the term ‘semi-sterile’, however, is not. For the purpose of these recommendations **the term ‘semi-sterile’ is intended to mean ‘free from reproductive human pathogens’**.

The following recommendations for hygienic reprocessing of medical devices for respiratory home therapy are based on the general hygiene requirements for the reprocessing of medical devices of the Commission for Hospital Hygiene and Prevention of Infection at the Robert-Koch-Institute , Germany (RKI) - and the German Federal Institution for Medicinal Products and Medical Devices (BfArM). They also take into consideration the special requirements and needs of patient care in a home environment. The purpose of these recommendations is:

- to instruct the manufacturers of these devices to provide the operators with all necessary information;
- to make the operators aware of possibilities on how to implement their tasks responsibly through appropriate delegation;
- to help all parties involved in patient care in a home environment to put into practice any applicable legal regulations and manufacturer’s instructions on the reprocessing of medical devices.

The responsibility for the reprocessing of medical devices always lies with the user / operator. This responsibility cannot be delegated. Only tasks resulting from this responsibility can be delegated. As many operators reusing medical devices are lacking experience, it is often reasonable and common to authorise or contract professional processors who meet the regional or national requirements.

These recommendations are also designed to provide any practical support to all those involved in patient care in a home environment with regard to implementing legal regulations and the hygiene measures required for the patient’s safety.

All medical devices contaminated with pathogens are a potential source of infection in humans. Reusing and handling such medical devices, in the following referred to as contaminated medical devices, must be preceded by careful hygienic reprocessing which is subject to clearly-defined requirements.

These requirements basically result from:

- the **legal requirements** to protect the patient, the user and third parties (e.g. persons in charge of reprocessing)
- the limits of the procedures used for reprocessing
- and the necessity to guarantee the proven standardised procedures in a consistently high and verifiable quality, based on an established **quality management system**.

The type of reprocessing is determined by the degree of danger of infection resulting from a medical device and the expected reuse of a medical device with another patient.

Any medical product that has already been used with another patient is potentially contaminated with reproductive human pathogens. Special handling and reprocessing of the device is essential to protect the next patient, user or third parties.

These recommendations are especially aimed at but are not limited to the reprocessing of the following medical devices for respiratory home therapy and parts of these devices, including their accessories.

- Respiratory therapy devices for mucus removal and elimination
- Percussion devices and PEEP systems
- Suction devices
- Aerosol inhalers for lower and upper respiratory tracts
- Monitors for babies, SIDS monitors
- Assisting or controlled respiration systems (continuous or intermittent)
- Ventilatory support devices
- Ventilators
- Humidifiers for tracheotomised patients
- Sleep apnea therapy devices
- Oxygen concentrators
- Gaseous Oxygen therapy Systems
- Liquid Oxygen systems
- Oxygen saving / conserving devices for GOX or LOX-systems
- Tracheotomy tubes

2. Purpose

These recommendations aim at the proper handling of medical devices that could be contaminated with pathogens. They concretise the „hygiene requirements for the reprocessing of medical devices“ published by the RKI and the BfArM in August 2001 with regard to respiratory home therapy. They are based on the fact that in respiratory home therapy the operator often authorises or contracts other people (third parties) to carry out the hygienic reprocessing.

When medical devices are used in respiratory home therapy special conditions apply. In particular, **in patient care in an ambulant / home environment medical products are commonly** to be used **semi-sterile, but not sterile**. Moreover, in contrast to treatment in a hospital or practice environment, in home therapy the operator responsible for the hygienic reprocessing is usually not on site. Operators of medical devices used at home have often delegated the tasks within their responsibilities to third parties (service providers). When delegating his tasks the operator has to ensure that these service providers meet the regional or national requirements.

These recommendations provide assistance with regard to **responsibilities** and **handling** in the reprocessing of home use medical devices as listed in the preamble (Chapter 1).

3. Scope

The requirements described in this document **apply to** the reprocessing of medical devices that are designed to:

- introduce ambient air, gases or aerosol into the human body.

These recommendations always apply when medical devices for respiratory home therapy or parts of such products including their accessories, which are to be used semi-sterile, must be hygienically processed. This is particularly the case:

- with continuous use in a patient,
- before maintenance and repair,
- after maintenance and repair,
- after using the medical device in a patient, and
- before using the medical device in another patient.

These requirements do not apply to the reprocessing of medical devices for respiratory home therapy that:

- are to be used sterile. This particularly relates to such devices that in their use penetrate the skin or mucous membranes and thus are in contact with blood, internal tissues or organs, including wounds, and
- are to be used neither semi-sterile nor sterile.

