

Technical Documentation IPM

Isolette 8000 plus



Warning

All servicing and/or test procedures on the device require detailed knowledge of this documentation. Use of the device requires detailed knowledge and observance of the relevant Instructions for Use.

Incubator

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1 General

This chapter contains general notes and definitions that are important for the use of this documentation.

1.1 General notes

1.1.1 Notes on use

Read through the following notes thoroughly before applying this documentation.

The warnings set out here apply to all parts of this documentation.

Dräger reserves the right to make changes to the device and/or to this documentation without prior notice. This documentation is intended solely as an information resource for maintenance personnel or technical specialists.

1.1.2 Copyright and other protected rights

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1.1.3 Definitions

WARNING

An important advisory indicating a potentially hazardous situation which may result in death or serious injury if not prevented.

CAUTION

An important advisory indicating a potentially hazardous situation which may result in minor or moderate injury to the user or patient or in damage to the medical product or other assets if not prevented.

NOTE

A NOTE provides additional information intended to avoid inconvenience during operation and/or servicing.

Term	Definition
Maintenance	Maintaining the operative condition of a medical product by suitable means
Inspection	Assessment of the actual condition of a medical product
Servicing	Maintaining the operative condition of a medical product by recurrent, specified measures
Repair	Restoring the operative condition of a medical product after failure of a device function

1.1.4 General safety precautions

Read through each section thoroughly before beginning servicing.

CAUTION

Incorrect use of tools

The device's function may be impaired, or the device may be damaged. Always use the correct tools and the specified test equipment.

WARNING

The device must be regularly inspected and serviced by maintenance personnel. Repairs and complex maintenance work on the medical product must be carried out by qualified specialists.

If you require a service contract, or for any necessary repair work, Dräger recommends DrägerService. Dräger recommends using original Dräger parts for servicing.

If the aforementioned instructions and recommendations are ignored, the correct functioning of the medical product may be put at risk. Pay attention to the "Servicing" section of the Instructions for Use.

WARNING

Non-conforming test values

If test values do not conform to specifications, the safety of the patient may be put at risk.

- Do not put the device into operation if test values do not conform to specifications.
- Contact your local service organization.

WARNING

Impermissible modifications to the device

If impermissible modifications are made to the device, the safety of the patient may be put at risk.

Do not modify the device without Dräger's permission.

WARNING

Risk of infection

The unit may transmit pathogens following use on the patient.

- Before carrying out any servicing, ensure that the device and its components have been handed over by the user cleaned and disinfected.
- Service only cleaned and disinfected units and unit components.

WARNING

Risk to patient.

Ensure that no patient is connected to the device before starting maintenance or repair work.

NOTE

Where reference is made to legislation, regulations and standards, in respect of devices used and serviced in Germany they are based on the laws of Germany. Users and technicians in other countries must comply with their national laws and/or international standards.

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2 Function descriptions

This chapter contains descriptions of the device's technical functions.

2.1 Function description

Glossary

Abbreviation	Explanation
A/D	Analog to Digital
ADC	Analog to Digital Converter
CPU	Central Processor Unit
EEPROM	Electrically Erasable Read-Only Memory
EMI	Electro-Magnetic Interference
ESD	Electro-Static Discharge
LCD	Liquid Crystal Display
LED	Light Emitting Diode
NAWI	Non-Automatic Weighing Instrument
OIML	Organisation Internationale de Metrologie Legale: An international regulatory body, concerned with metrology
PC	Personal Computer
PCB	Printed Circuit Board
PIC	Peripheral Interface Controller
PWM	Pulse Width Modulation
RH	Relative Humidity

The **Isolette**® 8000 plus permits simultaneous control of parameters affecting the infant including temperature, oxygen and humidity. It includes full air and skin temperature control, with 0, 1 or 2 patient skin temperature inputs. The **Isolette**® 8000 plus includes a Liquid Crystal Display to relay pertinent information to the caregiver.

During access from the front or rear of the incubator an air curtain spans the entire length of the hood to minimize the air temperature fluctuations during intervention.

Humidity control capability is established by a front-loading reservoir to allow easy refilling of the water. The humidity function can be added at a later time (modular construction). The humidity feedback and control loop incorporate a humidity sensor mounted in the sensor module in the incubator's hood.

The incubator stand (or trolley) is a variable height adjustable design (VHA). The VHA provides the capability to elevate the incubator and includes a motor driven actuator unit; it is activated by a momentary action foot switch. The VHA and incubator are powered through a single power cord. The VHA provides circuit protection fuses, EMI filtering and includes a short external cable to extend power to the incubator. There are AC power outlets mounted on the stand. Optional storage compartments are available.

The hood is large to allow for adequate working area. The hood shape includes front and rear sloped view panels. The hinging of the hood provides easy removal for cleaning and/or servicing, and resists leaking any condensation outside the hood.

The system uses cable management, to reduce the overall clutter of the system and its components. Sensors in the hood are inside the hood-mounted sensor module, which provides short cable lengths and a single cable required to go to the main controller. The scale cable is kept close to the hood, out of the way.

For oxygen control, the incubator employs oxygen sensors within the sensor module.

The access panel gaskets and port door cuffs are easy to remove, clean and install.

2.1.1 Structure of the Isolette® 8000 plus

Isolette® 8000 plus consists of the following modules:

- Hood assembly, including access panels
- Shell Assembly
- Controller Unit Assembly
- Sensor Module Assembly
- Variable Height Adjustable Trolley Assembly
- Humidifier Assembly (Option)
- Servo Oxygen Assembly (Option)
- Scale, Standard (Option)
- Scale, NAWI/OIML, (Option)
- Drawers (Option)
- IV Pole (Option)
- Utility Shelf (Option)
- Oxygen cylinder holder (Option).

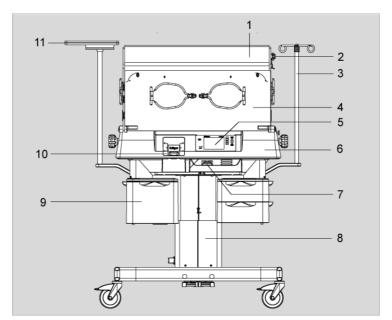


Fig. 1 Front side of **Isolette**® 8000 plus

Legend

Pos.	Designation
1	Hood
2	Sensor module
3	Option, IV pole
4	Access panel
5	Control unit
6	Shell assembly
7	Incubator On/Off switch
8	Variable height adjustable trolley
9	Option, Drawers (both sides)
10	Option, Humidification system
11	Option, Utility shelf
12	Option, Scale, NAWI/OIML (not shown)
13	Option, Scale, Standard (not shown)

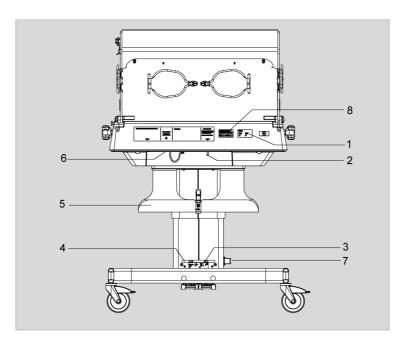


Fig. 2 Rear side of **Isolette**® 8000 plus

Legend

Pos.	Designation
1	Type label, Incubator
2	O2 inlet (Standard or Option)
3	Type label "Trolley"
4	Cable storage
5	Option, Gas cylinder mount
6	Air inlet micro filter
7	Mains power inlet and fuses
8	Option, NAWI/OIML scale location label

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2.1.2 Block diagram

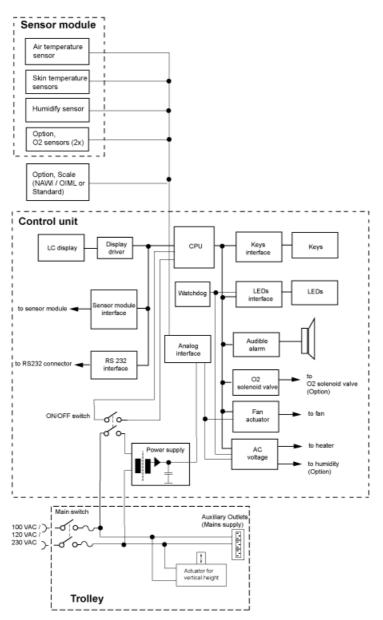


Fig. 3 Block diagram of Isolette® 8000 plus

2.1.3 Hood assembly including access panels

The hood assembly provides a temperature controlled environment for the patient, with control of oxygen concentration (standard flow control or optional servo control) and (optional) relative humidity. The hood is not airtight, but intentionally forces some internal air out, to provide CO2 exchange. The expelled air is replaced by either room air drawn in through the microfilter, or by external oxygen. However, if the hood has excessive gaps to the shell, or at the access door gaskets, or from missing or damaged grommets, it may not be possible to maintain the temperature, the temperature uniformity, the humidity, or the O2 concentration.

The Hood Assembly includes X-ray location labels on the end walls, and rear access panel. Together with similar labels in the X-ray drawer of the mattress tray, these labels permit locating the patient with respect to the X-ray cassette.

The hood has a small hole, on the top left, to permit a feeding tube to be introduced.

Access panels

The hood assembly includes front and rear access panels. These provide full access for loading or unloading the patient, and permit procedures to be performed in the incubator. The access panels are equipped with magnets in the hinges which actuate reed switches in the shell. When an access panel is opened, the controller is signaled, and responds by increasing the fan speed. This forms an "air curtain" over the access panel opening, helping to maintain the internal temperature. An icon appears on the controller in this case.

Heat shields

The access panels are equipped with heat shields. Each access panel plus its heat shield forms a channel, which routes the hot air up and then to the center of the incubator. The heat shield protects the patient from the hot air, and, by absorbing heat from the air stream, acts as a large warm radiator into the interior.

Access doors

Each access panel is equipped with 2 oval access doors, for hand access. Some hood assembly types include an access door in 1 or both ends of the hood Assembly. The hood-end access doors can be field-replaced by access doors with Grommets, permitting end-access for smaller tubes or cables.

Iris ports

Hood assemblies which do not have access doors on the ends of the hood assemblies have round Iris ports instead. These provide access for the hand, or for tubing, especially large or rigid tubing.

Grommets

The front corners of the hood are fitted with 3 grommets each, and the rear corners are fitted with 2 grommets each. The grommets provide access for tubes and cables. An optional kit permits adding grommets to hood-end access doors. The kit cannot be used on access panel mounted access doors

2.1.4 Shell Assembly

The shell assembly is the main structural and housing component of the incubator. It encloses most of the electronics, mechanics, and cabling. The housing consists of an upper shell and a lower shell. When fitted together, the upper and lower shells form 2 compartments. The small rear compartment isolates the fresh air valve and the oxygen control components from the main body of the housing. Between the upper and lower shells, there is an internal gasket, to assure that separation.

Main Air Heater

The main air heater is 400 W, and has 120 V, 230 V, and 100 V versions. The assembly includes a cylindrical housing, holding the heater itself, and a type "J" thermocouple. If the heater is operated without the radiator installed, the temperature of the cylinder will rise too high. The thermocouple monitors the temperature of the cylinder, and the controller monitors this temperature. In addition, a thermostat is included in the base of the assembly; it opens at 190 °C and closes at 140 °C.

The assembly includes an aluminum post, next to the heater cylinder, to prevent rotation, or installation of older, threaded radiators. The thermostat is attached to the base of this post, which acts as a heat pipe. The assembly also includes a gasket to seal any fluids in the heater well from the interior of the shell.

Impeller and motor

The impeller is a cylindrical type, with 3 permanent magnets sonic-welded into its lower face. The impeller is mounted to the motor shaft by a push-on fit. The motor is mounted on 4 vibration dampers. The motor speed (and thus the impeller speed) is controlled by PWM circuitry. The motor operates at 3 speeds; normal, faster when an access panel is open, and fastest when the set temperature is high (to prevent hot spots on the inner wall of the heat shield.). In the event of a watch-dog trip, the fan speed reverts to 1500 RPM +/-450 RPM, and an alarm sounds.

Impeller movement detector

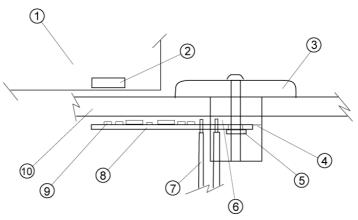


Fig. 4 Elevation view of impeller movement detector subassembly

Pos.	Designation
1	Impeller
2	Magnet
3	Plug
4	Step in plug

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Pos.	Designation
5	PEM fastener
6	Clearance for Wires
7	Wires
8	Printed circuit board
9	Hall Effect Sensor
10	Shell

The Isolette® 8000 plus Incubator Impeller Movement Detector is mounted on the underside of the upper incubator shell supported by a plastic plug. It is powered by 12 VDC from the controller. The PCB assembly is positioned so that magnets sonic-welded into the bottom of the impeller pass directly over a Hall Effect sensor mounted on the PCB. The circuit monitors the Hall Effect sensor pulse train produced by the magnets when the impeller is rotating. In this way, the speed of the impeller is measured and compared with pre-determined maximum and minimum limits. If the impeller rotation is too fast or too slow, an impeller error signal is generated. Also, an impeller speed error is created if one, two, or all three magnets are missing.

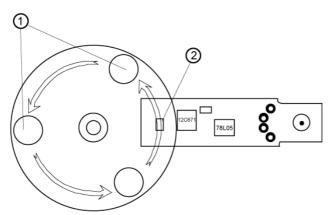


Fig. 5 Top view of impeller movement detector subassembly

Pos.	Designation
1	Magnets
2	Hall Effect sensor

If an impeller speed error is detected, the short probe voltage is made greater than the long probe voltage. The following chart illustrates the circuit's output voltages for various impeller speed conditions.

Impeller speed condition	Long probe (voltage, VDC)	Short probe (voltage, VDC)	Controller alarm indication
Impeller speed too slow	approx. 8.5	approx. 9.5	Low Air Flow
Impeller speed normal	approx. 8.5	approx. 7.5	(non, normal operation)
Impeller speed too fast	approx. 8.5	approx. 9.5	Low Air Flow
Missing 1, 2 or 3 magnets	approx. 8.5	approx. 9.5	Low Air Flow

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The long probe voltage is produced by a voltage divider, (from +12 VDC in the controller) consisting of a 301 ohm resistor on the controller's CPU PCB, and the load of the impeller movement detector "Long Probe" circuit as a whole. The short probe error voltage is produced by a voltage divider (from +12 VDC in the controller), consisting of a 332 ohm resistor on the controller's CPU PCB, and R4 (1.33 Kohms) of the impeller movement detector. The short probe normal voltage is produced by shunting R4 with R2 (953 ohms), by putting Q1 into conduction.

Tilt Mechanism system

The tilt mechanism system (also called Trendelenburg System) consists of a rightand a left-hand tilt mechanism, plus 2 shafts, 2 knobs, and 2 lift bars (which each have 2 end caps). The 2 identical knobs are on the right and left sides of the incubator, and engage the right and left shafts (different part numbers). The shafts engage the right and left tilt mechanisms (different part numbers), which engage the 2 identical lift bars.

Each tilt mechanism is intended to hold 15 pounds (6.8 kg) stably.

Each tilt mechanism consists of a housing, a drive chain (1/4 inch pitch), a 9 tooth drive sprocket, an external one-way-clutch/brake, and a pocket to carry the lift bar. Each lift bar is connected to one end of the mattress tray. One full turn of the knob moves the lift bar 2.25 inches (5.7 cm).

The knobs are arranged such that turning the left knob clockwise raises the left end of the mattress tray, and turning the right knob counterclockwise raises the right end of the mattress tray.

The 2 clutches are mounted such that each engages in the downward direction, and its brake thus prevents the mattress tray from lowering by itself. When the user turns the knob in the downward direction, the combination of user force and gravity overcomes the brake, and the mattress tray is lowered. In the upward direction, the one-way-clutch disengages, and the user's force raises the mattress tray, opposed only by gravity.

Mattress and tray

The "Soft Bed Mattress" is standard with Isolette® 8000 plus.

The mattress tray pivots on the tilt mechanisms when being raised. The raising of one end of the mattress tray increases the diagonal distance between the lift bars, but the mattress tray has an allowance for this.

The mattress tray can be extended through the open front access panel for improved patient access. When the mattress tray is extended, the lift bars engage it such that the extended section is supported. When the mattress tray is fully in the incubator, it can be lifted vertically and removed for cleaning.

The mattress tray includes an X-ray drawer, which accepts X-ray cassettes. The hood, mattress, and mattress tray are radio-translucent to permit clear radiography. In the Isolette® 8000 plus, the X-ray drawer includes positioning labels as standard. Also, the Isolette® 8000 plus includes standard positioning labels on the end walls of the hood, and on the rear access panel. Together, these labels permit accurate positioning of the patient and the X-ray cassette for radiography.

The mattress tray can accept either version of scale (NAWI/OIML, or the standard scale). The mattress is placed on the scale, and the scale on the mattress tray.

Fresh Air Valve

The fresh air valve is positioned above the air inlet microfilter housing, in the isolated rear compartment of the shell assembly. The inlet of the fresh air valve is connected to the air inlet housing. In normal operation (that is, when no external oxygen is being supplied), the fresh air valve conducts approximately 7 L/min of filtered air from the air inlet housing to a 22 mm corrugated hose. The hose leads to an opening in the upper shell, and thus connects the fresh air valve to the central plenum area between the upper shell and the deck. The suction of the Impeller draws hood air (and fresh air) from the central plenum area into the heater well, and then forces the warmed air into the patient space.

When oxygen is supplied (from either the standard inlet (with external flow control), or the optional servo oxygen system), the oxygen pressure causes the fresh air valve to disconnect the air inlet housing, and instead connect the supplied oxygen to the corrugated hose. This prevents the supplied oxygen from leaking out through the air inlet, and also prevents fresh air from diluting the supplied oxygen.

The supplied oxygen passes through 3 filter disks, mounted in the diaphragm of the fresh air valve, before entering the corrugated hose. The entire Fresh Air Valve is a maintenance part, because of the diaphragm and filter disks. It is replaced as a unit to assure proper reassembly.

Access Panel Sensors

Reed relay switches are mounted in the upper shell, on the user's right side. The 2 switches (front and rear) are positioned to be actuated by magnets enclosed in the hinges of the access panels. The switches signal the controller when an access panel is open; the controller responds by increasing the fan speed to form an air curtain over the access panel opening, reducing heat loss.

Rails

The Isolette® 8000 plus incorporates accessory rails at each end of the shell. These are available in DIN or Fairfield (Integris) profile. The ends of the rails are curved back against the shell.

No-Humidity System

The Isolette® 8000 plus, when configured without the optional servo humidity system, contains a blank cover plate to close the opening where the reservoir would be, a blank plug to close the condensation management drain in the heater well, and a blank "manifold" to close the opening in the heater well wall. The wiring for the humidity option is always included in the Isolette® 8000 plus, to permit easy upgrade if the humidity upgrade is ordered later.

2.1.5 Control unit

The control unit controls/monitors the function of the Isolette® 8000 plus. The control unit consists of the following parts:

- Incubator ON/OFF Switch
- Power Fail Alarm circuit
- Microcontroller (CPU PCB)
- Power Supply PCB
- Interface PCB
- LC Display
- Keys and LEDs
- Loud Speaker
- Fan Actuation (Impeller)
- RS-232 Interface
- Cooling fan
- Trend Indicators.

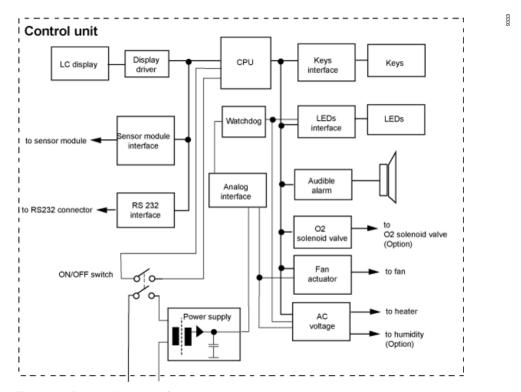


Fig. 6 Block diagram of the control unit

Incubator ON/OFF Switch

The incubator ON/OFF switch is used to switch the mains voltage on or off. The second pole of the incubator ON/OFF switch is sensed by the microcontroller. When the microcontroller senses loss of DC power, it checks this switch. If the switch is closed, the DC power loss is due to a power failure, and an alarm is generated. If the switch is open, the user has turned off the controller, and no alarm is generated.

Power fail

When a power failure is detected, the following occurs:

- The power fail indicator on the front panel illuminates.
- An alarm sounds.

A high energy storage capacitor powers the power failure detection circuitry and supplies power to the audible alarm and indicator for a minimum of 10 minutes. This capacitor charges while the unit is operating. When power is lost to the controller and the Power switch remains in the ON position, the Power Failure alarm circuitry activates. The power failure circuitry incorporates a timer circuit that periodically enables the audible alarm and Power Fail indicator until one of the following occurs:

- The power switch is turned off.
- The power is restored.
- The storage capacitor is depleted.

The Power Failure alarm silence is hardware-controlled. Pressing the Alarm Silence key during power failure silences the alarm for the duration of the power failure. The Power Fail indicator continues to flash until one of the following occurs:

- The storage capacitor is depleted.
- The power switch is turned off.
- The power is restored.

Microcontroller and CPU PCB

The microcontroller is an MC68331-144, with a 32.768 KHz quartz crystal, and a 16.7 MHz clock.

Functions on the CPU PCB include:

- Analog to Digital converter for sensors in the hood and shell
 - AC voltage
 - Long Air Flow Probe
 - Short Air Flow Probe
 - 2 ambient thermistors, inside the controller
 - AC current
 - voltage to the O₂ solenoid valve
- An audio oscillator for alarms
- The 4 front panel LEDs
- Watchdog circuitry
- Real Time Clock to provide data for Trend displays
- Serial communications with the Sensor Module
- Flash RAM
- System RAM
- Circuitry to support the Liquid Crystal display
- Controls for the Safety relay on the Interface PCB
- PWM control for the optional Oxygen Solenoid valve
- Interface circuitry for the keypad
- Control for the main air heater
- Control for the optional humidifier heater

- Control and tachometer for the main air fan
- Tachometer for the controller cooling fan.

Sensor communications

An interface enables communication between the controller module and the sensor module. The sensor module interface connector is a female DB-9, mounted on the rear of the controller and comprised of a bi-directional data line, a clock output line, and a reset output line. The data lines are fully isolated and optocoupled to the microprocessor. The controller provides isolated power to the sensor module.

Access Panel switches

The controller connects to the two Access Panel switches that are wired in parallel. The controller performs the following:

- Provides no more than 5 milliamperes (mA) of current to the switches.
- Provides less than 6V of power to the switches.
- Monitors the return current to determine if either Access Panel is open.

The switches are open when the Access Panel is closed. The input is protected with transorb diodes and is filtered to block EMI and prevent ESD damage to the controller.

Cooling fan (controller)

The cooling fan provides a continuous flow of air through the controller to remove heat generated by the various components inside the controller enclosure. The cooling fan operates whenever power is applied to the controller. The cooling fan is equipped with a tachometer output signal that is supplied to the microprocessor.

Ambient temperature sensors

The temperature sensors, located in the airflow of the cooling fan, are Negative Temperature Coefficient thermistors. The output signals of the redundant sensors feed into the A/D converter.

Watchdogs

The first watchdog timer is internal to the microprocessor. If the software does not update the watchdog timer within the required time frame, the internal watchdog resets the microprocessor and all peripherals connected to the external reset line.

The second watchdog timer circuit attaches to the microprocessor bus. The microprocessor continuously writes the following data to the watchdog timer:

- Data 55 hex (01010101 binary) to watchdog register # 1
- Data AA hex (10101010 binary) to watchdog register # 2.

The watchdog timer trips in 1 second +/-0.4 second unless the above sequence is completed. Once the watchdog timer trips, the following occurs:

- The safety relay turns off, removing power from the heater and the humidifier.
- The fan control reverts to closed loop control, maintaining a constant fan speed regardless of the Access Panel's position.
- The (optional) oxygen solenoid control from the microprocessor is overridden, and the oxygen solenoid turns off so that no oxygen enters the hood. (Oxygen supplied by external non-servo control is not interrupted).
- A constant alarm sounds for a minimum of 500 milliseconds.
- The system failure indicator illuminates.

The microprocessor resets the watchdog timer after a watchdog trip by sending the above data sequence.

Factory defaults

Factory defaults are stored in program memory, in flash EEPROM. System parameters are configured and stored in the real time clock (RTC) module or serial EEPROM. The RTC memory and random access memory (RAM) are protected against corruption during power failures and are battery-backed for a period of time.

The program is stored in reprogrammable memory and may be reloaded through a cable connected to the serial port of a computer. The program memory is stored in a flash EEPROM. The RS-232 serial port operates at speeds of 115,200 baud to expedite the speed of the program down-load.

Power Supply PCB

The power supply receives filtered AC power from the interface PCB. Both conductors are fitted with 2 Ampere fuses on the interface PCB.

The power supply can be used with voltages from nominal 100 VAC to nominal 240 VAC (absolute 90 VAC to 264 VAC), at frequencies from 48 Hz to 62 Hz. A transorb diode blocks voltage peaks which are beyond the safe range.

The power supply PCB includes circuitry to detect the AC voltage (120 V or 230 V), and passes that information to the microcontroller, via the interface PCB.

The r	ower	supply	provides	voltages	listed belov	v
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Voltage	Fuse value
+24 VDC	1.6 Ampere
-24 VDC	N/A
+12 VDC	1.6 Ampere
+5 VDC	N/A
VCC for RS-232	N/A
+15 VDC	N/A
-15 VDC	N/A
+12 VDC	N/A
-12 VDC	N/A
+5 VDC	N/A

Interface PCB

The Interface PCB provides distribution of AC and DC power, serial communications, and other I/O parameters.

