



#### WARNING

To properly use this medical device, read and comply with these instructions for use. Neonatal Incubator Software 2.n Instructions for Use

# Dräger

#### NOTICE

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## How to use these Operating Instructions

#### The headline ...

specifies the subject of the main chapter

to help you find your way around quickly.

#### The page body ...

#### contains instructions for use of the device

in a combination of text and illustrations. The information is translated directly into sequences of activities showing the user how to use the device.

#### The left-hand column ...

#### contains text

explaining the device and guiding the user directly to its uses through concise, ergonomically arranged instructions.

- Bullet points refer to individual actions.
- 1 numbers refer both to illustrations and the sequence of action when several steps are required to complete a task.

#### The right-hand column ...

#### contains illustrations

as a visual reference to the text, guiding the user to locate parts of the unit itself. Elements mentioned in the text are highlighted. Unnecessary details are omitted. Rendering of screen displays guide the user and allow to reconfirm actions performed.



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Operator's Responsibility for Patient Safety Definitions

# **Important Safety Information**

#### **Operator's Responsibility for Patient Safety**

# WARNING !

Strictly follow these Instructions for Use Any use of the product requires full understanding and strict observation of all portions of these instructions. This equipment is only to be used for the purpose specified under "Intended Use" (see page 19). Observe all WARNINGS and CAUTIONS as rendered throughout this manual and on labels on the equipment.

The design of the equipment, the accompanying literature, and the labeling on the equipment take into consideration that the purchase and use of the equipment are restricted to trained professionals, and that certain inherent characteristics of the equipment are known to the trained operator. Instructions, warnings, and caution statements are limited, therefore, largely to the specifics of the Dräger design.

This publication excludes references to various hazards which are obvious to a medical professional and operator of this equipment, to the consequences of product misuse, and to potentially adverse effects in patients with abnormal conditions. Product modification or misuse can be dangerous. Draeger disclaims all liability for the consequences of product alterations or modifications, as well as for the consequences which might result from the combination of this product with other products whether supplied by Dräger or by other manufacturers if such a combination is not endorsed by Dräger.

#### Patient monitoring

The operators of this infant incubator system must recognize their responsibility for choosing appropriate safety monitoring that supplies adequate information on equipment performance and patient condition. Patient safety may be achieved through a wide variety of different means ranging from electronic surveillance of equipment performance and patient condition to simple, direct observation of clinical signs. Responsibility for the selection of the best level of patient monitoring lies solely with the equipment operator.

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# Definitions

# WARNING !

A WARNING statement provides important information about a potentially hazardous situation which, if not avoided, could result in death or serious injury.

#### CAUTION !

A CAUTION statement provides important information about a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or in damage to the equipment or other property.

**NOTE:** A NOTE provides additional information intended to avoid inconveniences during operation.

#### Definition of target groups

Users, maintenance personnel and professionals are defined as the target groups for this medicine device.

These target groups were trained to handle the medical device and have the necessary specialized knowledge and training, the necessary know how to use, install, prepare, maintain or repair the medical device.

Dräger points out that only the defined target groups should use, install, prepare, maintain or repair the medical device. **User** 

Users are persons who may use the medical device in accordance with its intended purpose.

#### Maintenance personnel

Maintenance personnel are persons who are responsible to the owner or operator for the maintenance of the medical device. Maintenance personnel are persons who install, prepare or maintain the medical device in working condition. **Professionals** 

Professionals are persons who may perform repair jobs or complex maintenance jobs on the medical device.

#### Typing conventions in this manual

Display messages are printed as »message«, e. g: »confirm new mode with rotary knob«

Controller keys are designated as »Key Name«, e.g. »man.«

▲ indicates a reference to the operating manual on the incubator, e.g. for a control element.
Symbols
Please refer to "Glossary" on page 163 for explanations.
Labels on the equipment

Please refer to "Labels" on page 25.

# Summary of WARNINGS and CAUTIONS

# WARNING !

Strictly follow these Instructions for Use Any use of the product requires full understanding and strict observation of all portions of these instructions. This equipment is only to be used for the purpose specified under "Intended Use" (see page 19). Observe all WARNINGS and CAUTIONS as rendered throughout this manual and on labels on the equipment.

# WARNING !

This device may only be used by properly trained personnel under the supervision of qualified medical personnel familiar with the currently known risks and benefits of using an infant incubator.

# WARNING !

Dräger cannot warrant or endorse the safe performance of third party accessories for use with the Caleo incubator system.

Only use accessories that are qualified to the required specifications for an intended use in an oxygen enriched environment.

# WARNING !

This device is to be used only in rooms with line power installations complying with national safety standards for hospital patient rooms (e.g., IEC/EN 60601-1 "Medical Electrical Equipment - General Requirements For Safety").

To maintain grounding integrity, connect only to a "hospital grade" receptacle.

Always disconnect supply before servicing.

# WARNING !

DANGER, risk of explosion if used in the presence of flammable anesthetics.

This device is neither approved nor certified for use in areas where combustible or explosive gas mixtures are likely.

# WARNING !

The use of this device requires continuous supervision of the infant by trained nursing personnel in order to ensure immediate corrective action in situations with a risk of patient injury.

# CAUTION !

# **Restriction of Distribution**

Federal Law (U.S.) restricts this device to sale by or on the order of a physician.

#### CAUTION !

Device for use in health care facilities only and exclusively by persons with specific training and experience in its use.

#### CAUTION ! Maintenance

# The device must be inspected and serviced at regular 1 year intervals. A record must be kept on this preventive maintenance. We recommend obtaining a service contract with DrägerService.

For repairs of the Caleo incubators we recommend that you contact DrägerService.

#### **Precautions During Preparation**

#### WARNING !

Always observe all precautions against fire hazards from oxygen (see page 61).

#### WARNING !

Never leave infant unattended when access doors or access ports are open to avoid any risk of an infant falling out of an incubator.

#### WARNING !

Always ensure that access port catches are securely engaged in order to avoid any risk of an infant falling out of an incubator.

# WARNING !

When opening and closing front door, avoid pinching or jamming hoses and cables in the attached double wall.

# WARNING !

Always ensure that both knobs of the large access doors are engaged in position in order to avoid any risk of an infant falling out of an incubator.

The red catch behind each knob must no longer be visible!

# WARNING !

The attached double wall must be positioned parallel to the front door otherwise the ducted flow of warm air will be interrupted!

# WARNING !

When opening and closing side doors, avoid pinching or jamming hoses and cables in the attached double wall.

# WARNING !

Always ensure that both knobs of the side doors are engaged in position in order to avoid any risk of an infant falling out of an incubator.

The red catch behind each knob must no longer be visible!

#### WARNING !

Always observe the maximum load of the infant bed (5 kg, 11 lbs).

# WARNING !

Never leave infant unattended when the bed has been pulled out to avoid any risk of an infant falling out of an incubator.

# WARNING !

Do not lean on the bed when it is pulled out. Equipment damage with risk of patient injury may result.

# WARNING !

Always ensure that the bed is pushed all the way in! Otherwise the ducted flow of warm air will be interrupted, and the infant may be warmed or cooled excessively.

#### WARNING !

Do not use the X-ray drawer as a writing support or as a bed for the infant. Risk of equipment damage or patient injury.

#### WARNING !

Always ensure that the x-ray drawer is pushed all the way in! Otherwise the ducted flow of warm air will be interrupted, and the infant may be warmed or cooled excessively.

#### WARNING !

Make sure that the installed hoses are routed freely and safely.

# WARNING !

Do not reach between incubator housing and housing support while tilting the bassinet. Risk of injury!

Use only authentic, originally sealed OEM bags containing sterilized distilled or demineralized water. Do not use any additives for water intended for humidifying the incubator.

Do not use infusion solution bag for the humidification system.

# WARNING !

Output of the integrated power strip is not monitored! Do not connect life support devices which do not have their own power failure alarm.

 $\underline{\wedge}$  Do not exceed the maximum permissible power input for connected accessories

(all 4 sockets together: max. 2 A).

Do not exceed the maximum permissible total leakage current. For the leakage current of Caleo without socket strip see "Technical Data", page 166.

# WARNING!

Installation of the nurse call kit should only be performed by DrägerService or factory trained and authorized service personnel.

# WARNING!

Connect nurse call to a central hospital alarm system only while Caleo is properly grounded via its power cable and a grounded wall outlet or via the grounding pin on the rear panel of the control unit.

Otherwise, the risk of electric shock cannot be safely excluded.

# WARNING!

Only alarm messages with a high risk potential or serious device faults are transmitted via nurse call.

# WARNING!

Connection of a nurse call does not relieve staff of their duty to check patient data at regular intervals.

• Screen displays must be checked regularly.

# WARNING!

A fault in any of the components in the link between nurse call and central hospital alarm system (e.g. in the electronics for nurse call in Caleo, in the Caleo power supply, or in the enunciator of the central hospital alarm system, etc.) may result in failure of the nurse call.

# WARNING!

The system must meet the requirements about medical electrical equipment in accordance to IEC/EN 60601-1-1 and IEC/EN 60601-1-2.

# WARNING!

Connect external devices to the interfaces only while Caleo is properly grounded via its power cable and a grounded wall outlet or via the grounding pin on the rear panel of the control unit.

Otherwise, the risk of electric shock cannot be safely excluded.

# WARNING!

All data that are transmitted via medical devices are for information only and should not be used as the sole basis for clinical decisions.

# WARNING !

Do not use a power outlet strip for supplying power to the Caleo incubator!

Connecting the incubator via a power outlet strip may, in case of failure of the protective earth conductor, cause patient leakage currents to rise above permitted limits with a risk of electric shock to the patient.

# WARNING!

The Caleo incubator is ready for operation only when all checks have been performed successfully.

#### **CAUTION !**

Always verify that monitor shelves and other accessories are securely attached.

Always observe the following limits:

# Maximum overall load must not exceed 66 kg (145.5 lbs) (see page 170).

For items attached to column on swivel shelves, do not exceed load of 3 kg (6.6 lbs).

#### When installing accessories, please note:

- Accessory equipment must not collide with the unit when adjusting tilt angle and height of Caleo.
- Accessory equipment on the handle side does not move with the main unit during height adjustment of Caleo (Handle side, see page 170).

#### **CAUTION !**

#### Maximum loads for

- pole 38 mm/600 is 10 kg (22 lbs).
- pole 38 mm/310 is 10 kg (22 lbs).
- pole 25 mm/600 is 3 kg (6.6 lbs).

Max. distance between loads and pole: 150 mm (6 inches).

#### CAUTION !

When mounting control unit to its pole, ensure that there is sufficient space to swivel the control unit (see "Tilting the bed", page 48).

#### CAUTION !

Only qualified technical personnel may move the control unit from the wall side to handle side or vice versa.

#### **CAUTION !**

Do not remove cable to the control unit from the cable guides on the basic pole.

Make sure there is sufficient space to swivel and tilt the unit.

#### CAUTION !

Maximum load per hook is 3 kg (6.6 lbs).

#### CAUTION !

Maximum load for swivel tray is 3 kg (6.6 lbs).

Ensure sufficient space for swiveling!

#### **CAUTION !**

Maximum load for compact rail clamp is 5 kg (11 lbs).

# CAUTION !

Do not install incubator controller on telescoping column.

# CAUTION !

Maximum load for base pole is 10 kg (22 lbs). Max. distance between loads and pole: 150 mm (6 inches).

#### CAUTION !

Maximum load for instrument tray is 2 kg (4.4 lbs).

#### CAUTION !

#### Maximum loads for pole extensions

- 38 mm/600 is 5 kg (11 lbs).
- 38 mm/310 is 5 kg (11 lbs).
- 25 mm/600 is 3 kg (6.6 lbs).
- Max. distance between loads and pole: 150 mm (6 inches).

#### CAUTION !

Maximum load for notebook holder is 3 kg (6.6 lbs).

#### CAUTION !

Maximum load for monitor shelf is 20 kg (44 lbs).

#### Do not exceed the maximum installation height.

Vertical distance between monitor shelf and stand must not exceed 20 cm (7.8 inches) on the wall side and 100 cm (39 inches) on the handle side (see page 170).

#### **CAUTION !**

Always check that connecting O2 supply hose is of sufficient length when using independent O2 flowmeter, allowing for the height adjustments of the bassinet.

#### CAUTION !

The permissible O<sub>2</sub> inlet pressure is between 300 and 600 kPa (43.5 and 87 psi).

#### **CAUTION !**

Maximum load for drawer is 7 kg (15 lbs).

#### CAUTION !

Always take care not to damage sensor unit inside the incubator when manipulating canopy !

#### **CAUTION !**

Cables and hoses must be sufficiently long to avoid kinking, tear or pinching when adjusting the incubator height! Do not store anything underneath the drawer.

#### CAUTION !

The castor with direction lock does not have a brake. To secure Caleo, apply the brakes on all 3 castors with brakes.

#### **CAUTION !**

Cables and hoses must be carefully routed to avoid kinking, tear or pinching when adjusting the incubator tilt angle!

#### CAUTION !

A Exclusively use sterilized distilled or demineralized water for humidifying the incubator!

#### **Precautions During Operation**

# WARNING !

Make sure that all hoses and cables are routed correctly and safely without obstruction! Otherwise: Risk of extubation! Danger of disconnection!

# WARNING !

Never leave infant unattended when the canopy, double walls, front door, or access ports are open, when the bed has been pulled out, or when access grommets have been removed. Risk of patient injury.

Under these conditions, watch patient carefully to prevent any possibility of an infant falling out of the incubator.

#### WARNING !

Always observe the maximum load of the patient bed (5 kg, 11 lbs).

Do not lean on or apply weight to the bed when it has been pulled out.

#### WARNING !

Avoid additional external heat sources, such as direct sunlight, spot lamps, and electric pads or blankets. They cause the air temperature inside the incubator to increase in an uncontrolled fashion.

# WARNING !

The infant's central temperature must be regularly monitored with an independent thermometer.

# WARNING !

It is the responsibility of the attending physicians to draw conclusions from the measured skin temperature.

# WARNING !

Do not use skin temperature control mode for infants in shock, as their skin temperature is much lower than normal. Skin temperature control would increase the incubator air temperature too much, resulting in the risk of overheating the infant.

We recommend operating the Caleo incubator in air temperature control mode when caring for patients with such conditions – see page 65.

#### WARNING !

Do not use skin temperature control mode for infants with a fever, since their skin temperature is much higher than normal. Using skin temperature control would reduce the incubator air temperature too much, resulting in the risk of hypothermia.

#### WARNING !

Skin temperature control mode must not be used on twins, since Caleo controls only the temperature for one infant. Risk of hypothermia or overheating. Always use air temperature control mode when caring for twins.

#### WARNING !

Do not confuse skin sensor probe positions on the infant's body! The yellow skin temperature sensor (T1) is used for skin temperature control. Inappropriate positioning of this sensor could lead to overheating of the infant.

Do not place any blankets or sheets over the hot air vent. The temperature control system would be disrupted, causing a risk of overheating or burn if air from the hot air vent is channeled directly to the infant.

# WARNING!

Cleaning mode may only be used while Caleo is not occupied by a patient.

After use, allow Caleo to cool down before dismantling. Risk of burns when touching the heater!

# WARNING !

During a power failure, the lack of fresh air supply may cause an elevated CO<sub>2</sub> concentration inside the patient capsule. Risk of CO<sub>2</sub> poisoning.

# WARNING !

Beware of cross-infections when treating twins!

#### WARNING !

Fire hazards from oxygen !

- No open flames or cigarettes! Textiles, plastics, and oils readily ignite in an oxygen enriched atmosphere and burn with great intensity.
- Keep oxygen valves, connections, and seals free from oil and grease.
- Open valves on O2 cylinders slowly.
- Do not operate Caleo in the presence of flammable anesthetics or disinfectants. Risk of explosion!
- Do not use or store flammable liquids such as alcohol, ether, or acetone inside the Caleo incubator.
- Do not use electrical equipment inside the patient capsule unless this equipment is expressly designed for use in environments that present an explosion hazard.

# WARNING !

Due to the physiological risks from O<sub>2</sub>, it is mandatory to monitor O<sub>2</sub> concentrations continuously during the administration of O<sub>2</sub>, either using the integrated O<sub>2</sub> measurement and control system or an independent O<sub>2</sub> analyzer.

# WARNING !

Always take into consideration the physiological risks from the administration of oxygen.

Elevated oxygen concentrations inside the incubator may only be used by or on the order of a physician. Oxygen is classed as a drug.

It is absolutely essential that such oxygen therapy be selected and controlled on the basis of the arterially measured oxygen partial pressure in the infant's blood (SaO<sub>2</sub> or SpO<sub>2</sub>). This is the only way to minimize the risk of both hyperoxemia (with potential for damage to the eyes by retrolental fibroplasia) and hypoxemia (which might contribute to intraventricular hemorrhage and damage to the infant's brain).

# WARNING !

Medicated aerosols and similar substances must not be nebulized in the infant capsule.

The mist of nebulized substances may impair the proper function of the incubator.

#### WARNING !

When using Kangaroo Mode, central temperature of the infant, who is outside the controlled climate of the incubator, must be monitored constantly.

Particular attention must be paid to critical care patients' vital parameters, especially a critical O<sub>2</sub> partial pressure. Ensure that all cables and hoses are routed correctly and safely.

# WARNING !

Infant temperature must be monitored with particular care during phototherapy. Absorption of light through the infant's skin will supply heat to the patient which may increase central temperature.

# WARNING !

During phototherapy, the supply of fluids to the infant must be increased, e.g. by parenteral infusion, to compensate for the increased water loss.

# WARNING !

Never cover phototherapy lamp or incubator canopy with the intention to boost the phototherapeutic effect. A heat build-up will likely result with the danger of overheating the infant, because the incubator cannot be adequately cooled with ambient air under these conditions.

Always use eye protection for the infant when using phototherapy.

# WARNING !

Ensure that the ventilator circuit and all other cables, hoses and tubing are routed correctly and safely. Danger of extubation and disconnection! Hoses and/or cables are at risk of being trapped when tilting the Caleo, adjusting the height, and when opening and closing the front door.

# WARNING !

Cleaning mode must only be used when Caleo is empty. After use, allow Caleo to cool down before dismantling. Risk of burns when touching the heater!

# WARNING !

Caleo is to be used only in rooms with line power installations that comply with national safety standards for hospital patient rooms (e.g., IEC/EN 60601-1 "Medical Electrical Equipment - General Requirements For Safety").

To maintain grounding integrity, connect only to a "hospital grade" receptacle.

Always disconnect supply before servicing.

# WARNING !

Do not use a power outlet strip for supplying power to the Caleo incubator!

Connecting the incubator via a power outlet strip may, in case of failure of the protective earth conductor, cause patient leakage currents to rise above permitted limits with a risk of electric shock to the patient.

# WARNING!

Cleaning mode may only be used while Caleo is not occupied by a patient.

# WARNING!

Risk of burns upon contact with the heater! Do not disassemble Caleo while in cleaning mode.

# WARNING!

Always adjust audible alarm volume to a level that ensures the operator will be alerted when alarms occur. Failure to identify and correct alarm situations may result in patient injury.

# WARNING !

While alarm suppression is active, the operator of the incubator must still assume responsibility for proper patient care and safety in the event of an alarm. Failure to identify and correct alarm situations may result in patient injury.

# WARNING !

Only use auxiliary electromedical equipment which complies with national safety standards for hospital patient rooms (e.g., IEC/EN 60601-1 "Medical Electrical Equipment - General Requirements For Safety", UL 544). When using the integrated power strip to connect auxiliary devices, always observe total leakage current and current consumption limits! (See "Technical Data", page 166.)

# WARNING !

The output of the integrated power strip is not monitored!

Do not connect life support devices which do not have their own power failure alarm.

#### WARNING !

Regularly measure infant temperature! Do not leave canopy open for any length of time, otherwise the air temperature inside the incubator will drop.

# WARNING !

When the extended setpoint range for air temperature is used, the infant's temperature must be continuously monitored.

# WARNING !

Monitor infant constantly when canopy, doors, or access ports are open, to ensure infant cannot fall out of the incubator.

Always verify that temperature sensors are specified and approved for use with Dräger Caleo.

Disposable sensors must not be cleaned for re-use. If used more than once, the necessary measurement precision cannot be guaranteed.

# WARNING !

Do not use skin temperature sensor (yellow) or peripheral temperature sensor (white) to measure rectal (central) temperature!

Do not locate sensor under the infant, otherwise measurement and control would be performed with reference to infant central temperature instead of skin temperature.

# WARNING !

Regularly check that skin temperature sensor is properly attached to the infant's skin! A skin temperature probe that has fallen off would be measuring air temperature with a risk of overheating the infant (although the air temperature would not rise above 39  $^{\circ}$ C).

# WARNING !

When the extended setpoint range for skin temperature is used, particular care must be taken to monitor infant temperature.

# WARNING !

As long as 3 dashes remain on screen while the incubator is operated in skin temperature control mode, Caleo will not heat. Infant may become hypothermic.

# WARNING !

Always keep in mind the physiological risks and fire hazards associated with the use of high O<sub>2</sub> concentrations.

#### CAUTION !

When fitting accessories, please note:

- The accessory equipment must not collide with the unit when adjusting the tilt angle and height of Caleo.
- The accessory equipment on the handle side will not move with the main unit during height adjustment of Caleo (page 170).

Always observe maximum loads to avoid danger of unit tipping over.

#### CAUTION !

Use caution when moving the incubator over uneven surfaces, e.g. rough pavement outside the hospital or into an elevator, as castors may become damaged or dislodged.

#### CAUTION !

Never cover the sensor unit or hang anything from the openings in the sensor unit. Keep these openings free from dirt.

#### CAUTION !

Only use phototherapy units supplied with their own stand. Do not place phototherapy devices directly on Caleo canopy, as they may slip when the bed tilt is activated.

#### **Precautions During Care**

# WARNING !

Always follow accepted hospital procedures for handling equipment contaminated with body fluids.

# WARNING !

Always disconnect power supply before cleaning and disinfecting.

# WARNING !

Risk of burns from heater!

When the incubator is closed, the heater is still hot enough to inflict serious burns for a long time after switching off (70 °C = 158 °F after 1 hour).

# WARNING !

Always disconnect all supplies before disassembly.

Risk of burns upon contact with the heater. Allow Caleo to cool down before further disassembly.

#### WARNING !

The incubator is ready for operation only when all checks have been carried out successfully.

#### WARNING !

Always ensure that both knobs of the large access doors are engaged in position in order to avoid any risk of an infant falling out of an incubator.

The red catch behind each knob must no longer be visible!

# WARNING !

The attached double wall must be positioned parallel to the front door otherwise the ducted flow of warm air will be interrupted!

#### WARNING !

Always ensure that both knobs of the side doors are engaged in position in order to avoid any risk of an infant falling out of an incubator.

The red catch behind each knob must no longer be visible!

#### WARNING !

Always ensure that the bed is pushed all the way in! Otherwise the ducted flow of warm air will be interrupted, and the infant may be warmed or cooled excessively.

#### **CAUTION !**

Even accessories designed to be reused after cleaning have a limited life. For example, due to a number of factors connected with handling and preparation, disinfectant residues can attack the material more intensely during autoclaving; increased wear can occur and service life can be markedly shortened. Accordingly, these parts and accessories must be replaced when any external signs of wear – such as cracks, deformation, discoloration, peeling, etc., – become apparant.

#### **CAUTION !**

Certain components of the Caleo incubator consist of materials that are sensitive to certain organic solvents sometimes used for cleaning and disinfecting (e.g., alcohols, phenols, halogen releasing compounds, oxygen releasing compounds, strong organic acids, etc.). Exposure to such substances may cause damage that is not always immediately recognized. Sterilization of the incubator or components with ethylene oxide (EtO) or disinfection with formaldehyde is also not recommended.

#### **CAUTION !**

U-grommets cannot be autoclaved at 134 °C (273 °F).

#### **CAUTION !**

Take care not to damage the sensor unit when removing patient bed.

