breas vivo 40 clinical manual

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Book Descriptions:

breas vivo 40 clinical manual

Breas Medical AB reserves the right to make changes to this product without any prior notification. The Vivo 40 is intended for use in clinical settings e.g., hospitals, sleep labora tories, subacute care institutions and home environments. The Vivo 40 must always be prescribed by a licensed physician. Reference Reference to other manuals with additional information on a specific topic. Introduction Vivo 40 clinician's manual Doc. 003886 EnUs A1e. Attach the rear lid and place the swivel in a down position when placing the Vivo 40 in the bag. Safety Information Vivo 40 clinician's manual Doc. 003886 EnUs A1e. The low leakage alarm is not a substitute for operator vigilance in ensuring that the leakage ports remains clear at all times. Class II electrical equipment; double insulation Body floating IEC 606011 Type BF, Isolated Applied Part Read the clinician's manual thoroughly before. The home mode hides treatment settings, alarm limits and other selected information. The clinical mode is used by the clinician to control all mode choices, settings and limits. If the number of spontaneous patient breaths per minute is less than this number, Vivo 40 will uphold this rate. Functions and Parameters of the Vivo 40 Vivo 40 clinician's manual Doc. 003886 EnUs A1e. This is done by the pressure, rate, inspiration time, and rise time settings. Inspiration is started either when the ventilator initiates a breath, or when the patient triggers a breath if the trigger function is activated. Pressure IPAP EPAP seconds Insp.The delivered volume is calculated and compared to the set target volume on a breath by breath basis. Operating mode is defined as the state of the Vivo 40 when the fan is operating and producing an air flow. Check that a short sound signal is heard. If there is no signal, do not use the Vivo 40 and contact your service provider. Ensure that the settings are adjusted as prescribed. Press for 4 sec onds when using an external or inter nal battery.http://pumbacamp.co.za/userfiles/craftsman-wire-welder-manual.xml

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Read chapter "The Vivo 40's Front Panel" on page 24 for exact position of the buttons. The navigation buttons are used to view the different sections defined above each navigation button. Device Settings Navigate to the section "Others" and select "Device Settings" to reach the "Device Settings" page. 40 Using the Vivo 40 Vivo 40 clinician's manual Doc. 003886 EnUs A1e. Use the down arrow to navigate to the "Device Mode" setting. Using the Vivo 40 Vivo 40 clinician's manual Doc. 003886 EnUs A1e. It cannot be switched back to clinical mode by using the menu.Using the Vivo 40 Vivo 40 clinician's manual Doc. 003886 EnUs A1e. Instructions on how to manage data in the Breas Vivo PC Software can be found in the software help.The memory card is used for copying and transferring settings, detail logs, usage logs and breath logs. Insert the memory card in the memory card slot on the side of the Vivo 40. A common PC, which does not comply with IEC 606011, must comply with IEC 60950 and be placed outside the patient area i.e. Make sure it is fitted correctly. Connect the other end of the VivoiCom data cable to the iCom. Connect the iComPC data cable between the iCom and a PC. Do only use either the Dsub cable or the USB cable. The HA 01 humidifier can only be activated if the Vivo 40 is operating. When running on battery, the bat. Preparing the Vivo 40 for Use Vivo 40 clinician's manual Doc. 003886 EnUs A1e. Intentional Leakage 56 Preparing the Vivo 40 for Use Vivo 40 clinician's manual Doc. 003886 EnUs A1e. The configuration of the Vivo 40 therapy settings must always be pre scribed by a licensed physician and carried out by an authorized health care professional. Setting Up the Vivo 40 Vivo 40 clinician's manual Doc. 003886 EnUs A1e. Adjust the settings so that the flashing ceases. For more information

about how to use the menu, please read the chapter “Using the Menu”. Navigate to the section “Setup” and press “Setup” one more time to reach the “More Settings” page.http://dulcimarecords.com/images/uploads/craftsman-wood-shaper-manual.xml