The Interface PCB includes AC filtering circuitry, and distributes AC to the power supply PCB (via 2 fuses, F1 and F2, 2 A), and to the main air heater and the humidifier heater (combined on 2 fuses, F3 and F4, 6.3 A). A current transformer sends the controller information about the AC current being drawn. A safety relay, controlled by the microcontroller, can disconnect the heater and humidity loads.

The Interface PCB routes the signals from the CPU PCB to the loudspeaker (via a transformer), and to the cooling fan of the controller. It routes the access panel open switch circuit to the CPU PCB, after filtering it and limiting it to 5.6 VDC. The Interface PCB uses the O2 solenoid PWM signal from the CPU PCB to gate Q2, and drive the optional oxygen solenoid valve. The solenoid coil is shunted by a

diode and capacitor for EMI, and the circuit includes a mini fuse, F5. The Interface PCB routes the thermocouple voltage (from the main air heater) to the CPU PCB, after amplification by U1.

For the main air impeller, the Interface PCB processes the "FAN PWM" signal from the CPU PCB, and returns the "FAN TACH" signal to the CPU PCB. The "FAN PWM" signal is converted to pseudo-DC, and compared to the "FAN TACH" signal in U3. The output of U3 is sent to U2. This is a PCB, which functions as a 3 phase PWM motor driver, which runs the main air fan motor. The Interface PCB also manages communications with the sensor module, and with the (optically isolated) RS-232 interface.

LC Display

The LC display has a resolution of 320 x 240 dots. The LC display has an LED backlight, and supports 2 color schemes: white on blue, or yellow on black.

Keys and LEDs

The membrane keypad has a key matrix, containing 9 keys. With these keys parameters can be entered and the keypad lock can be released. The keypad unlock key contains an LED; when lit, this indicates that the keypad is locked. The Alarm Silence key also contains an LED; when lit, this indicates that alarms are being silenced. The other keys are DISPLAY SELECT, UP, DOWN, and 4 "soft keys", whose functions are variable according to the state of the controller, and whose labeling is shown in the display itself.

The other LEDs are ">37° C" (indicating a manual override of the default maximum temperature) and "Power Fail", indicating a loss of power to the controller, but with the ON/OFF switch still turned ON.

Loud Speaker

In the event of alarms or messages, the loudspeaker issues an audible alarm signal. A volume control and a soundchip control the loudspeaker.

Fan Actuation

The main air impeller (fan) has 3 modes; normal, a higher speed when an access panel is opened, and a still higher speed when an air temperature above 38.5 °C is selected. The fan speed is sensed by 3 magnets in the base of the fan, and monitored by a Hall Effect sensor (Impeller Movement Detector) in the shell.

RS-232 Interface

A port on the Interface PCB enables an RS-232 serial communication link. The serial port is fully isolated from the remaining controller circuitry. The power to the serial port interface circuitry derives from an isolated winding on the power supply transformer. The RS-232 interface connector is a female DB-9, mounted on the rear of the controller. An RS-232 transceiver converts the RS-232 to logic voltage levels and vice versa. Optocouplers provide the isolation barrier and interface the RS-232 transceiver to the PC16550 UART. The UART interfaces the serial port to the microprocessor bus. All lines connected to the RS-232 connector are filtered to block EMI. The RS-232 transceiver incorporates electrostatic discharge (ESD) protection.

The serial port is normally configured for 2400 Baud, 8 data bits, 1 stop bit, no parity and output only. The same port is used to download controller software, but in that case the port configuration is controlled from the downloading program, which runs in the computer which is doing the download.

RS-232 connector

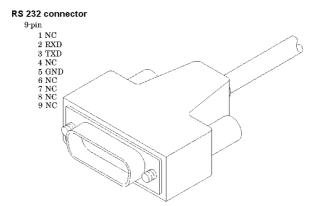


Fig. 7 Pins of RS-232 connector

The following parameters are available:

- Air and skin adjusted temperature
- Current air and skin temperature
- Oxygen desired value
- Oxygen concentration
- Humidity desired value
- Humidity level
- Weight of the baby.

During normal operation, a data packet transmits every 5 seconds. Each data packet is entirely in American Standard Code Information Interchange (ASCII) and is readable when displayed on any standard RS-232 terminal device.

A data packet consists of one 82-character line of text that is composed of a prefix, a data portion, a suffix, a checksum, and a carriage return/line feed (CR/LF) pair. The prefix identifies the data line. It consists of an opening bracket and an ID character that are unique to the data line. The format of the data portion depends on the specific data line. Any character positions within the data portion that are undefined transmit as spaces to enhance the readability of the output. The suffix limits the data portion and consists of a closing bracket.

The checksum is two ASCII hexadecimal digits and represents an 8-bit accumulation of the ASCII characters from the prefix to the suffix, inclusive. All monitored parameters, including temperature, oxygen, humidity, and weight, transmit at the 5-second interval. Asynchronous events, such as alarms or mode changes, transmit as they occur.

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Table A: RS-232 Serial port protocol

Characters	Description
1 to 2	Prefix: 2 characters, and either a space, or I. Space indicates normal mode; a I indicates a special or test mode; data may be invalid
4 to 11	Product ID: 8 characters
13 to 14	Mode bit flags; 2 hexadecimal digits (see Table B: Mode bit flags)
15 to 24	Alarm bit flags: 10 hexadecimal digits (see Table C: Alarm bit flags)
26 to 28	Setpoint temperature: 3 digits, 1 decimal, Celsius
29	Air/Skin Mode: 1 character "A" or "B"
31 to 33	Skin Temperature 1: 3 digits, 1 decimal, Celsius
35 to 37	Skin Temperature 2: 3 digits, 1 decimal, Celsius
39 to 41	Air Temperature: 3 digits, 1 decimal, Celsius
43 to 45	Ambient Temperature: 3 digits, 1 decimal, Celsius
47 to 49	Heater Power: 3 digits, range 0 to 250
51 to 52	Humidity: 2 digits, 0 decimal
54 to 55	Setpoint Humidity: 2 digits
57 to 58	Oxygen: 2 digits, 0 decimal
60 to 61	Setpoint Oxygen: 2 digits
63 to 66	Weight: 4 digits, 3 decimals, kilograms
78	Suffix: 1 character, "]"
79 to 80	Checksum: 2 hexadecimal digits
81 bis 82	CR/LF: 2 control characters

Table B: Mode bit flags

Bit	Description
01	Humidity ON
02	Oxygen ON
04	Baby mode (Skin mode)
08	0.5 °C Baby alarm limit
10	Reserved
20	Reserved
40	Reserved
80	Reserved

Table C: Alarm bit flags

Bit	Description
000000001	Low control temperature
0000000002	High control temperature
000000004	Low oxygen
8000000008	High oxygen
000000010	High temperature cut-out
0000000020	Skin 1 - Probe failure
0000000040	Skin probe - Disconnection

Bit	Description
080000000	Oxygen calibration required
000000100	Sensor out of position
000000200	Water level low
0000000400	Procedural silence
008000000	Motor failed
0000001000	Low air flow
0000002000	Heater failed
0000004000	EEPROM failed
00080000	Sensor module failed
0000010000	Controller failure 1
0000020000	Controller failure 2
0000040000	Controller failure 3
000080000	Controller failure 4
0000100000	Air probe failed
0000200000	Oxygen cells different
0000400000	Scale disconnected
0000800000	Too much weight
0001000000	Scale failed

Trend Indicators

The controller maintains trend (history) data for several parameters. The patient's weight data is retained for 7 days; all other parameters are retained for 24 hours. The trend data can be displayed graphically. The non-weight data can be displayed for the last 2, 4, 8, 12 or 24 hours. The weight data is only displayed on a 7 day basis.

The standard trend displays are:

- Air temperature
- Skin temperature (Central and Peripheral, on one display)
- Heater power (%).

Additional trend displays are available, if the incubator is equipped with the relevant option:

- Oxygen (%)
- Weight
- Humidity (%RH).

2.1.6 Sensor module

The sensor module provides the interface from the patient environment to the controller. The module reads and processes temperature, oxygen, humidity and weight information collected from sensors and from the optional scale. This information is updated periodically, and is transmitted to the main controller upon request.

Except for the (optional) oxygen cells, the sensor module requires no manual calibration - all calibrations are done automatically and periodically during normal operation. To provide safe monitoring and control, both the temperature information and oxygen information have redundant circuitry to mitigate single fault failures.

The design is such that all signals required by the main controller are available through serial data communications, reducing the wiring in the total system.

The sensor module main board connects to a connector board, which in turn connects to a humidity board.

Power Supply (sensor module)

Power is supplied to the sensor module through connector J4, providing +12 V and -12 V for use in this system. These voltages are further regulated by U21, U19 and U15, providing analog +5 V, digital +5 V and analog -5 V respectively. Additionally, reference U20 provides a precision +5 V source, to be used in analog signal conversions.

Position Detectors

To properly sample the incubator air temperature, the sensor module must be fully inserted into the hood. However, to calibrate the (optional) oxygen sensors, those sensors must be in an environment of known oxygen concentration. Such an environment can be achieved by withdrawing the sensor module such that the oxygen sensors are exposed to ambient air (at 21% oxygen), or, if the (optional) 100% calibration fixture is used, to a micro environment flooded to 100% oxygen. The sensor module detects its position in the hood by monitoring 4 Hall Effect sensors, which respond to permanent magnets in the slide mechanisms. The sensors U9 and U2 are used to detect calibration position and sensors U16 and U22 are used to detect in-hood (normal) position. These devices provide a "LOW" output if a significant south pole magnetic field is applied to their surface; otherwise, the outputs are "HIGH".

Alarm Light

LED DS1 provides a visual alarm indication. It is mounted on the top of the Sensor Module to maximize its visibility in the sometimes crowded NICU. It is illuminated by a positive signal (RMLITE) at "Q3" gate.

Scale Interface

Connector J3 provides the interface for the scale module, which supports serial data communications. The power for the scale is also distributed via this connection. The signal "SCCLK" is used for scale communications only, and is normally high when the scale is disconnected. The signal "SCDATA" is a bi-directional data line, and is normally "LOW" when the scale is not connected

Fan Control / Feedback Circuit / Sensor module

The sensor module includes a fan, to draw incubator environment air over the temperature and humidity sensors. To drive the DC fan on the sensor board, Q1 is pulsed on its gate by signal "FANON" at approximately 48 Hz to maintain proper speed and increase fan life. In addition, every 4 seconds, the microcontroller asserts "FANON" for 42 msec, and monitors "FANBMD" to determine fan speed. Additionally, the microcontroller monitors the approximate fan speed via "FANPUL". "FANPUL" is derived from the current pulses of the fan motor. The pulse detection is handled by U1A, which through resistors R7 and R3 sample the current spikes from the fan produced across R1. The amplifier operates as a differentiator, providing high gain for the current spikes. This signal is then rectified and filtered by D1 and C16, and then fed to the A/D converter as signal "FANPUL". This effectively provides a semi-DC level as a function of the fan rotation speed.

Temperature Measurement

General

The temperature data acquisition circuit starts with analog multiplexers U6 and U5, each allowing an 8 to 1 signal switching. The multiplexer channel selection is accomplished from the microcontroller by the signals "MSEL0", "MSEL1" and "MSEL2". Each multiplexer output can be inhibited by either the signal "TM1SEL" or "TM2SEL", depending on the multiplexer (only one multiplexer is active at a time). This data acquisition system can then be viewed as a 16 to 1 analog temperature selector. The microcontroller selects a new temperature channel every 21 msec.

Resistor R14 provides the constant voltage drive required for each thermistor as it is selected from the appropriate multiplexer. This voltage is amplified by a factor of 2.1083, and then sent to the A/D converter as signal "TCOM".

To provide automatic calibration of the circuit (and eliminate temperature and aging drifts), precise calibration values are introduced into each multiplexer. These values are provided by R45 and R44, which are read through the multiplexors and are used in software processing to eliminate the gain and offset errors of each multiplexer/amplifier combination. These values equate to 49.37 °C and 22.62 °C, which allows for precise circuit calibration.Resistor R43 is an additional "check" to the circuit - it provides a resistance simulating 36.085 °C.

Air Temperature Measurement

The sensor module supports three (3) air temperature sensors on the connector board, interfaced via J2-6 to J2-8 (AIRTE, AIRTC, AIRTM). These thermistors are then routed to temperature multiplexers U6 and U5, which provide analog signal processing into the A/D converter.

The three air thermistors are mounted at the lower end of the "Nose" supported by a support wire. The fine thermistor leads are soldered to pads on the PCB marked "COM", "E", "M", and "C". The temperature of the air drawn through the sensor module is measured by detecting the resistance of the thermistors, which changes in temperature.

The positioning of these thermistors is critical to the air temperature measurement. At the inlet of the air flow through the sensor module, the temperature of the air is the least effected by the heating of the sensor module circuitry and the fan. The thermistor temperatures are continually compared to detect a failure in one of the thermistors. If they differ by a too great a value, a diagnostic alarm is produced. Therefore, it is important that none of the air thermistors contact the inside wall of

the nose. This will cause a change in the time response of the contacting thermistor with respect to the other thermistors resulting in larger than normal temperature difference between the thermistors when the air temperature is changing.

Skin Temperature Measurement

The (optional) skin temperature probes contain dual thermistors, and the sensor module can support two probes which plug into J6 and J7. The two thermistors of the Central Skin Probe are connected to SKNT1M and SKNT1C, and the two thermistors of the Peripheral Skin Probe are connected to SKNT2M and SKNT2C, with a common connector at AGND. Both probes have high frequency filtering by inductor networks LN1 and LN2.

In addition, each skin probe has a resistor which is an input to the multiplexer. These signals (SKNT1D and SKNT2D) are used by the microcontroller to determine if the probes are installed.

Humidity Measurement

Humidity measurement originates with the humidity sensor on the humidity board, connected to J2-14 and J2-5 (HS2 and AGND respectively). The sensor changes capacitance as a function of humidity, over a range of approximately 160 pF to 200 pF. The sensor is self contained in such that it provides a 0-1 V signal representative of 0-100% RH and this signal is multiplied by 4 on the humidity option board. This signal is fed into the A/D converter U11-8.

RH Sensor Air Temperature

An air temperature sensor is mounted adjacent to the RH sensor on the humidity board, interfaced via J2-13 (HUMTEMP). This thermistor is then routed to temperature multiplexer U6-15, which provides analog signal processing into the A/D converter.

Although the humidity sensor is standard, it is only enabled when the humidifier option is installed.

Option Oxygen Measurement

When the optional servo oxygen system is installed, the sensor module board requires two (2) oxygen cells, connected to J5. Each cell operates as a fuel cell, with typical output voltages (at 21% normal ambient O2 levels) being from 7 mV to 13 mV. Each cell requires a 10 KOhm load resistor, as evidenced by R17 and R18.

As with temperature, the oxygen data and calibration information is inputted to a multiplexer U4, to make use of common gain circuitry. The multiplexer, an 8 to 1, is only used as a 4 to 1 in this system, controlled by the signals "MSEL0", "MSEL1" and "MSEL2". Two channels "OXCAL" and "OXGND" provide precision voltage levels used by the microcontroller for gain/offset correction. The voltages, 4.89 mV and 78.86 mV, are at the extreme ends of the measurement range to ensure precise compensation.

Amplification is provided by U12A, set up as a non-inverting configuration with a gain of 61.421.

It is important to note that the oxygen sensors do not measure percent O2 per se, but actually measure the O2 partial pressure. For this reason, the controller has a setting for high altitude, compensating for the reduced total ambient pressure.

Microcontroller (Sensor module)

Description

The microcontroller is a PIC 16x73, used for signal processing and control of all signals on the SENSOR MODULE. The device has three external ports, configurable as inputs, outputs, etc. The microcontroller operates from a precise time base by crystal Y1, operating at 4 MHz. The instruction cycle time of the PIC controller is 1/4 of that, namely at 1 MHz (1 usec).

Reset Control

To insure a "clean" power up, U10 provides a fixed power up reset to the microcontroller. In addition, this integrated circuit will generate a reset in the event the D+5 (Digital +5 VDC) falls below a predetermined threshold (brown-out condition).

The reset line of the microcontroller is also available to the main controller if the main controller determines that the sensor module requires reset intervention.

Watchdog

To insure correct program flow, the PIC device uses an internal watchdog timer, which asserts the reset line in the event the program execution is operating outside normal conditions.

Microcontroller Expansion Devices

Multiplexer

To allow additional digital signals for processor control, digital multiplexer U3 is employed. It is a dual, 4 to 1 multiplexer which allows the microcontroller to use 2 ports for 8 bits of information. Control of U18 is provided by signals "DVSEL0" and "DVSEL1".

Line Drivers

For signals that are going off-board, namely "SMDATA", "SCDATA" and "SCCLK", buffers are used (Q6, U13A/B and Q6, U13C respectively). The "SMDATA" line is used as a bi-directional line, which can be changed from input or output "on-the-fly" for data communications to the main controller. The "SCDATA" is similar, with connection to the scale at connector J3. "SCCLK" is the buffered clock line used for scale communications also.

Buffer U13D provides an inversion for TM1SEL producing TM2SEL, which alternately enables/disables temperature multiplexers.

A/D Converter

The A/D converter U11 is an 8 channel, 12 bit serial interface device. Control for the channels is software configurable by the serial communication lines "SSPCLK", "ADCDIN" and "COMOUT". The A/D converter is enabled for signal processing by the signal "ACEN" which is asserted twice every 21 msec (the A/D converter is read twice). In addition, the "ADCDIN" and "COMOUT" are also driven at 21 msec intervals. The "SSPCLK" is shared with the EEPROM on the sensor board and scale clock, therefore the timing is not periodic.

All temperature information is presented as a multiplexed signal on channel 0 and oxygen information is presented as a multiplexed signal on channel 2. Channel 4 allows the A/D converter to read its maximum input, and channel 5 allows the A/D converter to read its minimum input. This allows determination of proper A/D functioning.

The analog representation of fan pulses is applied to channel 6. Humidity is applied to channel 7. Channels 1 and 3 are spare.

2.1.7 Air Circulation System

The control unit presents the air temperature and the skin temperature on the LC display. Optionally, the humidity and the oxygen concentration within the hood environment, and the baby weight can be presented.

The continuous air circulation mixes the temperature, humidity and oxygen concentration. The impeller draws in 7 liters per minute of room air, when no O2 is being applied. When flow-controlled O2 is applied, or when servo-controlled O2 is applied and the controller has opened the O2 servo valve, the fresh air is cut off, and the O2 flows in its place.

The impeller provides internal circulation at a much greater flow than that of the fresh gas inflow. The total flow of fresh and recirculated air is directed to the radiator and heater. The air enters the infant compartment up through the slots at the front and rear of the main deck and then passes between the front and rear inner walls (heat shields).

The air circulates past the sensor module, which contains the temperature sensing thermistors. After circulating within the infant compartment, the air then re-circulates down through a slot in the right end of the main deck, and back to the impeller.

When either access panel of the hood is open, the impeller speeds up, and the air continues to flow upward past the opening, creating a warm air curtain to minimize the drop in air temperature in the incubator.

The temperature is regulated using either the incubator's air or the infant's skin temperature as the controlling parameter; the desired mode is selected by the front panel keys. In either mode of operation, the heater output is proportional to the amount of heat required to maintain the desired temperature.

To indicate which mode of operation, Air Mode or Skin Mode, is in control, the set temperature of the controlling parameter remains on adjacent to the actual displayed temperature. In addition, the rotating wheel in either the Air or Skin softkey designator rotates.

Air Mode

In Air Mode, the air temperature is maintained at a set point between 68 °F and 99 °F (20 °C to 37 °C), or, in Temperature Override Mode, between 99 °F and 102 °F (37 °C and 39 °C). The set point is selected by the Air Set Temperature Up and Down arrow keys on the front panel. A probe located in the sensor module monitors the incubator's air temperature and compares it with the set point temperature setting. The probe supplies this information to the heater control circuitry, which regulates the heater output to maintain the air temperature setting. The actual air temperature appears on the Air Temperature display. A second sensor within the air temperature probe serves as a backup to limit the maximum incubator temperature. If the high temperature limit activates, the heater shuts off. In Air Mode, the infant's temperature is a function of the air temperature and the

infant's ability to establish and maintain its own temperature. A small infant, or one with underdeveloped homeostatic control, may not be able to maintain a stable temperature at the desired level.

Skin Temperature Control Mode

In Skin Mode, the infant's set point temperature is selected between 93 °F and 99 °F (34 °C and 37 °C), or, in Temperature Override Mode, between 99 °F and 100 °F (37 °C to 38 °C). The Skin Temperature set point is set by the Skin Set Temperature Up and Down arrow keys on the front panel. The skin temperature is measured by the Central Skin Probe, which attaches directly to the infant's skin. The probe supplies information to the heater control circuitry, which adjusts the heater output to maintain the skin set temperature.

The air temperature still appears in Skin Mode, but as information only. If Air Mode is selected while the skin probe remains connected, the Skin Temperature display continues to display actual skin temperature, but it does not control.

A Peripheral Skin Probe can be used as well, but has no effect on the temperature control.

If the Central Skin Probe fails or disconnects from its receptacle while in Skin Mode, the Skin Temperature display goes blank, an alarm sounds, and the heater turns off

2.1.8 Variable Height Adjustment Trolley

The trolley with electrical height adjustment has an adjustable working height of 600 mm to 800 mm.

The trolley contains a main switch, an integrated connector strip with three convenience outlets and pedals for the vertical adjustment.

2.1.9 Options

2.1.9.1 **Humidity**

General

The optional Humidification System provides for the humidification of the Incubator from 30% to 95% relative humidity (RH) in 1% steps. The humidifier is not capable of lowering the incubator humidity, only raising it. In the absence of humidification, the warming of the incubator air will lower the relative humidity of the incubator air below the relative humidity of the ambient air. This low relative humidity, dependent upon room ambient and the incubator set temperature, is the minimum humidity attainable at any given time.

The optional Humidification System consists of a water and steam system, a condensation management system, and (standard) wiring and sensing. The water and steam system consists of a reservoir assembly, an evaporator (heater stick), and a manifold. The condensation management system consists of a disposable drain fitting with hose, a disposable collection bottle, and a permanent bottle bracket. The Humidification system is available in 3 voltages (100 VAC, 120 VAC, and 230 VAC). The 3 versions are identical except for the evaporator.

If the controller has been programmed to control humidity, and insufficient water is present in the reservoir, the humidity in the hood will gradually fall. After some time, the controller will report a "Low Humidity Alarm", acoustically and on the display.

Water and Steam System

In use, the evaporator is installed in the boiling chamber of the reservoir. The reservoir has a water capacity sufficient for over 24 hours without refilling, under normal conditions. A visual inspection of the water level is possible through the translucent front of the humidity reservoir, without withdrawing the reservoir. The reservoir is equipped with a 1/4 turn locking filler cap, and a removable lid, which has a recess forming a funnel at the filler cap. The reservoir can be removed, refilled, and reinstalled, without disrupting the operation of the incubator (of course, no humidity is produced while the reservoir is removed, but the effect on the incubator environment is minimal if the reservoir is reinstalled in a few minutes.) The reservoir, cap, and lid are autoclavable. The evaporator is not autoclavable.

The evaporator assembly consists of a cartridge heater (125 W) installed in an aluminum block. Installed on the same block is a thermostat to limit the block temperature by interrupting power to the heater if an over-temperature condition exists (such as can be caused by water level too low or empty) and re-establishing power once the block temperature cools to a lower temperature threshold (such as when water is added or block cools). This is normal cycling behavior.

As a safety measure, a thermal cutout that cannot be reset is installed in the block. This cutout is designed to permanently interrupt power to the heater if the temperature is excessive – in normal operation it will never trip. In the event that the thermal cutout operates, the evaporator must be replaced.

The steam outlet of the reservoir connects with the manifold. The steam flows from the boiling chamber of the reservoir, through a series of baffles to prevent spitting, and into the manifold. The manifold includes a check valve to isolate the mains power of the humidity wiring and evaporator from the incubator air, which is often oxygen-enriched. The manifold delivers the steam into the heater well, where it is mixed with the incubator air at the hottest and driest point in the air circulation.

Condensation Management System

The condensation management system collects the condensation from the hood and shell, and directs it into the heater well. At the bottom of the heater well, a disposable fitting with a hose collects the condensation and directs it out the bottom of the shell and into a disposable collection bottle. The bottle is hung on a bracket below the VHA stand top plate.

2.1.9.2 Oxygen Servo System

The oxygen servo system consists of an optional valve assembly, optional oxygen sensor cells, optional 100% calibration fixture, standard wiring, and standard fresh air valve.

The oxygen servo valve assembly consists of a regulator and a solenoid valve on a mounting plate. The oxygen enters through a detachable hose, attached to a NIST, DISS female, or DISS male fitting. The regulator drops the pressure to 40 psi (2.8 bar). When the solenoid valve is energized, the oxygen flows through it, into a flexible tube, and then to the fresh air valve. Within the fresh air valve, the pressure of the oxygen cuts off the fresh air inlet, and the oxygen flows to the impeller which distributes it into the incubator. Without oxygen pressure, the fresh air valve is open between the air micro filter and the impeller, and impeller suction draws in fresh air.

When the optional servo oxygen system is used, the sensor module contains two independent oxygen fuel cells, which are compared to each other to determine the oxygen concentration in the incubator. The sensors are replaced as a pair, so that they age equally. See the installation instructions of the Oxygen Cell Kit for other important information.

