In accordance with the Medical Devices Act (§14 para. 2 MPG) medical devices may not be operated or used if they show defects which could endanger patients, employees or third parties. As a result, medical devices inter alia which pose an infection risk (e.g. by pathogens) may not be operated nor used. For medical devices which have already been used on a patient, contamination with multipliable human pathogenic bacteria must always be assumed and the next patient, user or third party must be protected from infections, pyrogen-induced, allergic or toxic reactions and altered technical-functional characteristics of the medical device by relevant handling and conditioning. This applies particularly in the following instances:

- when used on a patient continuously;
- before maintenance and repair procedures;
- after maintenance and repair procedures;
- when a patient has finished using the medical device; and
- before the medical device is used on another patient

As a rule, new medical devices can be used without conditioning insofar as the manufacturer does not stipulate otherwise. Where contamination cannot be precluded, these medical devices must also be conditioned before use, taking into consideration the manufacturer's information for used medical devices. A separate risk assessment must be conducted for old devices in the absence of a manufacturer's risk assessment and information in the instructions for use.

In accordance with the Medical Devices Operator Ordinance (§4 MPBetreibV) the operator is responsible for the conditioning of medical devices. This responsibility cannot be delegated. Only tasks which arise from this responsibility can be delegated. Those who condition medical devices for others (§3 para.14 MPG), must comply with the disclosure obligation (§25 MPG). The operator may only commission those persons, companies or establishments with the conditioning of medical devices which possess the expertise, pre-requisites and necessary means for the proper execution of this task (§4 MPBetreibV para. 1 and 3).
The conditioning and constant fulfilment of the requirements presupposes a quality management system. Conditioning must occur in accordance with the recognized codes of practice (e.g. standards, industrial safety and accident prevention regulations) and take into consideration the generally recognized state of scientific and technological knowledge.

"Appropriately low-germ or sterile medical devices must be conditioned in compliance with the manufacturer's information with suitable procedures in such a way that success is comprehensibly guaranteed and the safety and health of patients, users and third parties is not endangered. Proper reconditioning is assumed if the joint recommendation of the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute and the Federal Institute for Pharmaceuticals and Medical Devices is complied with."
(§4 para. 2 MPBetreibV).

Before the conditioning decision is made, it must also be verified beyond a critical evaluation of objective feasibility that this is sensible from an economic and ecological perspective, taking into consideration the risk associated with the conditioning and use of the medical device and the expense and quality assurance, or whether it would be better to dispose of the medical device.

Conditioning generally comprises the following individual steps:

- the proper preparation (pre-treatment, collection, pre-cleaning) and, if necessary, the dismantling of the medical devices used and their rapid, securely packaged and safe transportation to the conditioning site;
- cleaning / disinfection, rinsing and drying;
- testing for cleanliness and integrity of the surfaces (e.g. corrosion, material properties) and the identification, e.g. for the purposes of decision on a new conditioning in the case of its restriction in numbers;
- maintenance (e.g. eradication of critical points) and repair;
- test of function and, if required;
- labelling; and
- packaging and transportation.

Manual cleaning and disinfection procedures must always be conducted in accordance with documented work instructions and with means and processes checked for effectiveness and tailored to the medical device. For mechanical cleaning and disinfection procedures it can be procedurally ensured that the parameters necessary to attain quantifiable cleaning and disinfection performance are complied with. In order to guarantee the continuous quality of manual and/or mechanical conditioning procedures it must be proven by at least periodical checks that the procedure is still effective and no unintentional changes have arisen.

Conditioning ends with the documented approval for use of the medical device. The chain of actions must be optimized as weaknesses in one of the necessary individual steps threaten the overall success. Transport and storage must not have a negative impact on the characteristics of the conditioned medical device. During transportation, it must be ensured that contamination of a conditioned or new medical device is precluded until its use by means of strict separation of clean/unclean devices.

All employees coming into contact with contaminated products must regularly consult a company doctor. Work clothing and personal protective equipment must be available in necessary quantities and be in proper condition. Reliable hand and surface disinfection must be ensured.

All detergents and disinfectants used must be effective, compatible with one another and be gentle on the materials used. Detergents used in the ultrasound bath must not foam. Relevant cleaning and disinfection baths must be regularly replaced at defined intervals in order to guarantee their effectiveness. Disinfectants used must conform to the disinfectant list of the Network for Applied Hygiene e. V. (http://vah.data-room.de) and the German Association for the Combat of Viral Illnesses e. V. (www.dvv-ev.de) with regard to their application time and concentration. Detergents and disinfectants must be selected in accordance with the equipment and facilities available in each instance in order to guarantee a reliable cleaning result.