62 Setting Up the Vivo 40 Vivo 40 clinician’s manual Doc. 003886 EnUs A1e. Setting Up the Vivo 40 Vivo 40 clinician’s manual Doc. 003886 EnUs A1e. In home mode the ramp can be activated by pressing the ramp soft key for more than 1 second. 64 Setting Up the Vivo 40 Vivo 40 clinician’s manual Doc. 003886 EnUs A1e. In home mode the HA 01 humidifier can be activated by pressing the humidity soft key for more than 1 second. Setting Up the Vivo 40 Vivo 40 clinician’s manual Doc. 003886 EnUs A1e. If an alarm condition cannot be corrected, discontinue use and refer the Vivo 40 for service. Alarms Vivo 40 clinician’s manual Doc. 003886 EnUs A1e. The Alarm History is maintained when the Vivo 40 is powered down. The last set alarm settings are retrieved after power has been off. Indication The alarm is given audibly with a tone and visibly by the red alarm LED and a display message. The Vivo 40 will then continue to give breaths with same settings. Indication The alarm is given audibly and visibly by the red alarm LED and a display message. Indication The alarm is given audibly with a tone and visibly by the red alarm LED and a display message. Indication The alarm is given audibly with a tone and visibly by the yellow alarm LED and a display message. Indication The alarm is given audibly with a tone and visibly by the yellow alarm LED and a display message. Setting Self adjusting Ventilator action The Vivo 40 tries to continue delivering breaths according to settings. Indication The alarm is given audibly with a tone and visibly by the yellow alarm LED and a display message. Setting Self adjusting Ventilator action The Vivo 40 tries to continue delivering breaths according to settings. Indication The alarm is given audibly with a tone and visibly by the red alarm LED and a display message. If the low bat tery alarm persists, the internal battery needs to be charged. Indication The alarm is given audibly with a tone and visibly by the red alarm LED and a display message.

Ventilator action The Vivo 40 will continue or stop the treatment depending on the type and priority of the alarm. Indication The alarm is given audibly with a tone and visible by a display message at least for 120 seconds. Chapter “Alarms” on page 66 has a detailed description of the alarm functions used for the Vivo 40. Enter operating mode by starting the treatment. Create pressure towards the Vivo 40 by blowing air into the mask or patient tube. The high pressure alarm shall be activated after 3 consecutive high pressure breaths. Treatment continues and the Vivo 40 runs on internal battery with the internal battery LED lit. Reconnect the power cord to the AC power supply. All replaced parts must be dis posed of in accordance with local environmental regulations regarding the disposal of used equipment and waste. Always replace the patient circuit with a new one when the Vivo 40 is to be used by a new patient. 84 Cleaning the Vivo 40 and Replacement of Accessories Vivo 40 clinician’s manual. Rinse thoroughly. Dry the filter by squeezing it out in a towel. Do not wring the filter. Cleaning the Vivo 40 and Replacement of Accessories Vivo 40 clinician’s manual Doc. 003886 EnUs A1e. If you do so, the manufacturer will no longer be responsible for the performance and safety of the Vivo 40. EVIATION FROM THESE SERVICE INSTRUCTIONS MAY LEAD TO RISK OF PERSONAL INJURY 11.1 Regular Maintenance Control. Service inspections must always be carried out after any repair of the device. Authorized service workshops can order the Vivo 40 Service Manual that con tains all technical documentation required for the maintenance and service of the Vivo 40. Audible alarm 1 to 9, where 1 is the lowest level and 9 is the highest volume setting.Technical Specifications Vivo 40 clinician’s manual Doc. 003886 EnUs A1e. The Vivo 40 and it’s packaging do not contain any natural rubber latex. 96 Technical Specifications Vivo 40 clinician’s manual Doc. 003886 EnUs A1e.

https://www.becompta.be/emploi/4-wheel-disc-brake-manual-master-cylinder

Breas Medical AB cannot guarantee the performance and safety for the use of other accessories with the Vivo 40. The following Breas accessories are currently available for the Vivo 40 ESCRIPTION