#### **CAUTION !**

Do not allow any moisture to enter the sensor unit. Do not disinfect sensor unit by immersion or spraying. Sensor damage may result.

#### **CAUTION !**

Do not allow any moisture to enter the control unit. Do not disinfect control unit by immersion or spraying. Equipment damage may result.

#### **CAUTION !**

Ensure that only recommended cleaning agents and disinfectants are used!

The acrylic and Makrolon material may develop stress cracks if other agents, such as alcohol, are used. Do not use UV radiation on the incubator. This also may cause cracks in the acrylic parts.

**Precautions During Maintenance** 

#### WARNING !

To avoid any risk of infection, clean and disinfect incubator and accessories before any maintenance according to established hospital procedures – this applies also when returning units or parts for repair.

In order to avoid risk of electric shock, always disconnect power supply before starting any maintenance procedures.

# WARNING !

Never operate the Caleo incubator, if it has suffered physical damage or does not seem to operate properly. We recommend that you contact DrägerService for maintenance service for the Caleo incubator.

# WARNING !

Treatment of batteries and O2 sensors

- Do not throw into fire! Risk of explosion.
- Do not force open! Cells contain corrosive acid that may cause caustic burns.
- Do not attempt to recharge battery. Risk of explosion.

#### CAUTION !

For disposal of batteries and O2 sensors follow all local, state, and federal legislation with respect to environmental protection.

#### **CAUTION !**

The device must be inspected and serviced at regular 1 year intervals. A record must be kept on this preventive maintenance. We recommend obtaining a service contract with DrägerService.

For repairs of the Caleo incubators we recommend that you contact DrägerService.

# **Intended Use**

# WARNING !

This device may only be used by properly trained personnel under the supervision of qualified medical personnel familiar with the currently known risks and benefits of using an infant incubator.

# Applications

Caleo<sup>®</sup> is an infant incubator system for premature babies and sick infants up to a body weight of 5 kg (11 lbs) or a body length of 55 cm (22 inches), providing a controlled environment of warmth, humidity<sup>\*</sup>, and elevated O<sub>2</sub> concentration<sup>\*</sup> in the patient area. The total body weight when treating twins is limited to 5 kg (11 lbs).

Caleo is intended for use in clinical environments where premature babies or infants are treated who require a controlled climatic environment.

#### Options for nursing and therapy:

- Convective heat therapy through control of incubator air temperature or infant skin temperature
- Humidification of the incubator air
- O2 therapy through controlled elevation of the O2 concentration in the patient environment
- Nursery and intensive care via access ports or two large access doors
- Pivoting bed for raising and lowering the infant's head (Trendelenburg and anti-Trendelenburg position)

#### With monitoring for:

- Air temperature
- Skin temperature
- Relative humidity
- O2 concentration
- Weight\*

# WARNING !

Dräger cannot warrant or endorse the safe performance of third party accessories for use with the Caleo incubator system.

Only use accessories that are qualified to the required specifications for an intended use in an oxygen enriched environment.

# **Restrictions of Use**

#### CAUTION ! Restriction of Distribution

Federal Law (U.S.) restricts this device to sale by or on the order of a physician.

#### CAUTION !

Device for use in health care facilities only and exclusively by persons with specific training and experience in its use.

# WARNING !

This device is to be used only in rooms with line power installations complying with national safety standards for hospital patient rooms (e.g., IEC/EN 60601-1 "Medical Electrical Equipment - General Requirements For Safety").

To maintain grounding integrity, connect only to a "hospital grade" receptacle.

Always disconnect supply before servicing.

# WARNING !

DANGER, risk of explosion if used in the presence of flammable anesthetics.

This device is neither approved nor certified for use in areas where combustible or explosive gas mixtures are likely.

# WARNING !

The use of this device requires continuous supervision of the infant by trained nursing personnel in order to ensure immediate corrective action in situations with a risk of patient injury.

Available option

Restrictions of Use

#### WARNING !

#### General information on electromagnetic compatibility (EMC) according to the international EMC standard IEC 60601-1-2

Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in the technical documentation available from DrägerService upon request.

Portable and mobile RF communications equipment can affect medical electrical equipment.



Pins of connectors identified with the ESD warning symbol shall not be touched and not be connected unless ESD precautionary procedures are used. Such precautionary procedures may include antistatic clothing and

shoes, the touch of a ground stud before and during connecting the pins or the use of electrically isolating and antistatic gloves. All staff involved in the above shall receive instruction in these procedures.

# What's What / Operating Concept

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Front View

# What's What

# **Front View**

- 1 Canopy (2M 51 108)
- 2 Access port
- 3 Front door
- 4 Transport handle
- 5 Bassinet frame
- 6 Drawer (2M 50 565)\*
- 7 Pedals for height adjustment\*
- 8 Height adjustable column\*/ bassinet mount
- 9 Connection for water heater (luer lock)\*
- **10** X-ray drawer / slide-out bed
- 11 Display
- 12 Control unit
- **13** Upright mounting support
- 14 Double wall\* (2M 51 150)



<sup>\*</sup> Available option

# Side View, Connections

- 1 Central alarm light
- 2 Sensor unit, temperature sensor connections
- 3 Line power connection
- 4 On/off switch
- 5 Air intake filter cover
- 6 O2 connection for O2 control\*
- 7 Water container (2M 50 040)\*
- 8 Twin access U-grommets (2M 50 385)
- 9 Side door
- **10** U-grommets (2M 50 412)
- **11** Feeding grommet, hood (2M 51 109)
- **12** Trolley castor with direction lock
- 13 Trolley castors with brakes



<sup>\*</sup> available option

# What's What

Top View

# **Top View**

- 1 Leveling guides
- 2 Heating air vents



# Connections\* on the back of the Control Unit

- 3 Nurse call
- 4 MEDIBUS\*
- 5 Service RSB (Remote Service Box)



<sup>\*</sup> Available option

#### Labels



# What's What

5



#### Caleo Infant Incubator

For detailed information, always refer to Caleo Operating Manual ! Before use, check device according to

Instructions in Operating Manual. Switch on device (rear side of mobile stand).

Select control mode by pressing button. Adjust settings with rotary dial knob. Confirm settings by pressing dial knob. See text messages in case of alarm.

#### DANGER!

Risk of explosion if used in the presence of flammable anesthetics.

#### WARNING - FIRE HAZARD!

Keep all sources of ignition out of the room in which the incubator is located. Higher risk of ignition and fire in air enriched with

All oxygen valves, connections and seals must be kept

free of oil and grease.

Open valves slowly. Do not use any electrical equipment inside the incubator other than equipment or instruments expressly designed and approved for use inside incubators.

#### WARNING!

Disconnect supply before servicing. Repairs on this equipment to be performed by DraegerService or factory trained and authorized personnel only.

#### CAUTION!

Opening of covers by DraegerService or factory trained and authorized personnel only.

To maintain grounding integrity connect only a 'hospital grade' power outlet.

Federal (US) Law restricts this device to sale by or on the order of a physician.

#### WARNING!

Danger of patient injury: never leave infant unattended when doors or handports are open.

#### WARNING!

Check infant temperature and skin condition at regular intervals and adjust temperature setting to individual patient needs.

Check incubator temperature, incubator function, and temperature sensor attachment at regular intervals. Improper attachment or location of the temperature sensor may cause cooling or overheating of the patient.

#### WARNING!

External radiant heat sources such as radiant heaters or sunlight may increase incubator air temperature above the set level

#### WARNING!

Never block or obstruct air vents! Risk of burning!

Dräger Medical, Inc. 3135 Quarry Road Telford, PA 18969



Labels

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Castor without brake function, page 47



Control Unit

# **Operating Concept**

# **Control Unit**

#### Hard keys (fixed function keys)

serve to allow the user to call various functions of the Caleo incubator:

- 1 Scale\*
- 2 Bed tilt
- 3 Menu list / configuration
- Toggle key: air/skin temperature control 4
- 5 Trend display
- 6 Audible alarm silence
- Keypad lock function 7
- 8 Rotary knob

#### Visual signals indicating alarm situations

- 9 Red bar LED\*\*
- 10 Yellow bar LED\*\*\*
- 11 Power failure alarm indicator



#### Soft keys (variable function keys)

guide the user through the unit's specific routines - from preparing for use to shutting down the incubator.

The active soft keys and their function change with the menu being used.

Only soft keys required for a currently active menu choice actually appear on screen. This helps to ensure that users don't become confused.

When a soft key is pressed, its function is activated and the relevant menu appears on screen.

In the standard screen, the soft key layout is as follows:

- 12 Air/skin temperature
- 13 Humidity\*
- 14 O2\*
- 15 Day and Night

#### Rotary knob

- for performing selections/settings with just one control.
- Turn rotary knob to select. •
- Press rotary knob to confirm selection. •



- Warning immediate action is required Caution rapid action is required
- \*\*\*

Operating Instructions Caleo, Software 2.n

Available option

Screen

# Screen

By default, incubator parameters are displayed as numerical values (standard screen).

- Setpoint and measured values for air temperature or skin temperature
- Setpoint and measured values for relative humidity\*
- Setpoint and measured values for O2 concentration\*
- Day and night (setting of screen brightness)
- Alarm and warning messages

The screen display can also include a trend graph.



<sup>\*</sup> Available option

# Preparation / Checking Readiness For Operation

Before Using Incubator For the First Time Installing Accessories

# Preparation

# Before Using Incubator For the First Time

- Check that all packaging materials have been removed completely.
- Check that line voltage matches that specification on rating plate (see page 25).
- Check that the elevation above sea level has been entered correctly for the location of the incubator (see page 106).

# **Installing Accessories**

#### CAUTION !

Always verify that monitor shelves and other accessories are securely attached.

Always observe the following limits:

# Maximum overall load must not exceed 66 kg (145.5 lbs) (see page 170).

For items attached to column on swivel shelves, do not exceed load of 3 kg (6.6 lbs).

#### When installing accessories, please note:

- Accessory equipment must not collide with the unit when adjusting tilt angle and height of Caleo.
- Accessory equipment on the handle side does not move with the main unit during height adjustment of Caleo (Handle side, see page 170).

#### Accessory poles

#### Screw on

pole 38 mm/600 (2M 50 691), or, alternatively pole 38 mm/310 (2M 50 688), or, alternatively pole 25 mm/600 (2M 50 689).

- Remove cover plate from the frame base.
- Screw pole fully into the frame base and tighten firmly. Check that it is securely held in position.

#### **CAUTION !**

#### Maximum loads for

- pole 38 mm/600 is 10 kg (22 lbs).
- pole 38 mm/310 is 10 kg (22 lbs).
- pole 25 mm/600 is 3 kg (6.6 lbs).

Max. distance between loads and pole: 150 mm (6 inches).



#### Moving the control unit to the opposite side

for 38 mm pole

- 1 Loosen clamping screw to remove control unit. (Support control unit to prevent it from dropping once clamping screw is loosened.)
- 2 Loosen clamping screw to remove holder.

Upon delivery, the control unit is attached to the 38 mm dia. tube of 310 mm length (38/310 pole).

This tube is secured for transport with a screw attachment. If required, the tube can be detached (recommendation: ask for assistance from qualified technical personnel):

Remove both caps from the tube. Insert a screwdriver into 3 the holes and release the tube.

To install control unit on the adjacent side:

- Slide holder over the other pole. •
- 2 Tighten clamping screw to fix holder in position.
- Set control unit to the desired working height •
- 1 Tighten clamping screw to secure control unit to the holder.

#### **CAUTION !**

When mounting control unit to its pole, ensure that there is sufficient space to swivel the control unit. (see "Tilting the bed", page 48).

#### Mounting the control unit on the handle side

#### **CAUTION !**

Only qualified technical personnel may move the control unit from the wall side to handle side or vice versa.

- Install basic pole (2M 50 680), see page 35.
- Screw in the extension pole 38/600 (2M 50 691) or . pole 38/310 (2M 50 688).
- Re-install the control unit as specified in the Assembly Instructions.

#### **CAUTION !**

Do not remove cable to the control unit from the cable guides on the basic pole.

Make sure there is sufficient space to swivel and tilt the unit.



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Installing Accessories

#### Infusion support attachment (2M 21 514)

for 38 mm pole

# CAUTION !

Maximum load per hook is 3 kg (6.6 lbs).

- Slide pole clamp of the IV support onto the pole.
- Push the IV support hook into the attachment clamp and secure by firmly tightening the clamp knob.



#### Swivel tray (2M 21 186)

for 38 mm pole for small items

#### **CAUTION !**

Maximum load for swivel tray is 3 kg (6.6 lbs). Ensure sufficient space for swiveling!

• Slide pole clamp of the swivel tray onto the base-mounted accessory pole and tighten clamp knob.



Installing Accessories

#### Compact mounting rail clamp (2M 85 337)

for 38 mm pole

#### CAUTION !

Maximum load for compact rail clamp is 5 kg (11 lbs).

# The compact mounting rail clamp may only be installed by qualified technical personnel.

For mounting such accessories as:

- O2 analyzer
- Adjust height of compact rail clamp to the required height of the accessories to be installed.
- 1 To attach compact rail to upright mounting support for accessories, slide over pole, and
- 2 secure with screws.



#### Base-mounted accessory pole (2M 50 680)

#### **CAUTION** !

Maximum load for base pole is 10 kg (22 lbs). Max. distance between loads and pole: 150 mm (6 inches).

# The base-mounted accessory pole may only be installed by qualified technical personnel.

• Mount as specified in the Installation Instructions.

For mounting such accessories as:

- additional pole extensions, see page 36,
- swivel table (2M 21 186), see page 34,
- monitor support shelf (2M 50 085), see page 37.



Installing Accessories

#### Instrument tray 3020 (M 24 678)

**CAUTION !** Maximum load for instrument tray is 2 kg (4.4 lbs).

• Hang tray from a standard (5 x 25 mm) rail on the wall or on the handle side and secure in position.



#### Pole extensions

The following poles can be attached to the base-mounted accessory pole as extensions:

- pole 38 mm/600 (2M 50 691) or
- pole 38 mm/310 (2M 50 688) or
- pole 25 mm/600 (2M 50 689).
- Screw pole into the base pole as far as it will go and tighten securely. Check that pole extension is securely held in place.

#### **CAUTION !**

Maximum loads for pole extensions

- 38 mm/600 is 5 kg (11 lbs).
- 38 mm/310 is 5 kg (11 lbs).
- 25 mm/600 is 3 kg (6.6 lbs).

Max. distance between loads and pole: 150 mm (6 inches).


### Monitor support shelf (2M 50 085)

The monitor shelf can be mounted on the wall side and/or the handle side.

### CAUTION !

Maximum load for monitor shelf is 20 kg (44 lbs).

**Do not exceed the maximum installation height.** Vertical distance between monitor shelf and stand must not exceed 20 cm (7.8 inches) on the wall side and 100 cm (39 inches) on the handle side (see page 170).

Shelf for monitor and ventilation equipment. The monitor support shelf may only be installed by qualified technical personnel.

Before attaching the monitor shelf:

- on the wall side, fit a second 38 mm pole (see page 32),
- on the handle side, fit a second base pole (see page 35) with a 38 mm pole extension (see page 36).
- Mount shelf as specified in its Installation Instructions.
- To attach monitor support shelf, slide shelf over both 38 mm poles and
- 1 secure in position with screws.

### Flexible ventilator circuit support arm (84 11 075)

- Open front door.
- Raise bed and pull it out of the incubator.
- Push mattress slightly to one side.
- Place the support arm in one of the mounting holes in the bed and fasten from underneath with its locking screw.
- Re-install the bed in the incubator and close front door.

**NOTE:** The circuit support arm may be installed in any of the four corners of the bed.

2 Clip ventilation circuits and cables into the clips at the end of the support arm.





### Preparing for O2 therapy with O2 control\*

- 1 Screw the O<sub>2</sub> high pressure supply hose into the port underneath the incubator. Make sure that it is securely tightened.
- 2 Connect quick connect probe to an outlet terminal of your medical gas pipeline O<sub>2</sub> supply. Use "standby position", if available (see respective Instructions for Use).

### **CAUTION !**

The permissible O2 inlet pressure is between 300 and 600 kPa (43.5 and 87 psi).



### O2 analyzer

For monitoring O<sub>2</sub> concentration inside the incubator, install an O<sub>2</sub> analyzer with alarm limits:

- Attach O2 analyzer to rail using the appropriate bracket.
- Place O<sub>2</sub> sensor capsule inside Caleo.
- Route sensor cable through one of the flexible hood grommets. Securely connect sensor plug to O<sub>2</sub> analyzer (see Instructions for Use of O<sub>2</sub> analyzer being used).



### Vacuum mattress (2M 17 909)

The contour of the vacuum mattress can be altered as required and is maintained after evacuation of the air inside.

This allows to obtain extreme positions for special applications. The mattress can remain in the incubator.

- Open front door.
- Insert and pre-form vacuum mattress.
- Place infant on mattress and shape mattress around desired infant position.
- Connect vacuum mattress to the vacuum supply hose of the suction equipment.
- 3 Open valve and evacuate vacuum mattress.
- 3 Close valve and disconnect hose.
- Close front door.



Available option

# Preparation

Installing Accessories

### Installing a drawer (2M 50 565)

### **CAUTION !**

Maximum load for drawer is 7 kg (15 lbs).

# The drawer may only be mounted by qualified technical personnel!

- Mount as specified in the Installation Instructions.
- To install, slide drawer box into the groove in the base frame.



# Use of Doors, Ports, and Bed Adjusting Mechanism

# WARNING !

Never leave infant unattended when access doors or access ports are open to avoid any risk of an infant falling out of an incubator.

### Access ports

To open access ports:

1 Press down the ribbed area of the lever: The access port opens.

To close access ports:

• Push access ports back into place until catch engages.

# WARNING !

Always ensure that access port catches are securely engaged in order to avoid any risk of an infant falling out of an incubator.



### Front door

To open front door:

2 Turn the two knobs inwards to the vertical position. The red catch will now be visible.



• Lower front door until it hangs down vertically towards the floor.

# WARNING !

When opening and closing front door, avoid pinching or jamming hoses and cables in the attached double wall.



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To close front door:

- Raise the front door and press into position,
- 1 Turn the two knobs outwards to the horizontal position until you feel them engage.

# WARNING !

Always ensure that both knobs of the large access doors are engaged in position in order to avoid any risk of an infant falling out of an incubator.

The red catch behind each knob must no longer be visible!



The attached double wall must be positioned parallel to the front door otherwise the ducted flow of warm air will be interrupted!

### Side door

• The side door is opened and closed in the same way as the large access doors (see page 40).

# WARNING !

When opening and closing side doors, avoid pinching or jamming hoses and cables in the attached double wall.

# WARNING !

Always ensure that both knobs of the side door are engaged in position in order to avoid any risk of an infant falling out of an incubator.

The red catch behind each knob must no longer be visible!



# Preparation

Use of Doors, Ports, and Bed Adjusting Mechanism

### Double wall\*

The double wall (2M 51 150) can only be fastened to the canopy (2M 51 108)!

Fitting the double wall:

- 1 Pull the pin up as far as it will go. The red section of the pin must be visible.
- Carefully place the double wall on the hood.



- 2 Position the centring sleeve lugs in the recesses of the hood.
- 3 Place the bore sleeve of the double wall assembly in the hole for the "feeding grommet" plug.
- Take care to assure a snug fit of the double wall seal with the contour of the hood.



Securing the double wall:

4 Push the pin down into the sleeve until it engages. The red section of the pin must no longer be visible.



Available option

Removing the double wall:

- 1 Pull the pin up as far as it will go. The red section of the pin must be visible.
- 2 Hold the double wall with both hands and lift it off.

Storing the double wall:

- Fix the holder (2M 51 152) to the compact rail of the Caleo.
- 3 Hook the double wall with the pin to the holder. Note the set height of the Caleo. Make sure that if the Caleo is lowered the double wall does not touch the floor.



### Canopy

To open the canopy:

- 4 Grasp handle on the canopy and
- 5 lift canopy upwards (approx. 60°).

**NOTE:** The canopy will only tilt back to a position where it is approximately upright. The hinges of the canopy will not allow it to tilt back beyond that point. Do not force the canopy further back than is required to engage the prop.



6 Raise canopy support prop, and lower canopy until prop is fixed in the slot of the canopy.

To close the canopy:

- 4 Grasp handle on the canopy and raise it slightly.
- 6 Fold down the prop and
- - close the canopy.

NOTE: The canopy can be opened from both sides.



# Preparation

To remove the canopy:

- 1 Grasp handles on the sides of the canopy with both hands.
- 2 Lift canopy horizontally off the supports.

Re-installing the canopy:

5 Place canopy horizontally, with the guide pins sliding into the holes in the canopy supports.

### **CAUTION !**

Always take care not to damage sensor unit inside the incubator when manipulating canopy !



# WARNING !

Always observe the maximum load of the infant bed (5 kg, 11 lbs).

• Open front door and fold it down.

Pull the bed out:

- 3 Turn both knobs to the vertical position marked  $\mathcal{C}_{+}$ ,
- 4 Pull bed out towards the front as far as it will go, using the recessed handle or the knobs.

# WARNING !

Never leave infant unattended when the bed has been pulled out to avoid any risk of an infant falling out of an incubator.

# WARNING !

Do not lean on the bed when it is pulled out. Equipment damage with risk of patient injury may result.

 Upon completion of infant care procedures, push the bed back in until it clicks into place. Turn knobs to the horizontal position marked in and close front door.

# WARNING !

Always ensure that the bed is pushed all the way in! Otherwise the ducted flow of warm air will be interrupted, and the infant may be warmed or cooled excessively.





### Using the x-ray drawer

**NOTE:** The x-ray drawer can be pulled out while the front door is either open or closed.

To open the x-ray drawer:

- 1 Turn both knobs to the horizontal position marked  $\dot{\boxtimes}$ ,
- 2 Pull drawer out by its recessed handle or by the knobs.
- Insert or remove the x-ray cassette.

**NOTE:** Recesses are provided in the x-ray drawer for positioning.

# WARNING !

Do not use the x-ray drawer as a writing support or as a bed for the infant. Risk of equipment damage or patient injury.

To close the x-ray drawer:

2 Push drawer inwards under the bed until you can feel it click into place.

# WARNING !

Always ensure that the x-ray drawer is pushed all the way in! Otherwise the ducted flow of warm air will be interrupted, and the infant may be warmed or cooled excessively.

### Incubator access grommets

- **3** Single U-grommet (2M 50 412)
- 4 Tubing grommet (2M 50 412) for high-frequency ventilation\*
- 5 Double U-grommets (2M 50 385)
- 6 Feeding grommet, hood (2M 51 109) can only be used if a double wall is not attached to the canopy.
- Route cables, hoses, or tubes through the flexible grommets.

To route ventilator circuits and cables through Caleo, use the ventilation circuit support arm (see page 37).





<sup>\*</sup> optional equipment feature

# Preparation

Use of Doors, Ports, and Bed Adjusting Mechanism

### Ventilation hose strain relieves\*

The ventilation hose strain relieves (2M 51 140) can only be attached to hose modules with pins (2M 51 139). Ventilation hose strain relieves act as guides for hoses and cables.



### Drainage module\*

The drainage module (2M 51 142) can only be mounted on the pillar elements (2M 51 154 and 2M 51 156). The drainage module can be used to fit hoses for draining off liquids.

- Open the side door.
- 1 Fit the hoses in the drainage module
- Close the side door.

# WARNING !

Make sure that the installed hoses are routed freely and safely.



### Drawer (2M 50 565)

Drawer for storing items required for nursing or treatment.

NOTE: The drawer is accessible from both sides.

To open the drawer:

- 2 Grasp drawer by its handle and pull it out as far as it will go.
- Place the required material in the drawer.

### To close the drawer:

2 Push drawer back in using the handle.



Available option

### Mobile stand with height adjustable column\*

- To use the height adjustment feature:
- Switch on Caleo (see page 64).
- 1 Press left pedal Caleo is lowered.
- 2 Press right pedal Caleo is raised.
- Adjust to a comfortable working height.
- When the height does not change any further, the end position has been reached. Release pedal.