4. Reprocessing - General

4.1. Pre-condition

Pre-conditions for the reprocessing are:

- The **suitability (product tolerance) of the reprocessing procedures used** has been verified. This means the functional and safety-relevant properties of the medical device can be guaranteed.
- For products which **are to be used semi-sterile** the **efficacy** of the standardised reprocessing procedures **has been verified** in product / product group-specific tests. The extent of such efficacy verifications must be adequate to the individual medical device and its area of use.

4.2. Provisions

When performing a risk analysis within the conformity evaluation procedure the manufacturer has to assess if a subsequent patient is at risk of infection when a medical device that is potentially contaminated with human pathogens is reused. During risk analysis to examine dangers of infection special focus is required on the possible contamination of aeriferous components due to the patient's reinhalation through the device, whether intended or by error. A possible result of the risk analysis is that the health of the next patient, users or third parties is compromiseed through the use of the contaminated medical device.

If such dangers of infection cannot be excluded, a standardised (and if possible validated) reprocessing procedure must be stated which guarantees the success of the measures in a comprehensible way. As medical devices for respiratory home therapy are usually processed manually, a validation is not possible. Standardised reprocessing procedures, whose efficacies have been verified through appropriate scientifically acknowledged methods and whose consistent efficacy has been ensured in practice through appropriate quality assurance measures, generally offer an adequate level of safety against dangers of infection for the next patient.

4.2.1 Risk evaluation and classification of the medical devices

When evaluating and choosing the reprocessing procedures the manufacturer has to consider the following criteria.

Reviewing the **amount and type** of **pathogens** to be expected with the medical device used and their **resistance** to the reprocessing procedures applied is decisive when considering the **efficacy limits of the planned procedures**.

The **risks** posed by processed medical devices are determined by the following factors:

a) undesired effects, which can result from

- the previous use,
- the previous reprocessing, and

- transportation and storage

and

b) the type of the subsequent use:

Risks can result from e.g.:

- **Residue from the previous use** (e.g. secretions and other bodily components, other drugs),
- **Residue from the previous reprocessing** (e.g. cleaning agents, disinfectants and other substances, including their reaction products),
- **Changes in physical, chemical or functional properties** of the medical product, or
- **Changes in the condition of the material** (e.g. accelerated wear and tear, embrittlement and changed surface conditions, changes in contact points and adhesive joints).

Regarding the **type of use** and the risk resulting thereof medical devices can be classified into uncritical, semi-critical and critical medical devices (see risk evaluation in the tables of the appendix):

- **Uncritical medical devices:**

  Medical devices that are in contact with intact skin only.

- **Semi-critical medical devices:**

  Medical devices that are in contact with mucous membranes or pathologically changed skin. **Construction or material-related details** of the product can make increased reprocessing requirements necessary. Therefore, this classification needs to be further specified into:

- **Semi-critical medical devices without special reprocessing requirements (group A)**
- **Semi-critical medical devices with increased reprocessing requirements (group B)**
- **Critical medical devices:**

  Medical devices for use of **sterile drugs**, and medical devices that penetrate the **skin or mucous membranes** and thus are in contact with blood, internal tissues or organs, including wounds. **Construction or material-related details** of the product can make increased reprocessing requirements necessary. Therefore, this classification needs to be further specified into:

- **Critical medical devices without special reprocessing requirements (group A)**
- **Critical medical devices with increased reprocessing requirements (group B)**
- **Critical medical devices with special reprocessing requirements (group C)**

  Note: In respiratory home therapy critical devices are generally not used.

4.2.2. Feasibility

The decision on the type of reprocessing must be preceded by **critical evaluation of proper feasibility**. Also, it must be examined if the entire process makes sense from an **economic**

and ecological point of view, **or if the medical product should be disposed**. Special consideration is required regarding the **risks** and **efforts necessary for efficacy verifications and quality assurance** involved in the reprocessing and use of the medical device (see appendix: table).

4.2.3 Efficacy verification and quality assurance in the reprocessing procedures used

Manual cleaning and disinfecting must at all times be carried out in accordance with **documented standard procedures**. All agents and procedures used must be tested with regard to their efficacy and suitability (i.e. their tolerance) for the respective medical device.

In **automated cleaning and disinfecting procedures** it can be procedurally ensured that the parameters essential for quantifiable cleaning and disinfecting are correct. Such parameters include water volume, water pressure, temperature, pH-value, dosage of cleaning agents and disinfectants, or residence time. Monitoring, control and warning systems of the machines are the basis of secured cleaning and disinfecting and thus reprocessing. Due to the high significance of cleaning and disinfecting only machines that have undergone successful type testing are recommendable. Please note that automated procedures vary in their cleaning performance.