Carry bag. Intended Use Contraindications About this Manual Safety Information General User Precautions Electrical Safety Environmental Conditions Usage of Patient Circuit Invasive Use Usage of Filters Humidification Cleaning and Maintenance Adverse Patient Symptoms Usage of Oxygen Product Description Main Components Accessories The Vivo 40 s Front Panel The Vivo 40s Back and Side Panels Equipment Designation and Safety Label Functions and Parameters of the Vivo Ventilation Mode Device Mode Settings The PCV Mode Pressure Control Ventilation The PSV Mode Pressure Support Ventilation The Difference between PCV and PSV Mode Target Volume The CPAP Mode Standby and Operating Mode Low Leakage Detection Humidifier optional Using the Vivo Set up the Vivo 40 Before Use Switching the Vivo 40 On and Off Using the Menu Monitoring Section Transferring Data between the Vivo 40 and a PC Using the HA 01 Humidifier Using Batteries Vivo 40 Operating Time Preparing the Vivo 40 for Use i Table of Contents BREAS 1 2 6.1 Installing the Vivo Placing the Vivo Connecting the Vivo 40 to the AC Power Source Connecting the Patient Circuit Setting Up the Vivo Settings Applicable for the Different Modes Selecting the Mode Setting the Parameters Alarms Alarm Function Physiological Alarm Technical Alarm Complete Function Check Preuse Check Alarm Check Cleaning the Vivo 40 and Replacement of Accessories Cleaning the Vivo Cleaning and Replacing the Patient Air Filters Change of Patient Maintenance Regular Maintenance Control Service and Repair Storage Disposal Technical Specifications System Description Data Compliance of Standards Delivery Settings Accessories Breas Accessories List Table of Contents BREAS i 3 1 Introduction WARNING.

Vivo 40 must only be used For the intended treatment in accordance with this operating manual and with the instructions given by the responsible clinical personnel. In accordance with the operating conditions specified in this operating manual. In original and unmodified shape and only with accessories specified or approved by Breas Medical AB. Every other use may lead to risk of personal injury. CAUTION! Read this operating manual thoroughly so that you completely understand how the Vivo 40 is operated and maintained before taking it into use, to ensure correct usage, maximum performance and serviceability. WARNING! Do not use the Vivo 40 for any kind of total ventilatory requirement. Breas Medical AB reserves the right to make changes to this product without any prior notification. Introduction 3 4 1.1 What is the Vivo 40. The Vivo 40 is a pressuresupported and pressurecontrolled ventilator. It has three modes of operation PCV Pressure Control Ventilation, PSV Pressure Support Ventilation and CPAP Continuous Positive Airway Pressure. The PCV and PSV modes have an adjustable inspiratory trigger sensitivity setting which allows the patient to initiate ventilatorassisted breaths. In the PCV mode Pressure Control Ventilation, the ventilator provides assisted or controlled pressureregulated breathing. In PCV mode, the clinician sets an inspiration time. The inspiratory pressure is set by the IPAP Inspiratory Positive Airway Pressure setting. The endexpiratory pressure is set by the EPAP Expiratory Positive Airway Pressure setting. In the PSV mode Pressure Support Ventilation, the ventilator s expiratory trigger can also be adjusted allowing the ventilator to more easily match each patient s needs. The inspiratory pressure is set by the IPAP setting. The endexpiratory pressure is set by the EPAP setting. In the CPAP mode Continuous Positive Airway Pressure, the ventilator provides a continuous positive airway pressure.

The Vivo 40 has a pressure sensor that continuously monitors output pressure to the patient and reference ambient pressure, so that the device automatically will compensate for altitude changes. The internal memory of the Vivo 40 can be downloaded to a PC where you can view the patient compliance data in the Breas Vivo PC Software. The Vivo 40 is not intended to provide the total ventilatory requirements of the patient. The Vivo 40 is intended to be used for both invasive and noninvasive applications. 4 Introduction 5 The Vivo 40 is intended to be operated by qualified and trained personnel. The Vivo 40 is intended for use in clinical settings e.g., hospitals, sleep

laboratories, subacute care institutions and home environments. The Vivo 40 must always be prescribed by a licensed physician. The CPAP function is intended to deliver continuous positive airway pressure therapy for the treatment of obstructive sleep apnea, via noninvasive nasal or fullface masks. 1.3 Contraindications The use of the Vivo 40 is contraindicated on patients with severe respiratory failure without a spontaneous respiratory drive. The use of the Vivo 40 for positive pressure therapy may be contraindicated on patients Incapable of maintaining life sustaining ventilation in the event of a brief circuit disconnection or loss of therapy. Unable to maintain a patent airway or adequately clear secretions. At risk for aspiration of gastric contents. With a history of allergy or hypersensitivity to the mask materials where the risk from allergic reaction outweighs the benefit of ventilatory assistance.