### CAUTION !

Cables and hoses must be sufficiently long to avoid kinking, tear or pinching when adjusting the incubator height! Do not store anything underneath the drawer.

**NOTE:** Adjustment of height and tilt angle cannot be performed at the same time.

**NOTE:** The height adjustment is designed for intermittent duty (max. 6 minutes during one hour).

### Trolley castor with direction lock

• Activate the lock lever: the castor will be locked in the lengthwise direction (longitudinal axis of device).

#### **CAUTION !**

The castor with direction lock does not have a brake. To secure Caleo, apply the brakes on all 3 castors with brakes.

**NOTE:** The castor with direction lock is visually distinct from the castors with brakes.





# Preparation

Use of Doors, Ports, and Bed Adjusting Mechanism

### Tilting the bed



To tilt the bed:

- Switch Caleo ON (see page 64).
- 1 Press button and the bed will be lowered on the sensor unit side.
- 2 Press button and the bed will be raised on the sensor unit side.
- Adjust the bed to the required tilt angle.

When the tilt angle stops changing, the end position has been reached. Release button.



NOTE: The entire Caleo bassinet is tilted.

# WARNING !

Do not reach between incubator housing and housing support while tilting the bassinet. Risk of injury!

### **CAUTION** !

Cables and hoses must be carefully routed to avoid kinking, tear or pinching when adjusting the incubator tilt angle!

**NOTE:** Adjustment of height and tilt angle cannot be performed at the same time.

### Adjusting the bed to the horizontal position

- Caleo must be switched on (see page 64).
- 1 Press button to raise bed on the control unit side.
- 2 Press button to lower bed on the control unit side.

The levels will indicate whether the bed is horizontal.

- **3** Level showing the horizontal position of Caleo in the transverse axis.
- 4 Level showing the horizontal position of Caleo in the longitudinal axis. When using the integrated infant scale (available option, see "Integrated Infant Scale", page 112), make sure that the incubator unit is on a level floor before making adjustments.





# **Using Humidification Systems**

### Using the water reservoir (2M 50 040)

### **CAUTION !**

A Exclusively use sterilized distilled or demineralized water for humidifying the incubator!

# WARNING !

Do not use any additives for water intended for humidifying the incubator.

### Water tank (2M 50 040):

- Disinfect hands.
- Open the water tank = lift up the cap.
- Fill the water tank with demineralized water (Aqua dest.). Always fill the water tank to the full level marking. Capacity: 2.8 L
   Do not use any additives!
- Close water tank = push down the cap.
- Prepare a fresh transfer set (MX 17 018).
- Close the clamp on the transfer set.
- Pierce the silicone nozzle of the water tank with the pin of the transfer set.
- Open the clamp on the transfer set.
- Bleed the transfer set (let sterilised water drain off).
- Close the clamp on the transfer set.
- Open the clamp on the transfer set.
- Switch on the humidification module on Caleo<sup>®</sup> and set the humidity value (page 59).
- Water tank empty = Water shortage alarm is triggered on Caleo<sup>®</sup>.

### Minimum water quality requirements

To avoid impairment of function and long-term material damages, please use only water with the following minimum quality for humidication:

- Demineralized water (e.g. Aqua dest.) or
- Demineralized water with a conductivity <20 µS/cm</li>

Do not use any mineral-containing water, e.g. tap water.

### Water heater

The water heater does not have any components that must be dismantled for the preparation.

Execute the Cleaning Mode after each change of patient. While preparing the interior of the incubator, ensure that no liquids such as detergents penetrate into the water heater.



Using Humidification Systems

### Using a water bag

### CAUTION !

 $\underline{\wedge}$  Exclusively use sterilized distilled or demineralized water for humidifying the incubator!

# WARNING !

Use only authentic, originally sealed OEM bags containing sterilized distilled or demineralized water. Do not use any additives for water intended for humidifying the incubator.

Do not use infusion solution bag for the humidification system.

- Disinfect hands.
- Prepare a new transfer set (MX 17 018) and a water bag with distilled water (e.g. Aqua dest.).
- Close the clamp on the transfer set.
- Insert the pin of the transfer set into the connector of the water bag.
- Open the clamp on the transfer set.
- Bleed the transfer set (let sterilized water drain off).
- Close the clamp on the transfer set.
- Open the clamp on the transfer set.
- Switch on the humidification module on Caleo<sup>®</sup> and set the humidity value (page 59).

Replacing the water bag:

Water bag empty = Water shortage alarm is triggered on  $Caleo^{\circledast}$ .

- Disinfect hands.
- Close the clamp on the transfer set.
- Replace the water bag and reopen the clamp.

Integrated power strip

### Integrated power strip

The integrated power outlet strip can be used to connect

- infusion pumps and
- SpO2 measuring equipment

as well as other equipment.

# WARNING !

Output of the integrated power strip is not monitored! Do not connect life support devices which do not have their own power failure alarm.

 $\underline{\wedge}$  Do not exceed the maximum permissible power input for connected accessories

(all 4 sockets together: max. 2 A).

Do not exceed the maximum permissible total leakage current. For the leakage current of Caleo without socket strip see "Technical Data", page 166.



Connecting the nurse call

### Connecting the nurse call\*

Connection on the rear panel of the control unit intended for the transmission of alarm signals to a central hospital alarm system.

### WARNING!

Installation of the nurse call kit should only be performed by DrägerService or factory trained and authorized service personnel.

- For details of the characteristics, refer to the Technical Data, page 169.
- The 6-pin round DIN plug (female connector) must be connected to the lead for the central alarm station in the hospital by a specialist.

Connection 3 to 5 will be closed and the nurse call is activated in the event of an alarm with a high risk potential or if there is a serious equipment fault.

### WARNING!

Connect nurse call to a central hospital alarm system only while Caleo is properly grounded via its power cable and a grounded wall outlet or via the grounding pin on the rear panel of the control unit.

Otherwise, the risk of electric shock cannot be safely excluded.

- 1 Connect plug to the receptacle marked » 🗍 « on the rear panel of the control unit and secure with screws.
- Take care to route the connection cable so that damage does not occur.
- Ensure that the connector plug cannot be pulled out accidentally.
- Check correct operation of connected nurse call system.

### WARNING!

Only alarm messages with a high risk potential or serious equipment faults are transmitted via nurse call.

- Warning messages\*\* are displayed in the top line of the screen.
- Caution\*\* and advisory messages\*\* are not transmitted.
- A power failure will not be reported by nurse call. Use a separate system to monitor the power supply.
- The nurse call is activated also when the original enunciator in the device is faulty.



<sup>\*\*</sup> See "Alarm Description", page 161



### Preparation

MEDIBUS interface

### WARNING!

Connection of a nurse call does not relieve staff of their duty to check patient data at regular intervals.

• Screen displays must be checked regularly.

### WARNING!

A fault in any of the components in the link between nurse call and central hospital alarm system (e.g. in the electronics for nurse call in Caleo, in the Caleo power supply, or in the enunciator of the central hospital alarm system, etc.) may result in failure of the nurse call.

The hospital connections to the central alarm typically use only one channel. The electronics for nurse call consequently also use only one channel.

### **MEDIBUS** interface\*

# WARNING!

The system must meet the requirements about medical electrical equipment in accordance to IEC/EN 60601-1-1 and IEC/EN 60601-1-2.

Serial interface for connecting up to medical devices which comply with IEC/EN 60601-1, for transmitting the incubator status data (actual values, set values, alarms). For details of the characteristics, refer to the Technical Data, page 168.

### WARNING!

Connect external devices to the interfaces only while Caleo is properly grounded via its power cable and a grounded wall outlet or via the grounding pin on the rear panel of the control unit.

Otherwise, the risk of electric shock cannot be safely excluded.

- 1 Connect plug to the receptacle marked »Medibus« on the rear panel of the control unit and secure with screws.
- Take care to route the connection cable so that damage does not occur.
- Ensure that the connector plug cannot be pulled out accidentally.

### WARNING!

All data that are transmitted via medical devices are for information only and should not be used as the sole basis for clinical decisions.



\* Available option

Before Using For the First Time Before Each Use

# **Checking Readiness For Operation**

# **Before Using For the First Time**

- Check that line voltage corresponds with the specification on the rating plate.
- Check that the elevation above sea level has been entered correctly for the location of the incubator (see page 106).

# **Before Each Use**

- Check that the equipment has been disinfected according to an approved hospital protocol.
- Check that an adequate gas supply is available for all equipment to be used.
- Check that all accessories and auxiliary therapy equipment required are at hand and in proper working condition.
   Only use components that have been properly processed.
   Check readiness for operation of auxiliary devices in accordance with their respective Operating Instructions.
- Check that there are no cracks or sharp, chipped edges on the incubator canopy.
- Check that the hinges and catches on the canopy are in proper working order.
- Check that cables and hoses have been routed correctly and safely.
- If the control unit is mounted on the handle side, check that the cable to the control unit is routed through the cable guides on the basic pole.
- Check that there is sufficient clearance for adjusting tilt and height of the incubator bassinet.
- Connect to line power supply.
- Check the nurse call system\* prior to each use. Trigger an appropriate alarm, e.g. switch Caleo to skin temperature mode and remove the skin temperature sensors. If the nurse call system does not sound an alarm, take unit out of service.
- Check that the openings in the sensor unit are not clogged with dirt.

# WARNING !

Do not use a power outlet strip for supplying power to the Caleo incubator!

Connecting the incubator via a power outlet strip may, in case of failure of the protective earth conductor, cause patient leakage currents to rise above permitted limits with a risk of electric shock to the patient.

Available option

Before Each Use

### Before using the unit, make sure that the following tests as well as the checks described under "Before Reusing With a Patient", page 129, have been performed:

Disinfect hands before each test!

### Check that access ports latch securely

- Perform this test on all 4 access ports
- 1 Press down the ribbed area of the lever to open access port.
- Close access port until lever engages in the locked position.
- Try to open the access port by pulling it outwards by its edge – it must not open.

If access port does not remain securely closed:

• Take unit out of service.



### Check that large access doors latch securely

- Perform this test on both doors
- Open door slightly.
- 2 Then, push door back into its closed position. Turn the two knobs outwards until they engage in the horizontal position.

# WARNING !

Always ensure that both knobs are engaged in position in order to avoid any risk of an infant falling out of an incubator.

The red catch behind each knob must no longer be visible!

# WARNING !

The attached double wall must be positioned parallel to the front door otherwise the ducted flow of warm air will be interrupted!

If the front door fails to remain engaged or if the red marking is visible or the double wall cannot be moved:

• Take unit out of service.



Before Each Use

### Check that the side door latches securely

- Perform this test on both side doors
- Open side door slightly.
- 1 Then, push door back into its closed position. Turn the two knobs outwards until they tangibly engage in the horizontal position.

# WARNING !

Always ensure that both knobs are engaged in position in order to avoid any risk of an infant falling out of an incubator.

The red catch behind each knob must no longer be visible!

If a side door fails to remain engaged or if the red marking remains visible:

• Take unit out of service.

# 

### Check that the double wall is firmly seated

2 Check that the double wall is securely attached to the hood. It should not move when slightly pushed.

If the double wall is not securely attached to the hood or the double wall or parts of the locking mechanism are damaged:

- Do not use the double wall.
- Take unit out of service.



### Check the bed tilting mechanism

3 Tilt the bed.

During the tilting process, the entire housing of the Caleo must move smoothly. Otherwise:

• Take unit out of service.

# WARNING !

Do not reach between incubator housing and housing support while tilting the bassinet. Risk of injury!

4 Return bed to a horizontal position (see page 48).



Before Each Use

• The levels in the bed indicate whether the bed is in a horizontal position. This is important when using the integrated infant scale (see page 112).

If the levels are damaged:

• Take unit out of service.



### Check the height adjustment mechanism\*

- Press both foot pedals in succession to raise and lower Caleo (see page 47).
- After the test, adjust to a comfortable working height.

When adjusting the height, the entire Caleo bassinet must lift up and down smoothly, otherwise:

• Take unit out of service.



### Check line power failure alarm

- Disconnect unit from line power.
- 1 The power failure LED should start blinking.

An intermittent audible alarm should start. Its volume must remain constant for at least 30 seconds.

If the volume decreases too soon:

- Leave incubator connected to power and switched on for 24 hours to recharge the NiCd battery of the power failure alarm.
- Repeat check.

If the volume decreases again too soon:

• Take unit out of service.



<sup>\*</sup> Available option

# Checking Readiness For Operation

Before Each Use

### Start self test, check all displays and sound.

- 1 To switch unit on, press the on/off switch until it engages.
- The incubator performs a self test.

It is the responsibility of the operator to verify screen displays, LEDs, and audible alarms (enunciator and tone sequence).

 The incubator will sound both an enunciator signal and alarm tone sequence.

If one of the audible alarms does not sound:

• Take unit out of service.



- Initially, screen and LEDs are dark, then illuminated.

If individual pixels on the screen or LEDs appear to be failing or images are "burnt" into the screen:

- Take unit out of service.
- The opening screen is displayed.

If no opening screen appears on the display:

• Take unit out of service.

The unit is now switched on.



# WARNING!

The Caleo incubator is ready for operation only when all checks have been performed successfully.

# Operation

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Precautions During Infant Care

# Operation

# **Precautions During Infant Care**

Before each use, check that the unit is ready for operation (see page 54, page 129).

# WARNING !

Make sure that all hoses and cables are routed correctly and safely without obstruction! Otherwise: Risk of extubation! Danger of disconnection!

# WARNING !

Never leave infant unattended when the canopy, double wall, front door, or access ports are open, when the bed has been pulled out, or when access grommets have been removed. Risk of patient injury.

Under these conditions, watch patient carefully to prevent any possibility of an infant falling out of the incubator.

Active infants must be observed with particular care.

# WARNING !

Always observe the maximum load of the patient bed (5 kg, 11 lbs).

Do not lean on or apply weight to the bed when it has been pulled out.

Do not use the x-ray drawer as writing support or bed for the infant.

Always allow sufficient time for incubator to warm up to the required temperature before use (see page 167).

# WARNING !

Avoid additional external heat sources, such as direct sunlight, spot lamps, and electric pads or blankets. They cause the air temperature inside the incubator to increase in an uncontrolled fashion.

# WARNING !

The infant's central temperature must be regularly monitored with an independent thermometer.

# WARNING !

It is the responsibility of the attending physicians to draw conclusions from the measured skin temperature.

# WARNING !

Do not use skin temperature control mode for infants in shock, as their skin temperature is much lower than normal. Skin temperature control would increase the incubator air temperature too much, resulting in the risk of overheating the infant.

We recommend operating the Caleo incubator in air temperature control mode when caring for patients with such conditions – see page 65.

# WARNING !

Do not use skin temperature control mode for infants with a fever, since their skin temperature is much higher than normal. Using skin temperature control would reduce the incubator air temperature too much, resulting in the risk of hypothermia.

# WARNING !

Skin temperature control mode must not be used on twins, since Caleo controls only the temperature for one infant. Risk of hypothermia or overheating. Always use air temperature control mode when caring for twins.

# WARNING !

Do not confuse skin sensor probe positions on the infant's body! The yellow skin temperature sensor (T1) is used for skin temperature control. Inappropriate positioning of this sensor could lead to overheating of the infant.

# WARNING !

Do not place any blankets or sheets over the hot air vent. The temperature control system would be disrupted, causing a risk of overheating or burn if air from the hot air vent is channeled directly to the infant.

### **CAUTION !**

The castor with direction lock does not have a brake. To secure Caleo, apply the brakes on all 3 castors with brakes.

### CAUTION !

To avoid bacterial contamination when reaching through the access ports into the patient capsule of Caleo, observe suitable hygiene measures and, if possible, do not touch the surface of the patient capsule.

# WARNING !

During a power failure, the lack of fresh air supply may cause an elevated CO<sub>2</sub> concentration inside the patient capsule. Risk of CO<sub>2</sub> poisoning.

The central alarm LED may be disabled in the system configuration. Always check bar LEDs on control unit, and the audible alarm.

When treating larger babies, their higher caloric output may cause the air temperature in the Caleo incubator to rise. In this case, the double wall should be removed.

# WARNING !

### Beware of cross-infections when treating twins!

**NOTE:** For proper temperature control of the incubator, room temperature must be at least 3 <sup>o</sup>C lower than the air temperature set for the incubator.

### Oxygen therapy

### WARNING !

Fire hazards from oxygen !

- No open flames or cigarettes ! Textiles, plastics, and oils readily ignite in an oxygen enriched atmosphere and burn with great intensity.
- Keep oxygen valves, connections, and seals free from oil and grease.
- Open valves on O2 cylinders slowly.
- Do not operate Caleo in the presence of flammable anesthetics or disinfectants. Risk of explosion!
- Do not use or store flammable liquids such as alcohol, ether, or acetone inside the Caleo incubator.
- Do not use electrical equipment inside the patient capsule unless this equipment is expressly designed for use in environments that present an explosion hazard.

### WARNING !

Due to the physiological risks from O<sub>2</sub>, it is mandatory to monitor O<sub>2</sub> concentrations continuously during the administration of O<sub>2</sub>, either using the integrated O<sub>2</sub> measurement and control system or an independent O<sub>2</sub> analyzer.

### WARNING !

Always take into consideration the physiological risks from the administration of oxygen.

Elevated oxygen concentrations inside the incubator may only be used by or on the order of a physician. Oxygen is classed as a drug.

It is absolutely essential that such oxygen therapy be selected and controlled on the basis of the arterially measured oxygen partial pressure in the infant's blood (SaO<sub>2</sub> or SpO<sub>2</sub>). This is the only way to minimize the risk of both hyperoxemia (with potential for damage to the eyes by retrolental fibroplasia) and hypoxemia (which might contribute to intraventricular hemorrhage and damage to the infant's brain).

### WARNING !

Medicated aerosols and similar substances must not be nebulized in the infant capsule.

The mist of nebulized substances may impair the proper function of the incubator.

### CAUTION!

Never cover the sensor unit or hang anything from the slits in the sensor unit. Keep slits in the sensor unit free from dirt.

### Doors

When closing the doors, make sure that the patient is not lying in the closing path.

# The doors are not properly shut until the red catches behind the knobs are no longer visible!

When opening and closing the doors, make sure that the hoses and cables are not caught in the moving double wall! The attached double wall must be positioned parallel to the front door otherwise the ducted flow of warm air will be interrupted!

### Side doors

When opening and closing the side access doors, make sure that the hoses and cables are routed safely and clear of any obstructions.

The side access doors are only properly shut when the red catches behind the release knobs are no longer visible.

### Canopy

The canopy must not be used as a shelf for placing clothing, instruments etc..

Do not hang any objects from the hooks for the double walls. Before moving the canopy, make sure that nothing has been laid on top of it.

When fitting and removing the incubator hood canopy, hold it firmly in your hand.

The canopy installation catch must engage correctly.

Do not try to lift the canopy when catch is engaged.

Do not tilt the canopy forwards.

When closed, make sure that the canopy sits firmly in place!

### **Control unit**

Position the control unit so that its screen is clearly visible from the working area.

Do not mechanically load the cable by, for example, hanging items from it.

If the control unit is mounted on the handle side, never remove the cable from the cable guides on the basic pole.

Do not place any liquid containers above the control unit.

### CAUTION !

### When fitting accessories, please note:

- The accessory equipment must not collide with the unit when adjusting the tilt angle and height of Caleo.
- The accessory equipment on the handle side will not move with the main unit during height adjustment of Caleo (page 169).

Always observe maximum loads to avoid danger of unit tipping over.

### Kangaroo Mode

# WARNING !

When using Kangaroo Mode, central temperature of the infant, who is outside the controlled climate of the incubator, must be monitored constantly.

Particular attention must be paid to critical care patients' vital parameters, especially a critical O<sub>2</sub> partial pressure. Ensure that all cables and hoses are routed correctly and safely.

When using phototherapy

### WARNING !

Infant temperature must be monitored with particular care during phototherapy. Absorption of light through the infant's skin will supply heat to the patient which may increase central temperature. For this reason:

- Decrease temperature setting for incubator air by approximately 2 °C at least 15 minutes before starting phototherapy.
- Lower humidity setpoint.
- Room temperature must be at least 3 °C lower than the Caleo air temperature.

This value applies for Dräger Model 4000 phototherapy units.

 The temperature of the incubator air may rise even more noticeably when using other phototherapy units, especially units without built-in fan.

### CAUTION !

Only use phototherapy units supplied with their own stand. Do not place phototherapy devices directly on Caleo canopy, as they may slip when the bed tilt is activated.

# WARNING !

During phototherapy, the supply of fluids to the infant must be increased, e.g. by parenteral infusion, to compensate for the increased water loss.

# WARNING !

Never cover phototherapy lamp or incubator canopy with the intention to boost the phototherapeutic effect. A heat build-up will likely result with the danger of overheating the infant, because the incubator cannot be adequately cooled with ambient air under these conditions.

# WARNING !

Always use eye protection for the infant when using phototherapy.

Tilting/height adjustment

# WARNING !

Ensure that the ventilator circuit and all other cables, hoses and tubing are routed correctly and safely. Danger of extubation and disconnection! Hoses and/or cables are at risk of being trapped when

tilting the Caleo, adjusting the height, and when opening and closing the front door.

### Weighing scale

Only use the built-in infant scale to determine patient weight. Failure to observe Instructions for Use of the scale (see page 112) may cause considerable measuring errors when determining patient weight. Consequently, to make sure that critical therapeutic decisions are based on correct patient weight, the weight indicated by the integrated scale must be checked against a reference measurement performed on an external scale.

#### In-house transport

### CAUTION !

Use caution when moving the incubator over uneven surfaces, e.g. rough pavement outside the hospital or into an elevator, as castors may become damaged or dislodged.

### High noise levels

Excessive noise levels that can disturb the patient may be caused by:

- using O2 head boxes and delivering pressurized gases,
- wear on the bearings of the fan motor,
- placing objects on the canopy.
- Observe the specified maintenance intervals see page 136.

#### **Cleaning mode**

### WARNING !

Cleaning mode may only be used while Caleo is not occupied by a patient.

After use, allow Caleo to cool down before dismantling. Risk of burns when touching the heater!

During or after cleaning mode, condensation could form under the aggregate housing of the Caleo!

Electrical safety

### WARNING !

Caleo is to be used only in rooms with line power installations that comply with national safety standards for hospital patient rooms (e.g., IEC/EN 60601-1 "Medical Electrical Equipment - General Requirements For Safety").

To maintain grounding integrity, connect only to a "hospital grade" receptacle.

Always disconnect supply before servicing.

### WARNING !

Do not use a power outlet strip for supplying power to the Caleo incubator!

Connecting the incubator via a power outlet strip may, in case of failure of the protective earth conductor, cause patient leakage currents to rise above permitted limits with a risk of electric shock to the patient.

### WARNING !

Only use auxiliary electromedical equipment which complies with national safety standards for hospital patient rooms (e.g., IEC/EN 60601-1 "Medical Electrical Equipment - General Requirements For Safety", UL 544). When using the integrated power strip to connect auxiliary devices, always observe total leakage current and current consumption limits! (See "Technical Data", page 166.)

### WARNING!

Connect external devices to the interfaces only while Caleo is properly grounded via its power cable and a grounded wall outlet or via the grounding pin on the rear panel of the control unit.

Otherwise, the risk of electric shock cannot be safely excluded.

### WARNING !

The output of the integrated power strip is not monitored! Do not connect life support devices which do not have their own power failure alarm.

# Operation

Switching Caleo On

# Switching Caleo On

- Connect unit to line power.
- 1 To switch unit on, press the on/off switch until it engages.
- 2 Position control unit so that its screen is clearly visible from the working area.



An audible alarm is emitted.

- The opening screen is displayed.

The incubator performs a self-test.

It is the responsibility of the operator to verify screen displays, LEDs, and audible alarm (see page 58).



- After the self-test, the standard screen for air temperature control is displayed.
- The currently activated function is always highlighted by a light background.

**NOTE:** In air temperature control mode, the unit takes 20 minutes to warm up. During this period, the alarm for "Air temp. deviation above 1.5 °C" is suppressed.