To ensure consistent quality of the reprocessing procedures periodic tests must at least verify the efficacy and that no unintended changes have occurred.

4.3. Responsibility

The manufacturer's responsibilities in the reprocessing of medical devices are stipulated in cause 8 and 13 of the ESSENTIAL REQUIREMENTS**,** i.e**.** Annex 1 of the Medical Device Directive 93/42/EEC. The operator's responsibilities are usually stipulated in regional or national law, decree or regulations.

4.3.1 The manufacturer's responsibilities

According to the ESSENTIAL REQUIREMENTS of Annex 1 of the Medical Device Directive 93/42/EWG" the **manufacturer must state on the label of the device if the device is designed for single-use only**. With reusable devices the **product instructions must provide information on suitable reprocessing procedures** and possible numeric limitations on reuse of the product.

The product instructions are the operator's basis for proper use of the product. In the product instructions the manufacturer must provide the following information:

- **if** the device can be **reused**
- the **risk evaluation and correct classification** of the medical device (see 4.2.1)
- type and procedure of the reprocessing (**product-specific hygiene scheme**) i.e.:
- details on reprocessing including detailed specifications on (see section 5):
- cleaning/disinfection
- cleansing

- drying
- transportation
- storage
- notes for the operator responsible for the reprocessing on the necessity to define the responsibilities for the reprocessing procedure.

  Please also see the tables in the appendix for risk evaluation, classification and reprocessing recommendation for use of the devices in the different areas.

4.3.2 The operator's responsibilities

The responsibility for the reprocessing of medical devices always lies with the operator. This responsibility cannot be delegated. The operator may process medical devices only in accordance with the regional or national law, decree or requirements.

The operator can delegate to third parties only such tasks that result from this responsibility. But the operator may only authorise persons, businesses or institutions to carry out the reprocessing if they posses the adequate know-how and necessary agents and meet all requirements for proper reprocessing. In such a care it should be made carefully sure that the **responsibilities** for all reprocessing steps are defined and agreed in a contract:

- Under consideration of the manufacturer's instructions on reprocessing the following should be agreed on in writing:
  - if the medical devices, after being used with a patient, can be processed;
  - the reprocessing procedure that a contaminated medical device requires;
  - the conditions that a contaminated medical device is to be processed under (e.g. rooms, work material, qualification of the personnel).
- Used devices whose instructions come without the manufacturer's risk evaluation or information require an extra risk evaluation. This evaluation and the choice of reprocessing procedure are the responsibility of the operator or the service provider contracted by the operator under consideration of the provisions for medical devices as described under 4.2.

  Please also see the tables in the appendix for risk evaluation, classification and reprocessing recommendation for use of the devices in the different areas.
- The **practical execution** of the reprocessing is to be determined in all of its individual steps (see section 5). The **qualification** of the person authorised to carry out the reprocessing is to be considered.
- This also applies to the **reprocessing by third parties (service providers)** and is to be agreed in a contract.

5. Procedural Steps in the Reprocessing of Contaminated Medical Devices

5.1 Procedural steps in reprocessing - general

Generally, new medical devices (e.g. coming from production or the warehouse) can be used without prior reprocessing unless otherwise instructed by the manufacturer.

If contamination **cannot** be excluded, these medical devices are to be processed like used products in accordance with the manufacturer's specifications and number 5.3 of this document.

In any case, however, a wiping-disinfection is recommended for the parts that will get in direct contact with the patient (general hygienic reprocessing). Please also note the regional or national recommendations on surface disinfection e.g. of the Commission for Hospital Hygiene and Prevention of Infection at the Robert-Koch-Institute (RKI).

In **cleaning/disinfection, cleansing and drying** it must be differentiated between manual and automated procedures. Automated procedures are to be preferred as they offer better possibilities to validate the individual procedural steps and more work safety (also see 5.3.3).

During manual cleaning/disinfection the **work safety requirements** (e.g. protective clothing, protective goggles, appropriate gloves or room air quality) are to be met.

5.2 Transportation and storage

Transportation and storage must not have any negative impact on the properties of the processed medical device. Storage of the processed medical devices must be based on the specifications of the manufacturer of the medical device and the manufacturer of the packaging material.

Generally, processed medical devices are to be stored dust-protected, in packaging that guarantees mechanical protection and in a dry (e.g. by keeping an adequate distance to floors and walls), dark and cool place.