If the sensor module is outside of the hood environment while in the oxygen mode, audible and visual alarms are given and the oxygen flow is interrupted.

If the oxygen concentration varies +/-3% from the set point, a visual and audible alarm is given. This alarm is suppressed for a period of time after the set point is changed, to provide time for the system to move to and stabilize at the new set point.

If the optional servo oxygen system is not installed, an inlet for non-regulated, non-servo administration of oxygen is provided. The use of this connection requires external regulation of the oxygen flow to achieve the desired patient environment oxygen concentration.

2.1.9.3 Scales

The Isolette® 8000 plus incubator supports weighing functionality by the use of a Weighing Platform (located under the mattress, on top of the mattress tray) and a Controller (providing processing and user interface). The Weighing Platform communicates only with the Sensor Module, which formats and relays information between the Weighing Platform and the Controller. Together, the Weighing Platform, Sensor Module (including software), Shell-to-Controller cable, and Controller (including software) form a scale system. There are 2 scale systems offered: Standard, and NAWI/OIML.

In these scale systems, the design is such that the 'empty' scale reads below 0, and gives an error. The scale systems are designed to be used with a mattress (MU12249, made with foam, about 300 g; or MP01401 Softbed ®, about 500 to 700 g). The use of either mattress brings the reading above the basic 'zero', and

into the normal measuring range. The taring process permits the user to subtract out any non-patient mass (such as positioning aids), as well as that part of the mattress mass that is above the basic zero, and make a measurement of 'net weight' (i.e., patient only). However, this means that, to verify the capacity of the scale, mass must be added to the empty (no mattress) scale until it just reads 0; then the full capacity of 7000 g above basic zero can be verified.

Scale Calibration

Calibration: There are 3 separate processes which are sometimes called "Calibration".

- Comparison or Checking (confirming the accuracy of the scale) is considered as an inspection, and is performed annually.
- If Comparison fails, Adjustment (correcting the accuracy of the scale) is needed. For Standard scales, Adjustment is considered Preventive Maintenance, and is described in the IFU. Under this procedure, the user adjusts the scale by using the "Calibration" process built into the controller. For scales subject to the OIML/NAWI directive, Adjustment is considered Repair. Because of the requirement to Adjust NAWI/OIML Weighing Platforms under Telford gravity, Adjustment can only be done at Telford, PA, USA.
- Verification (comparison of the scale to a legal standard) is required for OIML/NAWI scales after repair, after adjustment, and at a periodic interval determined by the local metrological authority. OIML/NAWI verification can only be done by the manufacturer ('initial') or by a local metrological authority ('subsequent'). Verification is not required for Standard scales.

Standard Scale

The Standard Scale is installable in any Isolette, without reprogramming or tools. It can be 'adjusted' (calibrated) by the user, with a 5 kg standard weight. It does not have a bubble level (water level) or leveling feet.

NAWI/OIML Scale

Specification EN 45501 governs Non-Automatic Weighing Instruments (NAWI/OIML).

The optional Isolette® scale which complies with this directive (also called the OIML directive) is available on the Isolette® 8000 plus. The NAWI/OIML scale contains a bubble level and leveling legs.

NAWI/OIML Weighing Platform

Each Weighing Platform has unique "spring constant" characteristics, which are stored in the Weighing Platform. These are essentially the ADC counts with a mattress on the Weighing Platform, and with mattress plus 5 kg on the Weighing Platform. The ADC counts vary, not only with the mass in grams, but also with local gravity. All NAWI/OIML Weighing Platforms are calibrated at Telford, PA, USA, and that gravity value is implied in the ADC counts always. The '0' and '5 kg' counts are transmitted to the controller during startup.

Since the Weighing Platform transfers its "spring constant" data to the controller, and all NAWI/OIML Weighing Platforms (ROHS and non-ROHS) are calibrated at Telford, (in Pennsylvania, USA), any NAWI/OIML Weighing Platform can be used with any Controller without loss of calibration data or accuracy, assuming that the controller has correct USE location programmed.

NAWI/OIML Controller

The NAWI/OIML Controller stores gravity adjustment coefficients (that is, the Calibration Location Latitude and Altitude (i.e., Telford)), and also the User Location Latitude and Altitude. From these, it calculates gravity values for the Calibration Location (Telford) and the User Location. At system startup, the NAWI/OIML Controller uploads the '0 g' and '5 kg' ADC count values from the NAWI/OIML Weighing Platform. (These are the values recorded at Telford, during the Adjustment.) The NAWI/OIML then uses the '0' and '5 kg' count values, with the 2 gravity values, to calculate the mass in grams on the Weighing Platform.

Since the Controller stores the User Location, it will only work properly at its programmed User Location, and cannot be used in a different location (City, Country, Latitude, Altitude), without reprograming.

The location to which the NAWI/OIML scale has been adjusted is shown on 2 labels, one on the rear of the incubator, and the other on the top of the controller (not visible in use.). The 'location' is only required to an accuracy of +/-1° of Latitude; this is equal to 60 nautical miles, 69 statute (land) miles, or 111 km. It should be noted that only distance North or South is important; distance East or West does not affect Latitude and thus not affect gravity force.

Location in Altitude is only required to an accuracy of +/-500 m vertically. Thus, all floors of a hospital are 'equal' in altitude, and virtually all locations in the same city are "equal".

On the NAWI/OIML scale, the weight is displayed continuously with a minimum once per second update rate.

For the NAWI/OIML scale, the controller "Calibration" display is only possible when the calibration jumper is in place, inside the controller.

A tamperproof label is applied on a screw of the controller to indicate if the controller were opened.

2.1.9.4 Trolley drawers

The trolley (stand) can accept optional swivel drawer systems, one on each side. The available swivel drawer systems are 1) a single deep drawer, or 2) a pair of shallow drawers. Both systems have approximately the same storage volume. Both systems include a swiveling writing surface, which doubles as a cover for the drawer.

2.1.9.5 IV Pole

The maximum weight for the IV pole is 5 kg (11 pounds). The minimum and the maximum heights from the floor are 137 cm to 184 cm (54 inches to 64.5 inches). The IV pole is available with a new Isolette® 8000 plus, or as an after sales upgrade or repair option.

2.1.9.6 Utility Shelf

The Utility shelf permits the mounting of monitors or other items. The maximum weight is 11 kg (25 pounds). The shelf height from the floor is 137 cm (54 inches). The Utility shelf is available with a Isolette® 8000 plus, or as an after sales upgrade or repair option.

2.1.9.7 Oxygen Tank Holder

An optional gas cylinder holder is available on the Isolette® 8000 plus. It can accept cylinders up to 110 mm (4.33 inches) in diameter. The clamp is adjustable for various cylinder diameters. Coarse adjustment is made by moving the fixed hook, and fine adjustment by the turning the threaded latch. The cylinder holder is available factory-installed with trolleys, or as an after-sales upgrade or repair kit.

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3 Maintenance instructions

This chapter describes the measures required to maintain the specified condition of the device.

3.1 Air filter

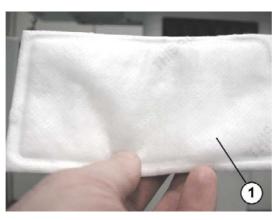


Fig. 8 Air filter with imprint

3.1.1 Safety precautions

CAUTION

If the air filter (Fig. 8/1) is dirty, do not clean it, but replace it with a new one.

CAUTION

A dirty air filter (Fig. 8/1) may impair the performance of the machine or lead to the accumulation of carbon dioxide (CO₂). The air filter must be replaced on a regular basis, in accordance with local regulations. It may be necessary to change the filter frequently, especially if the machine is used in an environment subject to unusually high dust levels. Failure to comply with this instruction may result in injury to the infant or damage to the machine!

NOTE

If the imprint on the air filter (Fig. 8/1) is no longer legible, or the air filter is dirty or damaged, replace the air filter.

3.1.2 Replacing the air filter

- 1 Check that there is no patient inside the Isolette.
- 2 If there is no patient inside the Isolette C2000/C2000e, switch it off.

3 Loosen the screws (Fig. 9/1) on the underside (rear) of the Isolette as far as possible.

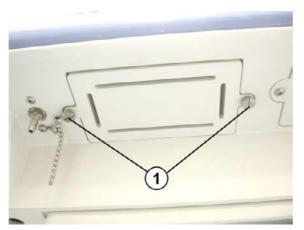


Fig. 9 Underside (rear) of Isolette; screws

NOTE

Used air filters can be disposed of as normal waste.

4 Take the used air filter (Fig. 10/1) out of the mounting frame and dispose of it in the normal waste.



Fig. 10 Mounting frame with air filter

- 5 Insert the **new** air filter in the mounting frame so that the imprint reading "This side out" points downwards; see Fig. 10. Note: When the air filter is fitted in the correct position the imprint is not legible!
- **6** Fix the mounting to the Isolette by the screws (Fig. 9/1).

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3.2 Option Oxygen sensors

3.2.1 Notes/Safety instructions

CAUTION

If preventive maintenance is carried out by untrained personnel it may result in personal injury or damage to property.

Preventive maintenance or repairs to the Isolette® infant incubator may only be carried out by properly, trained personnel.

- i The oxygen sensor is a sealed unit which uses potassium hydroxide as an electrolyte. If a leak occurs in the sensor it must be disposed of immediately. If electrolyte comes into contact with skin or clothing, the affected area must be rinsed with copious amounts of water. If electrolyte gets into the eyes, rinse them immediately for at least 15 minutes, keeping the eyes open as you do so. Immediately consult a doctor. Failure to comply with this instruction may result in personal injury or damage to the machine.
- i Only oxygen cells recommended by Dräger have been tested with the device and therefore we recommend only these cells be used otherwise the correct functioning of the device may be compromised.
- i Check the gas/oxygen service components at regular intervals for signs of corrosion or damage. Failure to comply with this instruction may result in personal injury or damage to the machine.
- i Check the oxygen cells regularly for loss of quality or leaks, and replace them as necessary. Failure to comply with this instruction may result in personal injury or damage to the machine.
- i Always replace both oxygen sensor cell, as a pair, at the same time, with new ones.

3.2.2 Replacing the oxygen sensors

3.2.2.1 Service equipment required

- Crosshead screwdriver

3.2.2.2 Procedure

- 1 Check that there is no patient inside the machine.
- 2 If there is no patient inside the Isolette®, switch it off.

3 Unplug the connector (Fig. 11/1) of the sensor module from the jack.

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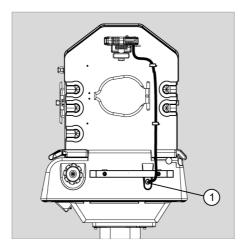


Fig. 11 Side view of Isolette®: sensor module connector

4 Remove the sensor module cable from the cable guides (Fig. 12/1).

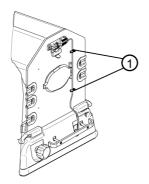


Fig. 12 Side view of Isolette®: cable guides

5 Turn the pawl latches (Fig. 13/1) to the "OPEN" position.



Fig. 13 Isolette®: pawl latches

6 Open the front access panel and lower it.

- 7 Unplug the connector(s) (Fig. 14/1) of any skin temperature probes (option) from the sensor module
- **8** Unplug the connector (Fig. 14/2) of the weighing scale (if present) from the sensor module

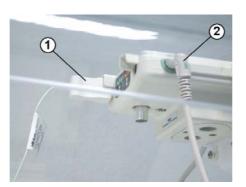


Fig. 14 Sensor module: Connectors for skin temperature sensor (1) and scale (2)

- **9** Lower the Sensor Module Locking Tab (Fig. 15/3).
- 10 Withdraw the sensor module partially out of the hood, until it stops.

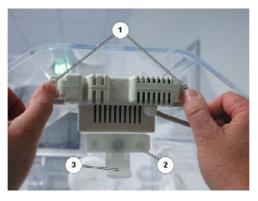


Fig. 15 Rear view of sensor module: locking tabs and sensor module lock plate

- 11 Hold the two locking tabs (Fig. 15/1) of the sensor module apart and at the same time withdraw the sensor module all the way out of the hood.
- 12 Remove and retain the screws (Fig. 16/1).

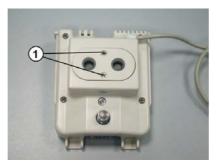


Fig. 16 Sensor module: screws

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13 Carefully detach the backing plate (Fig. 17/1) (Note: There are wires connecting the backing plate to the sensor module!).

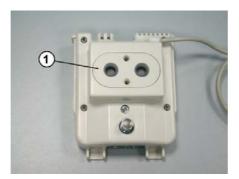


Fig. 17 Sensor module: backing plate

14 Unplug the jacks (Fig. 18/1) from the connectors of the oxygen sensors.

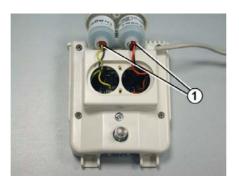


Fig. 18 Sensor module: jacks

15 Unscrew the oxygen sensors (Fig. 19/1) anti-clockwise out of the backing plate (Fig. 19/2).



Fig. 19 Backing plate with oxygen sensors

- i Used oxygen sensors are special waste. Used oxygen sensors must be disposed of in accordance with local waste disposal regulations.
- **16** Dispose of used oxygen sensors in accordance with local waste disposal regulations.
 - i Always replace both oxygen sensor cell, as a pair, at the same time, with new ones.

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- 17 Screw new oxygen sensors (Fig. 19/1) clockwise into the backing plate (Fig. 19/2) until a resistance is noticeable. (Note: The sealing rings of the oxygen sensors press against the backing plate!)
 - i The jacks on the ends of the oxygen sensor cables are not coded, and can be attached to either of the oxygen sensors when reconnecting!
- 18 Fit the jacks (Fig. 20/1) firmly onto the connectors of the new oxygen sensors.

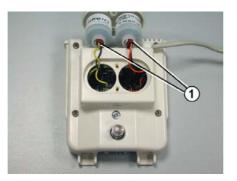


Fig. 20 Sensor module: jacks

19 Insert the backing plate (Fig. 21/1) with the oxygen sensors into the sensor module.

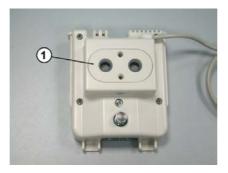


Fig. 21 Sensor module: backing plate

20 Fix the backing plate to the sensor module by the screws (Fig. 22/1).

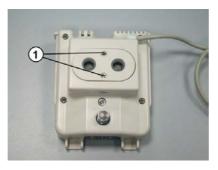


Fig. 22 Sensor module: screws

21 Insert the sensor module fully into the hood, ensuring correct positioning.

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- **22** Plug the connector(s) (Fig. 23/1) of any skin temperature probes (option) into the sensor module jack.
- **23** Plug the connector (Fig. 23/2) of the weighing scale (if present) into the sensor module jack.

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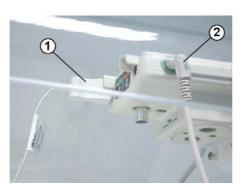


Fig. 23 Sensor module: Connectors for skin temperature sensor (1) and scale (2)

24 Close the front access panel and turn the pawl latches (Fig. 24/1) to the "CLOSED" position.



Fig. 24 Isolette®: pawl latches

25 Insert the sensor module cable into the cable guides (Fig. 25/1). All extra length of the cable should be between the lowest cable guide and the shell connection, see Fig. 26.

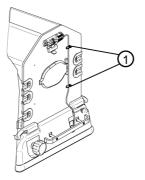


Fig. 25 Side view of Isolette®: cable guides

26 Plug the connector (Fig. 26/1) of the sensor module into the jack.

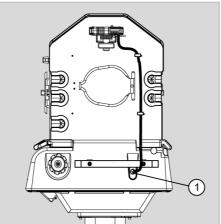


Fig. 26 Side view of Isolette®: sensor module connector **27** Calibrate the oxygen sensors; see 3.2.3 Calibrating the oxygen sensors.

3.2.3 Calibrating the oxygen sensors

3.2.3.1 Safety instructions for calibrating the oxygen sensors

CAUTION

Improper oxygen calibration can result in the display of false oxygen measurements. Death or serious injury could occur. If the "100% oxygen calibration fixture" is installed (Fig. 28/1), the Isolette® controller must be configured for "100% oxygen calibration", and the "100% oxygen calibration fixture" must be connected to a minimum 3 L/min of 100% oxygen during calibration. If the "100% oxygen calibration fixture" is **not** installed (Fig. 15/2), the Isolette® controller must be configured for "21% oxygen calibration", and no oxygen source shall be used. The "21% calibration" is made in ambient air.

3.2.3.2 **General**

After replacing oxygen sensors, be sure to calibrate the oxygen sensors at least once a week.

To calibrate the oxygen sensors, those sensors must be in an environment of known oxygen concentration. Such an environment can be achieved by withdrawing the sensor module such that the oxygen sensors are exposed to ambient air (at 21% oxygen), or, if the (optional) 100% calibration fixture is used, to a microenvironment flooded to 100% oxygen.

In order to calibrate the oxygen sensors, the calibration setting for oxygen and for any accessories connected to the Isolette® must be checked as follows:

3.2.3.3 Checking the calibration setting and accessories

- 1 Connect the Isolette® to the mains power supply.
- 2 Press and hold down the "alarm suppression" key and at the same time switch on the Isolette®.

The Isolette® starts up in configuration mode.

3 Check the oxygen calibration setting. Note: In Fig. 27/1 the calibration setting is "21%".

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Fig. 27 Close-up view of control panel: oxygen calibration point

If the oxygen calibration setting is "21%", the 100% oxygen calibration fitting (Fig. 28/1) must not be attached to the sensor module! For calibration with 21% O2, see 3.2.3.4 21% O2 calibration.

If the oxygen calibration setting is "100%", the 100% oxygen calibration fitting (Fig. 28/1) must be attached to the sensor module! For calibration with 100% O2, see Fig. 28 "100% O2 calibration".



Fig. 28 Sensor module with 100% oxygen calibration fitting

3.2.3.4 21% O₂ calibration

- 1 Connect the Isolette® to the mains power supply.
- 2 Press and hold down the "alarm suppression" key and at the same time switch on the Isolette®.

The Isolette® starts up in configuration mode.

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3 Check that the oxygen calibration point is "21%" (Fig. 29/1) and that the 100% oxygen calibration fitting (Fig. 28/1) is not attached to the sensor module.

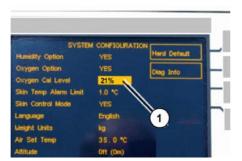


Fig. 29 Close-up view of control panel: oxygen calibration point

- 4 Switch off the Isolette® and wait 1 minute.
- 5 Switch on the Isolette®.
- 6 On the control panel touch the "Oxygen" softkey (Fig. 30/1).



Fig. 30 Close-up view of control panel: "oxygen" softkey.

7 On the control panel touch the "CALIBRATION" softkey (Fig. 31/1).



Fig. 31 Close-up view of control panel: "CALIBRATION" softkey

8 When the display prompts you the message slide out sensor module, slide the sensor module (Fig. 32/1) partially out of the hood, until it stops.

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Fig. 32 View of sensor module, partially slid out

The display shows a timer visually indicating the progress of the calibration, together with the message "21%" calibration.

After calibration the display shows the message that the calibration was successful.

9 Go to "Reinserting the sensor module".

3.2.3.5 100% O₂ calibration

- 1 Connect the Isolette® to the mains power supply.
- 2 Press and hold down the "alarm suppression" key and at the same time switch on the Isolette®.

The Isolette® starts up in configuration mode.

3 Check that the oxygen calibration point is "100%" (Fig. 33/1) and that the 100% oxygen calibration fitting (Fig. 28/1) is attached to the sensor module.



Fig. 33 Close-up view of control panel: oxygen calibration point "100%"

- 4 Switch off the Isolette®.
- 5 Switch on the Isolette®.
- **6** Connect 100% oxygen to the 100% calibration fixture, using 1/4" or 6 mm tube / hose.
- 7 Set a flow rate of 3 L/min to 5 L/min on the oxygen cylinder.
- 8 Open the oxygen feed on the oxygen cylinder.

9 On the control panel touch the "Oxygen" softkey (Fig. 34/1).



Fig. 34 Close-up view of control panel: "oxygen" softkey.

10 On the control panel touch the "CALIBRATION" softkey (Fig. 35/1).

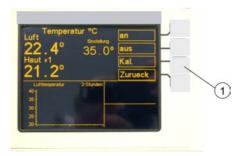


Fig. 35 Close-up view of control panel: "CALIBRATION" softkey

11 When the display prompts you to slide out the sensor module, slide out the sensor module (Fig. 36/1) partially out of the hood, until it stops.



Fig. 36 View of sensor module, partially slid out

The display shows a timer visually indicating the progress of the calibration, together with the message 100% calibration.

12 After calibration turn off and disconnect the oxygen source.

3.2.3.6 Reinserting the sensor module

- 1 Return the sensor module to its operational position, fully inside the hood.
- 2 If the O2 sensors were replaced, perform tests according to the Test Instructions. If the existing O2 sensors were used for the calibration, perform the operational checkout procedure from the Instructions for Use.

3.3 Heat Shield Locks

3.3.1 General

The Isolette C2000/C2000e has four heat shield locks. Two heat shield locks are mounted on the front door and two on the rear. Note: Fig. 37/1 shows only one heat shield lock!

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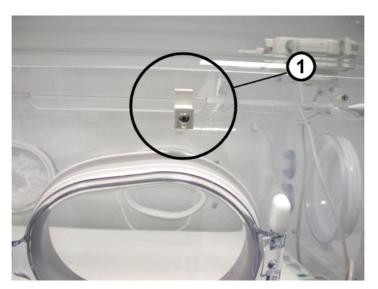


Fig. 37 Close-up view of Isolette C2000/C2000e; heat shield lock

3.3.2 Safety precautions

NOTE

Snapped-off heat shield locks will no longer hold the intermediate wall (heat shield) to the door, and in the worst-case scenario will fall inside the incubator. Immediately replace snapped-off heat shield locks with new ones.

3.3.3 Replacing heat shield locks

3.3.3.1 Service equipment required

Crosshead screwdriver

3.3.3.2 Procedure

The following procedure details how to replace a heat shield lock on the front door. The procedure is applicable in the same way to all heat shield locks (2x on the front door, 2x on the rear).

- 1 Check that there is no patient inside the Isolette C2000/C2000e.
- 2 If there is no patient inside the Isolette C2000/C2000e, switch it off.

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3 Turn the pawl latches (Fig. 38/1) to the "OPEN" position and carefully lower the front door.

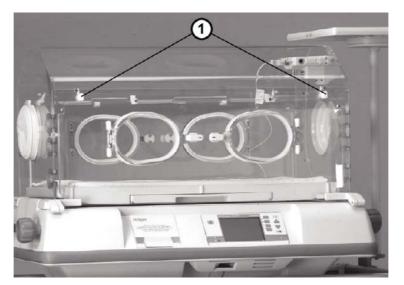


Fig. 38 View of Isolette C2000/C2000e; pawl latches

4 Lift the front door slightly and while doing so remove the screw (Fig. 39/1).

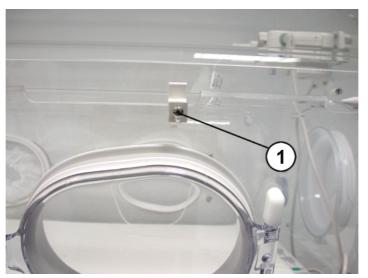


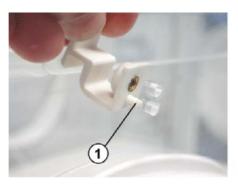
Fig. 39 Close-up view of front door; screw

NOTE

Faulty heat shield locks are special waste. Faulty heat shield locks must be disposed of in accordance with local waste disposal regulations.

5 Take out the faulty heat shield lock and dispose of it in accordance with local waste disposal regulations.

6 Insert the **new** heat shield lock into the front door so that the pin (Fig. 40/1) of the heat shield lock goes into the bottom hole in the front door and at the same time the heat shield lock locator (Fig. 40/2) is positioned over the intermediate wall (heat shield) (Fig. 40/3).



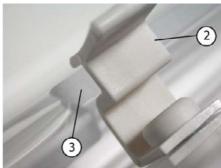


Fig. 40 Heat shield lock; fitting

- 7 Fix the heat shield lock to the front door by the screw (Fig. 39/1).
- 8 Lift the front door and turn the pawl latches (Fig. 38/1) to the "CLOSED" position.

3.4 Motor (for main fan) and Vibration Isolators

3.4.1 Notes/Safety instructions

CAUTION

Electrostatic discharge!

Electrostatic discharge may damage electrostatic sensitive devices.

When handling electrostatic sensitive devices, use an anti-static mat and wrist strap.

3.4.2 Replacement

3.4.2.1 Tools required

- Pliers
- Small flat head screwdriver
- Cross head screwdriver

3.4.2.2 Procedure

- 1 Unplug the unit from its power source.
- 2 Disconnect any oxygen sources and remove any equipment from shelves or IV poles.
- 3 If necessary, disconnect the scale cable assembly from the sensor module assembly (Fig. 41/2).

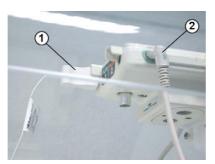


Fig. 41 Sensor module: Connectors for skin temperature sensor and scale

4 Disconnect the sensor module cable (Fig. 42/1) from the upper shell assembly.

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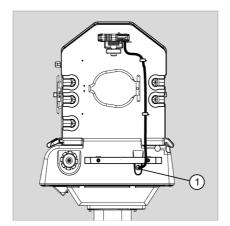


Fig. 42 Side view of Isolette®: sensor module connector

- **5** Unplug the power cord from the back of the controller assembly (Fig. 43/A).
- **6** If installed, remove the scale connector cable (Fig. 43/B) from the cable clamps (Fig. 43/C) on the end of the hood assembly (Fig. 43/D).