# Operation

### **Using Air Temperature Control**

### WARNING !

Regularly measure infant temperature! Do not leave canopy open for any length of time, otherwise the air temperature inside the incubator will drop.

### Adjusting air temperature setpoint

Standard setpoint range	28 °C to 37 °C
Extended selpoint range	20 °C to 27.9 °C
Default setpoint	33 °C

1 To adjust setpoint, press key.



- The current (measured) value and setpoint appear on screen both as bar graphs and numerical values.
- The message »set value with rotary knob« appears at the top of the screen.
- 2 Turn rotary knob clockwise to increase setpoint.
- 2 Turn rotary knob counterclockwise to decrease setpoint.
- **2** Press rotary knob to confirm new setting.

If you do not wish to change the settings:

Or

 Wait for 7 seconds: Caleo emits 4 short beeps to prompt the user to press the rotary knob. The display will immediately return to the standard screen. The previous setpoint will be retained.



### Using the extended air temperature setpoint range

If the standard setpoint range is exceeded:

- The advisory message »confirm extended range with rotary knob« will appear at the top of the screen.
- Press rotary knob to activate extended range.
- Turn rotary knob clockwise to increase setpoint further.

# WARNING !

When the extended setpoint range for air temperature is used, the infant's temperature must be continuously monitored.



- The advisory message » $\triangle$  >37.0 °C« appears on screen.
- The following message appears at the top of the screen: »set value with rotary knob«
- Press rotary knob to confirm the new setpoint.
- The display returns to the standard screen. The measured values are displayed.
- − The setpoint value and »set: >37.0 A « are displayed alternately.
- The yellow bar LED lights up.
- If the yellow bar LED starts flashing, the setpoint has been increased by more than 1.5 °C (see page 68), or other alarms are active.



If the specified setpoint is below the standard setpoint range:

- The advisory message »confirm extended range with rotary knob« appears on screen.
- Press rotary knob to activate extended range.
- Turn rotary knob counterclockwise to decrease set value further.



- The advisory message » $\Lambda$  <28.0 °C« appears on screen.
- The following message appears at the top of the screen »set value with rotary knob«.
- Press rotary knob to confirm new setpoint.



- The display returns to the standard screen. The measured values are displayed.
- The set value and »set: <28.0 ▲« are displayed alternately.</li>
- The yellow bar LED lights up.
  If the yellow bar LED starts flashing, the setpoint has been reduced by more than 1.5 °C or 2.5 °C (see page 68), or other alarms are active.



# Operation

Using Air Temperature Control

### Reducing air temperature inside the incubator

The cooling rate is determined by the incubator design and can be increased by

- removing the double wall,
- reducing the outside temperature (if possible),
- reducing the humidity setpoint, and
- partially or completely removing incubator canopy if used.

**NOTE:** Cooling is not accelerated by reducing the required air temperature below the value actually intended.

In case of an **urgent** need for cooling: Open canopy, large access doors, side doors, or access ports.

# WARNING !

Monitor infant constantly when canopy, doors, or access ports are open, to ensure infant cannot fall out of the incubator.

If you do not wish to activate the new setpoint:

1 Press button to cancel adjustment of the new setpoint.

The screen returns to the standard display mode and the former setpoint is retained.

Or

 Wait for 7 seconds: Caleo emits 4 short beeps to prompt the user to press the rotary knob. The display will immediately return to the standard screen. The previous setpoint will be retained.



### Alarms

Alarm limits can be changed in the configuration (see page 108).

If the deviation between set and measured air temperature values exceeds  $1.5 \, {}^{o}C^{*}$ :

- On screen, a warning message appears:
  »Air temp. deviation above 1.5 °C«
- an intermittent audible alarm (3 beeps) sounds
- 2 The central alarm indicator lights up\*\*.



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- \* The *numerical values* in this description are examples, see "Configuring alarm settings", page 107.
- \*\* The central alarm indicator light may be switched off. See "Configuring system settings", page 106

- 1 The measured value starts flashing.
- **2** The yellow bar LED starts blinking.

The intermittent audible alarm can be silenced for 15 minutes.

- 3 To silence audible alarm, press key,
- or
- 4 press rotary knob.
- The warning message remains on the screen,
- The intermittent alarm tone is muted,
- The central alarm indicator goes out,
- 1 The measured value continues to flash,
- 2 The yellow bar LED continues to flash.

When the measured value returns within the range  $\pm 1.5$  °C:

- The warning message disappears.
- The intermittent alarm tone is muted.
- The central alarm light goes out.
- 1 The measured value remains on-screen, without flashing.
- 2 The yellow bar LED goes out. If you are working in the extended setpoint range, the yellow bar LED will remain continuously lit.

In case air temperature is over 38  $^{\circ}$ C (or over 40  $^{\circ}$ C when using the extended setpoint range):

- The screen displays the warning message: »Air temperature too high«,
- An intermittent audible alarm sequence (5 beeps) sounds,
- The central alarm light is lit\*,
- 1 The measured value starts flashing,
- 5 The red bar LED starts blinking.

The audible alarm can be silenced for 5 minutes. Caleo heats up if necessary to reach the specified interior air temperature setting.

- 1 The measured value continues to flash,
- 5 The red bar LED continues to flash.

When the air temperature drops below the alarm threshold: **3** Press key and the alarm is cancelled.

For other alarms, see "Troubleshooting", page 142. See also "Alarm Description", page 161.





Using Skin Temperature Measurement

# **Using Skin Temperature Measurement**

### Checking proper function of the temperature sensors

Immediately before using the yellow skin temperature sensor or the white peripheral sensor, insert it into the yellow or white socket, respectively, and wait for a measurement signal to appear on screen.

- 1 Measurement signal from the yellow skin temperature sensor (T1)
- 2 Measurement signal from the white peripheral temperature sensor (T2)

If no measurement signal appears, the respective sensor must be replaced (page 145).

# Using skin temperature measurement in air or skin temperature control modes.

Connect the temperature sensors for measuring skin and peripheral temperature:

• Push **yellow** skin temperature connector into **yellow** socket on the sensor unit (T1, skin or "tummy" temperature) as far as it will go.

**NOTE:** When using skin temperature control mode, the servo control is performed with reference to this sensor.

- Push white peripheral temperature sensor connector into the white socket on the sensor unit (T2, peripheral or "toe" temperature, or when using air temperature control mode for twins, the skin temperature of the second infant).
- Route sensor cable through one of the flexible U-grommets.
- Remove protective foil from the adhesive pad and place skin temperature sensor on the pad.
- Using the adhesive pad, attach sensor tip to the appropriate part of the infant's skin.

Positioning the skin temperature sensor (yellow):

If the infant is lying on his/her back:

• With its adhesive pad, attach yellow sensor to the abdomen, near the liver.

If the infant is lying on his/her belly:

• Attach yellow sensor with its adhesive pad to the back, preferably near the kidneys.





Positioning the peripheral temperature sensor (white):

• With its adhesive pad, attach white sensor to the extremities, preferably the foot or arm.

Use only Dräger sensors or sensors authorized by Dräger for use with Caleo.

# WARNING !

Always verify that temperature sensors are specified and approved for use with Dräger Caleo.

Disposable sensors must not be cleaned for re-use. If used more than once, the necessary measurement precision cannot be guaranteed.

To attach temperature sensors to the patient, use only ThermoPad<sup>™</sup> adhesive pads or similar adhesive pads with aluminum film.

### WARNING !

Do not use skin temperature sensor (yellow) or peripheral temperature sensor (white) to measure rectal (central) temperature!

Do not locate sensor under the infant, otherwise measurement and control would be performed with reference to infant central temperature instead of skin temperature.

# WARNING !

Regularly check that skin temperature sensor is properly attached to the infant's skin! A skin temperature probe that has fallen off would be measuring air temperature with a risk of overheating the infant (although the air temperature would not rise above 39  $^{\circ}$ C).

**NOTE:** When a skin temperature sensor is attached, measured skin temperature is displayed even when "air temperature control" is the active mode. However, incubator temperature is not controlled as a function of skin temperature in this case.

# Switching Between Air and Skin Temperature Control

### WARNING !

Do not use skin temperature control mode for infants in shock, as their skin temperature is much lower than normal. Skin temperature control would increase the incubator air temperature too much, resulting in the risk of overheating the infant.

We recommend operating the Caleo incubator in air temperature control mode when caring for patients with such conditions – see page 65.

### WARNING !

Do not use skin temperature control mode for infants with a fever, since their skin temperature is much higher than normal. Using skin temperature control would reduce the incubator air temperature too much, resulting in the risk of hypothermia.

### WARNING !

Skin temperature control mode must not be used on twins, since Caleo controls only the temperature for one infant. Risk of hypothermia or overheating. Always use air temperature control mode when caring for twins.

# WARNING !

Do not confuse skin sensor probe positions on the infant's body! The yellow skin temperature sensor (T1) is used for skin temperature control. Inappropriate positioning of this sensor could lead to overheating of the infant.

# WARNING !

Regularly measure infant temperature! Do not leave canopy open for any length of time, otherwise the air temperature inside the incubator will drop.

# WARNING !

Regularly check that skin temperature sensor is properly attached to the infant's skin! A skin temperature probe that has fallen off would be measuring air temperature with a risk of overheating the infant (although the air temperature would not rise above 39 °C).
- 1 Press key to change temperature control mode.
- 1 The LED for the control mode will start blinking, thereby requesting confirmation of the mode change.



- The activated control mode is displayed on screen.
  Actual, measured value, and setpoint are displayed as bar graphs and numeric values.
- The upper part of the screen displays the message: »set value with rotary knob«.



Switching Between Air and Skin Temperature Control

After the new mode has been activated, you can set the desired value with the rotary knob.

- 1 The LED of the activated mode will start blinking.
- 2 Turn rotary knob to adjust setpoint.
- 2 Press rotary knob to confirm the new setpoint.



- The upper part of the screen displays the advisory message:
  »confirm new mode with rotary knob«.
- 2 Press rotary knob to confirm the new mode.



- The display returns to the standard screen.
- 1 The LED of the activated mode is now continuously lit.



If you do not wish to change the settings:

• Press and the new settings will be cancelled. The display returns to the standard screen. The previous setpoint is retained.

Or

 Wait for 7 seconds: Caleo emits 4 short beeps to prompt the user to press the rotary knob. The display will immediately return to the standard screen. The previous setpoint will be retained. Operating Instructions Caleo, Software 2.n

### **Using Skin Temperature Control**

### WARNING !

Do not use skin temperature control mode for infants in shock, as their skin temperature is much lower than normal. Skin temperature control would increase the incubator air temperature too much, resulting in the risk of overheating the infant.

We recommend operating the Caleo incubator in air temperature control mode when caring for patients with such conditions – see page 65.

### WARNING !

Do not use skin temperature control mode for infants with a fever, since their skin temperature is much higher than normal. Using skin temperature control would reduce the incubator air temperature too much, resulting in the risk of hypothermia.

### WARNING !

Skin temperature control mode must not be used on twins, since Caleo controls only the temperature for one infant. Risk of hypothermia or overheating. Always use air temperature control mode when caring for twins.

## WARNING !

Do not confuse skin sensor probe positions on the infant's body! The yellow skin temperature sensor (T1) is used for skin temperature control. Inappropriate positioning of this sensor could lead to overheating of the infant.

### WARNING !

Regularly measure infant temperature! Do not leave canopy open for any length of time, otherwise the air temperature inside the incubator will drop.

### WARNING !

Regularly check that skin temperature sensor is properly attached to the infant's skin! A skin temperature probe that has fallen off would be measuring air temperature with a risk of overheating the infant (although the air temperature would not rise above 39 °C).

Using Skin Temperature Control

### Adjusting the setpoint

Standard setpoint range	34 °C to 37 °C
Extended setpoint range	37.1 °C to 38 °C
Default setting	36.5 °C





- The actual measured value and setpoint are displayed on screen both as bar graphs and as numerical values.
- The following message is displayed in the top part of the screen:





- 1 Turn rotary knob clockwise to increase setpoint.
- 1 Turn rotary knob counterclockwise to decrease setpoint.
- 1 Press rotary knob to confirm the new setting.

If you do not wish to change the settings:

2 Press ← and the new settings will be cancelled. The display returns to the standard screen. The previous setpoint is retained.

Or

 Wait for 7 seconds: Caleo emits 4 short beeps to prompt the user to press the rotary knob. The display will immediately return to the standard screen. The previous setpoint will be retained.

# Using the extended setpoint range for skin temperature control

If the standard setpoint range is exceeded:

- The advisory message »confirm extended range with rotary knob« will appear on screen.
- 1 Press rotary knob to activate extended range.
- 1 Turn rotary knob clockwise to increase setpoint further.

# WARNING !

When the extended setpoint range for skin temperature is used, particular care must be taken to monitor infant temperature.

- The advisory message » $\triangle$  > 37.0 °C« appears on screen.
- The following message appears at the top of the screen: »set value with rotary knob«.
- 1 Press rotary knob to confirm the new setpoint.







Using Skin Temperature Control

- The display returns to the standard screen. The measured values are displayed.
- The setpoint and »set: > 37.0 A « are displayed alternately.
- The yellow bar LED lights up.
  If the yellow bar LED starts flashing, the setpoint has been increased by more than ±0,5 °C\* (see page 79), or other alarms are active.



If you do not wish to activate the new setpoint:

1 Press button to cancel adjustment of the new setpoint.

The screen returns to the standard display mode and the previous setpoint is retained.

- Or
- Wait for 7 seconds: Caleo emits 4 short beeps to prompt the user to press the rotary knob. The display will immediately return to the standard screen. The previous setpoint will be retained.



\*

May be set within the range of 0.3 to 1.0 °C. See page 108.

#### Alarms

Alarm limits can be changed in the configuration (see page 108).

Example: if the deviation between the set and measured skin temperature exceeds  $\pm 1.0$  °C\*:

- The screen displays the warning message
  »Skin 1 temp. deviation above 1.0 °C «,
- An intermittent alarm tone sequence (3 beeps) will sound.
- 1 The central alarm light will light up\*\*,
- 2 The measured value will start flashing,
- 3 The yellow bar LED will start blinking.

The intermittent alarm tone sequence can be silenced for 5 minutes:

4 Press key to silence intermittent alarm tone,

or

- 5 Press rotary knob.
- The warning message remains on the screen,
- The intermittent alarm tone is now silenced.
- 1 The central alarm indicator light goes out.
- 2 The measured value continues to flash.
- 3 The yellow bar LED continues to blink.

When the measured value returns within the range  $\pm 1.0$  °C:

- The warning message disappears.
- The intermittent audible alarm is cancelled.
- 1 The central alarm indicator light goes out.
- 2 The measured value remains on screen without flashing,
- 3 The yellow bar LED goes out. If you are working in the extended setpoint range, the yellow bar LED will remain continuously lit.

If the sensor plug is disconnected:

After 3 seconds:

- The screen displays the warning message »Connect skin 1 sensor«.
- An intermittent alarm tone sequence (5 beeps) is sounded,
- 1 The central alarm indicator lights up\*\*,
- 2 3 dashes are displayed in place of a temperature reading.
- 6 The red bar LED starts blinking.

In this case:

• Immediately plug in the sensor.

# WARNING !

As long as 3 dashes remain on screen while the incubator is operated in skin temperature control mode, Caleo will not heat. Infant may become hypothermic.





The *numerical values* in this description are examples.

See "Configuring alarm settings", page 107.
 \*\* The central alarm indicator light may be switched off. See "Configuring system settings", page 106.

Using Skin Temperature Control

If the sensor is defective:

- The screen displays the warning message »Skin 1 sensor fault«.
- The intermittent alarm tone sequence (5 beeps) is sounded,
- The central alarm indicator lights up\*,
- 1 3 dashes are displayed in place of a temperature reading.
- 2 The red bar LED starts blinking.

Then:

• Replace skin temperature sensor.

# WARNING !

As long as 3 dashes remain on screen while the incubator is operated in skin temperature control mode, Caleo will not heat. Infant may become hypothermic.

The alarm tone can be silenced for 5 minutes:

- **3** Press key to silence intermittent audible alarm,
- or
- 4 press rotary knob.
- The warning message remains on the screen,
- The intermittent alarm tone is silenced,
- The central alarm indicator light goes out,
- 1 3 dashes continue flashing,
- 2 The red bar LED continues to flash.



For other alarms, see "Troubleshooting – Error Messages", page 142.

See also "Alarm Description", page 161.

The central alarm indicator light may be switched off. See "Configuring system settings", page 106.

### **Using Humidity Control\***

- Connect the humidifier system (see "Using Humidification Systems", page 49).
- 1 Press key to set humidity control.



The actual value and current setpoint of the humidity control are displayed as bar graphs and numerical values. Soft key symbols:

2	←_	=	New setpoint has not been activated.
3	off	=	Humidity OFF

- 4 manual = Set target value manually.
- 5 auto = Set target value automatically (see page 159).

**NOTE:** Humidity inside the incubator is servo-controlled both when manually setting a target value and when using AUTO humidity.

On activating humidity control, AUTO mode is proposed as default.





Using Humidity Control

#### Setting AUTO humidity

In AUTO mode, the humidity setpoint is automatically calculated and set by the system as a function of the air temperature setting (see page 159).

The maximum relative humidity depends on the ambient temperature and incubator air temperature at max. 75 % relative humidity.

- 1 Press soft key to switch humidity control to AUTO mode.
- 2 Press rotary knob to activate AUTO humidity.



The display returns to the standard screen. The measured value and the automatic setpoint are displayed.

### Manually adjusting the setpoint

Standard setpoint range 30 % to 99 %

- 3 Press soft key to switch humidity control to manual mode.
- 4 Turn rotary knob clockwise to increase setpoint.
- 4 Turn rotary knob counterclockwise to decrease setpoint.
- 4 Press rotary knob to confirm setpoint.

The maximum humidity reached depends on air temperature and ambient humidity. At high air temperature or low ambient humidity, the maximum humidity level that can be reached inside Caleo will be reduced.



 Current measured value and setpoint for controlling humidity are displayed as bar graphs and numerical values.



air	[°C]	skin	[°C]
34.0		36.8 <sub>T1</sub>	
			36.5 <sub>T2</sub>
	59		
set: 36.9 skin [°C]	set: 62 humidity [%]	O2 <b>[%]</b>	¢.

 The display returns to the standard screen. Measured values and setpoints are displayed.

#### Using Humidity Control

#### Alarms

#### In the event of an empty water supply

- A message
  »Water empty, please refill« appears on screen.
- An alarm tone sequence (3 beeps) starts,
- The central alarm indicator lights up\*,
- 1 The measured value starts flashing,
- 2 The yellow bar LED starts blinking.

Replace water bag or fill water reservoir to the "Full" level mark, see page 49.

The intermittent alarm tone sequence can be silenced for 15 minutes:

- 3 Press key to silence intermittent alarm tone,
- or
- 4 Press rotary knob.
- The alarm message remains on screen,
- The intermittent alarm tone is silenced,
- The central alarm indicator light goes out,
- 1 The measured value continues to flash,
- 2 The yellow bar LED continues to blink.

When the cause of the alarm has been remedied:

- The warning message disappears.
- The intermittent audible alarm is cancelled.
- The central alarm indicator light goes out.
- 1 The measured value remains on screen without flashing.
- 2 The yellow bar LED goes out. If you are working in the extended setpoint range, the yellow bar LED will remain continuously lit.

For other alarms, see "Troubleshooting – Error Messages", page 142.

See also "Alarm Description", page 161.



The central alarm indicator light may be switched off. See "Configuring system settings", page 106.

### **Using O2 Control\***

### WARNING !

Fire hazards from oxygen !

- No open flames or cigarettes ! Textiles, plastics, and oils readily ignite in an oxygen enriched atmosphere and burn with great intensity.
- Keep oxygen valves, connections, and seals free from oil and grease.
- Open valves on O2 cylinders slowly.
- Do not operate Caleo in the presence of flammable anesthetics or disinfectants. Risk of explosion!
- Do not use or store flammable liquids such as alcohol, ether, or acetone inside the Caleo incubator.
- Do not use electrical equipment inside the patient capsule unless this equipment is expressly designed for use in environments that present an explosion hazard.

# WARNING !

Due to the physiological risks from O<sub>2</sub>, it is mandatory to monitor O<sub>2</sub> concentrations continuously during the administration of O<sub>2</sub>, either using the integrated O<sub>2</sub> measurement and control system or an independent O<sub>2</sub> analyzer.

## WARNING !

Always take into consideration the physiological risks from the administration of oxygen.

Elevated oxygen concentrations inside the incubator may only be used by or on the order of a physician. Oxygen is classed as a drug.

It is absolutely essential that such oxygen therapy be selected and controlled on the basis of the arterially measured oxygen partial pressure in the infant's blood (SaO<sub>2</sub> or SpO<sub>2</sub>). This is the only way to minimize the risk of both hyperoxemia (with potential for damage to the eyes by retrolental fibroplasia) and hypoxemia (which might contribute to intraventricular hemorrhage and damage to the infant's brain).

- Connect Caleo DISS oxygen connector via O2 supply hose to an O2 wall outlet (see page 38).
- **1** Press button to set O<sub>2</sub> control.



Using O2 Control

 The measured value and current setpoint for O2 control are represented by bar graphs and numerical values.

Soft key assignments:

- **2** off = Switch off O<sub>2</sub> control.
- **3** on = Switch on O<sub>2</sub> control.



- After the system is switched on, the oxygen sensors need a warm-up phase of at least 3 minutes. An hourglass symbol appears in the display.
- The following message is displayed at the top of the screen: »set value with rotary knob«.
- After confirming the selected O2 sensor and after completion of the warm-up phase, the automatic O2 control becomes active.

The current measured value is displayed after completing the warm-up phase.



#### Adjusting the setpoint

Standard setpoint range
Extended setpoint range
Default setpoint

21 vol.% to 40 vol.% 40.1 vol.% to 75 vol.% 21 %

- 4 Turn rotary knob clockwise to increase setpoint.
- 4 Turn rotary knob counterclockwise to decrease setpoint.
- 4 Press rotary knob to confirm setpoint.



Operating Instructions Caleo, Software 2.n

 The display returns to the standard screen. Current measured values and setpoints are displayed.

air [°C] skin [°C] **36.7 37.0**<sub>T1</sub> **36.8**<sub>T2</sub> **21** set: 36.9 skin [°C] humidity [%] O2 [%]

If value to be set exceeds the standard range:

- The following message is displayed at the top of the screen »confirm extended range with rotary knob«.
- Press rotary knob to confirm extended setpoint range.

### WARNING !

Always keep in mind the physiological risks and fire hazards associated with the use of high O<sub>2</sub> concentrations.

• Turn rotary knob clockwise to continue increasing the setpoint.



- The advisory message » $\Lambda$  >40 %« appears on screen.
- The following message appears at the top of the screen »set value with rotary knob«.
- Press rotary knob to confirm setpoint.



# Using O2 Control

- The display returns to the standard screen. The measured values are displayed.
- − The setpoint and »set: >40 △ « are displayed alternately.
- The yellow bar LED lights up.
  If the yellow bar LED starts flashing, the setpoint has been increased by more than 3 % or 5 % (see page 88), or other alarms are active.



#### Alarms

Alarm limits can be changed in the configuration (see page 108).

Example: if the deviation between the set and measured O2 concentration exceeds  $\pm 5$  %\*:

- The screen displays the warning message »Oxygen deviation above 5 %«,
- An alarm tone sequence (5 beeps) starts,
- The central alarm indicator lights up\*\*,
- 1 The measured value starts flashing,
- **2** The red bar LED starts blinking.

The intermittent audible alarm can be silenced for 2 minutes:

- 3 Press key to silence intermittent audible alarm,
- or
- 4 Press rotary knob.
- The warning message remains on screen,
- The intermittent alarm tone is silenced,
- The central alarm indicator goes out,
- 1 The measured value continues to flash,
- 2 The red bar LED continues to blink.