With regard to transportation it shall be ensured that contamination of a processed or new medical device is excluded until it is used by **strictly separating clean from unclean devices** (e.g. in the vehicle, warehouse, workshop). Separating unclean devices may be achieved by suitable packaging (e.g. by a sealed plastic bag which is suitable to withstand the rough handling during the transport)

Contaminated medical devices and parts of such devices including accessories are to be handled with single-use gloves. (consideration should be given to material the gloves are made of with regard to allergies caused by this material). This applies to the handing over of the devices (e.g. at the patient's place), the preparation for their transportation (e.g. by packing them into a sufficiently large and sealable plastic bag) and to their shipment.

They are to be handled in the same manner when they are treated for inspection, maintenance or restoration (repair) at the patient's home, at the hospital or in the service workshop.

These medical devices and their accessories are then to be taken into the individual reprocessing steps or immediately disposed accordingly.

5.3 Reprocessing

The **reprocessing** generally **comprises** the following steps:

a) appropriate **preparation (see 5.3.1) (pre-treatment, collection, pre-cleaning)** and, if applicable, disassembling of the used medical products and, protectively packaged, their timely and safe **transportation** to the place of reprocessing.

b) **cleaning (see 5.3.2) / disinfection (see 5.3.3), cleansing and drying (see 5.3.4),**

c) **examining their cleanliness** and **surface integrity** (e.g. corrosion, condition of the material), if applicable repeating step b) and identification, e.g. for the purpose of deciding on another reprocessing if there is a numeric limitation,

d) **service and maintenance (e.g. removing weak spots) and restoration / repair,**

e) **functional testing (see 5.3.5)** and, according to requirements,

f) **labelling (see 5.3.7)**, and

g) **packaging and transportation (see 5.3.6 and 5.2)**.

The reprocessing ends with the documented **clearance (see 5.3.8)** of the medical device for use.

The chain of measures to be taken must be optimised, as any weakness in the required steps can compromise the overall success.

Therefore, all individual steps of the reprocessing must be aligned with

- the medical device,
- the previous reprocessing, and
- the previous and subsequent use of the medical device.

They also have to **ensure the success in a comprehensible (see 5.3.9 Documentation) and reproducible way** by the use of at least standardised, if possible validated, procedures. For medical devices which are to be used semi-sterile the efficacy of these reprocessing procedures, with regard to the medical device and its area of use, is to be verified adequately.

For every single step **the instructions of the manufacturers of the cleaning agents, the disinfectants and the medical devices** are to be considered. This applies to the **organisation of the work processes**.

After its reprocessing the medical device must entirely fulfil its function in accordance with its **purpose**, and it must meet all **safety-relevant requirements** without restriction of any kind. The entire reprocessing procedure and the processed medical device must never compromise the safety of the patient, the user or a third party. This also means that any contamination of the environment during the reprocessing must be avoided and, if necessary, a disinfection must be carried out.

The reprocessing must ensure that no danger of health damage is posed by the processed medical product through the subsequent use thereof, with special regard to

- infections,
- pyrog
- enically caused reactions,
- allergic reactions,
- toxic reactions, or
- results from changed technical functional properties of the medical device.

Reprocessing and at all times meeting its requirements make a quality management system essential. The reprocessing must be carried out in accordance with acknowledged rules of technology (e.g. standards or regulations on work safety and accident prevention) under consideration of state-of-the–art science and technology.

5.3.1 Preparation of the Reprocessing

To ensure proper reprocessing several medical devices require **preparation**. This includes:

- Collection (e.g. for concurrent treatment of multiple devices),
- Pre-treatment (e.g. soaking),
- Pre-treatment (e.g. soaking), and if applicable
- Disassembling

To ensure that the hygienic safety and the functionality of the processed medical devices do not suffer any impairment, it is essential that, especially in cases when delays in cleaning/disinfection make **pre-cleaning** and perhaps **interim storage** necessary, the following requirements are met:

- Damage to the medical device caused during the transportation, pre-cleaning or possibly necessary interim storage must be considered.
- The agents and procedures used for pre-cleaning must be aligned with the subsequent reprocessing procedures.
- In all steps of the preparation work safety requirements must be met.

5.3.2 Cleaning

Outer and inner surfaces (as far as required according to instructions) must be **accessible** for the used cleaning agents and disinfectants. Complex **medical devices** must be disassembled if necessary.

An **effective and residue-free cleaning procedure** must be applied.

During all cleaning processes it must be ensured that there will be **no fixation** of residue (e.g. secretion) in the medical device.