Exchanged products and product components must be disposed of in accordance with their respective material composition.

Product	Preparation at the place of use	Preparation before cleaning	Cleaning	Disinfection
Bath lifts	Thorough pre-cleaning of the product with hot tap water. Pre-cleaning storage time must be as short as possible. Products to be cleaned must be protectively packed, e.g. sealed with adhesive tape in such a way that no more openings are visible on the packaging. Pathogens with which the product has been infected (even potentially) must be noted and visibly specified on the outer packaging.	Dismantling of the product into individual components and creation of an optimum item for cleaning and disinfection. Cover electrical connections with protective caps and seal any sites where water may leak in. Removal of superficial contamination.	**Decalcifying cleaning** of seat parts and backrests with sanitizing detergent. Manual brushing is permitted. **Rinse** with tap water until the detergent is completely removed. **De-oiling cleaning** of severely soiled seat parts and backrests with alkaline detergent. Also permitted with ultrasound treatment or manual brushing. **Rinse** with tap water until the detergent is completely removed. **Mechanical cleaning** of seat parts and backrests in industrial washing machine. Also permitted with hot water high pressure cleaner. **Rinse** with tap water until the detergent is completely removed. **Manually clean** drive trains, manual controls, loading devices, batteries, covers, electronic casing and other electrical components with universal cleaner. Supplementary manual brushing is also permitted. **Rinse** with tap water until the detergent is completely removed. **Ambient air drying** until there is no more superficial moisture on the product. *Replacement of cover and suction cups and other small components (suction caps, retaining brackets,*	**Disinfection by wiping** of seats, back rests (front side) and manual control units with disinfectant. **Ambient air drying** until there is no more superficial moisture on the product.

			sealing rubber, hose clips). *No further use of products in the case of water penetration or if these show discolorations which cannot be removed.* *For H605 RIO, cleaning and disinfection not permitted with very aggressive media (pH value less than 4.5 or greater than 8.5).*	
Shower chairs **Shower stools** **Shower wheelchairs**	Thorough pre-cleaning of the product with hot tap water. Storage time until cleaning must be as short as possible. Removal of components which do not belong to the product as standard (e.g. seat pads, add-ons, etc.). Products to be cleaned must be protectively packed, e.g. sealed with adhesive tape in such a way that no more openings are visible on the packaging. Pathogens with which the product has been infected (even potentially) must be noted and visibly specified on the outer packaging.	Dismantling of the product into individual components and creation of an optimum item for cleaning and disinfection. If present, cover electrical connections with protective caps and seal any sites where water may leak in. Removal of superficial contamination.	**Decalcifying cleaning** with sanitizing detergent. Manual brushing is permitted. **Rinse** with tap water until the detergent is completely removed. **Mechanical cleaning** of washable components (e.g. covers) in industrial washing machine. **Rinse** with tap water until the detergent is completely removed. **Manual cleaning** with universal detergent. Supplementary manual brushing is also permitted. **Rinse** with tap water until the detergent is completely removed. **Ambient air drying** until there is no more superficial moisture on the product. *No further use of products in the case of water penetration or if these show discolorations which cannot be removed.*	**Disinfection by wiping** generally accessible surfaces with disinfectant. Ambient air drying until there is no more superficial moisture on the product.
Commode chairs **Commode wheelchairs**	Thorough pre-cleaning of the product with hot tap water.	Dismantling of the product into individual components and creation	**Mechanical cleaning** of washable components (e.g. covers) in indus-	**Disinfection by wiping** generally accessible surfaces with disinfec-

	Pre-cleaning storage time must be as short as possible. Removal of components which do not belong to the product as standard (e.g. seat pads, add-ons, etc.). Products to be cleaned must be protectively packed, e.g. sealed with adhesive tape in such a way that no more openings are visible on the packaging. Pathogens with which the product has been infected (even potentially) must be noted and visibly specified on the outer packaging.	of an optimum item for cleaning and disinfection. If present, cover electrical connections with protective caps and seal any sites where water may leak in. Removal of superficial contamination.	trial washing machine. **Manual cleaning** with universal detergent. Supplementary manual brushing is also permitted. **Rinse** with tap water until the detergent is completely removed. **Ambient air drying** until there is no more superficial moisture on the product. *No further use of products in the case of water penetration or if these show discolorations which cannot be removed.*	tant. **Ambient air drying** until there is no more superficial moisture on the product.