When the measured value has returned to a value within the alarm threshold of  $\pm 5$  Vol.%:

- The warning message disappears.
- The intermittent alarm tone is cancelled.
- The central alarm indicator goes out.
- 1 The measured value remains on screen without flashing.
- 2 The red bar LED goes out.

For other alarms, see "Troubleshooting – Error Messages", page 142.

See "Alarm Description", page 161.

\*\* The central alarm indicator light may be switched off. See "Configuring system settings", page 106.



<sup>\*</sup> The *numerical values* in this description are examples. See "Configuring alarm settings", page 107.

# Using "Day" and "Night" Mode

With "Day" and "Night" mode settings, the screen can be displayed at 4 different brightness levels.

Upon starting the incubator, the screen is displayed with maximum brightness.

After restarting Caleo, e.g. after a power failure, the screen is displayed in the mode last selected.



1 To set the screen brightness, press key repeatedly until the desired brightness is obtained.



Selecting Menus

# **Selecting Menus**

1 Press »menu« key to select menus.



The required mode may be selected from the menu displayed.

- 2 Turn rotary knob to select item.
- 2 Press rotary knob to confirm selection (to activate item).



Kangaroo Mode<sup>®</sup>

# WARNING !

When using Kangaroo Mode, central temperature of the infant, who is outside the controlled climate of the incubator, must be monitored constantly.

Particular attention must be paid to critical care patients' vital parameters, especially a critical O<sub>2</sub> partial pressure. Ensure that all cables and hoses are routed correctly and safely.

**NOTE:** In Kangaroo Mode the incubator is always operating in air temperature control mode.

If Caleo was previously operating in air temperature mode, the air temperature setpoint will remain active while in Kangaroo Mode.

If Caleo was previously operating in skin temperature mode, the average of the last 3 minutes of air temperature values will be used as setpoint. The yellow skin (tummy) temperature sensor and the peripheral (toe) temperature sensor can be used in Kangaroo Mode to monitor the skin temperature of the infant. Several specific alarm limits are available for Kangaroo Mode and can be set individually in configuration mode. (see page 107).

The previously set values for

- Humidity (page 82) and
- O2 (page 86) are retained in Kangaroo Mode.

The previous set value for skin temperature control is stored in buffer memory.

#### Activating Kangaroo Mode

For a description of Kangaroo Mode, see page 156.

1 Press »menu« key to display the main menu.

Select "Kangaroo Mode" from the menu.

- 2 Turn rotary knob to select item.
- 2 Press rotary knob to confirm and activate item.
- The screen displays the following advisory message: »To leave the current mode please confirm the new Kangaroo Mode with rotary knob«.
- 2 Press rotary knob to confirm Kangaroo Mode.

- Kangaroo Mode is highlighted on screen by a light background when activated.
- The duration of Kangaroo Mode can be displayed on the screen in minutes and seconds (mm:ss).

Suppressing of audible alarms is automatically activated, i.e., alarms listed below occurring within the next 4 minutes are automatically displayed as "acknowledged" for the respective period:

- Air temperature too low
- Kangaroo Mode (see page 157)
- Humidity too low
- O2 concentration too low

If you are working in the extended setpoint range (Air or O2), the yellow bar LED will stay continuously lit. See "Suppressing Alarms", page 111.





### Selecting Menus

• Tubing grommets can be removed from the corner segments of the hood so that hoses and cables connected to the infant remain well organized during Kangaroo Mode.



#### Alarms

Alarm limits can be changed in the configuration (see page 107).

If the skin temperature of the yellow skin temperature sensor (skin 1) falls below the alarm limit set in the configuration:

- The screen displays the warning message:
  »Skin 1 temperature below 36.0 °C«\*
- An alarm tone sequence (3 beeps) starts.
- 1 The central alarm indicator lights up\*\*.
- **2** The measured value starts flashing.
- 3 The yellow bar LED starts blinking.

The intermittent audible alarm can be silenced for 15 minutes.

- 4 Press key to silence intermittent alarm tone
- or
- 5 Press rotary knob.
- The warning message remains on screen.
- The intermittent alarm tone is silenced.
- 1 The central alarm indicator goes out.
- 2 The measured value continues to flash.
- **3** The yellow bar LED continues to blink.

When the measured value returns above the alarm limit:

- The warning message disappears.
- The intermittent alarm tone is cancelled.
- 1 The central alarm indicator goes out.
- **2** The measured value remains on screen without flashing.
- 3 The yellow bar LED goes out. If you are working in the extended setpoint range, the yellow bar LED will stay continuously lit.

For other alarms, see "Troubleshooting – Error Messages", page 142. See also "Alarm Description", page 161.



\*\* The central alarm indicator light may be switched off. See "Configuring system settings", page 106.





Selecting Menus

#### Ending Kangaroo Mode

In the displayed menu, select

2 Turn rotary knob to select item.

Press rotary knob to activate item.

»Return to *Air* Mode«\* or »Return to *Skin* Mode«\*.

2

1 Press »menu« key to display menu list.





- The screen displays the advisory message:
  »To leave the Kangaroo mode and return to *Air* Mode confirm with the rotary knob«.
- 2 Press rotary knob to exit Kangaroo Mode.

The former operating status with the previously set values is reactivated. The display returns to the standard screen.

After quitting Kangaroo Mode, reinsert the tubing grommets in the corner segments of the hood.

- Wait for 7 seconds: Caleo emits 4 short beeps to prompt the user to press rotary knob. The display will immediately return to the standard screen. The previous setpoint will be retained.



<sup>\*</sup> the option displayed depends on the previously activated mode

Selecting Menus

#### Trend display

The display of trends serves to graphically and numerically illustrate measured parameters. The data window shows the most recent data in the selected time interval. In addition, the current measured values and setpoints are displayed.

#### Switching between standard and trend screen

1 Press » 🕅 « key to display trend.



- The air temperature trend of the last 3 hours is displayed. The data window on the right shows the current measured values of air and skin temperature.
- T1: Yellow skin temperature sensor (Skin 1)
- T2: White peripheral sensor (Skin 2)



2 Press »TREND parameter« key to select menu.



Select the desired trend display from the displayed list.

Defaults:

- Air temperature trend
- Zoom factor: 3 hours
- Turn rotary knob to select trend.
- Press rotary knob to activate trend.
- Press » ← \_ « key to return to menu selection.
- Press »  $\frac{888}{bc}$  « button to exit trend display mode.

The display returns to the standard screen.

#### Setting the displayed time interval (zoom)

1 Press »TREND parameter« button to display menu selection.







Select desired trend from the displayed list.

Press » ← \_ \_ « key to return to menu selection.

Selecting Menus

1 Press key to display zoom menu.



Select desired zoom factor from the menu.

- 2 Turn rotary knob to select zoom factor.
- 2 Press rotary knob to activate zoom factor.

select zoom with rotary knob		
ſ		
	3 h	
	6 h	
	12 h	
	24 h	
	48 h	
7 days		
•		
<b>-</b>	trend	

- Press » ← \_ « soft key to return to menu selection.
- Press »trend« soft key to return to Trend Main Page.
- In the illustrated example, the trend for the air temperature over the last 3 hours will be displayed.
- T1: Yellow skin temperature sensor (skin 1)
- T2: White peripheral sensor (skin 2)

mode: air		ai	r trend [°C]
37.0 36.2- 35.4-			air (*C) 35.6
34.8- 33.8- 33.0-		skin (*C) 36.8 T1 36.5 T2	
<u>8:16</u>	T	(11.10)	
35.6	55		
set: 35.7	set 56		TREND
air [*C]	humidity [%]	02 [%]	parameter

Selecting Menus

#### **Trend analysis**



Trend analysis is used for graphically and numerically displaying measurement parameters and associated setpoints. The data time window can be moved freely across the last 7 days.

Trend analysis can therefore be used to evaluate thermo-monitoring data.

The following parameters may be selected:

- Skin temperature 1 (yellow skin temperature sensor, skin 1, T1)
- Peripheral temperature or skin temperature 2 (for twins) (white temperature sensor, skin 2, T2)
- Air temperature
- Relative humidity (rel. %)\*
- O2 concentration (vol. %)\*.

**NOTE:** While trend analysis is in progress, no current measured values (air, skin, etc.) are displayed. The numerical values displayed are values from past readings.

If no key is pressed for 2 minutes, the display automatically reverts to the standard screen.

1 Hold key down for 4 seconds to activate trend analysis.

Dräger	00	
	0	

#### Selecting Menus

 The trend graph for the selected measured value is displayed on screen.

Default measured value:	
trend 1	Skin temperature
trend 2	Air temperature
zoom	3 hours

The selected value is displayed as a trend graph.

In this graph, the trend curve of the measured value is overlaid on the corresponding setpoint curve.

Time cursor:

The time cursor is displayed as a vertical dotted line marking a precise point of time on the graph's time axis.

• Turn rotary knob to move the time curve on the time scale.

The point in time marked by the cursor line is specified underneath the dotted line with date and time. Start and end time for the current time window are specified underneath the trend graph to the right and left, respectively.

If the time cursor is moved beyond the displayed time range, the screen adapts automatically and displays the new time range:

- Turn rotary knob counterclockwise to display a less recent time range.
- Turn rotary knob clockwise for a more recent time range.

#### Data window:

The time cursor is associated with a data window situated to the right of the displayed trend. This data window shows the numerical values pertaining to the time marked by the time cursor.

The following values are displayed in the data window:

- 1 Name of the selected parameter
- 2 Set value of this parameter at the marked time
- 3 Measured value of the parameter at the marked time





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#### **Trend selection**

1

A trend graph may be selected with soft keys.

Soft key assignments:

- 2 trend 1 = Select trend 1
- 3 trend 2 = Select trend 2
- 4 zoom = Select time interval







#### To select trend 1:

- 2 Press soft key to display trend 1 menu.
- The following parameters can be selected as "trend 1":
- air
- skin
- humidity\*
- oxygen\*
- weight\*
- 5 Turn rotary knob to select trend 1.
- 5 Press rotary knob to confirm (activate) selection.

The newly selected trend will be displayed on screen.

#### Select trend 2:

3 Press soft key to display trend 2 menu.

The following parameters can be selected as "trend 2":

- air
- humidity\*
- oxygen\*
- weight\*
- disable
- **5** Turn rotary knob to select trend 2.
- 5 Press rotary knob to confirm (activate) selection.

#### Selecting Menus

The newly selected trend is displayed on the screen below trend 1. In addition, a second data window containing the respective numerical parameters is opened next to trend 2. Time cursor and time range (zoom) are the same for both trend displays.

The »disable« option removes trend 2 from the screen, so that only trend 1 is displayed.

scroll with rotary knob			
37.0	trend 1		
35.4- 35.4-	air [°C]		
34.6-	set: 35.7		
33.87	35.6		
07.01.2000 11.01.2000 9:29 15.01.2000			
5000	trend 2		
	weight [g]		
2000-			
1000-	3680		
07.01.2000 11.01.2000 9:29 15.01.2000			
🕂 🕂 trend 1 🗍 trend 2	zoom		

#### Selecting the time interval (zoom)

1 Press soft key to open the zoom menu.



The following intervals of time can be selected for the time window (zoom) function:

3; 6; 12; 24; 48 hours, or 7 days

- 2 Turn rotary knob to select zoom interval.
- 2 Press rotary knob to activate zoom.

The selected trends will then be displayed in the newly selected time window.

All data going back a maximum of 7 days can be displayed. The individual measuring points together with the associated data for the data window are displayed.

When displaying the measured weight values, up to 30 values can be stored and displayed as a trend. Values between the individual measured values are interpolated.



Selecting Menus

#### **Ending trend analysis**

To exit trend analysis

- 1 Press » ← \_ \_ « soft key to return to menu, or
- 2 press key to terminate trend analysis.

Alternatively, if no key is pressed for 2 minutes, the display will automatically revert to the standard screen.



Cleaning mode\*

## WARNING!

Cleaning mode may only be used while Caleo is not occupied by a patient.

- Cleaning mode is only available if Caleo is equipped with humidity control.
- Only use cleaning mode with an ambient humidity of >10 % relative humidity.
- Close clamp on water supply connection kit before starting cleaning mode.
- Cleaning mode lasts about 60 minutes.
- The water heater is heated up during cleaning mode. The residue water evaporates. The water heater then cools down.
- During cleaning mode Caleo continues to measure the relative humidity. The value will not be displayed. If the relative humidity falls below 10 % the "Humidity sensor inoperable" alarm will be triggered. Cleaning mode cannot be ended in the correct manner. In order to maintain a relative humidity of >10 %, the front and side doors and the canopy should be open during cleaning mode.
- During or after cleaning mode, condensation could form under the aggregate housing of the Caleo!

Selecting Menus

1 Press »menu« key to display the main menu.



Select "Cleaning Mode" from the displayed menu.

- 2 Turn rotary knob to select item.
- 2 Press rotary knob to confirm (activate) item.



 The required operating steps are specified on screen: »disconnect Luerlock connector from apparatus make sure that no patient is inside start Cleaning Mode by pressing tttt keys.«



• Press both soft keys simultaneously to start cleaning mode.



The water heater is boiled dry. The heater is then cooled.

# WARNING!

Risk of burns upon contact with the heater! Do not disassemble Caleo while in cleaning mode.



- A screen message will indicate when the cleaning procedure has been completed.
- Press rotary knob to confirm end of cleaning mode.

Caleo performs a restart.



After ending Cleaning Mode:

 Disinfect and clean Caleo (see "Disinfecting / Cleaning / Sterilizing", page 118).

Configuration

# Configuration

In configuration mode, you may set:

- language, date, and time,
- system parameters, and
- alarm parameters.

Additionally, information may be obtained on:

- O2 sensors, and
- the software version.

#### Activating configuration mode

1 Hold down »menu« key for 4 seconds to display configuration mode.



The individual configuration parameters may now be selected.

- 2 Turn rotary knob to select configuration parameter.
- 2 Press rotary knob to activate configuration parameter.



- The display returns to the standard screen.

#### Configuring language/date/ time

1 Turn and press rotary knob to select language/date/time.



- The language selection is highlighted by a bold frame.
- 1 Turn rotary knob to select language.
- 1 Press rotary knob to confirm language.
- The selected language is displayed on screen.

Follow the same procedure to set the date format, date, and time.

- 1 To save settings, turn rotary knob to »back«, then press the rotary knob to confirm.
- To cancel selection, press » « soft key.
- The display returns to the configuration mode selection menu (see page 104).



Configuration

#### **Configuring system settings**

From the configuration mode selection menu:

1 Turn and press rotary knob to configure unit of temperature.



- The temperature unit is highlighted by a light background.
- 1 Turn rotary knob to select unit.
- **1** Press rotary knob to confirm unit.
- The selected unit is displayed on screen.

Unit of weight, display of dT/T2, central alarm indicator, elevation above sea level, and contrast are configured in the same fashion.

- The unit of weight can only be configured if Caleo is equipped with the integrated infant scale\*.
- When using two skin temperature sensors, T2 or the difference between T1 and T2 (dT) can be displayed in addition to the value of T1.
- If the central alarm LED is disabled, alarm situations are only indicated by the blinking display for the measured value, blinking bar LED on the control unit, and the audible alarm.
- Elevation above sea level can only be set if Caleo is equipped with integrated O2-control. An incorrectly set elevation will reduce the measuring accuracy of the O2 sensors (approximately 1.5 % additional error at 3280 ft / 1000 m).
- If the screen becomes difficult to read, the contrast setting can be adjusted.
- The display returns to the configuration mode selection menu (see page 104).



available option

#### Configuring alarm settings

From the configuration mode selection menu:

1 Turn and press rotary knob to configure alarms.



- The menu that is then displayed allows the user to select Kangaroo Mode alarm settings, the initial volume of audible alarms and the alarm thresholds for temperature control and O<sub>2</sub> control.
- 1 Turn rotary knob to select menu item.
- 1 Press rotary knob to confirm menu item.
- To cancel a selection, press » ← \_ \_ « soft key.
- The display returns to the configuration mode selection menu (see page 104).



#### Kangaroo Mode:

Setpoint ranges:33 °C to 37 °C and offSkin alarm T1 min33 °C to 37 °C and offSkin alarm T2 min33 °C to 37 °C and offdT alarm min-2 °C to 2 °C and offdT alarm max2 °C to 5 °C and off

Default values: last settings

The text items in the description that follows are examples:

- 1 Select skin alarm *T1 min* (lower alarm limit for skin temperature) = turn and press the rotary knob.
- When selected, the setting for "alarm skin *T1 min*" is highlighted by a bold frame.
- 1 Turn rotary knob to select alarm setting.
- 1 Press rotary knob to confirm alarm setting.

The display returns to the alarm settings menu (see above).

The other alarms are set using the same method.

- To cancel a selection, press » ← \_ \_ « soft key.
- The screen returns to the configuration mode selection menu (see page 104).

For a description of Kangaroo Mode alarms, please refer to page 157.



Configuration

#### Audible alarm volume:

Setpoint range:1 to 8Default:1

- The initial alarm volume is highlighted by a light background.
- Turn rotary knob to set audible alarm volume default to be in effect at start-up.
- Press rotary knob to confirm initial volume setting.

The screen returns to the alarm settings menu (page 107).

# WARNING!

Always adjust audible alarm volume to a level that ensures the operator will be alerted when alarms occur. Failure to identify and correct alarm situations may result in patient injury.

- The display returns to the configuration mode selection menu (see page 104).

#### Alarm limits:

Setpoint ranges:	
Air temperature deviation	–1.5 or –2.5 <sup>o</sup> C
Skin temperature deviation	±0.3 to 1.0 °C
O2 deviation*	±3 % or ±5 %
Default values:	

Air temperature deviation Skin temperature deviation O2 deviation\*

• Turn and press rotary knob to select alarm limit for air/skin temperature and O2\*.

-1.5 °C

±0.5 °C

±5 %

- The setting for the air temperature alarm threshold is highlighted by a bold frame.
- Turn rotary knob to select new air temperature deviation threshold.
- Press rotary knob to confirm threshold.
- The screen returns to the alarm settings menu (page 107).

The other alarm limits are set in the same fashion.

- The display returns to the configuration parameter menu (see page 104).





Operating Instructions Caleo, Software 2.n

Available option
#### Viewing O2 sensor information\*

From the configuration mode selection menu:

• Turn and press rotary knob to select "O2 sensor information".

The screen displays the following information for the O2 sensors used:

- Date of manufacture \_
- Date of last calibration
- Date of next calibration.

O2 sensor informat	ion
sensor 1 : manufacturing date last calibration : next calibration :	02.04.2000 03.04.2000 05.04.2001
sensor 2 : manufacturing date last calibration : next calibration :	01.04.2000 03.04.2000 05.04.2001

#### Viewing software information

From the configuration mode selection menu:

- Turn and press rotary knob to select "info screen".
- The software version and the number of operating hours are displayed on screen. Where applicable, this screen contains additional information on service intervals.

Further information on this subject is provided in the service documentation.



1	Press soft key to return to configuration mode selection
	menu,
or	

2 press rotary knob.

1

The display returns to the configuration mode selection \_ menu (see page 104).



Available option

# Operation

Keypad Lock

# Keypad Lock

#### Locking keypad

- 1 Press key to prevent any on-screen setting.
- 1 The LED in the key lights up.



- After 4 seconds, all screen functions are locked, except for:
- 2 Keypad lock
- 3 Alarm silencing
- 4 Rotary knob
- 5 Bed tilt.
- 1 The LED in the key remains lit.

#### Enabling keypad

- 1 Press key to enable on-screen settings.
- 1 The LED in the key goes out.
- After 4 seconds, the screen functions can be changed. The LED in the key remains off.



# Suppressing Alarms

- 1 When pressing this key while an alarm is active:
- The audible alarm is silenced.
- The central alarm indicator goes out.\*
- 1 The LED in the button is not lit.

The maximum duration for suppressing an alarm depends on the type of the alarm. Suppression of an alarm ends with the alarm, and does not continue on as preemptive silencing of alarms.

1 Pressing this key if no alarm is active (preemptive alarm silencing):

For a period of 4 minutes, if alarms occur due to deficient values of the following parameters:

- Air temperature,
- Skin temperature,
- Humidity,
- O2 concentration,

no audible alarm will sound and the central alarm indicator light will not light up\*.

**However:** The respective alarm messages will be displayed on screen, the measured value will start flashing, and the bar LED will start blinking.

**1** The LED in the button will be lit.

# WARNING !

While alarm suppression is active, the operator of the incubator must still assume responsibility for proper patient care and safety in the event of an alarm. Failure to identify and correct alarm situations may result in patient injury.

**NOTE:** Alarms that had already been silenced previously, will, regardless of their remaining silencing period, be muted also for the duration of 4 minutes.



<sup>\*</sup> The central alarm indicator light may be switched off. See "Configuring system settings", page 106.

### Operation

Integrated Infant Scale

# Integrated Infant Scale\*

The weighing scale is located directly underneath the bed. During the weighing process, the entire bed and all objects on it are weighed. By lifting the patient, all other weights are deducted, so that the baby's weight can be precisely determined.

The accuracy of the weight measurement is not limited by the objects placed on the bed. These additional objects only reduce the maximum displayable value of the scale by their combined weight. In the event of patients needing circuits and lines, e.g. ventilation circuits, the influence of these hoses on the measured weight, as with other types of scales, cannot be fully eliminated. In order to avoid fluctuating weighing results, the hoses should be removed from the ventilation circuit support arm, if installed, before weighing. Then, after placing the patient on the bed, the hoses should also be laid on the bed in as strainfree and horizontal a position as possible. Like items of clothing, if parts of the hose lines are weighed with the patient, they can lead to a slight increase in measured weight. Since these deviations are systematic, they do not affect trend observations.

Weight measurements will only be completely accurate where taring has been used. Without taring the level of accuracy will be reduced. Changes made between measurements, such as, changing in the tilt of the device or adding or removing objects from the bed, may result in inaccurate results.

For weight measurements without using tare, particular attention must also be paid to ensuring vibration free conditions. Pressing buttons on the control unit too forcibly may lead to vibration that may reduce the accuracy of the weight measurement. It is suggested that weighing should only be conducted when the trolley castors on Caleo are locked. This helps to cushion vibrations and increases the accuracy of weight measurements.

Before weighing, check that the bed is fully pushed in and is in the horizontal position.

The spirit levels show whether the bed is positioned horizontally.

- 1 Levels for the horizontal alignment of Caleo in the transverse axis.
- 2 Level for the horizontal alignment of Caleo in the longitudinal axis.

To level the bed horizontally, see page 48.



Operating Instructions Caleo, Software 2.n

<sup>\*</sup> Available option

## Operation

**NOTE:** If the following instructions are not observed significant weighing errors may occur:

- Before weighing, make sure that both knobs are set to the scale position <sup>1</sup>/<sub>2</sub>.
- During the weighing process, Caleo must not be exposed to any vibrations.
- During the weighing process, no objects may be placed on the bed surface.
- During the weighing process, no objects may be placed between the bed and the housing.
- Circuits routed over the ventilator circuit support arm may adversely affect weighing accuracy.

The infant scale must be regularly tested with a test weight. In some regions, the accuracy of the scales specified in the Technical Data is only attained if the scales are calibrated at the installation location.

#### Preparing for weighing

- Set Caleo to the horizontal position. Check with the aid of the built-in levels – see page 48.
- Remove all objects that touch both the bed and the fixed environment or the incubator frame.
- Set both knobs to the scale position  $\sqrt{2}$ , see page 45.
- Prepare infant for lifting.

#### Starting the weighing procedure

1 Press button to start the weighing procedure.

**NOTE:** If the scale is **not** ready for operation, this function cannot be activated.



Integrated Infant Scale

During weighing, the user is guided through the sequence of operating steps by the following prompts.

• Lift the baby off the bed.

The system waits until the scale has stabilized and has been at rest for 3 seconds.

1 beep is sounded.

• Place patient back on the bed.

Weighing then proceeds.

1 beep is sounded.

The weighing procedure is now complete.

 The current and last weighing results are displayed on the screen. If the measuring range has been exceeded, the symbol \_/ is displayed.