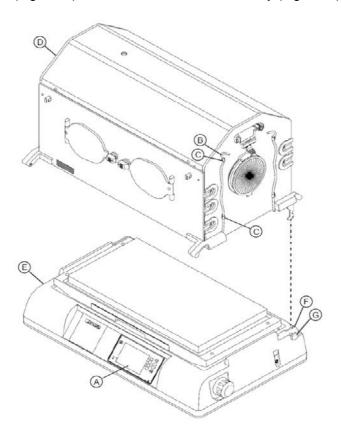


Fig. 43 Hood Assembly

7 Tilt the hood assembly (Fig. 43/D) back until it is fully open.

CAUTION

Two people are required to lift the hood assembly. Failure to use at least two people could result in personal injury or equipment damage.

- 8 Stand one person behind the incubator at each end of the hood assembly (Fig. 43/D), and have each person lift their end of the hood assembly (Fig. 43/D) straight up from the upper shell assembly (Fig. 43/E). The person at the sensor module end of the hood assembly (Fig. 43/D) **must** release the knob (Fig. 43/G) while lifting.
- 9 Carefully remove the hood assembly (Fig. 43/D) from the unit.
- **10** Remove the mattress, mattress tray, X-ray tray, and scale (if present) by lifting the mattress tray straight up.
- **11** Pull the two mattress tilt bars (Fig. 44/B) up through the main deck (Fig. 44/C), and remove them from the unit.

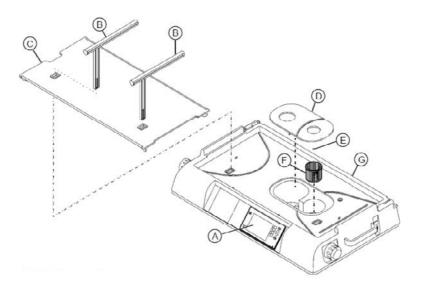


Fig. 44 Impeller Assembly

- 12 Remove the main deck (Fig. 44/C) from the unit.
- 13 Remove the heater/impeller cover (Fig. 44/D) from the unit.
- **14** Using pliers, remove the wire hose clamp (Fig. 44/E) (if present) that secures the impeller assembly (Fig. 44/F) to the upper shell assembly (Fig. 44/G).
- **15** Remove the impeller assembly (Fig. 44/F) from the upper shell assembly (Fig. 44/G).

16 Allow 45 minutes for the heater assembly (Fig. 45/D) to cool.

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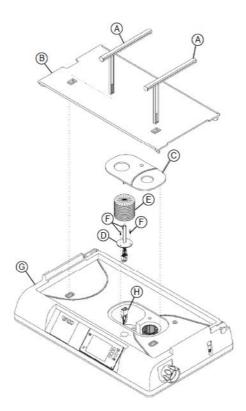


Fig. 45 Heater assembly

17 Remove the heater radiator (Fig. 45/E) from the heater assembly (Fig. 45/D).

CAUTION

Unplug the unit from its power source. Failure to do so could result in personal injury or equipment damage.

- **18** From under the upper shell assembly (Fig. 46/A), perform the following:
 - Disconnect the AC power cord from its connector (Fig. 46/B) on the back of the controller assembly (Fig. 46/C).
 - If necessary, disconnect the cable attached to the RS-232 port (Fig. 46/D).
 - Remove and retain the two wing nuts and flat washers (Fig. 46/E) located next to the AC power connector (Fig. 46/B) and the RS-232 port (Fig. 46/D).

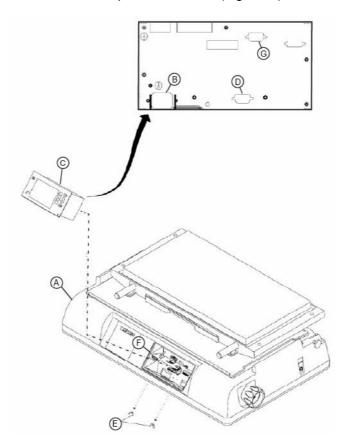


Fig. 46 Controller

- **19** Slide the controller assembly (Fig. 46/C) out from the upper shell assembly (Fig. 46/A) until its cable connectors are visible.
- 20 Disconnect the cables from the controller assembly (Fig. 46/C).
- **21** Remove the controller assembly (Fig. 46/C) from the upper shell assembly (Fig. 46/A).
- **22** If the unit is equipped with a humidity system, remove the reservoir.
- 23 Remove and retain the four Nylok® screws (Fig. 47/B) that secure the shell bottom (Fig. 47/C) to the upper shell assembly (Fig. 47/D).
 - i When reinstalling, apply fresh Loctite 242 to the screws.

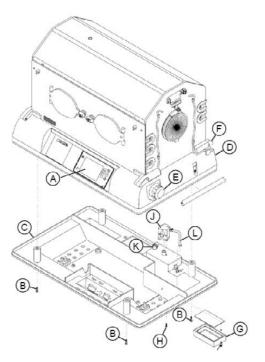


Fig. 47 Upper Shell Assembly

- **24** If present, remove the blue bumper gasket that separates the upper and lower shells.
- 25 Stand at the same end of the upper shell assembly (Fig. 47/D) as the controller (Fig. 47/A) and perform the following:
 - Using the mattress tilt knob (Fig. 47/E) and the rear hood hinge (Fig. 47/F), lift the upper shell assembly (Fig. 47/D) enough to access the corrugated hose (Fig. 47/K) at the fresh air valve (Fig. 47/J).
 - Using pliers, disconnect the corrugated hose (Fig. 47/K) from upper shell assembly.
 - Carefully remove the upper shell assembly (Fig. 47/D) from the shell bottom (Fig. 47/C) and place it upside down on a flat, padded surface.

26 Disconnect the motor assembly (Fig. 48/L) from the incubator motor-to-controller cable (Fig. 48/N).

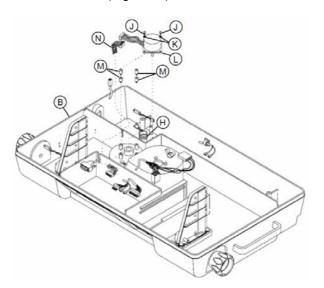


Fig. 48 Motor Assembly

- 27 Remove and retain the four screws (Fig. 48/J) and the four lockwashers (Fig. 48/K) that secure the motor assembly (Fig. 48/L) to the four Vibration Isolators (Fig. 48/M).
- 28 Remove and discard the motor assembly (Fig. 48/L).
- 29 Remove and discard the four Vibration Isolators (Fig. 48/M).
- 30 Reassemble by reversing the order of disassembly.
- **31** To ensure proper operation of the Isolette[®] Infant Incubator, perform the "Electrical safety tests" and the "Function Checks" according to the Test Instructions.

3.5 Fan (Sensor Module)

3.5.1 Notes/Safety instructions

CAUTION

Electrostatic discharge!

Electrostatic discharge may damage electrostatic sensitive devices.

When handling electrostatic sensitive devices, use an anti-static mat and wrist strap.

3.5.2 Replacement

3.5.2.1 Tools required

- Small crosshead screwdriver

3.5.2.2 Procedure

- 1 If necessary, disconnect the scale cable assembly from the sensor module assembly (Fig. 49/A).
- 2 If necessary, disconnect any skin temperature probes from the sensor module assembly (Fig. 49/A).
- 3 Disconnect the sensor module cable from the upper shell assembly (Fig. 49/B).
- 4 Remove the sensor module cable from under the 2 clips on the hood.

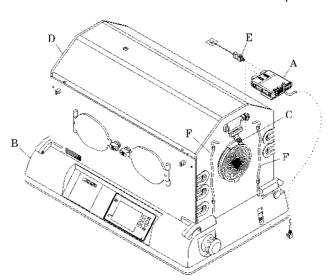


Fig. 49 Sensor Module

- **5** Lower the sensor module lock (Fig. 49/C). This may be secured by a sensor module lock plate (as in (Fig. 49), or by a 100% oxygen calibration fixture (not pictured).
- **6** Withdraw the sensor module assembly (Fig. 49/A) from the hood assembly (Fig. 49/D) until it stops.
- **7** Pull out the clip on the left side of the sensor module assembly (Fig. 49/A), and slide the sensor module assembly (Fig. 49/A) out of the hood assembly (Fig. 49/D).
- 8 Cut all labels that cross the seam of the Sensor Module along that seam.

- 9 Open the Sensor Module.
- 10 Partially remove the main PCB, and disconnect the ribbon cable.
- 11 Remove the Connector PCB (including fan) (Fig. 50/B) from the Sensor Module. Note the position and orientation of 2 tabbed washers (Fig. 50/C).

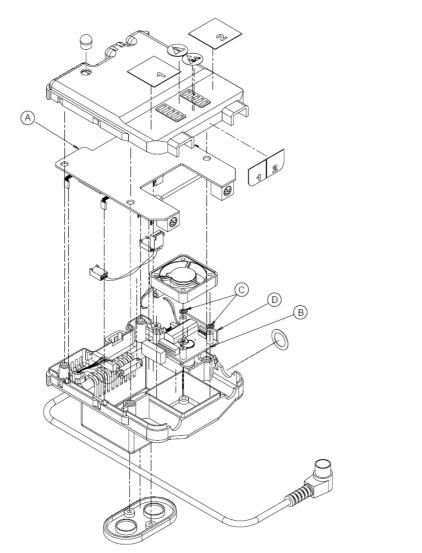


Fig. 50 Sensor Module

- **12** If the fan has a connector, disconnect it, install the replacement fan, and skip to reassembly.
- **13** If the fan is soldered in, remove and retain the Humidity PCB (if present) (Fig. 50/D) from the Connector PCB (Fig. 50/B).
- 14 Discard the Connector PCB (including fan) (Fig. 50/B).
- **15** Install the Humidity PCB (if present) (Fig. 50/D) into the new Connector PCB (including fan) (Fig. 50/B).
- 16 Install the new Connector PCB (Fig. 50/B) into the Sensor Module.
- 17 Reassemble by reversing the order of disassembly.

18 To ensure proper operation of the Isolette[®] Infant Incubator, perform the "Electrical safety tests" and the "Function Checks" according to the Test Instructions.

3.6 Controller Fan

3.6.1 Notes/Safety instructions

CAUTION

Electrostatic discharge!

Electrostatic discharge may damage electrostatic sensitive devices.

When handling electrostatic sensitive devices, use an anti-static mat and wrist strap.

3.6.2 Replacement

3.6.2.1 Tools required

- Cross head screwdriver
- Small flat screwdriver
- 7/32 inch socket or flat wrench

3.6.2.2 Procedure

1 CAUTION

Unplug the unit from its power source. Failure to do so could result in personal injury or equipment damage.

Unplug the unit from its power source.

- 2 From under the upper shell assembly (Fig. 51/A), perform the following:
 - Disconnect the AC power cord from its connector (Fig. 51/B) on the back of the controller assembly (Fig. 51/C).
 - If necessary, disconnect the cable attached to the RS-232 port (Fig. 51/D).
 - Remove and retain the two wing nuts (Fig. 51/E) and flat washers located next to the AC power connector (Fig. 51/B) and the RS-232 port (Fig. 51/D).

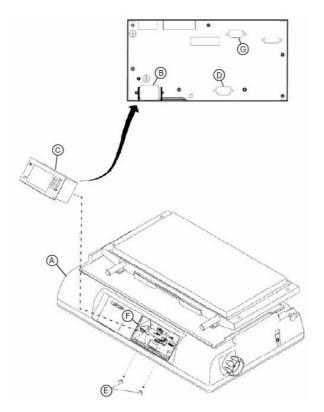


Fig. 51 Controller

- 3 Slide the controller assembly (Fig. 51/C) out from the upper shell assembly (Fig. 51/A) until its cable connectors are visible.
- 4 Disconnect the cables from the controller assembly (Fig. 51/C).
- **5** Remove the controller assembly (Fig. 51/C) from the upper shell assembly (Fig. 51/A).
- **6** Remove the four screws (Fig. 52/A) that secure the LC display front panel assembly (Fig. 52/B) to the controller assembly (Fig. 52/C).

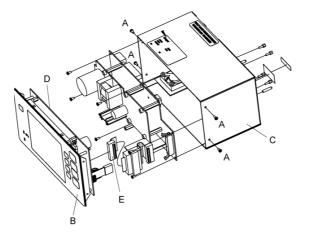


Fig. 52 LC Display Front Panel

- 7 Slide the LC display front panel assembly (Fig. 52/B) out of the controller assembly (Fig. 52/C), and disconnect ribbon cable assembly (Fig. 52/E) from the interface PCB.
- 8 Remove the LC display front panel assembly (Fig. 52/B) from the controller assembly (Fig. 52/C).
- 9 Using a 7/32" socket wrench, remove the four hex nuts (Fig. 53/A) and the four O-rings (Fig. 53/B) that secure the fan assembly (Fig. 53/C) to the controller assembly (Fig. 53/D).

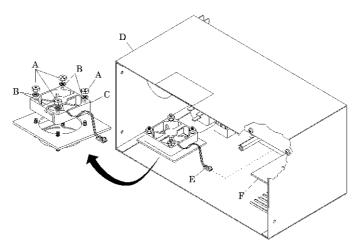


Fig. 53 Controller Fan Assembly

- **10** Disconnect the fan assembly cable (Fig. 53/E) from the interface/power supply module (Fig. 53/F).
- **11** Remove and discard the fan assembly (Fig. 53/C) from the controller assembly (Fig. 53/D).

CAUTION

When reconnecting the rear panel connectors, connect the sensor module-toconnector cable assembly to the sensor module connector **only**. Do **not** connect the sensor module cable to the RS-232 connector. Equipment damage could occur.

- 12 Reassemble by reversing the order of disassembly.
- **13** To ensure proper operation of the Isolette[®] Infant Incubator, perform the "Electrical safety tests" and the "Function Checks" according to the Test Instructions.

3.7 O2 Membrane and Filters

3.7.1 Notes/Safety instructions

CAUTION

Electrostatic discharge!

Electrostatic discharge may damage electrostatic sensitive devices. When handling electrostatic sensitive devices, use an anti-static mat and wrist strap.

i Older Isolette[®] (pre-2007) have a "Check Valve", for fresh air, with 2 O2 inlet hoses, and a metal body. Newer Isolette® (2007 thru 2016) have a "Fresh Air Valve", with 1 O2 inlet hose and a metal body. Isolette® after 2016 have a "Fresh Air Valve", with 1 O2 inlet hose and a molded body. All these versions are referred to here as "Fresh Air Valve". The figures are generic to all 3 versions.

3.7.2 Replacement

3.7.2.1 Tools required

- Pliers
- Small flat head screwdriver
- Cross head screwdriver
- Retaining ring pliers

3.7.2.2 Procedure

- 1 Unplug the unit from its power source.
- 2 Disconnect any oxygen sources and remove any equipment from shelves or IV poles.
- 3 If necessary, disconnect the scale cable assembly from the sensor module assembly (Fig. 54/2).

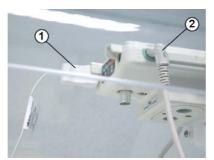


Fig. 54 Sensor module: Connectors for skin temperature sensor and scale

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4 Disconnect the sensor module cable (Fig. 55/1) from the upper shell assembly.

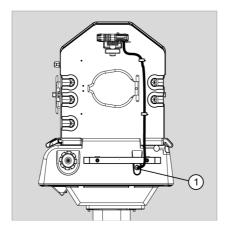


Fig. 55 Side view of Isolette®: sensor module connector

- **5** Unplug the power cord from the back of the controller assembly (Fig. 56/A).
- **6** If installed, remove the scale connector cable (Fig. 56/B) from the cable clamps (Fig. 56/C) on the end of the hood assembly (Fig. 56/D).

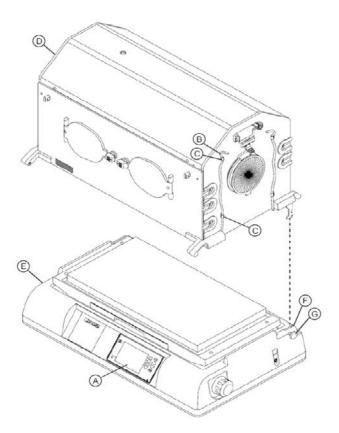


Fig. 56 Hood Assembly

7 Tilt the hood assembly (Fig. 56/D) back until it is fully open.

CAUTION

Two people are required to lift the hood assembly. Failure to use at least two people could result in personal injury or equipment damage.

- 8 Stand one person behind the incubator at each end of the hood assembly (Fig. 56/D), and have each person lift their end of the hood assembly (Fig. 56/D) straight up from the upper shell assembly (Fig. 56/E). The person at the sensor module end of the hood assembly (Fig. 56/D) **must** release the knob (Fig. 56/G) while lifting.
- 9 Carefully remove the hood assembly (Fig. 56/D) from the unit.
- **10** Remove the mattress, mattress tray, X-ray tray, and scale (if present) by lifting the mattress tray straight up.
- **11** Pull the two mattress tilt bars (Fig. 57/B) up through the main deck (Fig. 57/C), and remove them from the unit.

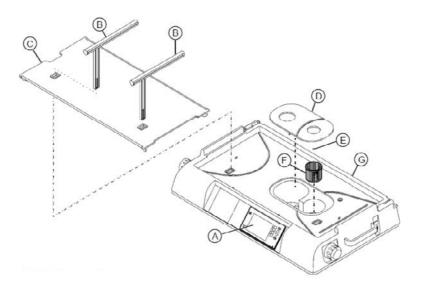


Fig. 57 Impeller Assembly

- 12 Remove the main deck (Fig. 57/C) from the unit.
- 13 Remove the heater/impeller cover (Fig. 57/D) from the unit.
- **14** Using pliers, remove the wire hose clamp (Fig. 57/E) (if present) that secures the impeller assembly (Fig. 57/F) to the upper shell assembly (Fig. 57/G).
- **15** Remove the impeller assembly (Fig. 57/F) from the upper shell assembly (Fig. 57/G).

16 Allow 45 minutes for the heater assembly (Fig. 58/D) to cool.

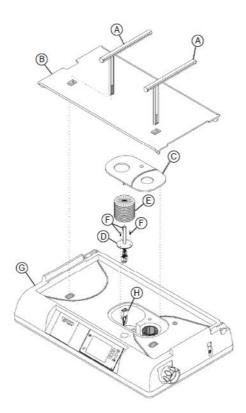


Fig. 58 Heater assembly

17 Remove the heater radiator (Fig. 58/E) from the heater assembly (Fig. 58/D).

CAUTION

Unplug the unit from its power source. Failure to do so could result in personal injury or equipment damage.

18 From under the upper shell assembly (Fig. 59/A), perform the following:

- Disconnect the AC power cord from its connector (Fig. 59/B) on the back of the controller assembly (Fig. 59/C).
- If necessary, disconnect the cable attached to the RS-232 port (Fig. 59/D).
- Remove and retain the two wing nuts and flat washers (Fig. 59/E) located next to the AC power connector (Fig. 59/B) and the RS-232 port (Fig. 59/D).

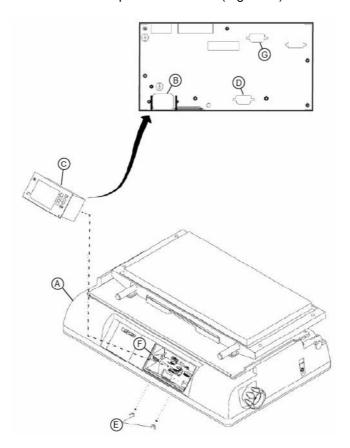


Fig. 59 Controller

- **19** Slide the controller assembly (Fig. 59/C) out from the upper shell assembly (Fig. 59/A) until its cable connectors are visible.
- 20 Disconnect the cables from the controller assembly (Fig. 59/C).
- **21** Remove the controller assembly (Fig. 59/C) from the upper shell assembly (Fig. 59/A).
- 22 If the unit is equipped with a humidity system, remove the reservoir.

- 23 Remove and retain the four Nylok® screws (Fig. 60/B) that secure the shell bottom (Fig. 60/C) to the upper shell assembly (Fig. 60/D).
 - i When reinstalling, apply fresh Loctite 242 to the screws.

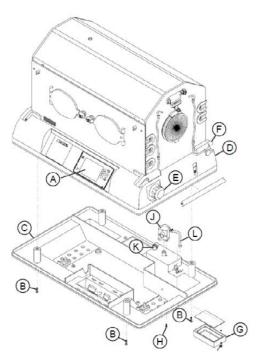


Fig. 60 Upper Shell Assembly

- **24** If present, remove the blue bumper gasket that separates the upper and lower shells.
- 25 Stand at the same end of the upper shell assembly (Fig. 60/D) as the controller (Fig. 60/A) and perform the following:
 - Using the mattress tilt knob (Fig. 60/E) and the rear hood hinge (Fig. 60/F), lift the upper shell assembly (Fig. 60/D) enough to access the corrugated hose (Fig. 60/K) at the fresh air valve (Fig. 60/J).
 - Using pliers, disconnect the corrugated hose (Fig. 60/K) from upper shell assembly.
 - Carefully remove the upper shell assembly (Fig. 60/D) from the shell bottom (Fig. 60/C) and place it upside down on a flat, padded surface.

- **26** Using pliers, disconnect the braided hose (Fig. 61/L) from the servo oxygen assembly (if present) or the oxygen inlet fitting (if present).
- 27 Remove the air intake microfilter cover (Fig. 61/G) and the air filter.

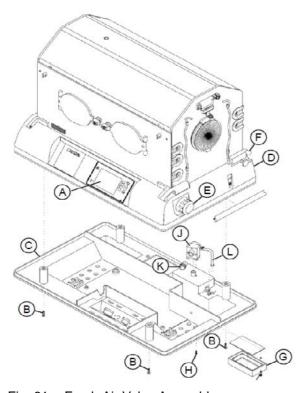


Fig. 61 Fresh Air Valve Assembly

- 28 Remove the screw (Fig. 61/H) that secures the fresh air valve assembly (Fig. 61/J) to the shell bottom (Fig. 61/C). The screw (Fig. 61/H) should be reused, but with a new application of Loctite 242.
- **29** Remove the fresh air valve assembly (Fig. 61/J) from the shell bottom (Fig. 61/C).
- 30 Remove and retain 3 screws holding the chamber to the valve body.
- 31 Remove and retain the chamber.
- **32** Note the position and folding of the diaphragm, and remove the diaphragm assembly.
- **33** Using retaining ring pliers, remove and retain the "C" type retaining ring. Remove and discard the 3 filter disks.
- **34** Remove and retain the internal tooth retaining ring and the nylon washer.
- 35 Remove and discard the old diaphragm.
- **36** Reassemble by reversing the order of disassembly, installing 3 new filter disks and the new diaphragm. Ensure the smooth motion of the diaphragm assembly within the valve body before reassembly.
- **37** To ensure proper operation of the Isolette[®] Infant Incubator, perform the "Electrical safety tests" and the "Function Checks" according to the Test Instructions.

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3.8 Tilt Bar O-Rings

3.8.1 Notes/Safety instructions

CAUTION

Electrostatic discharge!

Electrostatic discharge may damage electrostatic sensitive devices.

When handling electrostatic sensitive devices, use an anti-static mat and wrist strap.

3.8.2 Replacement

3.8.2.1 Tools required

- Pliers
- Small flat head screwdriver
- Cross head screwdriver
- Needle-nose pliers
- Retaining ring pliers

3.8.2.2 Procedure

- 1 Unplug the unit from its power source.
- 2 Disconnect any oxygen sources and remove any equipment from shelves or IV poles.
- 3 If necessary, disconnect the scale cable assembly from the sensor module assembly (Fig. 62/2).

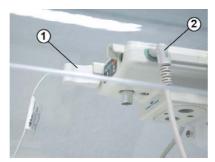


Fig. 62 Sensor module: Connectors for skin temperature sensor and scale

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4 Disconnect the sensor module cable (Fig. 63/1) from the upper shell assembly.

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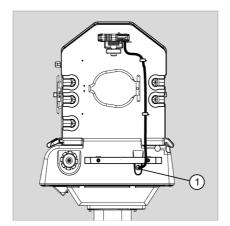


Fig. 63 Side view of Isolette®: sensor module connector

- **5** Unplug the power cord from the back of the controller assembly (Fig. 64/A).
- **6** If installed, remove the scale connector cable (Fig. 64/B) from the cable clamps (Fig. 64/C) on the end of the hood assembly (Fig. 64/D).

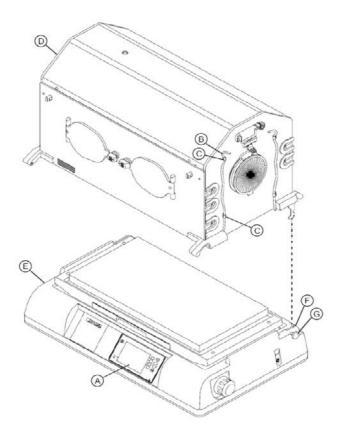


Fig. 64 Hood Assembly

7 Tilt the hood assembly (Fig. 64/D) back until it is fully open.

CAUTION

Two people are required to lift the hood assembly. Failure to use at least two people could result in personal injury or equipment damage.

- 8 Stand one person behind the incubator at each end of the hood assembly (Fig. 64/D), and have each person lift their end of the hood assembly (Fig. 64/D) straight up from the upper shell assembly (Fig. 64/E). The person at the sensor module end of the hood assembly (Fig. 64/D) **must** release the knob (Fig. 64/G) while lifting.
- 9 Carefully remove the hood assembly (Fig. 64/D) from the unit.
- **10** Remove the mattress, mattress tray, X-ray tray, and scale (if present) by lifting the mattress tray straight up.
- **11** Pull the two mattress tilt bars (Fig. 65/B) up through the main deck (Fig. 65/C), and remove them from the unit.