The **agents and procedures** must meet the required **cleaning performance** and must not result in adverse changes of the material.

Under certain conditions, the use of **ultra-sound** can enhance the cleaning performance.

Organic material and chemical residue contaminate the cleaning solution. To **avoid microbial reproduction** of lasting **cross-contamination** and impairment in the cleaning performance the cleaning solution is to be freshly prepared at least on every work-day and each time it visibly shows contamination. The cleaning basin should be thoroughly cleaned and disinfected on every workday.

5.3.3 Disinfection

The used disinfection procedures must be demonstrably **bactericidal, fungicidal and virucidal** for devices which are to be used semi-sterile (Scope AB in accordance with the terminology of the list of tested disinfectants and disinfection procedures of the Robert-Koch-Institute). The cleaned and disinfected medical device must not pose any danger of infection through reproductive human pathogens when it comes in contact with the skin or mucous membranes. For uncritical products please note the recommendations on surface disinfection of regional or national competent groups, e.g. of the Commission for Hospital Hygiene and Prevention of Infection at the Robert-Koch-Institute (RKI). For less complex surfaces of the product to be disinfected and to be used sterile or semi-sterile the information regarding the present efficacy verifications of the manufacturer of the disinfectant may be sufficient.

For their more reliable efficacy (e.g. lower impairment through residual contamination) **thermal procedures** in cleaning and disinfecting devices are to be preferred to chemical and chemo-thermal disinfection procedures. Disinfectants listed by regional or national authorities, e.g. by of the German Society for Hygiene and Microbiology (DGHM), are are mostly designed for manual disinfection of medical devices but not for automated disinfection. Therefore the manufacturer has to verify the efficacy in cleaning and disinfecting devices through expert opinion under the conditions of automated reprocessing.

Effective disinfection requires that the instructions for the disinfectant, especially with regard to **concentration and residence** time, are followed.

5.3.4 Cleansing and drying

Cleansing and disinfecting solutions must be removed **through intense rinsing with appropriate water** (at least drinking water quality) to avoid biological reactions and impairment in the material.

During rinsing and drying recontamination of the processed medical device must be excluded.

5.3.5 Functional testing

Subsequent to the above reprocessing steps **a safety and functional test of the medical product** (in accordance with the manufacturer’s specification in the instructions) must be

carried out. If necessary, safety-relevant functional testing must be carried out directly before use of the product.

Extent and type of the tests depend on the medical device and are to be defined in the instructions.

5.3.6 Packaging

Generally, the packaging consists of a **protective packaging** (against contamination) and, where necessary, an **outer packaging** (for storage and transportation). Its purpose is to prevent the medical device from being contaminated with reproductive human pathogens from the time after its reprocessing to its use.

5.3.7 Labelling

The medical device or its packaging must carry the **following label with regard to its reprocessing**:

- **Clearance status (cleared or not cleared)**
- **Processor's name and address**

The following labelling may be required:

- the applied **reprocessing procedure**,
- details on time-dependent aspects of the danger-free use of the medical device, e.g. **expiry date** where applicable (the date until which a danger-free use of the product is demonstrably possible)
- Notes on the technical functional **test and safety** before use.

If the manufacturer has specified a maximum number of possible reprocessings for a **medical device**, the **number and type of reprocessings performed** must be provided.

5.3.8 Clearance for use

The reprocessing of medical devices ends with the clearance for use.

5.3.9 Documentation and labelling

Within the scope of reprocessing the following have to be documented and stated on the product labels:

- the decision for clearance
- the clearing person.

The information must verify that the used **reprocessing procedure has been carried out in accordance with the standard work instructions and in compliance with the criteria and parameters specified therein**.

References

1) COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices THE COUNCIL OF THE EUROPEAN COMMUNITIES, including Amendments: 398L0079 (OJ L 331 07.12.1998 p.1) and 300L0070 (OJ L 313 13.12.2000 p.22

2) Recommendation by the Commission for Hospital Hygiene and Prevention of Infection at the Robert-Koch-Institute (RKI) - and the German Federal Institution for Medicinal Products and Medical Devices (BfArM) on the “Hygiene Requirements for the Reprocessing of Medical Devices” 8.2001 Bundesgesundheitsbl. (German Federal Health Register) 11/01 pp. 1115 - 1126

3) Hygiene requirements for the cleaning and disinfecting of surfaces - Recommendation by the Commission for Hospital Hygiene and Prevention of Infection at the Robert-Koch-Institute (currently being revised, expected publication in the 4th quarter of 2003)

4) DIN EN 1441 Medical devices – Risk analysis

5) DIN EN ISO 14971 Medical devices – Application of risk management to medical devices

6) EN ISO 17664 Sterilization of medical devices – information to be provided by the manufacturer for the reprocessing of resterilisable devices

Notes on the Following Tables

The following tables contain the specified medical product and the accessories that are commonly used with this product on the patient.