After 10 seconds, the display reverts to the standard screen. or

• Press rotary knob to display the standard screen.

The screen will display the last weight as advisory text for the next 10 minutes.



## Operation

#### Canceling the weighing procedure

Weighing is aborted if a minimum patient weight (250 g) is not removed or added back within 60 seconds.

- 3 short beeps are emitted.

#### Weighing without tare

If the last tare weight was obtained no longer than 60 minutes earlier and no objects have been placed on or been removed from the bed, a new tare weight does not have to be obtained again.

#### Preparing for weighing

- Set Caleo to the horizontal position. Check with the aid of the built-in water levels see page 48.
- Set both knobs to the horizontal position see page 45.

#### Starting the weighing procedure

1 Activate the weighing process = press soft key.



Caleo proposes to reweigh directly without obtaining a new tare weight.

- 2 Press »reweigh« key to weigh without obtaining a new tare weight.
- Place infant back on the bed.

Weighing then proceeds.

- 1 beep is emitted.



The weighing procedure is complete.

 The current and last weighing results are displayed on the screen. If the measuring range is exceeded, the symbol \_/<sup>\*</sup> is displayed.

After 10 seconds, the display reverts automatically to the standard screen.

- or
- Press rotary knob to display the standard screen.

The screen displays the last weight as advisory text for the next 10 minutes.



## **End of Operation**

 Before turning off Caleo, acknowledge all active alarms with high risk potential. Otherwise the nurse call system\* will continue to indicate the active alarm after the device has been switched off.

#### Switch off incubator

1 Press on/off switch to switch off the incubator.

The incubator is turned off.



If O2 supply hose is connected:\*\*

Disconnect probe from the outlet of the central O<sub>2</sub> supply pipeline and place it in the "standby" position, if available (follow respective Instructions for Use).

<sup>\*</sup> Available option

<sup>\*\*</sup> For available O2 option

# Care / Maintenance / Disposal

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Precautions Disinfecting / Cleaning / Sterilizing

# Care

## Precautions

The Caleo incubator system must be thoroughly cleaned and disinfected

- after each patient
- at least once a week

Perform any disinfection procedures according to established hospital protocols as well as to the following additional instructions.

# WARNING !

Always follow accepted hospital procedures for handling equipment contaminated with body fluids.

#### CAUTION !

Even accessories designed to be reused after cleaning have a limited life. For example, due to a number of factors connected with handling and preparation, disinfectant residues can attack the material more intensely during autoclaving; increased wear can occur and service life can be markedly shortened. Accordingly, these parts and accessories must be replaced when any external signs of wear – such as cracks, deformation, discoloration, peeling, etc., – become apparant.

For the cleaning and disinfecting of accessories, refer to their respective operating instructions.

# WARNING !

Always disconnect power supply before cleaning and disinfecting.

# WARNING !

Risk of burns from heater!

When the incubator is closed, the heater is still hot enough to inflict serious burns for a long time after switching off (70 °C =158 °F after 1 hour).

# **Disinfecting / Cleaning / Sterilizing**

# Testing of procedures and agents

Due to material incompatibilities, preparations based on

- halogen-releasing compounds
- strong organic acids
- oxygen-releasing compounds
- alcohol

are of only limited suitability.

The cleaning, disinfection and sterilization (reprocessing) of medical devices were checked with the following procedures and agents. On the date of the check, the following resources indicated good material compatibility:

Surface	Manufacturer
disinfectant	
Incidur®	Ecolab Deutschland GmbH
Dismozon <sup>®</sup> pure	Bode Chemie GmbH & Co., Germany
Virkon	Tetenal, Germany
Seculyse	Paragerm (Henkel Ecolab), France
Sekupoudre	Paragerm (Henkel Ecolab), France
Vaposeptol	Paragerm (Henkel Ecolab), France
Cidex	Johnson & Johnson, Taiwan
Habitane	Zeneca Limited, Norway
Kloramin	Norsk Medisinal Depot A/S, Norway
Sactiv	Diversey Lever, Finland
Viraclean	Whiteley, Australia
HYDROX	Diversey, Canada

Comply with the manufacturer's directions for use.

The following materials are used in the patient capsule:

Components	Material
Hood, flaps	Polycarbonate
Pillar elements	Styrene-butadiene thermo foam injection molded material ABS (acrylonitrile/butadiene/styrene)
Bed	Styrene-butadiene thermo foam injection molded material ABS (acrylonitrile/butadiene/styrene)
Trough	Styrene-butadiene thermo foam injection molded material ABS (acrylonitrile/butadiene/styrene)
X-ray drawer	Polystyrene thermo foam injection molded material
Housing	Polystyrene thermo foam injection molded material
Caleo <sup>®</sup> SoftBed <sup>™</sup>	Polyurethane/polyester

The following disinfectants have been tested and are **not** to be used because of material incompatibility:

Surface	Manufacturer
disinfectant	
PaMo dur	Dräger, Germany
PaMo dur rapid AF	Dräger, Germany
PaMo dur Spray	Dräger, Germany
PaMo sept Univ. AF.	Dräger, Germany
Daisy Des	Dräger, Germany
Incidin Extra N	Henkel, Germany
Terralin	Schülke & Mayr, Germany
Asphene Spray	Laborat, France
Korsolin 50	Bode, France
Minudes	Paragerm, France
Virufen	Paragerm, France
Osuban S	Japan
Taski Exact 300	Finland

# WARNING !

Risk of burning when touching the heater! When the incubator is closed, the heater is still hot enough to cause serious burns for a long time after switching off (still approx. 70 oC after 1 hour). Allow Caleo® to cool down sufficiently before stripping it down.

#### Manual cleaning and disinfection

Manual disinfection should preferably be carried out with disinfectants on the basis of Aldehydes.

Observe the applicable country-specific listings for disinfectants. The list of the German Association for Applied Hygiene (Verbund für Angewandte Hygiene VAH) applies in German-speaking countries.

The composition of the disinfectant is the responsibility of the manufacturer and can change over time.

Strictly observe the manufacturer's information on the disinfectant.

#### Carry out manual cleaning and disinfection

• Remove soilings with a wet wipe.

### WARNING !

Penetrating liquid may cause malfunction of or damage to the device, which may endanger the patient. Only wipe-disinfect items and make sure no liquids penetrate into the device.

- 1 Carry out surface disinfection.
- 2 After contact time, remove disinfectant residues.

#### Carry out machine cleaning and disinfection

- 1 Strictly observe Instructions for Use of washer-disinfector.
- **2** Position items so that all interior spaces are completely flushed and water can drain off freely.
- **3** Use suitable cleaning agent.
- 4 Select suitable device program.
- 5 Carry out final rinsing with deionized water.
- 6 Immediately remove items from the washer-disinfector.
- 7 Inspect items for visible soiling and damage. If necessary, repeat program or carry out manual cleaning and disinfection.
- 8 Allow items to dry thoroughly.

#### Visual inspection

 Inspect all items for damage and wear, e.g. cracking, embrittlement or pronounced hardening, and residual soiling. Testing of procedures and agents

Disinfect and clean accessories such as the aspiration unit in accordance with their specific Instructions for Use.

#### Water heater

The water heater does not have any components that must be dismantled for the preparation.

Execute the Cleaning Mode after each change of patient. While preparing the interior of the incubator, ensure that no liquids such as detergents penetrate into the water heater.

#### Skin temperature sensors (MX11000/MX11001)

Skin temperature sensors are disposable products and should not be reused, reprocessed or sterilized.

Any reuse, reprocessing or sterilising can lead to the failure of the medical device.

#### Hood, flaps and other plastic parts

To avoid impairment of function and long-term damages, use only suitable detergents or disinfectants and handle parts carefully.

Plastic parts, especially transparent flaps and hoods made of polycarbonate (PC), are sensitive to mechanical and chemical exposure.

When cleaning and disinfecting, do not exceed the reaction time specified by the manufacturer. Fully remove cleaning agent and disinfectant residue after the reaction time, even from the clearances.

#### Softbed

Clean and wipe-disinfect the softbed MX17012 as required, and after each patient change. In case of heavy soiling, the cover can be washed in the washing machine at 95  $^{\circ}$ C. A drier is suitable up to 95  $^{\circ}$ C.

In exceptional cases, the mattress core can get stained. The mattress core (foam) can then be washed in the washing machine with mild detergent at 30  $^{\circ}$ C.

#### Sterilization

Sterilization frees living microorganisms from semicritical medical products and removes residual water from the interior spaces of its items.

• Only sterilze cleaned and disinfected items.

Use a vacuum steam sterilizer (in accordance with DIN EN 285), preferably with fractional vacuum. Do not use gas sterilization with ethylene oxide (EO).

### Disassembly

#### Checking the air intake filter

- Tilt the unit (see page 48) for easy removal of the air intake filter.
- 1 Check expiration date: see label on the unit.



2 Press down the knurled part of the clip and open the filter cover.

If a filter is already in place:

• Check the condition of the filter.

#### Replace filter when

- it is dirty, damaged, or moist.
- the expiration date has been reached.
- the filter has been used with an infectious patient.
- Discard old filter.
- Install a new filter.

#### Inserting the filter

- Insert the filter in the open filter cover.
- 2 Close the filter cover.
  - Check that the filter cover is securely closed.
- Write down the expiration date of the new filter (2 months from date of installation) on the label.
- 1 Stick label to the device.

Disassembly

#### Removing the water supply

- Close clamp on the water supply connection kit. •
- Remove and dispose of water bag and water supply ٠ connection kit and dispose of properly.

Or:

- 1 Remove water container from its holder.
- 2 Detach water supply connection kit from the water container.
- Dispose of the water supply connection kit. •
- Either clean the water container in a parts washer at 93 °C • (200 °F)\*,

or

sterilize at 134 °C (273 °F)\*. •



- Tilt Caleo bassinet back to the horizontal position (see • page 48).
- Switch on cleaning mode\*\* (see page 101). •

Observe national and international standards regarding procedures for cleaning, disinfection, and sterilization. Available option

<sup>\*\*</sup> 

# After cleaning mode\* has completed or if humidity control is not provided:

• Switch off incubator. Disconnect from line power and disconnect the medical gas supply.

# WARNING !

Always disconnect all supplies before disassembly.

 Remove any auxiliary equipment installed (for care instructions see the particular Instructions for Use of the respective equipment).

# WARNING !

Risk of burns upon contact with the heater. Allow Caleo to cool down before further disassembly.

#### Removing the double wall

- 1 Pull the pin up as far as it will go. The red section of the pin must be visible.
- 2 Hold the double wall with both hands and lift it off.



- Remove the contour seal from the double wall.
- **3** Force the sleeve open and at the same time
- 4 pull out the pin.







- 1 Tilt the sleeve to one side and pull it out.
- 2 Tilt the centring lugs to one side and pull them out.
- Remove obvious soiling with a disposable cloth.
- Wipe-disinfect the double wall surfaces.
- After allowing disinfectant to take effect (see manufacturer's directions for prescribed exposure times), wipe surfaces with a clean, damp, disposable cloth, then rub dry.
- All other parts can be disinfected in a parts washer at 93 °C (200 °F)\*.



#### Remove canopy

- 3 Grasp handles on sides of canopy with both hands.
- 4 Keeping canopy level, lift it vertically off its supports.
- Remove obvious soiling with a disposable cloth and detergent.
- Wipe-disinfect all surfaces.
- After allowing disinfectant to take effect (see manufacturer's directions for prescribed exposure times), wipe surfaces with a clean, damp, disposable cloth, then rub dry.



The support (2M 51 141) is only mounted on the pillar elements (2M 51 154 and 2M 51 156).

- 5 Move the support to a vertical position and remove it.
- The support can be disinfected in a parts washer at 93 °C (200 °F)\*.





Observe national and international standards regarding procedures for cleaning, disinfection, and sterilization.

#### **Open front doors**

- 1 Turn the two locking knobs inwards as far as they will go and fold down the front door.
- Fold out the hinged double walls to clean them. •
- Open the side doors in the same way.
- Remove visible soiling with a disposable cloth and . detergent.
- Wipe-disinfect all surfaces.
- After allowing disinfectant to take effect (see manufacturer's • directions for prescribed exposure times), wipe surfaces with a clean, damp, disposable cloth, then rub dry.



#### **U-grommets**

- Remove all U-grommets and access port seals. •
- Clean parts in a parts washer at 93 °C (200 °F)\*.



- Push the drainage module\*\* out sideways by the drainage • clip.
- Push the drainage clip off the drainage unit. •
- The parts can be disinfected in a parts washer at 93 °C • (200 °F)\*.





\*\*

Observe national and international standards regarding

procedures for cleaning, disinfection, and sterilization. Available option

#### Mattress and bed

- Remove mattress from bed.
- 1 Remove bed.

#### CAUTION !

Take care not to damage the sensor unit when removing patient bed.

- Remove visible soiling with a disposable cloth and detergent.
- Wipe-disinfect all surfaces.
- After allowing disinfectant to take effect (see manufacturer's directions for prescribed exposure times), wipe surfaces with a clean, damp, disposable cloth, then rub dry.



- Using the recessed handle, pull x-ray drawer out as far as it will go.
- 2 Tilt drawer upwards and pull it out of the unit.
- Remove visible soiling with a disposable cloth and detergent.
- Wipe-disinfect all surfaces.
- After allowing disinfectant to take effect (see manufacturer's directions for prescribed exposure times), wipe surfaces with a clean, damp, disposable cloth, then rub dry.





#### Remove trough

3 Press both catches inwards and pull the trough upwards.



#### 1 Lift trough out.

- 2 Remove fan.
- Remove visible soiling with a disposable cloth and detergent.
- Wipe-disinfect all surfaces.
- After allowing disinfectant to take effect (see manufacturer's directions for prescribed exposure times), wipe surfaces with a clean, damp, disposable cloth, then rub dry.



- Turn trough over.
- 3 Lift air guide plate to the side to disinfect and clean.
- Remove visible soiling with a disposable cloth and detergent.
- Wipe-disinfect the surfaces.
- After allowing disinfectant to take effect (see manufacturer's directions for prescribed exposure times), wipe surfaces with a clean, damp, disposable cloth, then rub dry.



#### Chassis/incubator body

- Remove visible soiling with a disposable cloth and detergent.
- Wipe-disinfect the surfaces.
- After allowing disinfectant to take effect (see manufacturer's directions for prescribed exposure times), wipe surfaces with a clean, damp, disposable cloth, then rub dry.
- Remove any dirt near the openings of the sensor unit.

#### **CAUTION !**

Do not allow any moisture to enter the sensor unit. Do not disinfect sensor unit by immersion or spraying. Sensor damage may result.



#### **Control unit**

- Pull rotary knob from the control unit.
- Remove visible soiling with a disposable cloth and detergent.
- Wipe-disinfect the surfaces.
- After allowing disinfectant to take effect (see manufacturer's directions for prescribed exposure times), wipe surfaces with a clean, damp, disposable cloth, then rub dry.

#### **CAUTION !**

Do not allow any moisture to enter the control unit. Do not disinfect control unit by immersion or spraying. Equipment damage may result.

#### **CAUTION !**

Ensure that only recommended cleaning agents and disinfectants are used!

The acrylic and Makrolon material may develop stress cracks if other agents, such as alcohol, are used.

Do not use UV radiation on the incubator. This also may cause cracks in the acrylic parts.



### **Before Reusing With a Patient**

- Check that the system has been cleaned and disinfected in conformity with all applicable hospital protocols.
- Reassemble the equipment with disinfected hands.
- Reassemble all equipment and re-install accessories, see "Disassembly", page 121.

**NOTE:** When inserting the trough, make sure that both latches snap in place.

If the holders of the trough are damaged:

• Take unit out of service.

Before Reusing With a Patient

#### Assembling the double wall

- Check parts for damage and replace if necessary.
- Fit the parts into the double wall.

Fit in the following order:

- 1 Sleeve
- **2** Pin
- 3 Centring lugs
- 4 Seal



#### Insert the drainage module\* into the pillar element

- Check the parts for damage and replace if necessary.
- Reassemble the drainage unit and drainage clip. Make sure that they are correctly aligned.
- Insert the drainage module into the pillar element from the side until it engages.
  The lug of the drainage clip must be facing outwards, and the perimeter of the drainage module must be flush with the pillar element.
- Close the side door.



 Check that the incubator is ready for operation – Refer to the checks below and to "Before Each Use", page 54.

# WARNING !

The incubator is ready for operation only when all checks have been carried out successfully.

Available option

#### Check that access ports latch securely

- Perform this test on all 4 access ports
- 1 Press down the ribbed area of the lever to open access port.
- Close access port until lever engages in the locked position.
- Try to open the access port by pulling it outwards by its edge - it must not open.

If access port does not remain securely closed:

• Take unit out of service.



#### Check that large access doors latches securely

- Perform this test on both doors
- Open door slightly.
- Then, push door back into its closed position. Turn the two knobs outwards until they engage in the horizontal position.

# WARNING !

Always ensure that both knobs of the large access doors are engaged in position in order to avoid any risk of an infant falling out of an incubator.

The red catch behind each knob must no longer be visible!

### WARNING !

The attached double wall must be positioned parallel to the front door otherwise the ducted flow of warm air will be interrupted!

If the front door fails to remain engaged or if the red marking is visible or the double wall cannot be moved:

• Take unit out of service.



#### Check that the side door latches securely

- Perform this test on both side doors
- Open side door slightly.
- 1 Then, push door back into its closed position. Turn the two knobs outwards until they tangibly engage in the horizontal position.

# WARNING !

Always ensure that both knobs of the side doors are engaged in position in order to avoid any risk of an infant falling out of an incubator.

The red catch behind each knob must no longer be visible!

If the side door fails to remain engaged or if the red catch remains visible:

• Take unit out of service.

#### Check that the double wall is firmly seated

2 Check that the double wall is securely attached to the hood. It should not move when slightly pushed.

If the double wall is not securely attached to the hood or the double wall or parts of the locking mechanism are damaged:

- Do not use the double wall.
- Take unit out of service.



#### Check that the canopy is securely seated

- **3** Grasp handle and open canopy.
- **4** Tilt canopy back (approx. 60°).





Check all four corners of the canopy for any damage to the hinge.

- Tilt canopy up slightly, and
- 1 check canopy prop.
- Lower canopy back.
- Perform check from both sides.

If canopy does not open and close properly:

• Take unit out of service.



- 2 Grasp handles on the sides of the canopy with both hands.
- 3 Lift canopy horizontally off the side windows.

If the canopy holders are damaged:

• Take unit out of service.



#### Check that trough is securely seated

- Remove canopy.
- Remove mattress.
- Remove bed.
- 4 Check catches for trough.
- Place bed on trough.
- Place mattress on bed.
- Re-install canopy.

If catches for the trough appear damaged:

• Take unit out of service.



#### Slide the bed out

- Open front door and fold it down.
- 1 Turn both knobs to the vertical position marked  $\underline{C}$ .
- 2 Grasp bed by the recessed handle or by the knobs and pull it out towards the front as far as it will go.
- 2 Push bed back until it clicks into place,
- **1** Turn both knobs to the position marked  $\overset{\frown}{\boxtimes}$ .
- Close front door.

If the bed cannot be pulled out or pushed in or if the knobs are damaged:

• Take unit out of service.

# WARNING !

Always ensure that the bed is pushed all the way in! Otherwise the ducted flow of warm air will be interrupted, and the infant may be warmed or cooled excessively.

# To remove possible disinfectant residues, we recommend running the incubator in standby mode.

- Switch on Caleo (see page 64).
- Activate air temperature control (see page 65).
- Run Caleo at 37 °C with opened access ports.

#### If using a water container:

Do not refill the water container until just before placing a new infant in the incubator (see page 49)!

If using a water bag:

Do not connect the water bag until just before placing a new infant in the incubator (see page 50)!



### **Care List**

Applicable to non-infectious patients.

The list contains approximate values only. The instructions of the hospital's infection control officer shall prevail and must be observed by the user!

What	How				
		Disinfect and clean		Sterilize	
Reusable components	Care intervals	Wipe <sup>1</sup>	Cleaning and disinfecting machine (parts washer) <sup>2</sup> 93 °C (200 °F) <sup>3</sup>	Steam 134 <sup>o</sup> C (273 <sup>o</sup> F) <sup>3</sup>	
Water supply connection kit	Replace weekly and with each change of patient				
Water container	Change of patient/weekly		yes	yes	
Double wall	Change of patient/weekly	yes			
Sleeve, pin, centring lugs, seal	Change of patient/weekly		yes		
Canopy	Change of patient/weekly	yes			
Canopy support	Change of patient/weekly		yes		
Front door	Change of patient/weekly	yes			
Side doors	Change of patient/weekly	yes			
Double walls	Change of patient/weekly	yes			
U-grommets, seals	Change of patient/weekly		yes		
Drainage module, drainage clip	Change of patient/weekly		yes		
Bed	Change of patient/weekly	yes			
Mattress	Change of patient/weekly	yes			
X-ray drawer	Change of patient/weekly	yes			
Trough	Change of patient/weekly	yes			
Air Guide plate	Change of patient/weekly	yes			
Fan impeller	Change of patient/weekly	yes			
Chassis	Change of patient/weekly	yes			
Control unit	Change of patient/weekly	yes			
Rotary knob (control unit)	Change of patient/weekly	yes			
Air intake filter	Replace every 2 months				

1) Use the recommended (see page 118) or comparable surface disinfectants.

2) Use detergent only. Do not use disinfectants that release alkali or chlorine. Risk of corrosion!

3) Observe national and international standards regarding procedures for cleaning, disinfection, and sterilization.

# **Maintenance intervals**

This chapter describes the required maintenance measures to ensure correct functioning of the medical device. These measures should be performed only by maintenance personnel.

#### **CAUTION !**

Disinfect and clean the incubator or the relevant parts before each maintenance operation, even when returning the equipment for repair purposes!

#### CAUTION !

Danger of an electric shock and device failure Do not remove cover. Maintenance jobs must be performed only by maintenance personnel. Dräger recommends the DrägerService for this purpose.

#### Maintenance terms and definitions

Term	Definition
Maintenance	Combination of all technical and administrative measures during the life cycle of a medical device for retention or restoration of working condition, so that the medical device can perform the required function
Inspection	Measures for the determination and assessment of the real condition of a medical device, including determination of the causes of wear and tear, and derivation of the required consequences for future use
Preventative Maintenance	Recurrent specified measures intended to maintain the functional condition of a medical device
Repair	Measures for the restoration of a medical device to the functional condition except for improvements

## Safety checks

The safety-related checks do not substitute the maintenance specified by the manufacturer, with the preventive replacement of wearing parts.

#### **CAUTION !**

Perform safety-related checks in the specified intervals. The correct functioning of the medical device may be endangered otherwise.

- 1 Check the accompanying documentation:
  - Current Instructions for use are available
- 2 Check all functions according to the Instructions for Use.
- 3 Check to ensure that the device combination is in flawless condition:
  - Labels are complete and legible
  - No visible damages

Safety checks

- Fuses accessible from outside match the specified values
- 4 Check the equipment of the medical device fully in accordance with the Instructions for Use.
- 5 Check electrical safety conforming to IEC 62353.
- 6 Check safety systems Check the incubator temperature:
  - Check the thermometer: Measured value at the time of measurement should not deviate more than ±0.8 °C from the displayed atmospheric temperature
  - Accuracy of thermometer < 0.1 °C</li>
  - Steady state in the incubator: Fluctuations of not more than ±0.5 °C over a period of 20 minutes
  - Define measuring point:
    10 cm above the center of the horizontal bed
  - Carry out measurement: at set value 36 °C, ambient temperature 23 °C ±2 °C

Maintenance

### Maintenance

CAUTION !

This device must be inspected and serviced at manufacturerspecified intervals.