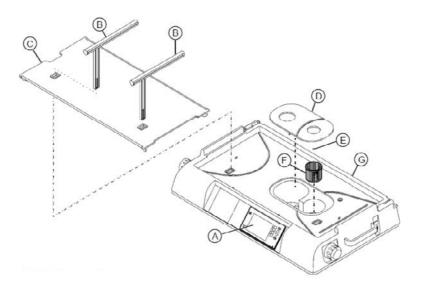


Fig. 65 Impeller Assembly

- 12 Remove the main deck (Fig. 65/C) from the unit.
- 13 Remove the heater/impeller cover (Fig. 65/D) from the unit.
- **14** Using pliers, remove the wire hose clamp (Fig. 65/E) (if present) that secures the impeller assembly (Fig. 65/F) to the upper shell assembly (Fig. 65/G).
- **15** Remove the impeller assembly (Fig. 65/F) from the upper shell assembly (Fig. 65/G).

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16 Allow 45 minutes for the heater assembly (Fig. 66/D) to cool.

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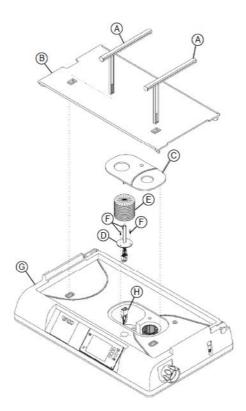


Fig. 66 Heater assembly

17 Remove the heater radiator (Fig. 66/E) from the heater assembly (Fig. 66/D).

CAUTION

Unplug the unit from its power source. Failure to do so could result in personal injury or equipment damage.

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18 From under the upper shell assembly (Fig. 67/A), perform the following:

- Disconnect the AC power cord from its connector (Fig. 67/B) on the back of the controller assembly (Fig. 67/C).
- If necessary, disconnect the cable attached to the RS-232 port (Fig. 67/D).
- Remove and retain the two wing nuts and flat washers (Fig. 67/E) located next to the AC power connector (Fig. 67/B) and the RS-232 port (Fig. 67/D).

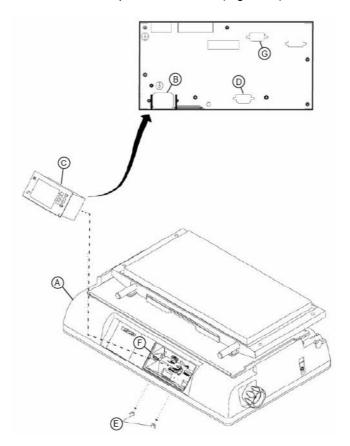


Fig. 67 Controller

- **19** Slide the controller assembly (Fig. 67/C) out from the upper shell assembly (Fig. 67/A) until its cable connectors are visible.
- 20 Disconnect the cables from the controller assembly (Fig. 67/C).
- **21** Remove the controller assembly (Fig. 67/C) from the upper shell assembly (Fig. 67/A).
- 22 If the unit is equipped with a humidity system, remove the reservoir.

- 23 Remove and retain the four Nylok® screws (Fig. 68/B) that secure the shell bottom (Fig. 68/C) to the upper shell assembly (Fig. 68/D).
 - i When reinstalling, apply fresh Loctite 242 to the screws.

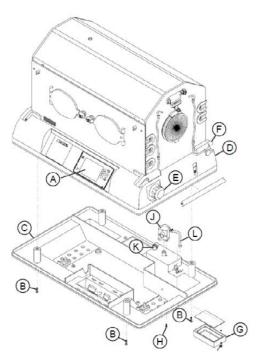


Fig. 68 Upper Shell Assembly

- **24** If present, remove the blue bumper gasket that separates the upper and lower shells.
- 25 Stand at the same end of the upper shell assembly (Fig. 68/D) as the controller (Fig. 68/A) and perform the following:
 - Using the mattress tilt knob (Fig. 68/E) and the rear hood hinge (Fig. 68/F), lift the upper shell assembly (Fig. 68/D) enough to access the corrugated hose (Fig. 68/K) at the fresh air valve (Fig. 68/J).
 - Using pliers, disconnect the corrugated hose (Fig. 68/K) from upper shell assembly.
 - Carefully remove the upper shell assembly (Fig. 68/D) from the shell bottom (Fig. 68/C) and place it upside down on a flat, padded surface.

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26 Perform this step on both sides of the incubator: Using retaining ring pliers, remove the e-ring (Fig. 69/M) and flat washer (Fig. 69/N) that secure the knob shaft (Fig. 69/O) to the upper shell assembly (Fig. 69/B).

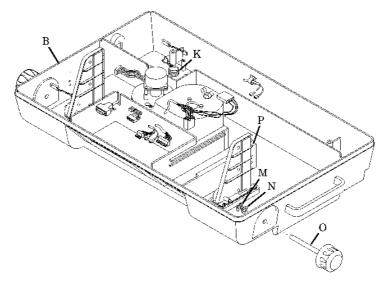


Fig. 69 Mattress Tilt Knob

- **27 Perform this step on both sides of the incubator:** Remove the knob shaft (Fig. 69/O) from the upper shell assembly (Fig. 69/B).
- 28 Perform this step on both sides of the incubator: Remove the three screws (Fig. 70/M) that secure the tilt mechanism (Fig. 70/N) to the upper shell assembly (Fig. 70/B). The screws (Fig. 70/M) should be reused, but with a new application of Loctite 242.

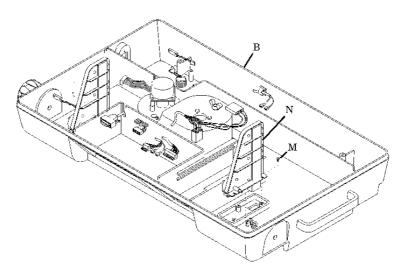


Fig. 70 Mattress Tilt Mechanism

- **29 Perform this step on both sides of the incubator:** Remove the tilt mechanism (Fig. 70/N) from the upper shell assembly (Fig. 70/B).
- 30 Remove and discard existing Tilt Bar O-rings
- 31 Install a new Tilt Bar O-ring onto each Tilt Bar mechanism.
- 32 Reassemble by reversing the order of disassembly.

33 To ensure proper operation of the Isolette[®] Infant Incubator, perform the "Electrical safety tests" and the "Function Checks" according to the Test Instructions.

4 Parts catalog

Parts catalog

This chapter contains a list of the device's orderable parts.

4.1 Isolette 8000 plus



Parts catalog

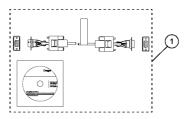
Isolette 8000 plus

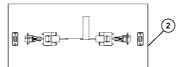
Revision: 00 6016.157

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			-			
			Parts cat Isolette 800	alog 00 plus		
Item No.	Order No. MX46532 MQ50597 MQ50378 MQ50377 MQ50596 MQ50605	Oderable	Description Tools 18+ Basic unit Modification kits/Options Maintenance parts/Service kits 18+ Accessories/consumables Identif.of parts in kit Iso8+	Qty.	Qty.unit St St St St St St	Remark
	Items th	nat are showr	n in the illustration but are not listed b Isolette 800		e not available a	as spare parts

Parts catalog Tools





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Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
0	7911718	~	Univers. USB-RS232 Adapter	1.000	St	
0	MU14789	~	WRENCH,L,3/8 HEX,BALL END STUB	1.000	St	
0	7910594	~	VDE tester GMC Secutest 0751	1.000	St	
0	7901161	~	Flowm., bl. , 0.02 - 14 L/min.	1.000	St	
1	MU26084	~	KIT,NC&T SOFTWARE UPDATE TOOL	1.000	St	
2	MU13549	✓	Cable assembly, programming	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts Isolette 8000 plus

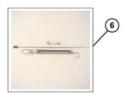
Revision: 00

Parts catalog Tools







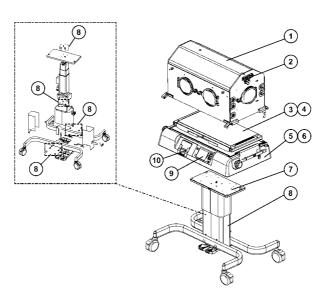


Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
3	MU01732	~	Test weight	1.000	St	
4	7910980	~	Temperature-humidity meter set	1.000	St	
5	7911955	~	MX 300-i Oyxgen Monitor	1.000	St	
6	7911370	~	Spring balance with press. kit	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts Isolette 8000 plus

Revision: 00

Parts catalog 18+ Basic unit



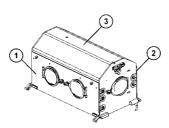
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Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
1	MQ50384		Incubator Hoods	1.000	St	Not orderable.Parts available,see assembly
2	MQ50598		I8+ Sensor Module spare	1.000	St	Not orderable.Parts available,see assembly
3	MQ50573		Scale standard,ROHS	1.000	St	Not orderable.Parts available,see assembly
4	MQ50568		Scale(EU)verifiable,RoHs	1.000	St	Not orderable.Parts available,see assembly
5	MQ50599		I8+ Shell Assembly	1.000	St	Not orderable.Parts available,see assembly
6	MQ50392		Oxygen Systems	1.000	St	Not orderable.Parts available,see assembly
7	MX46518		Attachment Shell/Pedest.Stand	1.000	St	Not orderable.Parts available,see assembly
8	MQ50604		Trolley Perform.dual castor	1.000	St	
9	MQ50600		I8+ Controller	1.000	St	Not orderable.Parts available,see assembly
10	MQ50391		Humidity/Condensation Systems	1.000	St	Not orderable.Parts available,see assembly

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

Isolette 8000 plus Revision: 00

Parts catalog Incubator Hoods



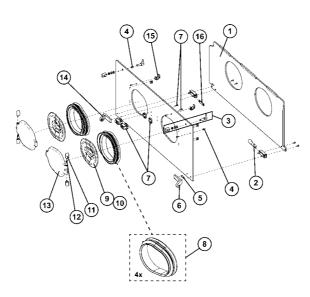


Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
1	MX46500		Front Access Panel,high,I8	1.000	St	not for order,available parts,see assembly
2	MX46502		Rear Access Panel,high,l8	1.000	St	not for order,available parts,see assembly
3	MX46493		Hood Assy,HI,Dual Acs,AD I+r	1.000	St	not for order,available parts,see assembly
4	MQ50393		Hood high double Acc.Pan.2Iris	1.000	St	not for order,available parts,see assembly

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts Isolette 8000 plus

Revision: 00

Parts catalog Front Access Panel,high,l8



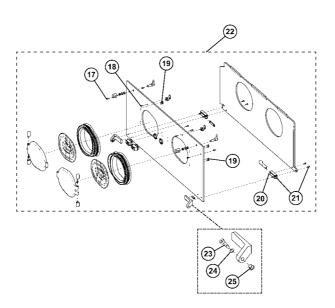
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Item No.	Order No.	Oderable	Description	Qty	. Qty.uı	nit Remark
1	MU12258	✓	Repl heat shield,ACS PNL,PAWL	1.00	00 St	
2	MU12684	~	Bracket,heat shield,front	1.00	00 St	
3	MU08534	~	Knob & latch repl kit, ACS PNL	2.00	00 St	
4	MU12717	✓	Spacer,6-32,.31OD,.50LG	2.00	00 St	
5	MU12697	✓	Magnet,.25SQ X 1.00lg ALNICO	1.00	00 St	
6	MU21361	~	Hinge Access Panel Rgt Frnt I8000	1.00	00 St	
7	MU13393	~	Repl kit,access door latch	2.00	00 St	
8	MU22201	✓	Kit Gasket Port Door Non Drip	1.00	00 St	
9	MU12702	✓	Cuff,ACS door,reuse,ISO,Box/10	1.00	00 St	wahlweise/optional;
10	MU06570	✓	Acs port cuffs,0V,repl,box/100	1.00	00 St	
11	MU08163	~	Pivot hinge	4.00	00 St	
12	MU08164	~	Spring,Trsn,.270OD,.030W,.365L	2.00	00 St	
13	MU12677	✓	Door_access_Isolette	2.00	00 St	
14	MU21362	✓	Hinge Access Panel Lft Frnt I8	1.00	00 St	
15	MU12681	✓	Latch,heatshield	2.00	00 St	
16	MU12676	~	Plate,backup,hinge,heat shield	1.00	00 St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

Isolette 8000 plus Revision: 00

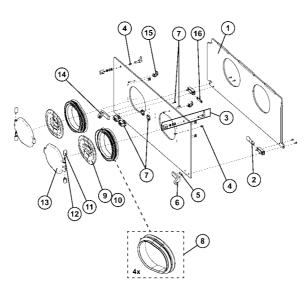
Parts catalog Front Access Panel,high,l8



Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
17	MU15130	✓	Scr,6-32X7/16 TR PH SS	2.000	St	
18	MU15127	~	Scr,6-32X3/8, TR PH SS Nylok	2.000	St	
19	MU15131	✓	Scr,6-32X7/16,TR PH SS Nylok	8.000	St	
20	MU15248	~	Scr 10-32X5 8 TR PH SS Nylok	4.000	St	
21	MU13400	~	Kit,heat shield hinge Isolette	1.000	St	
22	MU21253	✓	PANEL ASM ACS FNT NOCUFF SPARE	1.000	St	
23	MU12267	✓	Bearing, 25ID .29OD .41Flg NY	1.000	St	
24	MU15580	✓	Wshr,Fl,.25ID .38OD .02T Ny	1.000	St	
25	MU15729	✓	Scr,Shldr,.25D.35L 10-24SS Nlk	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts Isolette 8000 plus Revision: 00

Parts catalog Rear Access Panel,high,l8



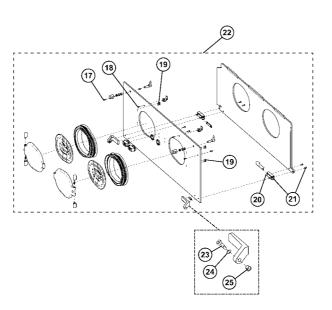
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Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
1	MU12258	✓	Repl heat shield,ACS PNL,PAWL	1.000	St	
2	MU12676	~	Plate,backup,hinge,heat shield	1.000	St	
3	MU08534	~	Knob & latch repl kit, ACS PNL	2.000	St	
4	MU12717	✓	Spacer,6-32,.31OD,.50LG	2.000	St	
5	MU12697	✓	Magnet,.25SQ X 1.00lg ALNICO	1.000	St	
6	MU21363	~	Hinge, Access panel, RHT left ,18000	1.000	St	
7	MU13393	~	Repl kit,access door latch	2.000	St	
8	MU22201	▽	Kit Gasket Port Door Non Drip	1.000	St	
9	MU12702	▽	Cuff,ACS door,reuse,ISO,Box/10	1.000	St	wahlweise/optional;
10	MU06570	✓	Acs port cuffs,0V,repl,box/100	1.000	St	
11	MU08163	~	Pivot hinge	1.000	St	
12	MU08164	~	Spring,Trsn,.270OD,.030W,.365L	2.000	St	
13	MU12677	▽	Door_access_Isolette	2.000	St	
14	MU21364	✓	Hinge, Access panel, RHT rear, 18000	1.000	St	
15	MU12681	✓	Latch,heatshield	2.000	St	
16	MU12685	~	Bracket,heat shield,rear	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

Isolette 8000 plus Revision: 00

Parts catalog Rear Access Panel,high,l8

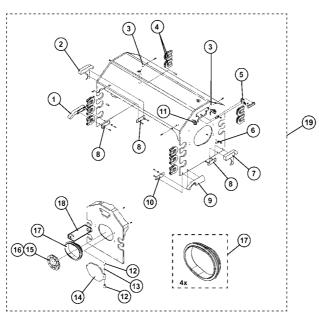


Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
17	MU15130	~	Scr,6-32X7/16 TR PH SS	2.000	St	
18	MU15127	✓	Scr,6-32X3/8, TR PH SS Nylok	2.000	St	
19	MU15131	~	Scr,6-32X7/16,TR PH SS Nylok	8.000	St	
20	MU15248	~	Scr 10-32X5 8 TR PH SS Nylok	4.000	St	
21	MU13400	~	Kit,heat shield hinge Isolette	1.000	St	
22	MU21254	✓	PANEL ASM ACS REAR NOCUFF SPARE	1.000	St	
23	MU12267	✓	Bearing, .25ID .29OD .41Flg NY	1.000	St	
24	MU15580	~	Wshr,Fl,.25ID .38OD .02T Ny	1.000	St	
25	MU15729	$\overline{\mathbf{v}}$	Scr,Shldr,.25D.35L 10-24SS Nlk	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

Isolette 8000 plus Revision: 00

Parts catalog Hood Assy,HI,Dual Acs,AD I+r



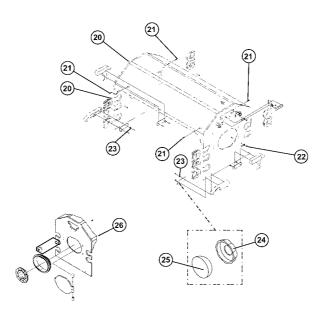
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Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
0	MU13413	✓	X-ray tray label/non slip	1.000	St	
1	MU19802	~	Hinge,Access Pnl,Left Frt-C2KP	1.000	St	
2	MU19805	✓	Hinge,Access Pnl,Left Rear-C2KP	1.000	St	
3	MU12716	✓	Spacer,6-32ID .31OD .38L ACTL	4.000	St	
4	MU12609	✓	Grommet_access	10.000	St	
5	MU13461	~	Sensor module look kit, Isolette	1.000	St	
6	MU11061	~	Clamp,Cable,Spr Ty,Ny .38ID	2.000	St	
7	MU19804	✓	Hinge,Access Pnl,Rgt Rear C2KP	1.000	St	
8	MU12607	✓	Plate,backup hinge, LF RR	2.000	St	
9	MU19801	✓	Hinge,Access Pnl,Rgt Frt-C2KP	1.000	St	
10	MU12608	✓	Plate,backup hinge, LR RF	2.000	St	
11	MU12626	✓	Slide assy,sensor module	2.000	St	
12	MU08163	✓	Pivot hinge	4.000	St	
13	MU08164	✓	Spring,Trsn,.270OD,.030W,.365L	2.000	St	
14	MU12677	~	Door_access_Isolette	2.000	St	
15	MU06570	~	Acs port cuffs,0V,repl,box/100	1.000	St	
16	MU12702	✓	Cuff,ACS door,reuse,ISO,Box/10	1.000	St	wahlweise/optional;
17	MU22201	✓	Kit Gasket Port Door Non Drip	1.000	St	
18	MU13393	✓	Repl kit,access door latch	2.000	St	
19	MU21284	✓	Hood Asm 6 Access Doors Spare	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

Isolette 8000 plus Revision: 00

Parts catalog Hood Assy,HI,Dual Acs,AD I+r

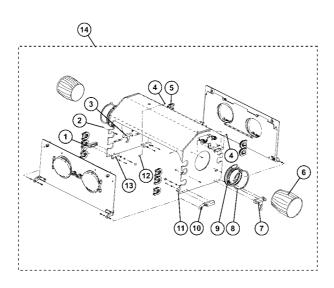


Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
20	MU15141	~	Scr,6-32x9/16 TR PH SS	2.000	St	
21	MU15129	~	Scr,6-32x7/16,FL PH SS	4.000	St	
22	MU15421	~	Nut,acorn,6-32 AL	2.000	St	
23	MU05563	~	Base,screw,1/4-20 PN	2.000	St	
24	MU05562	~	Cover,screw,LT Gray,1/4-20 PN	1.000	St	
25	MU15525	~	Wshr,FL,.150ID .31OD .06T nyl	4.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts $\frac{1}{2}$

Isolette 8000 plus Revision: 00

Parts catalog Hood high double Acc.Pan.2Iris



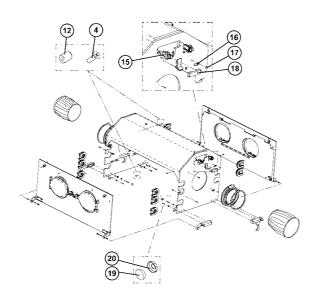
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Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
0	MU13413	✓	X-ray tray label/non slip	1.000	St	
1	MU19802	~	Hinge,Access Pnl,Left Frt-C2KP	1.000	St	
2	MU15141	~	Scr,6-32x9/16 TR PH SS	1.000	St	
3	MU19805	✓	Hinge,Access Pnl,Left Rear-C2KP	1.000	St	
4	MU15129	✓	Scr,6-32x7/16,FL PH SS	1.000	St	
5	MU12609	~	Grommet_access	10.000	St	
6	MU06570	~	Acs port cuffs,0V,repl,box/100	1.000	St	
7	MU19804	✓	Hinge,Access Pnl,Rgt Rear C2KP	1.000	St	
8	MU06545	✓	Ring,retaining, Iris port, clear	1.000	St	
9	MU06573	✓	Ring assy, Iris port, Ig flange	1.000	St	
10	MU19801	~	Hinge,Access Pnl,Rgt Frt-C2KP	1.000	St	
11	MU12608	~	Plate,backup hinge, LR RF	1.000	St	
12	MU12716	✓	Spacer,6-32ID .31OD .38L ACTL	1.000	St	
13	MU12607	✓	Plate,backup hinge, LF RR	1.000	St	
14	MU21430	✓	Hood Asm 4AD 2IP no cuff spare	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

Isolette 8000 plus Revision: 00

Parts catalog Hood high double Acc.Pan.2Iris

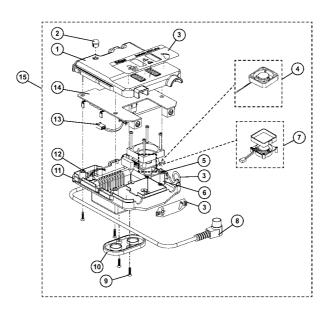


Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
4	MU15129	~	Scr,6-32x7/16,FL PH SS	1.000	St	
12	MU12716	~	Spacer,6-32ID .31OD .38L ACTL	1.000	St	
15	MU12626	~	Slide assy,sensor module	1.000	St	
16	MU11061	~	Clamp,Cable,Spr Ty,Ny .38ID	1.000	St	
17	MU15421	~	Nut,acorn,6-32 AL	1.000	St	
18	MU13461	~	Sensor module look kit, Isolette	1.000	St	
19	MU05562	~	Cover,screw,LT Gray,1/4-20 PN	1.000	St	
20	MU05563	~	Base,screw,1/4-20 PN	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts Isolette 8000 plus

Revision: 00

Parts catalog 18+ Sensor Module spare



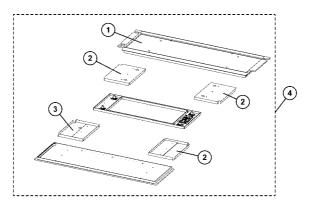
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Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
0	MU25913	~	KIT,FIRMWARE,SENSOR MOD,I8000+	1.000	St	
1	MU26024	✓	TOP COVER,SENSOR MODULE,I8000plus	1.000	St	
2	MU12288	~	Lens,LED,white,sensor module	1.000	St	
3	MU26027	~	LABEL KIT,SENSOR MOD,I8000plus	1.000	St	see Identification of parts in kits MQ50605
4	MU25464	~	FAN ASSY,40MM X 40MM X 10MM	1.000	St	
5	MU15503	~	Wshr_TAB_#624OD03T_SS	1.000	St	
6	MU23133	~	PCB Assy, humidity board, I8K	1.000	St	
7	MU23129	✓	PCB Assy, connector board, I8K	1.000	St	
8	MU26030	~	CABLE ASSY,SENSOR MODULE,I8000plus	1.000	St	
9	MU15137	~	Scr,6-32X1/2, FL PH SS	1.000	St	
10	MU12305	V	Plate,w/o 02,sensor module	1.000	St	
11	MU12304	~	Bottom cover,sensor module	1.000	St	
12	MU03629	~	Strain RLF,rtang,.250290 DIA	1.000	St	
13	MU12289	~	Cable assy,O2 cell	1.000	St	
14	MU25914	✓	PCB ASSY,SENSOR MODULE,I8000plus	1.000	St	
15	MU26026	✓	REPL,SENSOR MODULE,I8000plus	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

Isolette 8000 plus Revision: 00

Parts catalog Scale standard,ROHS



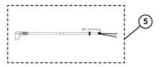
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Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
0	MU25554	~	Field HW kit,scale,Isolette	1.000	St	
1	MU25401	~	Tray,top,scale,Isolette	1.000	St	
2	MU25548	~	2 hole shield,scale,Isolette	1.000	St	
3	MU25549	$\overline{\mathbf{v}}$	1 hole shield,scale,Isolette	1.000	St	
4	MU25476	~	Scale assy,serial,Isolette	1.000	St	

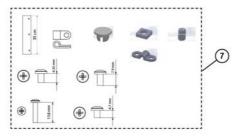
Items that are shown in the illustration but are not listed below the illustration are not available as spare parts Isolette 8000 plus

Revision: 00

Parts catalog Scale standard,ROHS





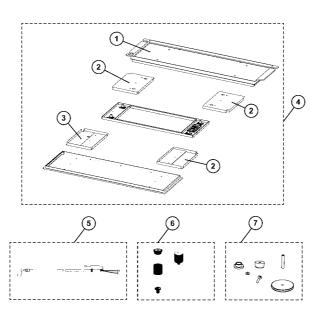


Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
5	MU25551	~	Cable assembly,scale,Isolette	1.000	St	
6	MU25582	~	Load mount,scale,Isolette	1.000	St	
7	MU25552	~	Kit,hardware,scale,Isolette	1.000	St	see Identification of parts in kits MQ50605