Therapy with the Vivo 40 should not be prescribed when the following specific diseases or conditions are present Bullous lung disease Pathologically low blood pressure Severe cardiac arrhythmias Coronary artery disease Unstable angina pectoris Decompensated cardiac failure or hypotension, particularly if associated with intravascular volume depletion Recent thoracic surgery Pneumothorax Pneumomediastinum Introduction 5 6 Massive epistaxis or previous history of massive epistaxis risk of recurrence Pneumoencephalus, recent trauma or surgery that may have produced cranionasopharyngeal fistula Cerebral spinal fluid CSF leaks Acute or unstable respiratory failure or insufficiency Conditions predisposing to a risk of aspiration of gastric contents Impaired ability to clear secretions Caution should be used when prescribing positive airway pressure therapy for susceptible patients, such as patients with abnormalities of the cribriform plate, or prior history of head trauma. The use of CPAP therapy may be temporarily contraindicated if the patient exhibits signs of a sinus or middle ear infection. 1.4 About this Manual Always read this manual before setting up and using the Vivo 40 or performing maintenance on the machine, to ensure correct usage, maximum performance and serviceability. Breas Medical AB reserves the right to make changes to the contents of this manual without any prior notification. Audience This manual is primarily intended for care providers, clinical personnel, physicians and others who require a working knowledge of the Breas Vivo 40 system. The manual comprises detailed information on the settings and functions of the Vivo 40 to be handled by trained health care personnel only. Patients and other lay users operating the Vivo 40 will find all the information they need in the User Manual. Service personnel may order the Vivo 40 Service Manual that contains detailed technical information for maintenance, service and repair.

6 Introduction 7 Icons In this manual, icons are used to highlight specific information. The meaning of each icon is explained in the table below. ICON EXPLANATION Warning. Risk of death and serious personal injury. Caution! Risk of minor or moderate injury. Risk of equipment damage, loss of data, extra work, or unexpected results. Note Information that may be valuable but is not of critical importance, tips. Reference Reference to other manuals with additional information on a specific topic. Introduction 7 8 2 Safety Information 2.1 General User Precautions The Vivo 40 must be switched off and on at least once a day. This is necessary in order for the Vivo 40 to perform a self test. U.S. Federal law restricts this device for sale by or on order of a physician. The Vivo 40 should not be used for any kind of total ventilatory requirement. The Vivo 40 shall only be used by patients with spontaneous breathing. Advice contained in this manual should not supersede instructions given by the prescribing physician. If the patient is admitted to a hospital or is prescribed any other form of medical treatment, always inform the medical staff that the patient is on mechanical ventilation treatment. Vivo 40 must only be used for the intended treatment in accordance with this operating manual and with the instructions given by the responsible clinical personnel; in accordance with the operating conditions specified in this operating manual; in

original and unmodified shape and only with accessories specified or approved by Breas Medical AB. Do not use the Vivo 40 in the event of suspected damage to the device, unexplainable or sudden pressure, performance or sound changes during operation, or if the delivered air from the Vivo 40 is abnormally hot or emits an odor. Contact your responsible care provider for an inspection. Inadequate use of device or accessories may cause loss of treatment or decreased performance.

The Vivo 40 therapy settings must always be based on medical supervision and must be changed by authorized clinical personnel only. Blood gas measurement should be performed when changing settings or changing to another device. 8 Safety Information 9 Always perform the procedure Set up the Vivo 40 Before Use on page 35 before using the Vivo 40. Only use accessories recommended by Breas Medical AB. Clinical personnel must read the Clinician s manual thoroughly and understand the Vivo 40 operation before setting up and using the machine. The user must read the user manual thoroughly and understand the Vivo 40 operation before using the machine. All the physiological alarms of the Vivo 40 must be set at safe levels that will effectively warn the user of any risk. The alarm levels should be assessed considering the patient settings. Any change of settings or components may require the readjustment of the alarm levels. Handle the Vivo 40 with care. Make sure to place and pack the device in a way that prevents unintentional start of the machine. Do not use the Vivo 40 while in a carry bag. Attach the rear lid and place the swivel in a down position when placing the Vivo 40 in the bag. If using the Vivo 40 for a short intra hospital or vehicle transportation, the following cautions need to be observed Do not mount the Vivo 40 on a wheelchair or in a vehicle. Make sure that the Vivo 40 stands securely in a upright position and cannot tilt or fall. Do not use the Vivo 40 outdoors during rain or snowfall. If the HA 01 humidifier is attached, make sure that it is not in use and that it is empty. Safety Information 9 10 2.2 Electrical Safety Do not operate the Vivo 40 if it has a damaged power cord or casing. The Vivo 40 may not work properly if any part has been dropped, damaged or submerged in water. To avoid electrical shock, disconnect the electrical supply to the Vivo 40 before cleaning. Do not immerse the Vivo 40 into any fluids.