The following table shows the maintenance intervals:

	Interval times					Who?		
	when necessary	weekly	every 2 months	every 6 months	once a year	every two years		
Replaceable parts:								
Fresh air filter	Х		Х				User	
Grommets	X <sup>1</sup>						User	
Fan motor						X <sup>2</sup>	Professionals	
Lithium battery						X	Maintenance personnel	
O2 sensors						Х	Professionals	
Skin temperature sensors		X <sup>3</sup>					User	
Adhesive pads		X <sup>4</sup>					User	
Mattress	Х						User	
Maintenance:								
Inspection				Х			Maintenance personnel	
Safety inspections <sup>5</sup>					X <sub>6</sub>		Maintenance personnel	
Measaurement checks						X <sup>7</sup>	Maintenance personnel	
Calibration:	alibration:							

O2 sensors			Х	Professionals
Scales			Х	Professionals

1) Replace if the material becomes brittle or sticky or if strips of material have become detached

2) Replace after 18000 – 20000 operating hours

3) At the latest when changing patient

4) At the latest when changing patient

 Designation is applicable in the Federal Republic of Germany; in the Republic of Austria this corresponds to the "Recurring safety-related check"

6) Provided it is prescribed by national law, e. g., §6 MPBetreibV in Germany.

7) Provided it is prescribed by national law, e. g., §11 MPBetreibV in Germany.

#### Disposal

Maintenance

# Disposal

Disposal of the water supply connection kit and air intake filter

with household waste.

Disposal of O2 sensors and batteries

#### WARNING !

Treatment of batteries and O2 sensors

- Do not throw into fire! Risk of explosion.
- Do not force open! Cells contain corrosive acid that may cause caustic burns.
- Do not attempt to recharge battery. Risk of explosion.

#### **CAUTION !**

For disposal of batteries and O<sub>2</sub> sensors follow all local, state, and federal legislations with respect to environmental protection.

Information can be obtained from local environmental and public health authorities or from approved waste disposal companies.

#### Disposal of the incubator

At the end of its service life:

- dispose of the incubator in accordance with local, state, and federal waste disposal regulations
- or
- deliver incubator to an approved waste disposal company for disposal.

Further information can be obtained from national and local environmental and public health authorities.

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# Troubleshooting

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Troubleshooting – Error Messages

# Troubleshooting

# **Troubleshooting – Error Messages**

All error messages are displayed on screen. They are listed below in **alphabetical** order. See also "Alarm Description", page 161.

Message	Cause	Remedy	Audible alarm silence
Adjust. inoperable Yellow bar LED lights up on the control unit. Audible alarm sounded (1x).	Height adjustment faulty. Motor tilt position faulty. Servomotor drive faulty.	Take unit out of service.	15 min
Air heater inoperable Measured value starts flashing on screen. Red bar LED on the control unit starts blinking. Central alarm indicator lights up.* Intermittent audible alarm (5 beeps).	Faulty air heater.	Take unit out of service.	1 min
Air temp. deviation above 1.5 °C (see "Configuration", page 108) Measured value starts flashing on screen. Yellow bar LED on the control unit starts blinking. Central alarm indicator lights up.* Intermittent audible alarm (3 beeps).	Specified alarm threshold for deviations from the setpoint has been exceeded.	Reduce/increase humidity. Close canopy, front door, and access ports. Check setpoint. Check configuration (page 104).	15 min
Air temp. sensor inoperable 3 flashing dashes on the screen. Central alarm indicator lights up.* Intermittent audible alarm (5 beeps).	Faulty air temperature sensors.	Take unit out of service.	1 min
Air temperature too high Measured value starts flashing on screen. Red bar LED on the control unit starts blinking. Central alarm indicator lights up.* Intermittent audible alarm (5 beeps).	Incubator temperature above 38 °C Incubator temperature above 40 °C <sup>1</sup>	Remove external heat sources. Take unit out of service.	5 min
Calibrate O2 sensor Three dashes flashing on screen in place of the measured value. Yellow bar LED on the control unit starts blinking. Central alarm indicator lights up.* Intermittent audible alarm (3 beeps).	O2 calibration time window expired.	Switch off O2 module. Take unit out of service.	1 min
Calibrate scale before weighing	The scales are not calibrated.	Take unit out of service.	

\* The central alarm light may be switched off. See "Configuring system settings", page 106.

Message	Cause	Remedy	Audible alarm silence
Connect skin 1 sensor Three dashes flashing on screen in place of the measured value. Red bar LED on the control unit starts blinking. Central alarm indicator lights up.* Intermittent audible alarm (5 beeps).	Probe for skin temperature (yellow) not connected.	Check connection and correct if necessary.	5 min
<b>Device Error</b> with numeric display. Continuous alarm tone. Red bar LED lights up.	Device fault.	Switch off device and then switch on again. Take unit out of service.	_
<b>Device error 31</b> Short-circuit in multiplexer Continuous alarm tone Red bar LED lights up.	Skin temperature sensor is defec- tive. Device fault.	Replace skin temperature sensor. Switch off device and then switch on again. If no skin temperature sensor is defective, i.e., the error occurs even without the sensor: Call DrägerService.	
Fan inoperable Red bar LED on the control unit starts blinking. Central alarm indicator lights up.* Intermittent audible alarm (5 beeps).	Faulty fan.	Check fan impeller. Take unit out of service.	5 min
<b>Goldcap accumulator fault</b> Yellow bar LED on control unit lights up. Audible alarm sounded (1x).	Goldcap rechargeable battery faulty. Goldcap battery connection faulty.	Take unit out of service.	10 min
Heater temp. sensor inoperable Red bar LED on the control unit starts blinking. Central alarm indicator lights up.* Intermittent audible alarm (5 beeps).	Faulty air heater temperature sensors.	Take unit out of service.	1 min
Humidifier inoperable Measured value of humidity flashing on screen. Red bar LED on the control unit starts blinking. Central alarm indicator lights up.* Intermittent audible alarm (5 beeps).	Faulty water heater.	Switch off humidity module. Take unit out of service.	1 min
Humidity deviation above 10 %	Canopy, doors, or access ports are open. Sensor faulty.	Wait for start-up phase. Set value <85 %. Close canopy, front door, or access ports. Check connection of water supply. Take unit out of service.	-

\* The central alarm indicator light may be switched off. See "Configuring system settings", page 106.

#### Troubleshooting – Error Messages

Message	Cause	Remedy	Audible alarm silence
Humidity sensor inoperable 3 flashing dashes on the screen. Red bar LED on the control unit starts blinking. Central alarm indicator lights up.* Intermittent audible alarm is sounded (5 beeps).	Faulty humidity sensor.	Switch off humidity module. Take unit out of service.	1 min
Key pad locked Message displayed and yellow bar LED lights up for 2 seconds on pressing a key.	Key functions (setpoint input/ weighing/ menu key) disabled.	Activate keypad functions (page 110).	-
Oxygen concentration below 18 %	O2 concentration less than 18 vol.%.	Check that the correct gas is connected. Take unit out of service.	1 min
Oxygen deviation above 5 % (may be set to 3 or 5 % – see "Configuration", page 108) Measured value starts flashing on screen. Red bar LED on the control unit starts blinking. Central alarm indicator lights up.* Intermittent audible alarm (5 beeps).	Deviation of measured O2 concen- tration from setpoint greater than 3 or 5 %, respectively. Values above 65 % O2 have been set.	Close the canopy, front door, removable bed, x-ray drawer, access ports, or filter cover. Check O2 connection. Check O2 supply via central medical gas pipeline or O2 cylinder. Check configuration (page 104). Reduce O2 setting to 65 %. Take unit out of service.	2 min
Oxygen module inoperable 3 flashing dashes on the screen. Red bar LED on the control unit starts blinking. Central alarm indicator lights up.* Intermittent audible alarm (5 beeps).	Faulty O2 module controller.	Switch off oxygen module. Take unit out of service.	1 min
Oxygen sensor deviation above 3 % Measured value starts flashing on screen. Red bar LED on the control unit starts blinking. Central alarm indicator lights up.* Intermittent audible alarm (5 beeps).	Sensor 1 or sensor 2 faulty.	Switch off oxygen module. Take unit out of service.	1 min
Oxygen sensor 1 inoperable 3 flashing dashes on the screen. Red bar LED on the control unit starts blinking. Central alarm indicator lights up.* Intermittent audible alarm (5 beeps).	Faulty sensor for oxygen measurement. Sensor 1 faulty.	Switch off oxygen module. Take unit out of service.	1 min
Oxygen sensor 2 inoperable 3 flashing dashes on the screen. Red bar LED on the control unit starts blinking. Central alarm indicator lights up.* Intermittent audible alarm (5 beeps).	Faulty sensor for oxygen measurement. Sensor 2 faulty.	Switch off oxygen module. Take unit out of service.	1 min

\* The central alarm indicator light may be switched off. See "Configuring system settings", page 106.
Message	Cause	Remedy	Audible alarm silence
Oxygen valve fault Measured value starts flashing on screen. Yellow bar LED flashes on control unit. Central alarm indicator lights up.* Intermittent audible alarm (3 beeps).	O2 valve faulty.	Switch off O2 module. Take unit out of service.	1 min
Scale inoperable 3 short alarm tones	The scales are faulty.	Take unit out of service.	
Skin 1 less than 0.5 °C above skin 2 (see "Configuration", page 107) The measured values for skin temperatures flashing on-screen. Yellow bar LED on the control unit starts blinking. Central alarm indicator lights up.* Intermittent audible alarm (3 beeps).	Kangaroo Mode alarm: Temperature difference between the central skin temperature (yellow) and peripheral temperature (white) too low.	Check infant's heat exchange. Check configuration (page 104).	15 min
Skin 1 more than 4.0 °C above skin 2 (see "Configuration", page 107) Measured values for skin temperatures flash on-screen. Yellow bar LED on the control unit start blinking. Central alarm indicator lights up.* Intermittent audible alarm (3 beeps).	Kangaroo Mode alarm: temperature difference between the skin temperature (yellow) and peripheral temperature (white) too high. Temperature sensor incorrectly attached to patient.	Check infant's heat balance. Check configuration (page 104). Check that temperature sensor is correctly attached to the patient.	15 min
Skin 1 sensor fault 3 flashing dashes on the screen. Red bar LED on the control unit starts blinking. Central alarm indicator lights up.* Intermittent audible alarm (5 beeps).	Sensor 1 for skin temperature (tummy) measurement faulty.	Replace sensor.	5 min
Skin 1 temp. deviation above 0.5 °C (can be set between 0.3 and 1.0 °C – see "Configuration", page 108) Measured value starts flashing on screen. Yellow bar LED on the control unit starts blinking. Central alarm indicator lights up.* Intermittent audible alarm (3 beeps).	The specified threshold for deviations from the setpoint has been exceeded.	Check that sensor is correctly attached to the infant. Close canopy, front door, or access ports. Switch off external heat sources. Remove double walls. Change configuration (page 104).	5 min
Skin 1 temperature above 39 °C Measured value starts flashing on screen. Red bar LED on the control unit starts blinking. Central alarm indicator lights up.* Intermittent audible alarm (5 beeps).	Central skin temperature too high.	Check that sensor is correctly attached to the infant. Switch off external heat sources. Check whether double walls can be removed.	2 min

\* The central alarm indicator light may be switched off. See "Configuring system settings", page 106.

#### Troubleshooting – Error Messages

Message	Cause	Remedy	Audible alarm silence
Skin 1 temperature below 36.0 °C (see "Configuration", page 107) Measured value starts flashing on screen. Yellow bar LED on the control unit starts	Kangaroo Mode alarm: Skin temperature is falling below the alarm limit.	Increase heat supply to the infant. Check configuration.	15 min
blinking. Central alarm indicator lights up.* Intermittent audible alarm (3 beeps).	Temperature sensor incorrectly attached to patient.	Check that temperature sensor is correctly attached to the patient.	
Skin 2 sensor fault 3 flashing dashes on the screen. Red bar LED on the control unit starts blinking. Central alarm indicator lights up.* Intermittent audible alarm (5 beeps).	Sensor 2 for peripheral skin temperature (toe) measurement faulty.	Replace sensor.	5 min
Skin 2 temperature above 39 °C Measured value starts flashing on screen. Red bar LED on the control unit starts blinking. Central alarm indicator lights up.* Intermittent audible alarm (5 beeps).	Peripheral skin temperature too high.	Check that sensor is correctly attached to the infant. Switch off external heat sources. Check whether double walls should be removed.	2 min
Skin 2 temperature below 34.0 °C (see "Configuration", page 107). Measured value starts flashing on screen. Yellow bar LED on the control unit starts blinking. Central alarm indicator lights up.* Intermittent audible alarm (3 beeps).	Kangaroo Mode alarm: Peripheral skin temperature falling below the alarm limit. Temperature sensor incorrectly attached to patient.	Increase heat supplied to the infant. Check configuration. Check that temperature sensor is correctly attached to the patient.	15 min
Water empty, please refill Measured value starts flashing on screen. Yellow bar LED on the control unit starts blinking.	Water supply is empty.	Fill water reservoir to the "Full" level mark. Replace water bag.	15 min
Central alarm indicator lights up.* Intermittent audible alarm (3 beeps).	Air bubble in water supply connection kit.	Remove air bubble from water supply connection kit.	
Wrong oxygen sensor 1 Message flashing on screen. Red bar LED on the control unit starts blinking. Central alarm indicator lights up.* Intermittent audible alarm (5 beeps).	Wrong sensor in O2 module. No measurement can be performed with the replacement oxygen sensor.	Take unit out of service. Switch off O2 control.	1 min
Wrong oxygen sensor 2 Message flashing on screen. Red bar LED on the control unit starts blinking. Central alarm indicator lights up.* Intermittent audible alarm (5 beeps).	Wrong sensor in O2 module. No measurement can be performed with the replacement oxygen sensor.	Take unit out of service. Switch off O2 control.	1 min

\* The central alarm indicator light may be switched off. See "Configuring system settings", page 106.

## **Troubleshooting – Faults**

All faults are listed in the table below in **alphabetical** order. See also "Alarm Description", page 161.

Fault	Likely Causes	Remedy
Bassinet cannot be set to the tilted position.	Motor overheating.	Wait for at least 2 minutes. After this period, tilting is again possible for a few seconds (10 %). The full duty cycle is only available after a pause of 54 minutes.
	Motor faulty.	Take unit out of service.
Height adjustment does not switch off.	Switch faulty or loose contact. Motor faulty.	Take unit out of service.
Height adjustment not possible.	Lifting motor overheating.	Wait for at least 2 minutes. After this period, height adjustment is again possible for a few seconds (10 %). The full duty cycle is only available after a pause of 54 minutes.
	Lifting motor faulty.	Take unit out of service.
Red bar LED on control unit is lit. Continuous audible alarm tone. Audible alarm cannot be silenced.	Serious device fault.	Take unit out of service.
Red LED at ⊐o- symbol flashing, intermittent alarm tone.	Power failure alarm.	Check power supply. – Connect to line power. Take unit out of service.
Short beep signal (3X) is sounded.	While setting a set value, the rotary knob is not pressed within 20 seconds.	Press rotary knob or cancel input.
The yellow LED in the alarm button is lit.	Alarm suppression is active.	Deactivate alarm suppression.

If any other faults not listed in this table occur, or in case Caleo does not respond as expected: Take unit out of service.

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# Theory of Operation

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*Operating Principle Accessibility* 

## Theory of Operation

## **Operating Principle**

Inside the Caleo patient "capsule" (Caleo Calmcapsule<sup>™</sup>), premature and sick infants are supplied with a controlled amount of heat and, if necessary, humidity<sup>\*</sup> and oxygen<sup>\*</sup>. The user/operator can adjust the incubator climate to suit the needs of the infant, by adjusting air temperature, relative humidity<sup>\*</sup> and oxygen content<sup>\*</sup>. Since the patient capsule acts as a specially protected zone for the infant, the ambient air is filtered before it enters the interior of the incubator.

## Accessibility

Caleo provides excellent accessibility to the infant for all regular and intensive care activities: for this purpose, the four access ports (two on each longitudinal side) have been designed with especially large dimensions (Caleo JumboPorts<sup>™</sup>).

The two large access doors can be completely folded down. In addition, two smaller side doors at the head and foot ends of the patient bed can be folded down. If necessary, the hood canopy can also be propped up from two different sides or can be fully removed in an emergency – in order to provide free accessibility to the infant from above.

A total of ten generously dimensioned access grommets ensure clear organization and routing of hoses and cables into the incubator. Each corner features two such grommets, which can be easily removed, especially during "kangaroo care" (when the infant rests in direct skin contact on the mother's or father's chest). This ensures easily manageable cable and hose routing even when the infant is outside the patient capsule. Two additional large tubing ports are located in the side doors at the head and foot end. In addition, the hood canopy contains a hole, e.g. for feeding the infant. The four U-grommets in each corner segment of the incubator hood allow HFV tubing to be inserted, therefore allowing the treatment of infants with a high frequency ventilator while in the incubator without compromising the microenvironment (temperature, humidity, oxygen, noise level).

<sup>\*</sup> Available option

Bed and Mattress Twins in the Caleo (Caleo® Twincubator™) Taking X-Rays

#### **Bed and Mattress**

The bed is especially wide in order to provide sufficient space for the infant under a variety of conditions – such as installation of hoses, when using supports and storage aids, when treating twins in a single incubator and also when turning the infant, e.g. for reintubation in the incubator.

To prevent decubitus, an extra-soft mattress is used (SoftBed<sup>TM</sup> Caleo<sup>\*</sup>).

The bed can be pulled out when the front door is open. The bed electrically tilts in order to obtain either a head-up (Trendelenburg) or head-down (reverse Trendelenburg) position  $(\pm 13^{\circ})$ .

## Twins in the Caleo (Caleo Twincubator®)

Twins can be placed together in Caleo if there are no medical objections and if their total combined weight does not exceed 5 kg. When treating twins in a single incubator, Caleo must be operated in air control mode.

The treatment of twins together in a single incubator may help to prevent post-natal separation trauma. Direct skin contact between the twins can have positive effects on the development of the infants similar to those associated with "Kangaroo" Mode (see page 156). If necessary, the incubator air temperature may have to be reduced, because the infants mutually warm each other by direct contact and would therefore be at risk of becoming overheated.

During operation in air temperature mode, skin temperature of the first infant can be monitored with the yellow temperature sensor, while the second temperature channel (white probe) can be used to monitor skin temperature of the second infant.

Possible dangers of treating twins in a single incubator include the risk of cross-infection, and from possible confusion between the two patients when administering medicine or food. Always take the appropriate protective precautions when using X-rays. If twins require different ambient temperatures or ambient air with different oxygen or humidity saturation levels, they should be placed in two separate incubators.

## **Taking X-Rays**

The infant may be x-rayed inside the incubator without having to be removed or lifted using the x-ray drawer, which is accessible from outside the incubator. The x-ray drawer can be pulled out without having to open the Caleo front door. Unnecessary disturbance of the infant is therefore avoided. A grid is provided on the x-ray drawer to help align x-ray cassettes. Integrated Infant Scale

## Integrated Infant Scale<sup>\*</sup>

With the optional, fully integrated incubator infant scale, patient weight can be determined without having to remove the infant from the protective climate of the incubator. Even with the builtin scale, the use of the x-ray drawer remains possible. In order to be weighed, the infant must be lifted once in order to reset the scale to zero (tare weight). The infant can then be placed back on the mattress. The current and previous weights are displayed for information. The results of the last 30 weighings can be graphically represented in the trend display.

Weighing without lifting the infant again (i.e. without obtaining a new tare weight) is possible. This option is useful when the weight has to be taken again for verification purposes shortly after the first weighing, or if, e.g. the weight with full and empty diaper needs to be determined. The entire weighing procedure is guided by brief audible signals, so that the operator's full attention can remain with the patient.

When weighing the infant inside an incubator, great care must be taken that no hoses or cables are jammed by the bed or otherwise distort the weight measurement. If the weight is determined with hoses and cables attached to the infant, best results are obtained if hoses and cables are removed from the ventilator circuit support arm of the bed and laid onto the bed surface as horizontally and as strain-free as possible.

The infant scale in the Caleo comprises four weighing cells located underneath the bed, an electronic measuring and analysis unit and a special page on the control monitor. In normal mode, the entire bed rests on these four weighing elements under the bed. A safety system prevents the weighing elements being damaged if loads of more than 10 kg are applied. When removing the bed, it is first raised slightly by turning two knobs so that it can then be pulled out gently.

<sup>\*</sup> Available option

*Airflow Air Temperature Control* 

#### Airflow

The heated and humidified air flows into the incubator hood from both sides. It is guided up the inside of the front door, along the hood canopy and then down the two transverse sides by suction. The air from the interior is mixed with fresh ambient air by an air filter and is circulated by a fan. Along this path, the air is channeled past an electrically powered heater and is humidified if necessary<sup>\*</sup>.

The infant lies in a calm zone with low airflow velocity. Convective heat loss is therefore kept to a minimum. When the large access doors or access ports (Caleo JumboPorts<sup>™</sup>), are open, an efficient warm air curtain prevents cooling of the patient capsule.



## **Air Temperature Control**

The user sets the desired air temperature in the patient capsule on the incubator control unit (setpoint for air temperature in air temperature mode). The current air temperature is measured by the air temperature sensor in the patient capsule (at the infant's head end of the incubator) and is then compared to the setpoint. If the set value is greater than the actual measured air temperature, the heater receives the signal to apply more heat. The air temperature inside Caleo therefore increases. If the setpoint is lower than the actual measured air temperature, the heater receives the signal to apply less heat. The air temperature inside Caleo drops. If the current air temperature deviates from the set value by more than  $\pm 1.5$  °C<sup>\*\*</sup>, an alarm is triggered.

The audible signal of this alarm can be muted by the user. As soon as the deviation in the measured air temperature is within  $\pm 1.5$  °C <sup>\*\*</sup> of the set value (see above), the alarm is cancelled.

<sup>\*</sup> Available option

<sup>\*\*</sup> Other configurations possible, see "Configuring alarm settings", page 107.

## Theory of Operation

Skin Temperature Measurement ThermoMonitoringTM

#### Caleo temperature control characteristics

The desired temperature increase is achieved rapidly due to the high heating power of Caleo. Lowering air temperature takes longer, due to the good thermal insulation of the incubator.

#### Note on setting air temperature setpoint for Caleo:

Inside the incubator, the infant has limited

- convective heat loss, because air velocity above the mattress is low.
- heat loss through the mattress, because the mattress is well insulated.
- evaporative heat loss, provided that humidity<sup>\*</sup> is set relatively high (above 60 %).
- radiant heat loss, provided that the canopy double wall<sup>\*\*</sup> is installed.

## **Skin Temperature Measurement**

Two skin temperature sensors can be connected to measure central (tummy) skin temperature (yellow skin temperature sensor) and peripheral temperature (white skin temperature sensor). The measured value of the yellow skin temperature sensor is used to regulate the incubator heater in "skin temperature control mode".

## ThermoMonitoring<sup>®</sup>

The term ThermoMonitoring refers to the continuous measurement and display of a central temperature and a peripheral temperature. Instead of the true central (core) temperature, a central (near-core) skin temperature can be used, as it is measured for the incubator's skin temperature control.

The continuous display of the difference between these two temperatures permits early detection of cold stress. However, heat stress, thermoregulation problems, and, e.g., infections can also be more rapidly detected by displaying the two temperature values and evaluating their difference.

Consequently, Caleo provides the possibility of switching between a standard screen with large numeric digits and a trend screen showing trend graphs of a maximum of two temperatures. In this way, the difference between central skin temperature and peripheral skin temperature essential for ThermoMonitoring can be displayed continuously.

In addition, trend analysis allows to call up values from the past when looking to explain, in hindsight, the development of disease symptoms or the development of hypothermal stress. Values going back a maximum of seven days can be accessed. In addition, the desired time window can be set (between 3 hours and seven days).

<sup>\*</sup> Available option

<sup>\*\*</sup> See Caleo accessories

Skin Temperature Control

With the "Trend Main Page" option selected from the main menu, the user can preconfigure which trend to display when switching from numerical to trend display.

In addition to displaying the two skin temperatures, the display can show the following parameters: air temperature, humidity<sup>\*</sup>, oxygen<sup>\*</sup> and the weight<sup>\*</sup>, with a memory of up to 30 weight readings.