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

Isolette 8000 plus Revision: 00

Parts catalog Scale(EU)verifiable,RoHs



Pos. 0 (wenn vorhanden) ohne Abbildung/ Item 0 (if available) without illustration/ Pos. 0 (si existe) sin ilustración/ Pos. 0 (si existant) sans illustration

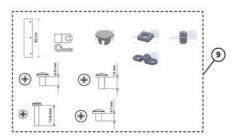
Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
0	MU25554	✓	Field HW kit,scale,Isolette	1.000	St	
1	MU25401	✓	Tray,top,scale,Isolette	1.000	St	
2	MU25548	✓	2 hole shield,scale,Isolette	1.000	St	
3	MU25549	~	1 hole shield, scale, Isolette	1.000	St	
4	MU25530	~	SCALE ASSY,SERIAL OIML,ISOLETTE	1.000	St	verifiable
5	MU25551	✓	Cable assembly,scale,Isolette	1.000	St	
6	MU25582	✓	Load mount,scale,Isolette	1.000	St	
7	MU25546	✓	Kit,HW,OIML adjust,Isolette	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts Isolette 8000 plus

Revision: 00

Parts catalog Scale(EU)verifiable,RoHs



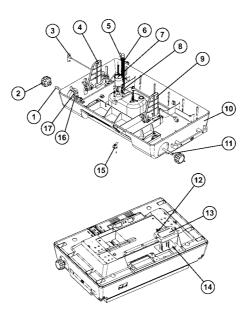


Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
8	MU13098	~	Label,tamper proof	1.000	St	
9	MU25552	✓	Kit,hardware,scale,Isolette	1.000	St	see Identification of parts in kits MQ50605

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

Isolette 8000 plus Revision: 00

Parts catalog 18+ Shell Assembly



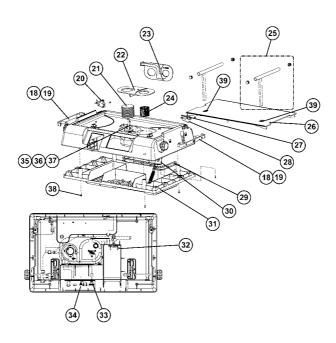
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Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
0	MU15222	~	Scr,10-32X5/16 PN PH S ZI Nylk	1.000	St	MU15222 holds in MU21490 and MU21491
1	MU12571	~	Shaft,knob,rh	1.000	St	
2	MU19725	~	Knob, Mattress tilt	2.000	St	
3	MU26031	$\overline{\mathbf{v}}$	CABLE ASSY,8 PIN,SENSOR MDL TO CONTR	1.000	St	
4	MU21491	~	Replac,tilt mech assy,RH,C2000	1.000	St	
5	MU19730	~	CLAMP, HOSE .860 - 1.03 ID	1.000	St	
6	MU12460	~	Hose_corrugated_22mm_ID_x_12_00lg	1.000	St	
7	MU13477	~	Kit,repl motor,C2000	1.000	St	
8	MU07138	~	Isolator,VIB,.44OD .44LG 4LB	4.000	St	
9	MU21490	~	Replac,tilt mech assy,LH,C2000	1.000	St	
10	MU25911	~	BANC_SHELL_TOP_W_WIRE_CLIPS_I8000plus	1.000	St	
11	MU12569	~	Shaft,knob	1.000	St	
12	MU12493	~	Bead chain assy	1.000	St	
13	MU22531	~	Repl.Filter Door Access Assy	1.000	St	
14	MU12504	~	Filter,repl,lsolette,BOX/ 4	1.000	St	
15	MU12541	~	Probe,impeller movement detect	1.000	St	
16	MU03319	~	Switch,SPST,NC,magnetic reed	1.000	St	
17	MU12447	~	Plate,MTG,hall effect	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

Isolette 8000 plus Revision: 00

Parts catalog 18+ Shell Assembly

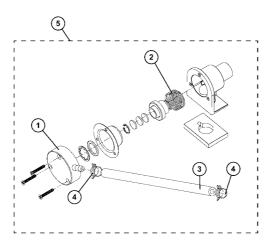


Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
18	MU21043	~	Fairfield Rail Asm C2P	1.000	St	
19	MU21044	✓	Din Rail Asm C2P	1.000	St	
20	MU21426	✓	BRACKET_PIVOT_LEFT_PAINTED BLU	1.000	St	
21	MU12500	✓	Radiator, heater machining	1.000	St	
22	MU13396	✓	Repl kit,scroll cover,lsolette	1.000	St	
23	MU21854	~	Heater/Impeller Cover w.duct	1.000	St	
24	MU12543	~	Impeller assy	1.000	St	
25	MU13395	~	Lift bar kit, Isolette	1.000	St	
26	MU12443	~	Deck,Isolette	1.000	St	
27	MU15241	~	Scr,10-32X1/2 PN PH SS Nylok	1.000	St	
28	MU21485	~	Brkt Pivot Hood Lock Asm Spare	1.000	St	
29	MU21051	✓	Gasket, C2P shell	1.000	St	
30	MQ50408		Fresh Air Valve	1.000	St	Not orderable.Parts available,see assembly
31	MU19980	✓	Shell, lower Isolette 8000	1.000	St	
32	MU21029	✓	Humidity, wiring harness, AC, Isolette, 8000	1.000	St	
33	MU12482	~	Cable assy,AC harness to contr	1.000	St	
34	MU12488	✓	Wire harness, AC	1.000	St	
35	MU12514	✓	Heater assembly, 240V	1.000	St	
36	MU12517	~	Heater assembly, 100V	1.000	St	
37	MU12510	~	Heater assembly,120V	1.000	St	
38	MU15296	✓	Scr,1/4-20X1/2 TR PH S ZI Nylk	1.000	St	
39	MU22251	✓	O-RING 1.062 ID,.093 DIA SILICONE	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

Isolette 8000 plus Revision: 00

Parts catalog Fresh Air Valve



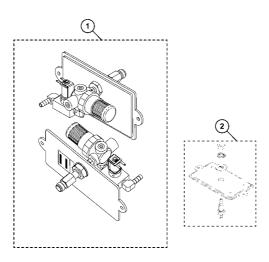
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Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
1	MU06680	✓	CAP,OXY,W/HOSE NIPPLE	1.000	St	
2	MU12583	~	Spring,cprs,1.04OD .040W 1.00L	1.000	St	
3	MU13257	~	Hose,braided,PVC,CLR,1/4 ID	1.000	m	
4	MU13252	▽	Clamp,hose,.460545 I.D.	1.000	St	
5	MU21522	✓	Spare,fresh AIR valve,C2000	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts Isolette 8000 plus

Revision: 00

Parts catalog Oxygen Systems



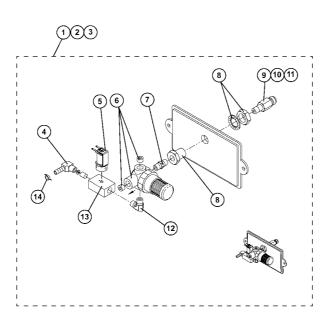
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Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
1	MQ50394		Oxygen Servo Systems	1.000	St	Not orderable.Parts available,see assembly
2	MU17552	✓	Pneumatic access door assy	1.000	St	,

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

Isolette 8000 plus Revision: 00

Parts catalog Oxygen Servo Systems



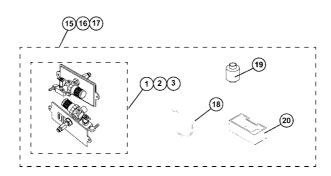
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Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
1	MU16672	~	Oxy cntl valve assy,diss male	1.000	St	
2	MU16673	~	Oxy cntl vlv assy,diss female	1.000	St	
3	MU16720	~	Oxy cntl valve assy,nist male	1.000	St	
4	MU03746	~	Elbow,90DEG,1/4hose-1/8NPT(M)	1.000	St	
5	MU03664	~	Valve,solenoid,12VDC,50PSI,O2	1.000	St	
6	MU13249	~	Regulator,pressure,40 psi	1.000	St	
7	MU05925	~	Nipple,.12NPTM,1.0LG,brass	1.000	St	
8	MU19017	~	Anchor coupling .12NPTF .96L	1.000	St	
9	MU16670	~	Adapter, diss O2 M, 1/8 NPT M	1.000	St	
10	MU16671	~	Adapter,diss O2 F,1/8 NPT M	1.000	St	
11	MU04892	~	Adapter,1/8NPT M-O2 NIST F,SS	1.000	St	
12	MU19022	~	Elbow .12NPTM	1.000	St	
13	MU13255	~	Block,solenoid mount	1.000	St	
14	MU13252	V	Clamp,hose,.460545 I.D.	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts Isolette 8000 plus

Revision: 00

Parts catalog Oxygen Servo Systems

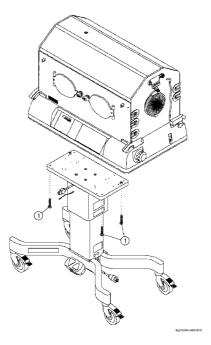


Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
1	MU16672	~	Oxy cntl valve assy,diss male	1.000	St	
2	MU16673	~	Oxy cntl vlv assy,diss female	1.000	St	
3	MU16720	✓	Oxy cntl valve assy,nist male	1.000	St	
15	MU16946	~	Oxygen assy, diss fmale,C2000	1.000	St	
16	MU16947	~	Oxygen assy,nist male,C2000	1.000	St	
17	MU16945	~	Oxygen assy, diss male, C2000	1.000	St	
18	MU13243	~	Hook,oxygen hose	1.000	St	
19	MU24903	~	Oxygen sensor kit	1.000	St	
20	MU13260	~	Oxygen calib. fix asy,locking	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

Isolette 8000 plus Revision: 00

Parts catalog Attachment Shell/Pedest.Stand

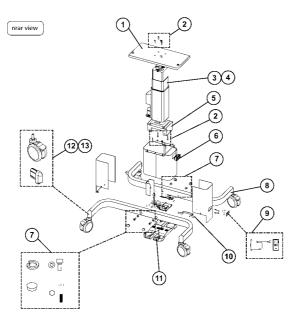


Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
1	MU15330	V	Scr.1/4-20X1.50 CP HX SS Nvlok	4.000	St	C2000

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

Isolette 8000 plus Revision: 00

Parts catalog Trolley Perform.dual castor



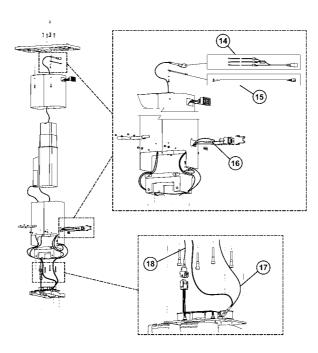
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Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
0	MU19319	~	Fuse 5mmx20mm 10 Amp Slow Blow	1.000	St	
1	MU19128	✓	Plate-Top Transition-Machined	1.000	St	
2	MU19897	~	Kit,C2000 VHA Stand Hardware	1.000	St	see Identification parts in kits MQ50605
3	MU19344	✓	Actuator_120V_Telescopic	1.000	St	
4	MU19354	~	Actuator_230V_Telescopic	1.000	St	
5	MU19184	~	Mount_VHA_Stand_Machined	1.000	St	
6	MU19182	~	Outlet-3 position	1.000	St	
7	MU19898	~	Kit,C2000VHA Leg Mntg Hardware	1.000	St	see Identification parts in kits MQ50605
8	MU25841	~	REPL,LEG, THREADED,I8000	1.000	St	
9	MU21056	✓	Pwr entry mod. assy., VHA C2000	1.000	St	
10	MU12758	~	Cleat,power cord	1.000	St	
11	MU21157	~	Spare Kit, Foot Pedal Assy VHA	1.000	St	
12	MU25845	✓	REPL,STEERING CASTER,MEDCASTER	1.000	St	
13	MU25846	~	REPL,TOTAL LOCK CASTER,MEDCAST	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

Isolette 8000 plus Revision: 00

Parts catalog Trolley Perform.dual castor

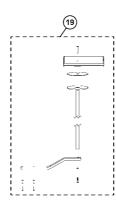


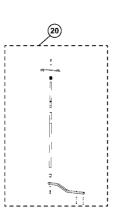
Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
14	MU19406	~	Cable assy,cont PWR,VHA C2000	1.000	St	
15	MU12783	~	Cable assy, Ground, 6.25 grn	1.000	St	
16	MU19402	~	Cable Assy Pwr Input VHA C2000	1.000	St	
17	MU19405	▽	Wire Assy Grnd VHA Stand C2000	1.000	St	
18	MU19400	~	Cable Assy SKF Actuator C2000	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

Isolette 8000 plus Revision: 00

Parts catalog Trolley Perform.dual castor



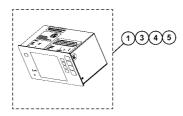


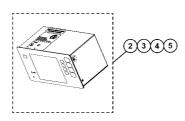
Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
19	MU12937	✓	Monitor shelf assy,HI,Isolette	1.000	St	
20	MU12955	✓	I.V.POLE ASSY,ISOLETTE	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts Isolette 8000 plus

Revision: 00

Parts catalog 18+ Controller





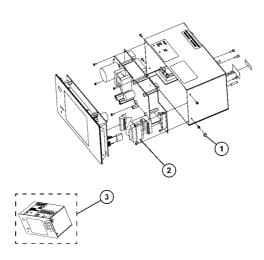
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Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
1	MQ50601		I8+ Controller OIML RoHs	1.000	St	Not orderable.Parts available,see assembly
2	MQ50603		I8+ Controller non-OIML RoHs	1.000	St	Not orderable.Parts available,see assembly
3	MQ50554		Interface power supply Ass.	1.000	St	Not orderable.Parts available,see assembly
4	MQ50404		Enclosure C2 LCD	1.000	St	Not orderable.Parts available,see assembly
5	MQ50602		I8+ Front panel CPU Ass.	1.000	St	Not orderable.Parts available,see assembly

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

Isolette 8000 plus Revision: 00

Parts catalog 18+ Controller OIML RoHs



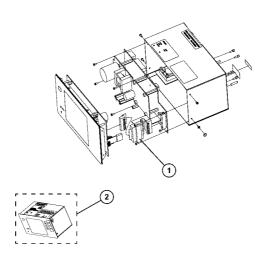
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Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
1	MU13098	~	Label,tamper proof	1.000	St	
2	MU23393	~	Cable assy,interface/CPU	1.000	St	
3	MU26033	✓	BANC,CTRL ASSY,I8000plus,OIML	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

Isolette 8000 plus Revision: 00

Parts catalog 18+ Controller non-OIML RoHs



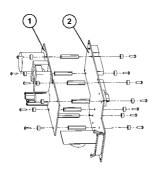
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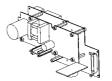
Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
1	MU23393	~	Cable assy,interface/CPU	1.000	St	
2	MU26034	✓	REPL,CTRL ASSY,I800+,NON-OIML	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

Isolette 8000 plus Revision: 00

Parts catalog Interface power supply Ass.





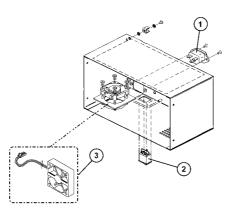
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Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
1	MU23383	✓	PCB ASSY,POWER SUPPLY,C2K/I8K	1.000	St	
2	MU23379	✓	PCB ASSY, INTERFACE,C2K/I8K	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

Isolette 8000 plus Revision: 00

Parts catalog Enclosure C2 LCD



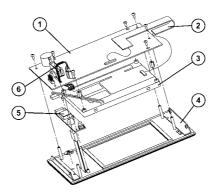
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Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
1	MU12410	~	Cable assy,IEC conn,AS contro	1.000	St	
2	MU12411	~	Cable assy,power switch	1.000	St	
3	MU12409	~	Fan assy,AS controller	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts Isolette 8000 plus

Revision: 00

Parts catalog 18+ Front panel CPU Ass.



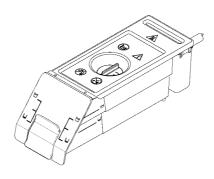
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Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
0	MU21616	~	PCB Assy, Real-Time Clk Repl	1.000	St	
1	MU26015	~	PCB ASSY,CPU,I8000plus	1.000	St	
2	MU18059	~	Cable-Ribbon, Display/CPU C2000	1.000	St	
3	MU23385	~	PCB, LCD with LED backlight	1.000	St	
4	MU19702	~	Front panel subassy, LCD_C2P	1.000	St	
5	MU23386	~	PCB, LED driver circuit	1.000	St	
6	MU25443	✓	Cable-inverter/CPU,C2K/I8K	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

Isolette 8000 plus Revision: 00

Parts catalog Humidity/Condensation Systems

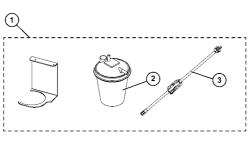


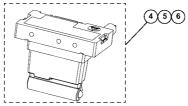
Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
	MQ50396		Servo-Conrolled HS	1.000	St	not for order,available parts, see assembly
	MQ50397		No-Humidifier System	1.000	St	not for order,available parts, see assembly

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts $\frac{1}{2}$

Isolette 8000 plus Revision: 00

Parts catalog Servo-Conrolled HS





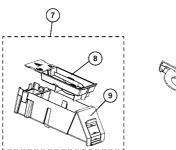
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Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
1	MU21857	~	Condensation Mngt Sys Option	1.000	St	
2	MU10918	~	Suction bottl.800ml,disp,box 20	1.000	St	
3	MU21120	~	Cond Mgmt hose asm, 20 pack	1.000	St	
4	MU21858	~	Evaporator Option ASM, 120 V	1.000	St	
5	MU21859	~	Evaporator Option ASM, 230V	1.000	St	
6	MU21860	~	Evaporator Option ASM, 100V	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

Isolette 8000 plus Revision: 00

Parts catalog Servo-Conrolled HS



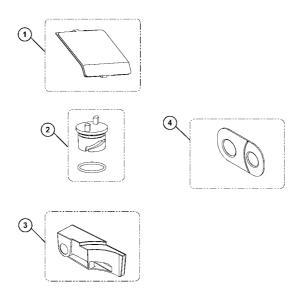


Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
7	MU21571	~	Humidity Reservoir Asm I8000	1.000	St	
8	MU22123	~	Repl.Lid Reserv.Isolette 8000	1.000	St	
9	MU22122	~	Repl, Humid,Reservir Assy, I8000	1.000	St	
10	MU21854	~	Heater/Impeller Cover w.duct	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts Isolette 8000 plus

Revision: 00

Parts catalog No-Humidifier System

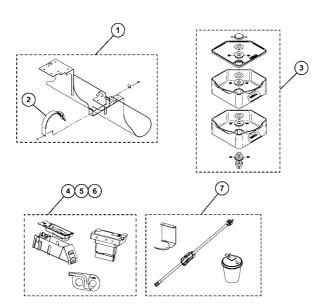


Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
1	MU21047	~	Cover no Hum. Isolette 8000	1.000	St	
2	MU21156	~	Plug Asm,Con Mgmt,C2P	1.000	St	
3	MU21237	~	No humidity,manifold	1.000	St	
4	MU13396	~	Repl kit,scroll cover,Isolette	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

Isolette 8000 plus Revision: 00

Parts catalog Modification kits/Options



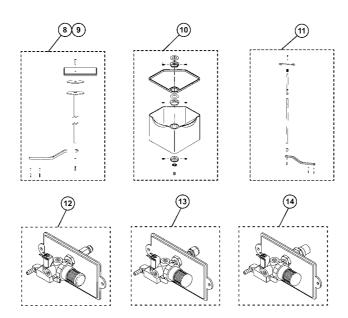
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Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
1	MU12952	~	Oxygen Tank Brkt Assy, Isolette	1.000	St	
2	MU12954	✓	Clamp assy, tank	1.000	St	
3	MU17880	✓	Swivel drawer assy,small	1.000	St	
4	MU21850	~	Humidity Option, I8000, 120V	1.000	St	
5	MU21851	~	Humidity Option, I8000, 230V	1.000	St	
6	MU21852	~	Humidity Option, I8000, 100V	1.000	St	
7	MU21857	✓	Condensation Mngt Sys Option	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts Isolette 8000 plus

Revision: 00

Parts catalog Modification kits/Options

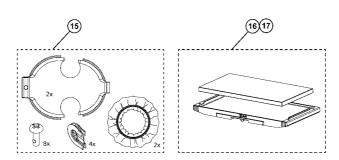


Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
8	MU12937	~	Monitor shelf assy,HI,Isolette	1.000	St	
9	MU12948	~	Monitor_shelf_assy,LO,Isolette	1.000	St	
10	MU17879	~	Swivel drawer assy,large	1.000	St	
11	MU12955	~	I.V.POLE ASSY,ISOLETTE	1.000	St	
12	MU16945	~	Oxygen assy, diss male, C2000	1.000	St	
13	MU16946	✓	Oxygen assy, diss fmale,C2000	1.000	St	
14	MU16947	~	Oxygen assy,nist male,C2000	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

Isolette 8000 plus Revision: 00

Parts catalog Modification kits/Options

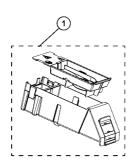


Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
15	MU18916	~	Kit, Access door with grommets	1.000	St	
16	MU25476	~	Scale assy,serial,Isolette	1.000	St	
17	MU25530	~	SCALE ASSY,SERIAL OIML,ISOLETTE	1.000	St	

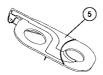
Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

Isolette 8000 plus Revision: 00

Parts catalog Maintenance parts/Service kits









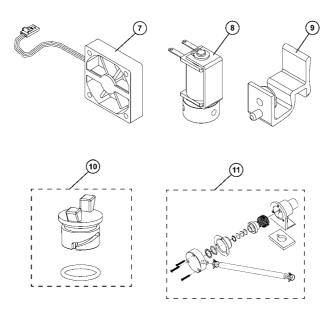
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Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
1	MU21571	~	Humidity Reservoir Asm I8000	1.000	St	
2	MU21858	~	Evaporator Option ASM, 120 V	1.000	St	
3	MU21859	~	Evaporator Option ASM, 230V	1.000	St	
4	MU21860	~	Evaporator Option ASM, 100V	1.000	St	
5	MU21854	~	Heater/Impeller Cover w.duct	1.000	St	
6	MU22251	~	O-RING 1.062 ID,.093 DIA SILICONE	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

Isolette 8000 plus Revision: 00

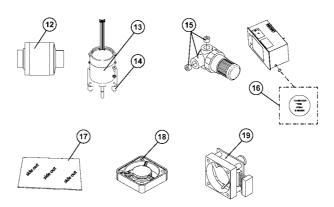
Parts catalog Maintenance parts/Service kits



No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
7	MU12409	~	Fan assy,AS controller	1.000	St	
8	MU03664	✓	Valve,solenoid,12VDC,50PSI,O2	1.000	St	
9	MU12681	~	Latch,heatshield	1.000	St	
10	MU21156	~	Plug Asm,Con Mgmt,C2P	1.000	St	
11	MU21522	✓	Spare,fresh AIR valve,C2000	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts Isolette 8000 plus Revision: 00

Parts catalog Maintenance parts/Service kits

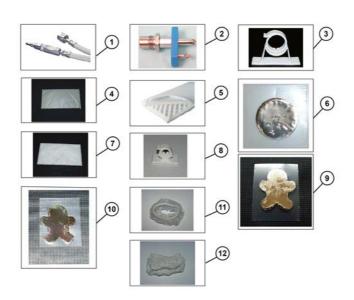


Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
12	MU24903	~	Oxygen sensor kit	1.000	St	
13	MU13477	~	Kit,repl motor,C2000	1.000	St	
14	MU07138	✓	Isolator,VIB,.44OD .44LG 4LB	1.000	St	
15	MU13249	~	Regulator,pressure,40 psi	1.000	St	
16	MU13098	~	Label,tamper proof	1.000	St	
17	MU12504	~	Filter,repl,lsolette,BOX/ 4	1.000	St	
18	MU25464	✓	FAN ASSY,40MM X 40MM X 10MM	1.000	St	
19	MU23129	~	PCB Assy, connector board, I8K	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

Isolette 8000 plus Revision: 00

Parts catalog 18+ Accessories/consumables



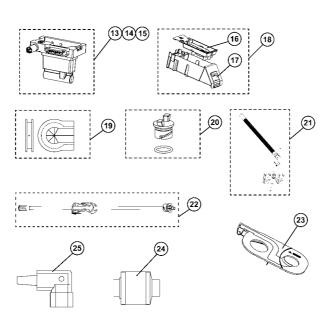
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Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
0	MQ50461		Non-Locking Mains Cables	1.000	St	Not orderable.Parts available,see assembly
0	MQ50401		Int/Fairfield rail Accessories	1.000	St	Not orderable.Parts available,see assembly
0	MQ50402		DIN Rail Accessories	1.000	St	Not orderable.Parts available,see assembly
1	MQ50463		O2-Hoses,wall to device	1.000	St	Not orderable.Parts available,see assembly
2	MQ50467		Oxygen Hose Adapter Assy.US	1.000	St	Not orderable.Parts available,see assembly
3	MU06560	~	Neat-clips,1.00" dia, box/10	1.000	St	
4	MU12249	~	MATTRESS, FOAM, C2000	1.000	St	
5	MP01401	~	SoftBed C2000	1.000	St	
6	MX11002	~	ThermoPad (50St)	1.000	St	
7	MU12504	~	Filter,repl,lsolette,BOX/ 4	1.000	St	
8	MU06558	~	Neat-clips, 0.38" dia, box/10	1.000	St	
9	MU06944	V	Cover,probe,cfm,std,box/100	1.000	St	
10	MU06943	$\overline{\mathbf{v}}$	Cover,probe,cfm,lge,box/100	1.000	St	
11	MU06570	~	Acs port cuffs,0V,repl,box/100	1.000	St	
12	MU12702	✓	Cuff,ACS door,reuse,ISO,Box/10	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