The recommendations on the reprocessing of medical devices and their accessories are divided up into common areas of use and the situations:

In-patient and out-patient area without change of the patient: Temporary use of the medical products in the in-patient area, e.g. within the scope of setting, customisation, proving, training within initial care and out-patient check-ups without a change of the patient.

Medical care at home without a change of the patient: Use of the medical devices at the patient's home or in institutions that are to be considered a home environment for the patient, e.g. in old people's homes and nursing centres without a change of the patient.

Use after service without a change of the patient: Use of the device after inspection, maintenance or restoration, regardless whether this service has been rendered at the patient's place, at the place of use, in a service provider's workshop or on the manufacturer's site, however, under the provision that there is no change of the patient.

With a change of the patient, independent of the area of use: These recommendations apply to any case that the patient changes, regardless where the medical device was used or whether a service was rendered in this connection. In this situation the highest hygiene requirements for the reprocessing are necessary, as contamination with human pathogens can be expected and the patient must be protected.

Also, the Department of Respiratory Home Therapy supplies empiric values that have been collected in the use of these products over the last few years. These tables also contain details on the recommended reprocessing frequencies and the expected average life of these medical devices. These specifications apply to the regular use of the medical devices in an in-patient/out-patient area and in medical care at home.

Reprocessing frequency: The specified reprocessing frequencies are considered sufficient for average use and contamination, e.g. with body secretion. As a consequence, this value should be considered a guide value, which, however, could deviate considerably under the special conditions of individual cases. If the manufacturer has provided details regarding the reprocessing frequency for the medical device and the accessories needed for its use, they are to be considered.

Useful life of a device: The values specified for the useful life of a device are based on the number of reprocessing cycles with regard to the hygienic innocuousness of the medical device resulting from the reprocessing frequency. The life of a device is strongly dependent on the surrounding conditions and the conditions of use in the individual cases. The values provided are therefore merely empiric average values, which are generally reached under normal conditions of operation and use. If the manufacturer has specified details regarding the life of the medical device and the accessories needed for its use, they are to be considered. The detail "spu" means that this accessory is not fit for reuse with another patient. This component should be disposed, as the reprocessing does not make any sense from an economic and ecological point of view regarding the risks and efforts necessary for

efficacy verifications and quality assurance involved in the reprocessing and use of the medical device.

The Department of Respiratory Home Therapy has carried out a risk evaluation for the listed medical devices and their accessories under consideration of their proper use and the normal conditions of use and environmental conditions. The results of this evaluation have been entered into the tables.

Risk evaluation: The risk evaluation and classification of the medical devices and their accessories has been carried out in accordance with the criteria specified in section 4.2.1 of these recommendations. With regard to the type of use and the resulting risk the medical devices and their accessories have been classified as: uncritical medical devices (--) and semi-critical medical devices without any special requirements (A).

Note: The classifications semi-critical medical devices with special requirements and critical medical devices, as mentioned under section 4.2.1 of these recommendations have not been determined.

Appendix: Tables

Oxygen concentrator — Risk evaluation and recommendations on reprocessing in areas

X = necessary
(x) = optional

Medical device including accessories	Risk evaluation	In-patient and out-patient area without change of patient				Medical care at home without change of patient				Use after service without change of patient				With change of patient independent of area of use and/or service				Recommended reprocessing frequency	Average useful life	Critical procedural steps, special requirements
		Disposal	Cleaning	Disinfection	Sterilisation	Disposal	Cleaning	Disinfection	Sterilisation	Disposal	Cleaning	Disinfection	Sterilisation	Disposal	Cleaning	Disinfection	Sterilisation			
Oxygen concentrator	–		X	X			X	(X)			X	X			X	X				
Accessories:																				
Respiratory gas humidifier	–		X	X	(X)		X	X			X	X		X				daily	spu	
Respiratory gas humidifier – non-reusable	–	X				X				X				X				daily	spu	
Rack for humidifier	–		X	X			X	(X)			X	X			X	X		weekly	---	
Extension tube	–	X				X				X				X				---	1 mth.	
Tube connector	–	X				X				X				X				---	1 mth.	
Water trap	–	X				X				X				X				---	1 mth.	
Nasal cannula	A	X					X	(X)		X				X				daily	1 mth.	
Mask	A	X					X	(X)		X				X				daily	1 mth.	
Mask with oxygen reservoir	A		X	X			X	X		X				X				daily	1 mth.	
Air filter	–		X				X			X				X				weekly	12 mths.	