## **Skin Temperature Control**

When Caleo is operated in skin temperature mode, this mode can be set on the control unit. At least the yellow skin temperature sensor (Skin 1) must be plugged in and be properly attached to the infant. The user sets the setpoint for skin temperature on the control unit. The infant's actual skin temperature is measured by the yellow skin temperature sensor (Skin 1) and compared with the setpoint.

The difference between setpoint and measured actual value is used to control the air temperature in Caleo between a minimum of 20 °C and a maximum of 39 °C. If the setpoint is higher than the currently measured skin temperature (skin too cold), the heater receives a signal to supply more heat. The air temperature in Caleo rises, thereby also increasing the infant's skin temperature. If the setpoint is lower than the actual measured skin temperature (skin too hot), the heater receives a signal to apply less heat. The air temperature inside Caleo drops, thereby also reducing the infant's skin temperature.

The longer the deviation between the set value and the actual measured value persists, the more powerfully heat is supplied by the heater (if the skin is too cold) or the more the air temperature in Caleo is reduced (if the skin is too warm).

#### Wait for the controller to reach steady state.

The infant's skin temperature varies frequently, e.g. due to food intake or medical care. Deviations of a few tenths of a degree are normal.

Therefore:

Only change the set value of the skin temperature if the intention is to change the infant's (central) temperature. If the actual skin temperature deviates from set skin temperature by more than  $\pm 0.5 \, {}^{\circ}C^{**}$ , an audible alarm is triggered. This audible alarm can be silenced by the user. As soon as the measured value deviates from the set value by less than  $\pm 0.5 \, {}^{\circ}C^{**}$  (see above), the alarm is deactivated again.



Operating Instructions Caleo, Software 2.n

<sup>\*</sup> optional equipment feature

<sup>\*\*</sup> other configurations possible

Kangaroo Mode

## Kangaroo Mode

Kangaroo Mode (Caleo Kangaroo Mode) simplifies the operation of the incubator when the infant is removed to have direct skin contact with the mother or father ("skin-to-skin care"). This mode provides the user with extended monitoring functions in order to detect infant hyperthermia or hypothermia even when the infant is outside the patient capsule.

Other Caleo features designed to ensure easier removal of the infant from Caleo for "kangarooing":

- removable tubing grommets in the corners of the incubator,

- ability to lower the patient bed down to 80 cm (31.5") (with height adjustment<sup>\*</sup>)
- minimal space requirement of the fold-down access door of the Caleo.

The incubator switches to Kangaroo Mode after pressing the "Menu" key on the control unit. Once Kangaroo Mode is activated, the following functions are automatically activated:

#### • Switchover to "Standby" mode

Since the infant is no longer inside Caleo during "kangarooing", the infant's skin temperature should no longer be used as a measure for controlling the air temperature inside the incubator. Instead, the incubator should be set up so that when "kangarooing" is concluded and the infant is put back inside Caleo, the incubator will be heated to the same temperature and climate as when the infant was taken out of the incubator. Consequently, during "Standby" mode, the following logic is applied:

If Caleo was previously operated in skin temperature mode, it is switched to air temperature mode for the duration of Kangaroo Mode. The setpoint for air temperature is automatically determined as the average air temperature over the last three minutes. The previous setpoint for skin temperature is stored in buffer memory.

If Caleo was previously operated in air temperature mode, the setting remains unchanged.

#### • Automatic alarm muting

Since, usually, after switching over to Kangaroo Mode, the door is opened and the infant taken out of the incubator, alarms triggered by opening the doors are no longer meaningful. Consequently, all alarms that would normally be activated by opening the large doors are automatically muted for the next 4 minutes - see page 91.

<sup>\*</sup> Available option

Kangaroo Mode

#### Activation of special Kangaroo Mode alarms

During Kangaroo Mode, the skin (and central) temperature of the infant is frequently found to rise. However, in some cases, the infant becomes cooler. Consequently, the infant's central or skin temperature must be regularly monitored. In order to perform this monitoring with as little nuisance alarms as possible to mother/father and infant, Caleo allows to activate special Kangaroo Mode alarms during operation in Kangaroo Mode. These alarms are set in the configuration. The following alarm limits are set:

- Lower alarm limit for the skin temperature (Skin 1; T1) = Skin T1 min.
- Lower alarm limit for the peripheral temperature (Skin 2; T2) = Skin T2 min.
- Lower alarm limit for the difference between T1 and T2 =  $\Delta T$  min.
- Upper alarm limit for the difference between T1 and T2 =  $\Delta$ T max.

These kangaroo alarms have the following significance:

#### Skin T1 min.:

The alarm is triggered as soon as the (central) skin temperature (T1, yellow skin temperature sensor) falls below this alarm threshold.



Skin T2 min.:

The Skin T2 min. alarm is triggered as soon as the peripheral skin temperature (T2, white temperature sensor) falls below this alarm threshold.



 $\Delta T$  min.:

This alarm is triggered if the difference between Skin T1 and Skin T2 is less than this alarm threshold (risk of hyperthermia).



## Theory of Operation

#### O2 Therapy

∆T max.:

This alarm is triggered if the difference between Skin T1 and Skin T2 is greater than this alarm threshold (risk of hypothermia).



Each of these alarms can either be set or switched to "OFF" in advance.

However, immediately after switching over to Kangaroo Mode, automatic alarm muting is active for the first four minutes, which includes all special Kangaroo Mode alarms. This allows the infant time to adapt to the new environment.

## O<sub>2</sub> Therapy

With closed-loop oxygen control in the patient capsule, oxygen delivery is metered by a microprocessor controlled valve. In this fashion, the oxygen is introduced into the air ducting system where it is heated and humidified

Humidity Control

## Humidity Control<sup>\*</sup>

Caleo provides a means for hygienic humidification of the incubator air<sup>\*</sup> by evaporating (boiling) water from a separate supply (water bag or water reservoir).

With closed-loop humidity control, only the desired relative humidity setpoint is entered, and Caleo then automatically controls the evaporator output of the humidifier to maintain the preset relative humidity in the patient capsule.

Caleo allows to control humidity in two different fashions:

- manual adjustment of humidity setpoints, or
- automatic humidity control (AUTO humidity).

#### Manual humidity setpoints

A value between 30 % and 99 % relative humidity can be set. The actual humidity level is measured by a humidity sensor in the patient capsule (integrated into the sensor module at the head end of the patient capsule). If the setpoint is higher than the actual measured relative humidity (air too dry), the humidifier receives a signal to allow more water vapor into the patient capsule. Relative humidity inside Caleo therefore rises. If the set value is lower than the actual measured relative humidity (air too humid), the humidifier receives a signal to allow less water vapor into the patient capsule. Relative humidity inside Caleo therefore falls.

#### AUTO humidity

In closed-loop humidity control, the user can choose between setting relative humidity setpoints manually (see above) and AUTO setting. In AUTO mode, the setpoint for the relative humidity is calculated and set automatically by the system as a function of air temperature (see graph to the right). This function is based on the observation that small and relatively immature infants require both a higher air temperature and higher relative humidity than larger infants. Consequently, in AUTO mode, the set value for relative humidity is calculated and set as a function of air temperature. The lower the air temperature setting, the lower the set value for relative humidity.



Cleaning Mode Safety Systems

## Cleaning Mode<sup>\*</sup>

Cleaning mode is only provided if Caleo is equipped with humidity control.

The Cleaning Mode (Caleo<sup>®</sup>CleanSwitch<sup>TI</sup>) simplifies the cleaning of Caleo<sup>®</sup>. The Cleaning mode must be used after ending operation of Caleo<sup>®</sup> (see page 116), after the water supply has been disconnected (see page 124).

Cleaning mode may only be used if Caleo is empty.

Cleaning mode is activated from the control unit by pressing the "Menu" key and selecting the "Cleaning Mode" option.

In Cleaning mode, the water heater is forced to run dry. For this purpose, the humidifier is heated to above 100  $^{\circ}$ C (212  $^{\circ}$ F) for 20 minutes, so that all remaining water in the humidifier is evaporated. After the residual water has been evaporated, the temperature in the humidifier is maintained at a temperature above 100  $^{\circ}$ C (212  $^{\circ}$ F) for approximately another 10 minutes. Afterwards, the humidifier is allowed to cool down.

During or after cleaning mode, condensation could form under the aggregate housing of the Caleo!

When there is no longer any danger of burns, a message is displayed on screen to inform the user that Cleaning Mode has concluded and that the incubator may now be dismantled for disinfecting and cleaning (see "After cleaning mode is complete", page 123).

## Safety Systems

After switching on the incubator, it performs a self-test to check all memory addresses of the microprocessor control system and the proper running of all program segments. Functions of the control elements and feedback messages are tested by switching them on and off. This test is also performed at ten-minute intervals during operation. In this test, all modules installed in the incubator are tested. Any error message will be displayed even when the module found to be faulty was switched off at the time.

As a safety precaution, any non-permissible operating condition will cause Caleo to switch off its main heater or water heater, respectively.

An additional temperature sensor in the warm air vent limits heater output in cases where the heater control would generate maximum output over an extended period of time. Typical situations are, e.g., opening of access doors for an extended period of time, high setpoints (39 °C) in the presence of low ambient temperatures (<22 °C), or a partially obstructed warm air vent.

This safety feature significantly reduces the risk of burns caused by excessively hot surfaces in the area of the air vents or by vented warm air.

<sup>\*</sup> Available option

Alarm Description

## Alarm Description

#### Visual signals on the control unit

- Red bar LED\* 1
- Yellow bar LED\*\* 2
- 3 Red power failure LED next to the \_\_\_\_\_ symbol

Caleo distinguishes between 5 different alarm priorities that are accompanied by audible alarms:

#### Serious device faults

#### Device fault:

- Continuous audible alarm that cannot be silenced, and
- 1 red bar LED lighting up.

#### Power failure:

- Intermittent alarm tone that cannot be silenced, and •
- red power failure LED next to the  $\neg$  symbol lighting up. 3

#### Warning (higher risk level)

- Alarm tone sequence (5 beeps), which can be silenced, •
- 1 Red bar LED blinking,
- central alarm light lighting up\*\*\*, and •
- measured value flashing. .

For example:

Skin 1 temperature above 39 °C \_

#### Caution (medium risk level)

- Alarm tone sequence (3 beeps), which can be silenced, •
- 2 Yellow bar LED blinking,
- central alarm light lighting up\*, and
- measured value flashing.
- For example:
- Air temp. deviation above 1.5 °C

#### Advisory (low risk potential)

- Alarm tone (1x), which can be silenced. •
- 2 Yellow bar LED lighting up.

#### For example:

Adjust. inoperable \_

#### Indication of extended setting ranges

- No alarm tone \_
- 2 Yellow bar LED lighting up
- For example:
- Extended temperature range >37 °C activated. \_
- Warning immediate action is required Caution rapid action is required
- \*\* \*\*\*
- The central alarm indicator light may be switched off. See "Configuring system settings" page 106.











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## Theory of Operation

Alarm Description

#### Information

No bar LED lit, no audible alarm. For example: - Humidity deviation above 10 %

Information messages regarding the active alarm are displayed on screen.

If another alarm occurs while an audible alarm is silenced, the audible alarm will be reactivated. See "Suppressing Alarms", page 111.

#### Central alarm indicator light

- 1 The central alarm lights up whenever an alarm occurs.
- 1 The central alarm indicator does **not** light up with an alarm
- if the alarm silencing key had been pressed, or
- if the central alarm indicator has been deactivated in the Configuration. See "Configuring system settings", page 106.



## Glossary

Key to Symbols Used

# Glossary

## Key to Symbols Used

Ø	Alarm silence/suppression
←」	Cancel, stop setting procedure
d'à	Weighing scale
$\bigcirc$	Bed tilt
, <del>CÍ</del>	Bed can be pulled out
	Radioscopy, x-ray drawer can be pulled out
$\triangle$	Caution: please note special information on this function in the User Instruction Manual (this document).
×	Туре ВF
i	Information
	Please wait. Function will be activated shortly.
	Keypad lock
$\bigcirc$	Waiting for input from rotary knob
-ch	Day and Night
_/	Measurement range overflow, see page 114
Å	Nurse call

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# Technical Data / Ordering Information

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Ambient Conditions Operating Data

## **Technical Data**

## **Ambient Conditions**

Normal operation				
Temperature	20 °C to 35 °C (59 °F to 95 °F)			
Air pressure	600 hPa to 1060 hPa			
Rel. humidity	10 to 95 % without condensation			
Storage / transport				
Temperature	–20 °C to 60 °C (–4 °F to 140 °F)			
Air pressure	210 hPa to 106	0 hPa		
Rel. humidity	10 to 95 % with	out condensation		
Operating Data				
Electrical power supply	100 V / 110 V /	120 V / 127 V / 22	0 V to 240 V	/
	(please specify	in your order) 50 l		v
Max. current consumption at 120 V	8.7 A*	,	/ 00 /	
Leakage current 100 – 127 V / 50 Hz / 60 Hz	150 µA			
Heater power				
Line voltage connection	100 V/120 V	110 V/127 V	230 V	240 V
Air heater max.	525 W	588 W	525 W	572 W
Water heater max.	147 W	165 W	147 W	160 W
Built-in power socket strip				
Max. permissible total power				
consumption for all sockets	2 A			
▲ Max. leakage current:				
By connecting devices to the power socket strip the o Where applicable, national limits must be observed. T leakage current.	verall leakage cur The operator is res	rent may be increa ponsible for adher	ised to an u ing to the sp	nacceptably high level. becified maximum overa
LISA (III. 60601-1) <sup>.</sup>				
Permissible overall ground leakage current	500 uA			
Max ground leakage current of the socket strip	350 µA			
	000 p. (			
Height adjustment and tilting				
Duty cycle	10 %			
Shut-off mode	6 minutes ON,	54 minutes pause	(intermittent	t duty)
O2 inlet pressure	min. 300 kPa (4	3.5 psi), max. 600	) kPa (87 ps	i)

<sup>\*</sup> Values include power consumption of the integrated power strip

#### Technical Data

Performance Data Measurement and Control Parameters

### **Performance Data**

Warm-up time	20 minutes from 20 °C to 31 °C (at 20 °C ambient temperature)
Increase in O2 concentration from 21 to 60 vol.%	<10 min
Humidification	Evaporation of sterile distilled or demineralized water
Air speed over the bed	<8 cm/second (3.1 inch/second)
Fresh air flow	up to 30 L/min
CO2 elimination according to IEC/EN 60 601-2-19 / 105.1 Max. CO2 concentration in the incubator	<0.5 vol.%
Bed tilting	Infinitely adjustable up to $13^{\circ} \pm 2^{\circ}$ tilt angle at both ends
Noise level inside the canopy	47 ±2 dB(A)
Particle filter	NaCl pass volume ≤6 %

#### **Measurement and Control Parameters**

The specified values depend on ambient conditions

#### Air temperature control

Measuring principle Measuring range Measuring accuracy Setpoint range

Skin temperature control Measuring principle

Measuring range

Setpoint range

O<sub>2</sub> control

Measuring accuracy

Measuring principle

Measuring range Measuring accuracy

Cross-sensitivity

Setpoint range

NTC, 2 x 13 °C to 42 °C (55.4 °F to 107.6 °F)  $\pm 0.8$  °C (1.44 °F) 20 °C to 39 °C (68 °F to 102.2 °F) in increments of 0.1 °C \* <28 °C (82.4 °F) and >37 °C (98.6 °F), extended range (with confirmation)

NTC 13 °C to 43 °C (55.4 °F to 109.4 °F) ±0.3 °C (0.54 °F) 34 °C to 38 °C (93.2 °F to 100.4 °F) in increments of 0.1 °C >37 °C (98.6 °F), extended range (with confirmation)

Electrochemical sensor (capillary) 18 vol.% to 99 vol.% ±3 vol.% Humidity <1.5 % 21 vol.% to 75 vol.% in 1 vol.% increments >40 vol.%, extended range (with confirmation) With a gas pressure of 400 kPa, the actual values are between 65 and 77 vol.%.

<sup>\*</sup> Setpoint must be at least 3 °C (5.4 °F) above ambient temp. Under conditions of low ambient temperatures, high settings (39 °C) may not completely be reached. Use double wall.

## Technical Data

#### Measurement and Control Parameters

Humidity control Measuring principle Measuring range Measuring accuracy Setpoint range	Capacitive 10 % rel. humidity to 99 % rel. humidity ±10 % in set value range 30 % rel. humidity to 99 % rel. humidity in 1 % increments*
Integrated infant scale Measuring range	max. 10 kg (22 lbs)
	min. 0 g (0 oz) without tare measurement
Measuring accuracy** (e)	2 = (0.071  oz) from 250 a to 2.5 kg (8.7 oz to 5.5 lbs)
– with taring	5 g (0.176 oz) from 2.5 kg to 10 kg (5.5 lbs to 22 lbs)
<ul> <li>without taring</li> </ul>	5 g (0.176 oz) from 0 kg to 2.5 kg (0 lbs to 5.5 lbs) 10 g (0.353 oz) from 2.5 kg to 10 kg (5.5 lbs to 22 lbs)
Resolution (d)	1 g (0.035 oz) from 0 kg to 10 kg (0 lbs to 22 lbs)
MEDIBUS interface (optional)	Dräger communication protocol for medical devices Serial interface for connecting up to medical devices which comply with IEC 60601-1, for transmitting the incubator status data (actual values, set values, alarms). All signals are electrically isolated from the patient section (electric strength 1500 V). For a detailed description of the interface protocol please see the manual "Dräger RS 232 MEDIBUS Protocol Definition" 90 28 258 and "MEDIBUS for Dräger Paediatric Devices" 90 29 205
	Caleo Monitor Pin $5$ $GND$ $GND$ $Pin 5$ 2 $RxD$ $TxD$ $3$ 3 $TxD$ $RxD$ $2$

Service interface (optional)

For connecting to the Remote Service Box for service purposes

Connector casing

9-pin sub-D

socket

9-pin sub-D

connector

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<sup>\*</sup> Maximum humidity attained depends on air temperature and ambient humidity. With high ambient air temperature and low ambient humidity, respectively, the maximum humidity that can be reached inside Caleo will decrease.

<sup>\*\*</sup> The measuring accuracy depends on the geological and geographical conditions at the installation site. Calibration before delivery is not sufficient to guarantee the specified accuracy in some regions. On-site calibration is recommended in such cases.

#### Nurse call (optional)

Output for connection to in-house P.A. systems (nurse call) Connection 3 to 5 will be closed and the nurse call is activated in the event of an alarm with a high risk potential or if there is a serious equipment fault.

Connection 1 to 3 will be closed and the nurse call is not activated in the event of an alarm with a medium or low risk potential.



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## Central alarm (optional)

Potential-free changeover contact

Operating voltage Current Power Output for connection to in-house P.A. systems (nurse call) max. 24 V max. 250 mA max. 3 W

## **Physical Characteristics**

#### Dimensions

Incubator (width x depth) Height overall with height adjustable column Height overall with fixed column Height of mattress surface (variable height) Height of mattress surface (fixed height)

Bed (width x depth)

#### Weight

Overall weight max. basic configuration

Overall load capacity

1167 mm x 687 mm (45.9" x 27.0") 1220 mm to 1520 mm (48.0" x 59.8") 1270 mm / 1370 mm / 1470 mm (50" / 53.9" / 57.9") 800 mm (31.5") to 1100 mm (43.3") 875 mm (34.4") / 950 mm (37.4") / 1050 mm (41.3"), depending on fixed height column installed 645 mm x 500 mm (25.4" x 19.7")

230 kg (507 lbs) 130 kg (286.6 lbs)

66 kg (142.5 lbs)

Physical Characteristics

Overview of max. loads



or alternatively with installed monitor support tray (2M 50 085)



Standards Enclosure protection class Electromagnetic compatibility

Skin temperature sensor Standards

Incubator conforms to IEC/EN 60601-1, IEC/EN 60601-2-19

tested to IEC/EN 60601-1-2 and IEC/EN 60601-2-19 (36.202.2.1) 10 V/m

T

Type BF Device conforms to IEC / EN 60601-1, IEC / EN 60601-1-2 IEC / EN 60601-2-19

# **Ordering Information**

## **Incubator and Accessories**

Designation and description	Part No.
Caleo	2M 50 555 /
Caleo incubator with air and skin servo modes, ThermoMonitoring <sup>®</sup> (temperature probes optional). With large front and rear access doors	2M 50 000
6 extra large access ports (Jumbo Ports <sup>™</sup> ), detachable hood which opens to either side, electric bed tilt (±13°):	
10 extra large tubing ports, integrated	
x-ray tray, integrated power strip	
Draeger rotary knob, trend display and large numerical display, central alarm light.	
Available options	
Mobile stand with fixed height	Feature
Mobile stand with variable height	Feature
Servo controlled humidity	Feature
Servo controlled oxygen	Feature
Double wall	Feature
Integrated bed scale	Feature
Drawer	Feature
Interface (2xRS232, 1x nurse call)	Feature
Caleo canopy set	Feature
Caleo canopy set HFV	Feature
Accessories for oxygen therapy	
MiniOx 3000	2M 22 464
Accessories for servo controlled oxygen	
DISS oxygen hose, 10 foot (available in USA)	45 30 807
Shelves, holders, infusion accessories	
Monitor shelf	2M 50 085
Swivel table	2M 21 186
Pole 38/600	2M 50 691
Pole 38/310	2M 50 688
Pole 25/600	2M 50 689
Base pole	2M 50 680

## Ordering Information

Incubator and Accessories

Designation and description	Part No.
Infusion support, 38 mm pole	2M 21 514
Rail-mounted infusion holder	M 20 790
Compact rail	2M 85 337
Tray 3020	M 24 678
Accessories for bed area	
Ventilation circuit support arm	84 11 075
Caleo SoftBed <sup>™</sup>	MX 17 012
Wire basket 510	M 24 670
Wire basket 150	M 26 146
Wire basket 300	M 26 145
Wire basket 600	M 25 121
Accessories for phototherapy	
Phototherapy 4000 (110, 127 V)	2M 21 700
Stand for phototherapy unit 4000	2M 21 100
	210121190
Accessories for care	
Cally	2M 30 462
"Caleo" incubator hood	2M 30 467
lingrade kits	2M 50 900
Serve controlled humidity	2M 50 735
Serve controlled axygen	2M 51 092
Bed scale integrated	2M 50 745
	2M 50 7 10
Double wall, complete	2M 51 150
Drawer	2M 50 565
Interface RS 232	2M 50 750
Ventilation has strain relieve (ontional)	211 50 750
	2111 01 140
Technical Documentation	upon request

Replacement Parts

## **Replacement Parts**

Designation and description	Part No.
Spare parts and consumables	
Caleo canopy	2M 51 108
"Feeding grommet" plug	2M 51 109
Double wall, complete	2M 51 150
Water reservoir, complete	2M 50 040
Cap for water reservoir	2M 50 042
Nozzle for water reservoir	2M 50 039
Infusion sets Caleo (20 pcs)	MX 17 018
Caleo air intake filter (20 pcs)	MX 17 015
ThermoTrace <sup>™</sup> , central (set of 5), yellow	MX 11 000
ThermoTrace <sup>™</sup> , peripheral (set of 5), white	MX 11 001
ThermoPad <sup>™</sup> (set of 50)	MX 11 002
Oxy-Trace <sup>™</sup> Incu.	MX 01 050
Tubing grommets, large	2M 50 385
Tubing port	2M 50 412
Caleo SoftBed <sup>™</sup>	MX 17 012
Vacuum mattress	2M 17 909
Lithium batteries, 3V/1400 MAH	18 35 343
Cally	2M 30 462
As an alternative to the part numbers listed above, the following parts and devices, which are no longer supplied by Draeger, may be used.	
Adhesive pads	2M 21 735

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These Operating Instructions apply only to **Caleo**<sup>®</sup> with Serial No.: If no Serial No. has been filled in by Dräger, these Operating Instructions are provided for general information only and are not intended for use with any specific machine or device.



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