Isolette 8000 plus Revision: 00

Parts catalog 18+ Accessories/consumables



Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
13	MU21860	~	Evaporator Option ASM, 100V	1.000	St	
14	MU21859	~	Evaporator Option ASM, 230V	1.000	St	
15	MU21858	~	Evaporator Option ASM, 120 V	1.000	St	
16	MU22123	~	Repl.Lid Reserv.Isolette 8000	1.000	St	
17	MU22122	~	Repl, Humid,Reservir Assy, I8000	1.000	St	
18	MU21571	~	Humidity Reservoir Asm I8000	1.000	St	
19	MU12609	~	Grommet_access	1.000	St	
20	MU21156	~	Plug Asm,Con Mgmt,C2P	1.000	St	
21	MU18660	~	Kit,vent tube supt,Isolette	1.000	St	
22	MU21120	~	Cond Mgmt hose asm, 20 pack	1.000	St	
23	MU21854	~	Heater/Impeller Cover w.duct	1.000	St	
24	MU24903	~	Oxygen sensor kit	1.000	St	
25	MU04774	~	Conn,plug,male,rtang,AC,10A250	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

Isolette 8000 plus Revision: 00

Parts catalog 18+ Accessories/consumables







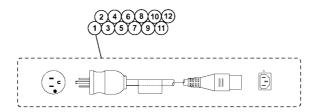


Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
26	MU21237	~	No humidity,manifold	1.000	St	
27	MU26042	~	PROBE, SKIN TEMP, PERPH BX10	1.000	St	
28	MU26041	~	PROBE,SKIN TEMP,CENTRL,BX10	1.000	St	
29	MU10918	✓	Suction bottl.800ml,disp,box 20	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts Isolette 8000 plus

Revision: 00

Parts catalog Non-Locking Mains Cables



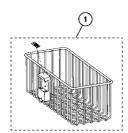
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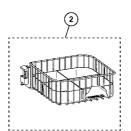
Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
1	1841793	✓	PWR Cord 10A,3m,gr,USA/J RoHS	1.000	St	
2	1868160	~	Power cable 10A 3m C13 bk RoHS	1.000	St	
3	1886274	✓	Power cord AR 10A 3m C13 bk RoHS	1.000	St	
4	1851691	✓	Mains cable Swiss ,3m,10A	1.000	St	
5	1859714	~	Power cable 10A,3m,black,China	1.000	St	
6	1868950	✓	PWR Cord DK,3m,10A,C13,HG RoHS	1.000	St	
7	1851713	~	Cable Great Britian,3m,10A	1.000	St	
8	1851705	~	Cable Australia,3m,10A,C13	1.000	St	
9	MU16872	~	Cable assy,AC PWR/NL,Israel	1.000	St	
10	MU16870	~	Cable assy,AC PWR/NL,Italy	1.000	St	
11	1869833	✓	Pwr Cord IL,3m,10A,C13 RoHS	1.000	St	
12	1875523	✓	Mains cable BR,3m,C13,BK RoHS	1.000	St	

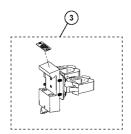
Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

Isolette 8000 plus Revision: 00

Parts catalog Int/Fairfield rail Accessories







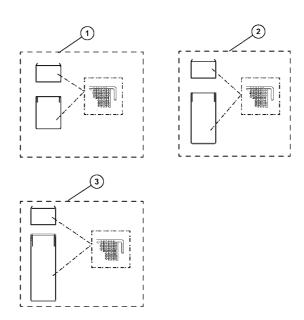
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Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
1	MU14808	~	BASKET 11.0W 4.0D 4.0H ASSY	1.000	St	
2	MU14810	~	BASKET - PIVOTING ASSY	1.000	St	
3	MU14818	✓	CABLE ORGANIZER ASSY	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

Isolette 8000 plus Revision: 00

Parts catalog DIN Rail Accessories



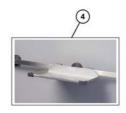
Pos. 0 (wenn vorhanden) ohne Abbildung/ Item 0 (if available) without illustration/ Pos. 0 (si existe) sin ilustración/ Pos. 0 (si existant) sans illustration

Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
1	M26146	~	Basket 200	1.000	St	
2	M26145	~	Basket	1.000	St	
3	M25121	✓	Basket 600	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

Isolette 8000 plus Revision: 00

Parts catalog DIN Rail Accessories



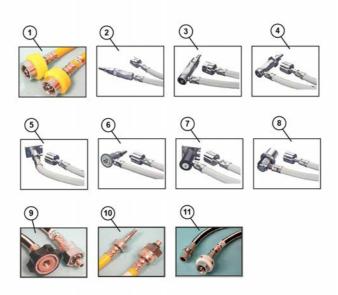


No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
4	M24678	~	Tray 3020	1.000	St	
5	M24695	✓	Holder for litter bags	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts Isolette 8000 plus

Revision: 00

Parts catalog O2-Hoses,wall to device



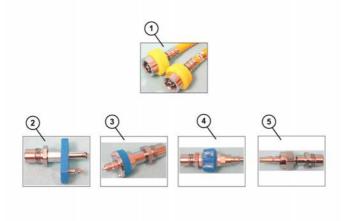
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Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
1	4199592	✓	Hose ASM-02 DISS HAND 10L	1.000	St	
2	M35376	~	O2 CS-hose 3.0m NIST EN SS	1.000	St	
3	M35390	✓	O2 CS-hose 3.0m NIST EN BS	1.000	St	
4	M35408	✓	O2 CS-hose 3.0m NIST EN UNI	1.000	St	
5	M35459	~	O2 CS-hose 3.0m NIST EN Parco	1.000	St	
6	M35472	~	O2 CS-hose 3.0m NIST EN Carba	1.000	St	
7	M35481	~	O2 CS-hose 3.0m NIST EN Medec	1.000	St	
8	M36020	~	O2 CS-hose 3m NIST EN Carburos	1.000	St	
9	M36152	✓	O2 ZV-Hose 3m NIST EN AS	1.000	St	
11	M36291	~	O2 ZV-Hose 3m DISSB EN HAND	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

Isolette 8000 plus Revision: 00

Parts catalog Oxygen Hose Adapter Assy.US

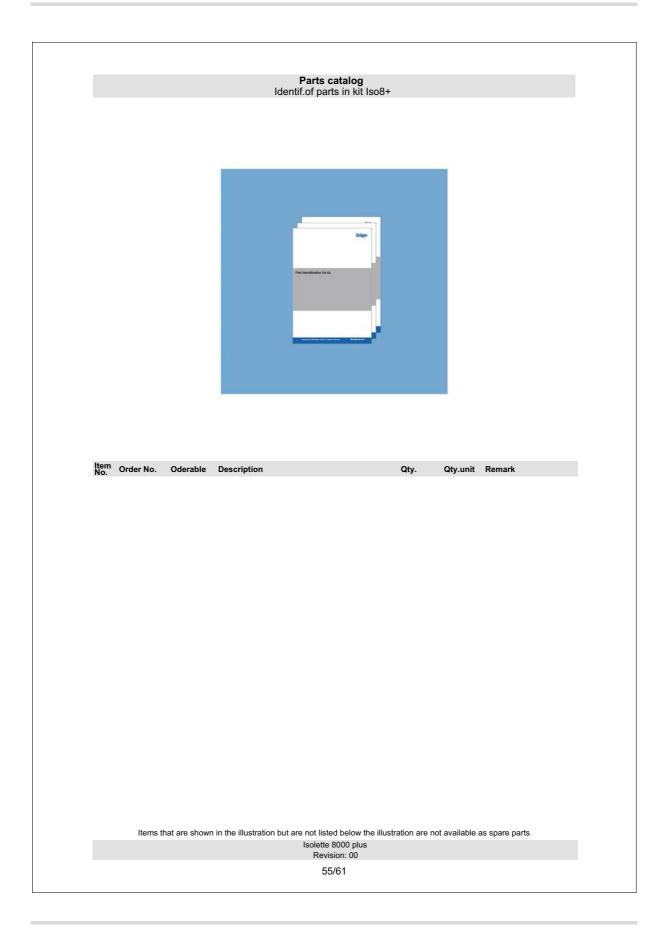


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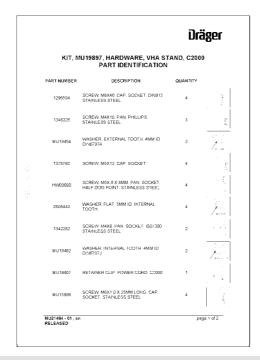
Item No.	Order No.	Oderable	Description	Qty.	Qty.unit	Remark
1	4199592	✓	Hose ASM-02 DISS HAND 10L	1.000	St	
2	4119068	~	Adapter-DISS M/QC-O2-Chemetron	1.000	St	
3	4119073	~	Adapter-DISS M/QC-O2-Ohmeda	1.000	St	
4	4119078	▽	Adapter-DISS M/QC-O2-Pur Ben	1.000	St	
5	4119083	✓	Adapter-DISS M/QC-O2-Schrader	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts Isolette 8000 plus

Revision: 00



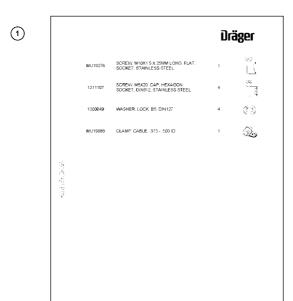




No.	Order No.	Oderable	Description	Qty.	Qty.unit Remark
1	MU19897	✓	Kit,C2000 VHA Stand Hardware	1.000	St

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts Isolette 8000 plus

Revision: 00

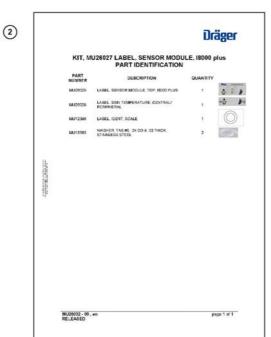


No.	Order No.	Oderable	Description	Qty.	Qty.unit Remark
1	MU19897	V	Kit,C2000 VHA Stand Hardware	1.000	St

MU21484 - 01 , en RELEASED

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

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No.	Order No.	Oderable	Description	Qty.	Qty.unit Remark	
2	MU26027	\checkmark	LABEL KIT, SENSOR MOD, 18000 plus	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

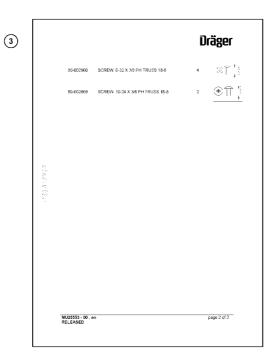
Isolette 8000 plus Revision: 00



No.	Order No.	Oderable	Description	Qty.	Qty.unit Remark
3	MU25552	✓	Kit,hardware,scale,Isolette	1.000	St

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts Isolette 8000 plus

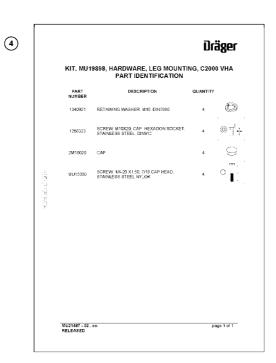
Revision: 00



No.	Order No.	Oderable	Description	Qty.	Qty.unit Remark
3	MU25552	✓	Kit,hardware,scale,Isolette	1.000	St

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

Isolette 8000 plus Revision: 00



Item No.	Order No.	Oderable	Description	Qty.	Qty.unit Remark	
1	MULARAR	1.0	Kit C2000VHA Lea Mota Hardware	1 000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts Isolette 8000 plus

Revision: 00

5 Test instructions

Test Instructions

This chapter contains the measures required to determine the actual condition of the device.

5.1 Test Instructions / Service Card IPM

Dräger

Test Instructions / Service Card IPM

Isolette 8000 plus



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Warning

All servicing and/or test procedures on the device require detailed knowledge of this documentation. Use of the device requires detailed knowledge and observance of the relevant Instructions for Use.

Revision 1.0

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Isolette 8000 plus Important notes

Important notes

NOTE

Prior to using these test instructions, check that they are the latest revision (compare revision with current service documentation).

All results and inputs must be documented in the "Result Sheet", as applicable.

NOTE

Do not use these test instructions for testing after a repair procedure.

NOTE

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NOTE

These test instructions apply to software versions 5.00 or greater.

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Isolette 8000 plus Device configuration

Device configuration

This chapter is used to record the device configuration.

1.1 **Device configuration Isolette 8000 plus**

The basic unit configuration covers the following components:

- Incubator Isolette 8000 plus
- Sensor module (options: O₂ sensors)
- Skin-temperature sensors (Reusable Central MU26041, reusable Peripheral MU26042)
- Hood and access panels
- Mattress tray
- Mattress
- Auxiliary AC outlets
- Variable Height Stand
- Accessory rail.

Options:

- External additional O₂ (Flow controlled O₂)
- Servo-controlled Oxygen module
- Compressed-gas hose "O2"
- Compressed-gas cylinder (O2) and holder, pressure regulator, flowmeter
- Drawer(s)
- Ventilator hoses support
- Utility shelf
- IV pole
- Scale
- Humidity module.

1.1.1 Serial numbers (SN)

- Enter the serial number of the following Components:
- Isolette 8000 plus (Note: The serial number is located on the rating plate on the rear of the basic housing.)

Result Isolette 8000 plus

_txt]

NOTE

Enter the serial number only during or after an installation or repair of the Controller.

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	Result	Sensor module firmware	[txt]
		ware" line and record it into the "Test result" sheet.		
	Action	The "DIAG INFO" menu is displayed. Read the sensor module firmware version from the "Sensor Module Firm-		
		Press the "Diag Info" softkey.		
	Action	 Press and hold the "alarm silence" button and, at the same time, switch the unit on and keep the "alarm silence" button pressed until the "System Con- figuration" menu appears on the display. 		
F	Prerequisites	The unit is connected to the AC power supply.		
.1.3		nodule firmware		
	Result	Software version	[txt]
	Action	Read and record the software version into the "Test result" sheet.		
		The unit completes its self-test. The software version is displayed during the self-test.		
	Action	Switch the unit on.		
F	Prerequisites	The unit is connected to the AC power supply.		
.1.2	Software	version	-	
			[txt]
	Result	located on the face of the housing, bottom rear of the incubator.) Option Servo-controlled Oxygen module		
	Action	Option Servo-controlled Oxygen module (Note: The serial number is	<u></u>	txt]
	Result	Option Scale	г	4v41
	Action	Option, Scale (Note: The serial number is located on the rating plate underneath the scale.)		
	resuit	Sensor module	[txt]
	Result	Sensor module (Note: The serial number is located on the rating plate on the bottom of the basic housing.) Sensor module		
	Action	Sensor module (Note: The serial number is located on the rating plate on	[txt]
	Result	base of the variable height stand.) Variable Height Stand (VHA)		
	Action	Variable Height Stand (VHA) (Note: The serial number is located on the	L	txt]
	Result	Controller	r	tv+1
	Action	Controller (Note: The serial number is located on the rear of the controller, which must be removed from the incubator.)		
	configuration			

Isolette 8000 plus Device configuration 1.1.4 **Heater thermocouple** Press the "Data summary" softkey. • Press the "display selection" button. Test Within 5 minutes, the "heater thermocouple" value increases from approx. zero (cold heater) to approx. 5 to 25. Result Heater thermocouple _OK] Action · Switch-off the unit. No.1507_0000010139 7 / 43 | Revision 1.0 | Test Instructions / Service Card IPM

2 Maintenance parts

This chapter contains interval-related maintenance parts, measures, and tests that can only be performed on an open device.

2.1 Maintenance intervals, overview

The following table presents an overview of the required sets and maintenance parts over 12 years. After 12 years the table is worked through again starting with the first year.

Designation	Part number	1	2	3	4	5	6	7	8	9	10	11	12
Heat shield latches	MU12681		Х		Х		х		Х		Х		Х
Service kit Impeller motor	MU13477			Х			х			х			Х
Vibration dampening rubbers	MU07138			Х			х			х			Х
Fan assembly (Sensor Module)	MU23129			Х			Х			Х			Х
Fan assembly (Controller)	MU12409			Х			Х			Х			Х
Fresh Air Valve	MU21522			Х			Х			Х			Х
Tilt Bar O-rings	MU22251						Х						Х
Option Servo oxygen control													
(Option) Oxygen sensors	MU24903	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х
(Option) O ₂ solenoid valve	MU03664		Х		Х		х		Х		Х		Х
(Option) O ₂ pressure regulator	MU13249						х						Х

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2.2 Maintenance parts by specified interval

2.2.1 (Option) Oxygen sensors

Quan- tity	Designation	Part num- ber	Location/Remark
1	Oxygen sensor	MU24903	Inside the Sensor Module / Replacement by service personnel.

Result Oxygen sensors

Next replacement: [_____dat

2.2.2 Heat shield latches

Quan-	Designation	Part num-	Location/Remark
tity		ber	
4	Heat shield latch	MU12681	2 on each Access Panel /
			Replacement by service per-
			sonnel.

Result Heat shield latches

Next replacement: [____dat]

2.2.3 (Option) O₂ solenoid valve

Quan- tity	Designation	Part num- ber	Location/Remark
1	O ₂ solenoid valve		Oxygen inlet plate, rear of main housing / Replacement by service personnel.

Result O₂ solenoid valve

Next replacement: [_____dat

2.2.4 Impeller motor spare parts kit

The Service kit (Quantity 1), part number MU13477, includes the following items:

Quan- tity	Designation	Part num- ber	Location/Remark
1	Motor assembly	MU12672	Inside main housing / Replacement by service personnel.
1	Installation instruc- tion	MU13478	

Result Service kit

Next replacement:	[dat]
-------------------	--------

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2.2.5 Vibration dampening rubbers for impeller motor

Quan- tity	Designation	Part num- ber	Location/Remark
4	Vibration dampening rubbers	MU07138	Inside main housing / Impeller motor (4 rubbers are necessary) / Replacement by service personnel.

Vibration dampening rubbers Result

Next replacement: [___ _dat]

2.2.6 Fan assembly (Sensor module)

Quan- tity	Designation	Part num- ber	Location/Remark
1	Fan assembly		Inside Sensor Module / Connector PCB with fan / Replacement by service personnel.

NOTE

It is recommended to clean the interior of the Sensor Module with a vacuum cleaner during this procedure.

NOTE

It is also possible to use fan assembly MU25464, but this must be soldered

Fan assembly (Sensor module) Result

Next replacement: [____ _dat]

2.2.7 Fan assembly (Controller)

NOTE

It is recommended to clean the interior of the Controller with a vacuum cleaner during this procedure.

Quan- tity	Designation	Part num- ber	Location/Remark
1	Fan motor		Inside Controller / Replace- ment by service personnel.

Result Fan assembly (Controller)

Next replacement: [____dat]

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2.2.8 Fresh Air Valve

Quan- tity	Designation	Part num- ber	Location/Remark
1	Fresh Air Valve	MU21522	Inside main housing / Replace-
			ment by service personnel.

Result Fresh Air Valve

Next replacement: [____dat]

2.2.9 Tilt Bar O-Rings

Quan- tity	Designation	Part num- ber	Location/Remark
2	Tilt Bar O-Ring		Inside main housing / Replacement by service personnel.

Result Tilt Bar O-Ring

Next replacement: [____dat]

2.2.10 (Option) O₂ Pressure regulator

Quan- tity	Designation	Part num- ber	Location/Remark
1	O ₂ pressure regulator		Oxygen inlet plate, rear of main housing / Replacement by service personnel.

Result 02 pressure regulator

Next replacement: [____dat]

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2.3 Maintenance parts as required

NOTE

The replacement of the maintenance parts listed in this section is described in the Instructions for Use and must be carried out by the user.

2.3.1 Air Filter

Quan- tity	Designation	Part num- ber	Location/Remark
0,25	Air Filter (4-pack)	MU12504	Rear of main housing / Replace when damaged or dirty or at the latest every 3 months.

Result Air Filter

Replaced on: [_____dat]

2.3.2 Drain plug with O-ring (Isolette 8000 plus without humidity system)

Quan- tity	Designation	Part num- ber	Location/Remark
1	Drain plug with O- ring (Isolette 8000 plus without humidity system)	MU21156	Top of main housing, bottom of the well / Replacement by users.

Result Drain plug with O-ring (Isolette 8000 plus without humidity system)

Replaced on: [_____dat]

2.3.3 Manifold (Isolette 8000 plus without humidity system)

Quan- tity	Designation	Part num- ber	Location/Remark
1	Manifold (Isolette 8000 plus without humidity system)	MU21237	Top of main housing, below the deck/ Replacement by users.

Result Manifold (Isolette 8000 plus without humidity system)

Replaced on: [____dat]

2.3.4 Reservoir and Cover (Isolette 8000 plus with humidity system)

Quan- tity	Designation	Part num- ber	Location/Remark
1	Reservoir and Cover	MU21571	Front of main housing /
	(Isolette 8000 plus		Replacement by users.
	with humidity system)		·

Result Reservoir and Cover (Isolette 8000 plus with humidity system)

Replaced on: [_____dat]

2.3.5 Heater Cover and Duct (Isolette 8000 plus with humidity system)

Quan- tity	Designation	Part num- ber	Location/Remark
1	Heater Cover and Duct (Isolette 8000 plus with humidity system)	MU21854	Top of main housing, below the duct / Replacement by users.

Result Heater Cover and Duct (Isolette 8000 plus with humidity system)

Replaced on: [____dat]

2.3.6 Humidity evaporator (100 VAC) (Isolette 8000 plus with humidity system)

Quan- tity	Designation	Part num- ber	Location/Remark
1	Humidity evaporator (100 VAC) (Isolette 8000 plus with humidity system)		For 100 VAC models: Inside the reservoir, front of main housing / Replacement by users.

Result Humidity evaporator (100 VAC) (Isolette 8000 plus with humidity system)

Replaced on: [____dat]

2.3.7 Humidity evaporator (120 VAC) (Isolette 8000 plus with humidity system)

Quan- tity	Designation	Part num- ber	Location/Remark
1	Humidity evaporator (120 VAC) (Isolette	MU21858	For 120 VAC models: Inside the reservoir, front of main
	8000 plus with humidity system)		housing / Replacement by users.

Result Humidity evaporator (120 VAC) (Isolette 8000 plus with humidity system)

Replaced on: [____dat]

2.3.8 Humidity evaporator (230 VAC) (Isolette 8000 plus with humidity system)

Quan- tity	Designation	Part num- ber	Location/Remark
1	Humidity evaporator (230 VAC) (Isolette 8000 plus with humidity system)	MU21859	For 230 VAC models: Inside the reservoir, front of main housing / Replacement by users.

Result Humidity evaporator (230 VAC) (Isolette 8000 plus with humidity system)

Replaced on: [____dat]

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3 **Electrical safety**

This chapter contains tests that need to be performed in order to verify that the medical electrical system is operational.

3.1 **Electrical safety according to IEC 62353**

NOTE

The device conforms to the conditions of protection class I, type BF.

Introduction

The following subsections provide descriptions of device checks, recurrent testing and testing after servicing of medical electrical (ME) devices.

NOTE

The tester, e.g. SECUTEST, must be correctly configured for all measurements. If implausible measurement results are obtained, such as a leakage current of 0.0 µA, check the tester configuration in addition to the test setup!

NOTE

In testing to IEC 62353, the medical electrical device (ME device) or the medical electrical system (ME system) must be tested.

ME systems must be treated like ME devices.

An ME system is a combination of several devices, as specified by the manufacturer, of which at least one must be an ME device, which are interconnected by a functional connection or by means of a multiple socket outlet.

NOTE

In the case of devices connected to other devices by a data cable, this connection must be disconnected prior to performing the electrical safety test, in order to avoid false measurements.

3.1.1 Visual check

Prerequisites The tester and the device under test are switched off.

Action

· Disconnect the power plug from the mains socket.

WARNING

Hazardous voltage.

Touching live components can lead to serious injury or death.

▶ Disconnect the power cord from the AC outlet before checking the power fuse-links.

- The power fuse-links, if present, of the device under test match the specifi-Test cations on the rating plate.

- The power cable and plug are not dirty or damaged.

Condition checked Result

OK1

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3.1.2 Protective earth conductor resistance

Test set-up

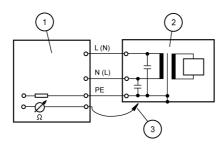


Fig. 1 Protective conductor resistance

Item	Designation
1	Tester
2	Device under test
3	Tester probe cable
L	Conductor
N	Neutral conductor
PE	Protective earth conductor

Action

- Prepare the test setup.
- · Switch the tester on.
- Configure the tester appropriately and follow the instructions on the tester.
- Using the tip of the probe cable, scan each of the points on the device under test listed under Protective earth conductor resistance measurement points one after the other, moving the mains power cable along the entire length during the measurement. The resistance must not change when you do so.

Test The protective conductor resistance of devices with detachable but connected mains power cables must not exceed **0.3** Ohm in each case.

____Ω]

est If other optional power cables are fitted, the respective protective conductor resistance must not exceed **0.1** Ohms. Move the power cable along the entire length during the measurement. The resistance must not change when you do so.

____Ω]

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3.1.3 Protective earth conductor resistance measurement points

- · Scan the following measurement points for protective earth conductor resistance measurement one after the other using the tip of the probe cable:
- Wing nut on the controller
- Device with variable height stand:
 - screws located near the main power switch
 - all protective earth conductor contacts on all power sockets of the multiple-socket outlet.