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Sleep apnea therapy device Risk evaluation and recommendations on reprocessing in areas

Medical device including accessories	Risk evaluation	In-patient and out-patient area without change of patient				Medical care at home without change of patient				Use after service without change of patient				With change of patient independent of area of use and/or service				Recommended reprocessing frequency	Average useful life	X = necessary (x) = optional Critical procedural steps, special requirements
		Disposal	Cleaning	Disinfection	Sterilisation	Disposal	Cleaning	Disinfection	Sterilisation	Disposal	Cleaning	Disinfection	Sterilisation	Disposal	Cleaning	Disinfection	Sterilisation			
nCPAP / BiLevel sleep apnea device	–		X[1]	(X)			X[1]	(X)			X[1]	X[1]			X[2]	X[2]				1 = outside 2 = outside and all respiratory gas conducting components
Accessories:	–																			
Tubing system, reusable	–		X	X	(X)		X	(X)			X	X		X				monthly	12 mths.	
Tubing system, non-reusable	–	X				X				X				X				---	7 days	
Pressure measuring tube, reusable	–		X	X	(X)		X	(X)			X	X		X				monthly	6 mths.	
Air inlet filter	–		X				X			X				X				weekly	6 mths.	
Air inlet filter for small particles	–	X				X				X				X				---	1 mth.	
Nasal mask	A		X	(X)			X	(X)			X	X		X				daily	12 mths.	
Mouth / nasal mask	A		X	(X)			X	(X)			X	X		X				daily	12 mths.	
Exhalation system	–		X	(X)			X	(X)			X	X		X				daily	12 mths.	
Head gear or head strap	–		X				X			X				X				weekly	12 mths.	
Respiratory gas humidifier, reusable*	–		X	X			X	(X)			X	X			X	X	(X)	daily	spu	* respiratory gas conducting components only
Particle filter	–	X				X				X				X				---	1 day	
Device bag	–		X	(X)			X				X	(X)		X				---	spu	

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Aerosol inhaler — Risk evaluation and recommendations on reprocessing in areas

Medical device including accessories	Risk evaluation	In-patient and out-patient area without change of patient				Medical care at home without change of patient				Use after service without change of patient				With change of patient independent of area of use and/or service				Recommended reprocessing frequency	Average useful life	X = necessary (x) = optional Critical procedural steps, special requirements
		Disposal	Cleaning	Disinfection	Sterilisation	Disposal	Cleaning	Disinfection	Sterilisation	Disposal	Cleaning	Disinfection	Sterilisation	Disposal	Cleaning	Disinfection	Sterilisation			
Aerosol inhaler for lower respiratory tract	–		X	(X)			X	(X)			X	X			X	X				
Aerosol inhaler for upper respiratory tract	–		X	(X)			X	(X)			X	X			X	X				
Accessories:																				
Tubing system, reusable	–		X	X			X	(X)			X	X		X				daily*	6 moths.	* after each use
Tubing system, non reusable	–	X				X				X				X				---	7 days	
Nebuliser chamber, reusable	–		X	X			X	X			X	X		X				daily*	6 moths.	* after each use
Nebuliser chamber, non reusable	–	X				X				X				X				---	7 days	
Mouth piece, reusable	A		X	X			X	(X)			X	X		X				daily*	6 moths.	* after each use
Mouth piece, non reusable	A	X				X				X				X				---	7 days	
Ultrasonic unit	–		X	X			X	(X)			X	X		X				daily*	spu.	* after each use
Device bag	–		X	(X)			X				X	(X)		X				---	spu	

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Home care ventilator — Risk evaluation and recommendations on reprocessing in areas