The operator shall not touch accessible contacts of connectors and the patient simultaneously. When handling the HA 01 humidifier, always turn off the Vivo 40 and disconnect the Vivo 40 from the AC power supply. Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards e.g. IEC for data processing equipment and IEC for medical equipment. Furthermore, all configurations shall comply with the valid version of the system standard IEC Therefore, everyone who connects additional equipment to the signal input part or signal output part configures a medical system is responsible that the system complies with the requirements of the valid version of the system standard IEC If in doubt, consult the technical service department or your local representative. If an external battery is used, always disconnect it when the Vivo 40 is switched off. Otherwise there is a risk that the battery will discharge. If the AC power source fails and the internal or the external battery activates, the HA 01 humidifier will be turned off automatically. It must be activated again manually, if humidification during battery use is necessary. Only use the data connection to connect the Vivo 40 to the icom or a PC. 10 Safety Information 11 2.3 Environmental Conditions Do not use the Vivo 40 in any toxic environment. Do not use the Vivo 40 in environments where there are explosive gases or other flammable anesthetic agents present. The air flow for breathing produced by the Vivo 40 can be as much as 10 F 5 C higher than room temperature. Caution should be exercised if the room temperature is greater that 95 F 35 C. If a room humidifier is used, place it at least 6 feet 2 meters away from the Vivo 40. The performance of the Vivo 40 may deteriorate at ambient temperatures below 41 F 5 C and above 100 F 38 C. Do not use the Vivo 40 while positioned in a warm place, such as direct sunlight.

The device complies with the EMC requirements of standards listed in Compliance of Standards on page 95. Measures should include but not be limited to normal precautions with regard to relative humidity and conductive characteristics of clothing in order to minimize the buildup of electrostatic

charges.Examples include radio emitting devices such as cellular or cordless telephones, microwave ovens and highfrequency surgery apparatus. The Vivo 40, all accessories and replacement parts must be disposed of in accordance with the local environmental regulations regarding the disposal of used equipment and waste. The performance of the Vivo 40 and treatment of the patient may deteriorate if the operation conditions in Technical Specifications on page 89 are not fulfilled. Do not use the Vivo 40 immediately after storage or transport outside the recommended operating conditions. Safety Information 11 12 2.4 Usage of Patient Circuit Only use the Vivo 40 with a mask, patient tube and leakage port recommended by Breas Medical AB and your health care professional. The Vivo 40 requires an intentional leak port instead of an actively controlled exhalation valve to remove exhaled gases from the patient circuit. Therefore, specific masks and patient circuits using an intentional leakage are required for normal operation. The pressurized air from the Vivo 40 causes a continuous flow of air to exhaust from the leak ports, flushing exhaled gas from the circuit. The Vivo 40 should be turned on and the intentional leak ports should be checked before application. Do not breathe in the connected patient circuit unless the Vivo 40 is turned on and operating properly. Do not use patient hoses or tubes made of static or electrically conductive material. Always use a new mask, tube and leakage port when the Vivo 40 is to be used by a new patient. Patient connected parts and filter must be replaced regularly to ensure correct function of the Vivo 40.