Medical device including accessories	Risk evaluation	In-patient and out-patient area without change of patient				Medical care at home without change of patient				Use after service without change of patient				With change of patient independent of area of use and/or service				Recommended reprocessing frequency	Average useful life	Critical procedural steps, special requirements
		Disposal	Cleaning	Disinfection	Sterilisation	Disposal	Cleaning	Disinfection	Sterilisation	Disposal	Cleaning	Disinfection	Sterilisation	Disposal	Cleaning	Disinfection	Sterilisation			
Ventilator for dependent patients	–		X[1]	X[1]			X[1]	(X)			X[1]	X[1]			X[2]	X[2]				1 = outside 2 = outside and all respiratory gas conducting components
Ventilatory support device	–		X[1]	X[1]			X[1]	(X)			X[1]	X[1]			X[2]	X[2]				
Intermittent ventilatory support device	–		X[1]	X[1]			X[1]	(X)			X[1]	X[1]			X[2]	X[2]				
Accessories:																				
Tubing system, reusable	–		X	X	(X)		X	(X)			X	X		X				daily	12 mths.	
Tubing system, non-reusable	–	X				X				X				X				----	1 mth.	
Water trap, reusable	–		X	X	(X)		X	(X)			X	X		X				daily	12 mths.	
Water trap, non-reusable	–	X				X				X				X				----	7 days	
Particle filter	–	X				X				X				X				---	1 day	
Heat and moisture exchanger	–	X				X				X				X				---	1 day	
Gooseneck extension tube, reusable	A		X	X	(X)		X	(X)			X	X		X				daily	3 mths.	
Gooseneck extension tube, non-reusable	A	X				X				X				X				---	2 days	
Air inlet filter	–		X				X			X				X				weekly	6 mths	
Respiratory gas humidifier, reusable	–		X	X	(X)		X	(X)			X	X		X				daily	spu	* respiratory gas conducting components only
Respiratory gas humidifier, non-reusable	–	X				X				X				X					7 days	
Device bag	–		X	(X)			X				X	(X)		X				---	spu	

X = necessary
(x) = optional

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Baby monitors — Risk evaluation and recommendations on reprocessing in areas

Medical device including accessories	Risk evaluation	In-patient and out-patient area without change of patient				Medical care at home without change of patient				Use after service without change of patient				With change of patient independent of area of use and/or service				Recommended reprocessing frequency	Average useful life	X = necessary (x) = optional Critical procedural steps, special requirements
		Disposal	Cleaning	Disinfection	Sterilisation	Disposal	Cleaning	Disinfection	Sterilisation	Disposal	Cleaning	Disinfection	Sterilisation	Disposal	Cleaning	Disinfection	Sterilisation			
Baby monitor	–		X	X			X	(X)			X	X			X	X				
Accessories:																				
Breathing sensors, reusable	A		X	X			X	X			X	X		X				daily	12 mths.	
Breathing sensors, non- reusable	A	X				X				X				X				---	7 days	
ECG electrodes, reusable	A		X	X	(X)		X	X			X	X	(X)	X				daily	6 mths.	
ECG electrodes, non- reusable	A	X				X				X				X				---	2 days	
Pulse oximeter sensor, reusable	A		X	X			X	X			X	X			X	X		daily	12 mths.	
Pulse oximeter sensor, non- reusable	A	X				X				X				X				---	2 days	
Connection cable for breathing sensor	–		X	X			X	(X)			X	X		X				daily	spu	
Connection cable for ECG electrodes	–		X	X			X	(X)			X	X		X				daily	spu	
Connection cable for pulse oximeter	–		X	X			X	(X)			X	X		X				daily	spu	
Device bag	–		X	(X)			X				X	(X)		X				---	spu	

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Oxygen systems — Risk evaluation and recommendations on reprocessing in areas

X = necessary
(x) = optional

Medical device including accessories	Risk evaluation	In-patient and out-patient area without change of patient				Medical care at home without change of patient				Use after service without change of patient				With change of patient independent of area of use and/or service						Critical procedural steps, special requirements
		Disposal	Cleaning	Disinfection	Sterilisation	Disposal	Cleaning	Disinfection	Sterilisation	Disposal	Cleaning	Disinfection	Sterilisation	Disposal	Cleaning	Disinfection	Sterilisation	Recommended reprocessing frequency	Average useful life	
Liquid oxygen system, base unit	–		X	X			X	(X)			X	X			X	X				
Liquid oxygen system, mobile unit	–		X	X			X	(X)			X	X			X	X				
Pressure regulator for gas cylinders	–		X	X			X	(X)			X	X			X	X				
Oxygen saving system	–		X	X			X	(X)			X	X			X	X				
Accessories:																				
Nasal cannula	A	X					X	(X)		X				X				daily	1 mth.	
Extension tube	–	X				X				X				X				---	1 mth.	
Tube connector	–	X				X				X				X				---	1 mth.	
Water trap	–	X				X				X				X				---	1 mth.	
Respiratory gas humidifier, reusable	–		X	X			X	(X)			X	X		X				daily	spu	
Respiratory gas humidifier, non-reusable	–	X				X				X				X				---	spu	
Device bag	–		X	(X)			X				X	(X)		X				---	spu	

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