All replaced parts must be disposed of according to local environmental regulations regarding the disposal of used equipment and parts. Periodically check for moisture in the patient circuit. When present, remove the moisture. Before attempting to dry the circuit, disconnect it from the Vivo 40 to ensure no water will flow back into the Vivo 40. The frequency at which these checks must be performed will depend on the patient s own condition and the device used. You should assess this on an individual basis in accordance with the patient s needs. If the patient needs assistance to take off the patient interface, the patient shall not be left alone. This is to avoid the risk of rebreathing of CO 2 in case of accidental ventilator failure. If the patient is using a full face mask covering mouth and nose, the mask must be equipped with a safety entrainment valve. 12 Safety Information 13 Make sure that the ventilation holes in the mask or the leakage ports are never blocked or obstructed. These ports are used to prevent rebreathing of exhaled air. Rebreathing of exhaled gases for longer than several minutes can, in some circumstances, lead to suffocation. At low CPAP pressures, the air flow through the ventilation holes in the mask or the leakage ports may be inadequate to clear all exhaled gases. Some rebreathing may occur. Do not leave long lengths of air tubing around the top of the bed. It could twist around the patient s head or neck while sleeping. Always follow the instructions of the mask manufacturer. Safety Information 13 14 2.5 Invasive Use For invasive applications, assure that an intentional leakage port is present in the patient circuit. Install the leakage port as close as possible to the patient connection, to reduce the risk of rebreathing CO 2. When using the Vivo 40 invasively the low volume alarm and the low breath rate alarm must be carefully set, to ensure safe use. The Vivo 40 is equipped with a low leakage alarm.

The low leakage alarm is not a substitute for operator vigilance in ensuring that the leakage ports remains clear at all times. Periodically check the leakage ports during therapy. In general as pressure decreases the potential of rebreathing increases. Lower pressures produce less flow through the leakage ports which may not clear all CO 2 from the circuit to prevent rebreathing. In general as inspiratory time increases the potential of CO 2 rebreathing increases. A higher inspiratory time decreases the expiratory time allowing less CO 2 to be cleared from the circuit before the next breath. IE inspiration time expiration time ratios close to 11 increase the potential of CO 2 rebreathing. Only use filters that are specified in this manual. Replace or clean the filters regularly to ensure correct function of the Vivo 40, especially when changing patient. Failure to replace or clean a dirty filter may cause the Vivo 40 to operate at higher temperatures than intended. When operating the Vivo 40, make sure that the air inlet and filters are not obstructed or occluded. If the Vivo 40 is used in a clinic by several patients, a low resistance bacteria filter is

recommended between the air outlet and the patient circuit to prevent patient crosscontamination. Breas Medical AB recommends the usage of the Breas filter, see Breas Accessories List on page 99. Reuse of mask or bacteria filter may expose patients to contagious agents. The use of a high resistance bacteria filter on the output of the device may interfere with the operation of the patient disconnect function. It may also interfere with the device trigger function. Do not connect any filter to the HA 01 humidifier. Safety Information 15 16 2.7 Humidification The HA 01 humidifier is intended for noninvasive use only. Do not place the Vivo 40 with the HA 01 humidifier in a bag. When the HA 01 humidifier is installed, the Vivo 40 must be located below the patient and on a flat surface.

This is to prevent personal injury from accidental spillage or from excess water or condensation flowing down the patient tube and into the patient s mask. Extra cautions should be taken for patients who are unable to guard their airways or cannot pull off the mask. When using an external heated humidifier, it should be located below the Vivo 40 and the patient to prevent injury from accidental spillage. If the condensation in the patient circuit is excessive, the use of a heated humidifier may require the installation of a water trap in the circuit. The water trap prevents any condensated water in the patient circuit from running into the patient airways and causing personal injury. The use of an HME Heat and Moisture Exchanger, artificial nose or an external humidifier may require readjustment of the Vivo 40 s lowpressure alarm. Certain HME s and HCH s Hygroscopic Condenser Humidifiers are sufficient to provide humidification when the Vivo 40 is used invasively. Check specific suppliers recommended use. 16 Safety Information 17 2.8 Cleaning and Maintenance The Vivo 40 should be cleaned and maintained in accordance with this operating manual. Do not attempt to autoclave or sterilize the Vivo 40. Vivo 40 should be subjected to maintenance, service and control and any applicable upgrades, in accordance with Breas service instructions. Vivo 40 shall only be repaired or modified in accordance with Breas service manuals, technical bulletins, and any special service instructions, by service technicians authorized by Breas Medical AB. Do not under any circumstances attempt to service or repair the Vivo 40 yourself. If you do so, the manufacturer will no longer be responsible for the performance and safety of the Vivo 40. Furthermore, no warranty will be valid. Safety Information 17 18 2.