Result Measurement points scanned

OK]

3.1.4 **Equipment leakage current**

NOTE

The equipment leakage current can be tested by the differential measurement method or the direct measurement method.

In direct measurement, set up the equipment under test with insulation and scan all accessible conductive components using the probe (the protective earth is internally interrupted in the tester).

Prerequisites

The tester is switched on.

Test set-up

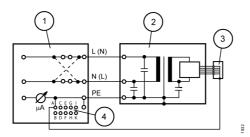


Fig. 2 Equipment leakage current

Item	Designation
1	Tester
2	Equipment under test
3	(Applied part) Device-specific test adapter for tester
4	(Applied part) Configurable ports for applied part
L	Conductor
N	Neutral conductor
PE	Protective earth

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Action

- · Prepare the test setup.
- (Applied part) Connect the device-specific test adapter on one end to the device under test and on the other end to the tester's configurable port "A" for applied parts (paying attention to the configuration!).
- · Follow the instructions on the tester.

NOTE

For symmetrical mains plugs that have no preferential position in the socketoutlet, perform the test twice! Perform the second test with the plug rotated 180° in the socket. In many test devices the mains plug rotation is simulated by means of a built-in selector switch. Document the higher measured value.

NOTE

Always enter the reference value (initial value measured) in the "Test Report" or "Result Sheet" document.

NOTE

If the measured values are between 90% and 100% of the permissible limit value, the reference value and the previously measured values of the recurrent test should be applied to assess electrical safety!

Test The initial value must not exceed **500** μA.

Result Initial value

μA]

Test The recurrent value must not exceed **500** μA.

Result Recurrent value

uA1

3.1.5 Applied part leakage current, mains on applied part, type BF

Prerequisites The tester is switched on.

Test set-up

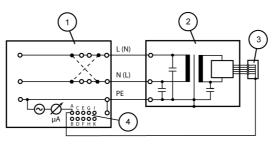


Fig. 3 Leakage current on applied part

Item	Designation
1	Tester (test device)
2	Device under test
3	Application component, device-specific test adapters for tester

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Item	Designation
4	Configurable connection sockets for applied parts (A - K)
L	Conductor
N	Neutral conductor
PE	Protective earth conductor

- Action Prepare the test setup.
 - (Applied part) Connect the device-specific test adapter on one end to the device under test and on the other end to the tester's configurable socket "A" for applied parts (paying attention to the configuration!).
 - · Follow the instructions on the tester.

NOTE

The test must be performed twice! The second test is performed with the plug rotated 180° in the socket. In many test devices the mains plug rotation is simulated by means of a built-in selector switch. The higher measured value must be documented.

NOTE

The reference value (initial measured value) must always be transmitted!

NOTE

If the measured values are between 90% and 100% of the permissible limit value, the reference value and the previously measured values of the recurrent test should be applied to assess electrical safety!

Test The reference value must not exceed 5000 µA.

Result Reference value

_µA]

The recurrent test value must not exceed 5000 µA. Test

Recurrent test Result

___µA]

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3.2 Electrical safety according to IEC 60601-1

NOTE

The device conforms to the conditions of protection class I, type BF.

NOTE

An optional multiple socket-outlet, if any, must be included in the individual tests (medical elctrical system).

NOTE

With devices that are connected to other devices by means of a data cable, this connection must be disconnected prior to performing the electrical safety check, in order to avoid incorrect measurements.

3.2.1 Visual check

Prerequisites The tester and the device under test are switched off.

Action

Test

· Disconnect the power plug from the mains socket.

WARNING

Hazardous voltage.

Touching live components can lead to serious injury or death.

► Disconnect the power cord from the AC outlet before checking the power fuse-links.

- The power fuse-links, if present, of the device under test match the specifi-

cations on the rating plate.

- The power cable and plug are not dirty or damaged.

Result Condition checked

OK]

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3.2.2 Protective earth conductor resistance

NOTE

The protective earth conductor resistance is measured with the power cord connected.

Test set-up

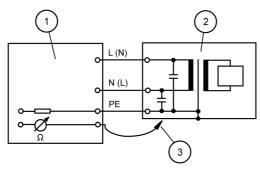


Fig. 4 Test set-up for the protective earth conductor resistance

Pos.	Designation
1	Tester
2	Device under test
3	Test probe with tip
L	Conductor
N	Neutral conductor
PE	(Protective earth) conductor

- Action Prepare the test set-up.
 - · Switch on the tester and the device under test.
 - · Configure the tester appropriately, and follow the instructions on the tester.
 - Using the tip of the test probe, scan each of the following points on the device under test one after the other:
 - Wing nut on the controller
 - Device with variable height stand:
 - screws located near the main power switch
 - all protective earth conductor contacts on all power sockets of the multiple-socket outlet.

Test The protective earth conductor resistance must not exceed 0.2 ohms (including power supply cord) in each case.

Result Record the highest protective earth conductor resistance.

___Ω]

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3.2.3 Earth leakage current

NOTE

In order to avoid incorrect measurement, set up the device under test so that it is insulated.

Test set-up

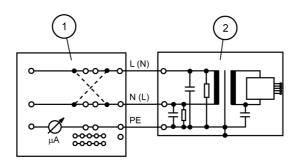


Fig. 5 Test set-up for earth leakage current

Pos.	Designation
1	Tester
2	Device under test
L	Conductor
N	Neutral conductor
PE	(Protective earth) conductor

Action

- · Prepare the test set-up.
- Follow the instructions on the tester.

NOTE

For symmetrical mains plugs that have no preferential position in the socketoutlet, the device leakage current test must be performed twice! The second test shall be performed with the plug reversed 180° in the socket. In many test devices the mains plug rotation is simulated by means of a built-in selector switch. The higher measured value shall be documented.

Test Normal condition (N.C.): The value must not exceed **5000** μA.

Result Normal condition (N.C.)

____μΑ]

Test The value must not exceed 10000 μA.

Result Single fault condition (S.F.C.)

μΑ]

Action • In the following steps the test is repeated, but with the power plug turned over. This condition can be established internally on some testers.

Test Normal condition (N.C.): The value must not exceed 5000 µA.

Result Normal condition (N.C.)

____μΑ]

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The value must not exceed 10000 µA.

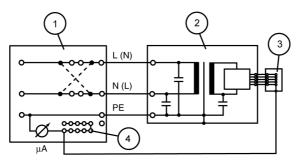
Result Single fault condition (S.F.C.) (The power conductor is interrupted.)

3.2.4 Patient leakage current

NOTE

Perform the test for both skin temperature probes and enter the highest value.

Test set-up



Patient leakage current test set-up Fig. 6

Pos.	Designation
1	Tester
2	Device under test
3	Device-specific adapter
4	Sockets for applied parts
L	Conductor
N	Neutral conductor
PE	(Protective earth) conductor

Action

- · Prepare the test set-up.
- · Follow the instructions on the tester.

NOTE

For symmetrical mains plugs that have no preferential position in the socketoutlet, the device leakage current test must be performed twice! The second test shall be performed with the plug reversed 180° in the socket. In many test devices the mains plug rotation is simulated by means of a built-in selector switch. The higher measured value shall be documented.

Test Normal condition (N.C.) DC: The value must not exceed 100 µA.

Result Normal condition (N.C.) DC

Normal condition (N.C.) AC: The value must not exceed $100\ \mu\text{A}.$ Test

Normal condition (N.C.) AC Result

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Action

 If possible perform the second test with the plug reversed 180° in the socket. (In many test devices the mains plug rotation is simulated by means of a built-in selector switch.)

Test Single fault condition (S.F.C.) DC: The initial value must not exceed 500 µA.

Result Single fault condition (S.F.C.) (The power conductor is interrupted.) DC

____μA]

Test Single fault condition (S.F.C.) AC: The value must not exceed 500 μ A.

Result Single fault condition (S.F.C.) (The power conductor is interrupted.) AC

μA

22240

3.2.5 Touch current

Test set-up

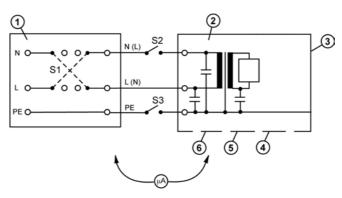


Fig. 7 Test set-up for touch current

Pos.	Designation
1	Tester
2	Device under test
3	Enclosure, protectively earthed
4	Part of the enclosure, not protectively earthed
5	Part of the enclosure, not protectively earthed
6	Part of the enclosure, not protectively earthed
S1	Commutator Switch, DPDT, for reversing polarity
S2	Switch, SPST, opening power conductor
S3	Switch, SPST, opening Protective Earth (PE)
uA	Measuring device with 2 free leads
L	Conductor
N	Neutral conductor
PE	Protective earth conductor

Action

- · Prepare the test set-up.
- Switch on the tester and the device under test.
- $\bullet\,$ Configure the tester appropriately and follow the instructions on the tester.
- Using the tips of both probe cables, scan each of the pairs of points on the device under test listed under "Touch Current Measurement Points" one after the other.

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Isolette 8000 plus Electrical safety NOTE The test must be performed twice! The second test is performed with the plug rotated 180° in the socket. In many test devices the mains plug rotation is simulated by means of a built-in selector switch. The higher measured value must be documented. Normal condition (N.C.): (S2 and S3 are closed, and S1 is in Normal Polarity) Test The value must not exceed 100 µA. Result Normal condition (N.C.) _µA] Action · Adjust S2 closed, S3 open, and S1 in Normal Polarity. · Using the tips of both probe cables, scan each of the pairs of points on the device under test listed under "Touch Current Measurement Points" one after the other. · Repeat the test with S1 in Reverse Polarity. Record the highest of the values. Test Single fault condition (S.F.C.): The Protective Earth wire is interrupted. The value must not exceed 500 µA. Result Single fault condition (S.F.C.) The Protective Earth wire is interrupted. μAΊ Action · Adjust S2 open, S3 closed, and S1 in Normal Polarity. Using the tips of both probe cables, scan each of the pairs of points on the device under test listed under "Touch current measurement points pairs" one after the other. · Record the highest of the values. Single fault condition (S.F.C.): The Neutral wire is interrupted. The value must Test not exceed 500 μA Single fault condition (S.F.C.) The Neutral wire is interrupted. Result μAl 3.2.6 Touch current measurement point pairs Action · Scan the following pairs of measurement points for touch current one after the other, using the tips of the 2 probe cables: - wing nut on controller to left handle - left handle to right handle - right handle to hood latch pin. Result Measurement point pairs scanned. __OK] No.1507_0000010139 24 / 43 Test Instructions / Service Card IPM | Revision 1.0 |

Isolette 8000 plus Function and condition test

4 Function and condition test

This chapter contains tests that need to be performed in order to verify that the function and condition of the device and the accessories used meet the specifications according to the Instructions for Use.

4.1 Condition tests

4.1.1 Accompanying documents

 Check that the following documents are available (according to user/owner).

- Instructions for Use
- Medical Products Log (applicable in Germany only)

Result The documents are available (according to user/owner)

____OK]

4.1.2 Power-on self test

Prerequisites The unit is connected to the AC power supply.

Action • Switch the unit on.

Test The unit completes its self-test. No error messages appear on the display after completion of the self-test.

If the unit fails the self-test, the audible alarm sounds and one or several "system failure" messages appear on the display.

Result Power-on self test

____OK]

4.1.3 Secure attachment of trolley to basic unit

Action • Check mechanical attachment (basic unit/trolley).

Test The basic unit is securely attached to the trolley by means of four screws.

Action • Check mechanical attachment (column/legs).

Test The column is firmly attached to the legs.

Result Secure attachment of trolley to basic unit

OK]

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4.1.4 Pre-heating the unit

NOTE

When using the temperature and humidity meter set 7910980 (meter 7910989), use the combination temperature and humidity probe 7910982, not the surface temperature probe to make air temperature measurements.

Action

- Prepare the air temperature function as follows:
- Place a test thermometer at the center of the mattress tray at a height of 10 cm from the surface.
- Position the ends of both skin probes near the test thermometer.
- Set the air temperature to "35 °C".
- Close all access doors and, if fitted, IRIS access ports.
- Using the "air" button, set the air temperature to "35 °C", and allow the unit to warm up.
- Connect both skin-temperature sensors into the respective sockets "Central" and "Peripheral" on the sensor module.
- Prepare the humidity function if present as follows:
- Remove the humidity reservoir from the unit.
- Press the "humidity" button.
- Press the "ON" button.
- Set the humidity to "75%".

NOTE

The low humidity alarm will not occur until 30 minutes after water remaining in the system is evaporated. The air temperature test may take up to 60 minutes to warm.

NOTE

Keep the unit in operating mode during the following tests. If the unit is switched off in between, the humidity system must be switched on everytime!

Result Pre-heating the unit

OK]

Action

· Proceed with the following tests.

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Isolette 8000 plus Function and condition test

4.1.5 **General condition**

· Check that the following devices/parts and accessories as well as their connections and switches (etc.) are not contaminated or damaged. Device parts and accessories are complete as specified in the Instructions for Use manual.

NOTE

If applicable, clean contaminated devices/parts using the specified cleaning

- Incubator Isolette 8000 plus
- Hood
- Access panels
- Mattress tray
- Mattress
- Variable Height Stand
- Accessory rails
- Skin temperature sensor, if installed
- external additional O2 (Flow controlled O2), if installed
- Impeller cover with duct (if humidity is installed)
- Blank cover on the front housing (if no humidity system is installed)
- Plug in the bottom of heater well (if no humidity system is installed)
- Blank manifold in the top shell (if no humidity system is installed)
- Sensor module (Option: O₂ sensors).

Options:

- Compressed-gas hose "O2"
- Compressed-gas cylinder (O2) and holder, pressure regulator, flowmeter
- Drawer(s)
- Ventilator hoses support
- Utility shelf
- IV pole
- Servo-controlled oxygen module
- Scales
- Humidity system.

Result General condition

[OK]

4.1.6 Impeller, fan shaft and detector seal

Action

- · Remove the heater/impeller cover.
- · Remove the impeller from the shaft of the fan motor.
- · Check the impeller.

The impeller is not contaminated or damaged. The impeller has three magnets on its underside.

· Check the shaft of the fan motor. Action

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Isolette 8000 plus Function and condition test There is a retaining ring on the shaft of the fan motor. Action · Visually check that there is a seal underneath the impeller detector cover. Test There is a seal underneath the cover of the impeller detector. Result Impeller, fan shaft and detector seal OK] Action · Replace the impeller onto the shaft of the fan motor. · Replace the heater/impeller cover. 4.1.7 Labeling Isolette 8000 plus · Check the following labeling for completeness and legibility. Perform the Action check according to the test step below, whichever is applicable. - 1x Central / Peripheral Isolette 8000 plus label (located on the top of the Sensor Module) - 1x Central / Peripheral connection label (located on the front of the Sensor - 2x label "Do not leave baby" (located on the hood) - 1x data tag label (located on the rear side of the incubator) - 1x oxygen label (located on the rear bottom side of the incubator) - 2x hot surface label (located on and under the heater/impeller cover) For French version only - French obstruction label (located on the top of the hood) Stand: - 1x data tag label - 1x fuse label - 1x ground reliability label - 1x auxilliary outlet label For 120 V version (on VHA stand) only: - 1x FTI label Versions with OIML/NAWI scales: - OIML/NAWI scale ID label (located on the rear side of incubator) Result Labeling [____OK] 4.1.8 Hood and locking pivot Action • Check the hood and the locking pivot. The hood and the locking pivot are not contaminated or damaged. The hood engages in the end position. The hood can be closed again when the hood locking pivot is pulled. 1507_0000010139 Result Hood and locking pivot OK] 28 / 43 Test Instructions / Service Card IPM | Revision 1.0 |

Isolette 8000 plus Function and condition test 4.1.9 **Grommets/tubing ports** Action · Check all grommets/tubing ports. All grommets/tubing ports are fitted. The grommets/tubing ports are not con-Test taminated or damaged. Grommets/tubing ports Result OK] 4.1.10 Front and rear access panels NOTE The following test checks the front access panel. Repeat the test for the rear access panel using the same method if applicable. Action • Unlock the front access panel latches (2x) by moving them into an horizontal position. · Open the front access panel a bit. The front access panel latches (2x) are not damaged. The heat shield, the latches and the hinges are neither contaminated nor damaged. Action · Fold the front access panel all the way down. The front access panel can be folded smoothly and is suspended vertically. Test Action · Close the front access panel. · Lock the front access panel latches by moving them into a vertical position. · Repeat the tests with the rear access panel if applicable. Result Front and rear access panels _OK] 4.1.11 **Access doors** Action Press on the latches of all access doors The access doors spring open. Test Action Replace the cuffs, if applicable. Test If cuffs are present, they are neither contaminated nor damaged. Action · Check the large access door gaskets for damage and proper seating. The seals are not contaminated, porous or torn. The seals are seated prop-Test erly; adjust position as necessary. Action · Close each access door, and check that is fully latched. · Reach inside the hood with the force gage from another door or port. • Using a force gage, apply an horizontal force of 2.0 kg to 2.5 kg (20 N to 25 N) for 5 seconds at the middle of each closed access door. The access doors must not open. Test Result Access doors No.1507 0000010139 OK] | Revision 1.0 | Test Instructions / Service Card IPM 29 / 43

Isolette 8000 plus Function and condition test 4.1.12 **IRIS** ports cuffs · Check the IRIS ports cuffs if applicable. Test The cuffs of the IRIS ports on the sides of the hood are neither contaminatednor damaged; if necessary, clean or replace the cuffs. Action · Rotate the outer rings of the IRIS ports. Test The cuffs of the IRIS ports open and close during the rotation. Result IRIS ports cuffs OK] 4.1.13 Sensor module with cable and clamp Action • Disconnect the skin-temperature sensor(s) from the sensor module connector(s), if installed. Disconnect the connector of the scale (option) from the sensor module. · Pull down the latch of the sensor module. · Pull the sensor module out of the hood as far as it will go. · Disconnect the sensor module connector from the basic housing. Press both latches on the sides of the sensor module outwards and, at the same time, pull the sensor module including its connecting line out of thehood Check the sensor module. The sensor module can be easily pulled out of the hood. The sensor module, the connections, the cable, the connector, and the socket on the incubator housing are neither contaminated nor damaged. The Air inlet nozzle is free of dust. If the unit is equipped with the O2 module, the two O2 cells are inside the sensor module. Check the cable clamps (scale) and the cable clamps of the sensor mod-Action Test The clamps are undamaged. Sensor module with cable and clamp Result OK] · Replace the sensor module to the unit. Action 4.1.14 **Mattress tray** Action · Check the mattress tray. Test The mattress tray is not contaminated or damaged. Action · Pull the mattress tray out of the unit as far as it will go. · Carefully exert downwards pressure on the mattress tray. The mattress tray can only be pulled out of the unit as far as the mechanical Test stop. The mattress tray is supported properly. Result Mattress tray 0000010138 OK] Action · Push the mattress tray back into the unit. 30 / 43 Test Instructions / Service Card IPM | Revision 1.0 |

Isolette 8000 plus Function and condition test 4.1.15 X-ray tray Action · Open the front access panel. · Pull the X-ray tray out of the mattress tray as far as it will go. Test The X-ray tray can only be pulled out of the mattress tray as far as the mechanical stop. Result X-ray tray ____OK] Action · Push the X-ray tray back into the mattress tray. · Close the access panel. 4.1.16 Mattress tray tilt mechanism Action Check the mattress tray tilt mechanism (mattress tray adjusting linkage and both mattress tray tilting actuators). Test The mattress tray tilt mechanism is neither contaminated nor damaged. Action · Turn the right-hand mattress tray tilting actuator counter-clockwise as far as it will go. The right-hand end of the mattress tray is tilted to approximately 12° angle. Test · Turn the right-hand mattress tray tilting actuator clockwise as far as it will Action The mattress tray is back to horizontal position. Test Action · Turn the left-hand mattress tray tilting actuator clockwise as far as it will go. The left-hand end of the mattress tray is tilted to approximately 12° angle. Test Action · Turn the left-hand mattress tray tilting actuator counter-clockwise as far as it will go. Test The mattress tray is back to horizontal position. Mattress tray tilt mechanism Result OK] 4.1.17 Control unit and power switch Action · Check the control unit and the power switch. Test The control unit and the power switch are not contaminated or damaged. Action · Check the protective earth connection between the stand and the control-The protective earth connection is mechanically attached to the stand and the Test controller Result Control unit and power switch _OK] No.1507 0000010139 | Revision 1.0 | Test Instructions / Service Card IPM 31 / 43 Isolette 8000 plus Function and condition test

4.1.18 Power failure alarm test

The unit is connected to the mains power supply and is switched on. The Prerequisites

device must have been in operation for at least 10 minutes for the capacitor (that activates this alarm) to be charged.

Action · Take power plug out of mains socket.

The "power failure alarm" LED is flashing. An intermittent alarm sounds. Test

Action · Plug the mains plug into the socket outlet.

The unit completes its self-test and then switches to normal operating mode. Test

Power failure alarm test Result

OK]

4.1.19 **Castors**

Action · Check that all castor holders are secured properly to the stand.

All castor holders are secured properly to the stand and have no play. Test

Action · Lock all castors if a lock is provided.

Test All castors can be locked and are not damaged. The unit cannot be moved back and forth.

Action · Release all locks if applicable.

Result Castors

OK]

4.1.20 **Pedals**

Action · Check the housings of the pedals.

The housings of the pedals are attached properly to the trolley. Test

Result Pedals

_OK]

4.1.21 Air filter (air inlet) on the incubator

- Loosen the screws on the air filter cover. Note: The cover is installed on the back, at the bottom of the basic unit.
- · Remove the air filter cover.
- · Remove and check the air filter.

Test The air filter is neither contaminated nor damaged. Labeling is legible. (Recommendation: The air filter should be replaced with a new one every 3 months)

If the air filter labeling is no longer legible or if the air filter is contaminated or damaged, replace the air filter.

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Isolette 8000 plus Function and condition test NOTE Ensure that the air filter is fitted properly (orientation is correct). The labeling of the air filter points outwards. Air filter (air inlet) on the incubator Result OK] · Insert the air filter into the housing. Action · Secure the cover to the unit using the screws. 4.1.22 Blanking plug on basic housing (if no humidity is installed) Check that a blanking plug is present when no humidity is installed. The plug is located where the condensation drain would be (near main heater) and is secured by a half-turn thread. The O-ring is in place, and in good condition. Blanking plug on basic housing (if no humidity is installed) Result OK] 4.1.23 Blank manifold (if no humidity is installed) Check that a blank manifold is present when no humidity is installed. Result Blank manifold (if no humidity is installed) _OK] No.1507_0000010139 33 / 43 | Revision 1.0 | Test Instructions / Service Card IPM

Isolette 8000 plus Function and condition test

4.2 **Functional Tests**

4.2.1 Low air flow alarm

Prerequisites The unit is connected to the mains power supply.

WARNING

The heater can be sufficiently hot to cause burns; avoid removing or touching the heater until the unit has been switched off for at least 45 min-

- Action Switch off the unit using the ON/OFF switch.
 - Disconnect the scale, if present, from the sensor module.
 - · Tilt back the hood.
 - Remove the mattress assembly, lift bars and main deck.
 - · Remove the heater/impeller cover.
 - Remove the impeller from the shaft of the fan motor and place it aside.
 - Switch on the unit using the ON/OFF switch and allow the self-test phase to complete.

Within 5 minutes (within 30 seconds as of software version 2.09) the unit displays the alarm "low Airflow". The audible alarm sounds.

Result Low air flow alarm

OK]

- Action Switch off the unit using the ON/OFF switch.
 - · Fit the impeller onto the shaft of the fan motor.
 - · Fit the heater/impeller cover.
 - · Fit the mattress tray, main deck, lift bars, and scale if present.

Flow controlled External O₂ (if present) 4.2.2

Prerequisites The unit is connected to the mains power supply and is switched on.

Action

- · Supply 9 L/min oxygen into the external oxygen connector of the unit.
- · Place a calibrated oxygen analyzer into the incubator.
- · Wait until the oxygen concentration inside the incubator has stabilized.

Test

The oxygen concentration specified in the flow table (9 L/min correspond to 45 vol.% O₂ to 75 vol.%O₂) matches the oxygen concentration displayed on the external oxygen analyzer. (Note: The flow table can be found on the label attached to the rear of the incubator.)

Flow controlled External O₂ (if present) Result

OK]

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Isolette 8000 plus Function and condition test

4.2.3 Servo-controlled oxygen module (if present)

NOTE

Before the oxygen measurement is checked for proper functioning, the oxygen sensors must be calibrated to 21 vol.% O_2 (ambient air) or to 100 vol.% O_2 . Which calibration is applied depends on the user's configuration of the unit.

NOTE

If the user has fitted an oxygen mount below the sensor module, then carry out a calibration to "100 vol.% $\rm O_2$ " .

If the user has not fitted an oxygen mount below the sensor module, then carry out a calibration to "21 vol.% $\rm O_2$ ".

Calibration (21 vol.%O₂)

Prerequisites

The unit is connected to the mains power supply and is switched on.

Action

- Press the "oxygen" button.
- · Press the "Cal." button.

Test The message "slide out sens" is displayed.

Action

- Unlock the latch of the sensor module.
- Pull the sensor module to the calibration position.

Test Oxygen calibration starts. The message "21% cal." is displayed. The "Cal Pass" is displayed at the end of the calibration phase.

Result Calibration (21 vol.%O₂)

____OK]

Calibration (100 vol.%O₂)

Prerequisites

The unit is connected to the mains power supply and is switched on.

Action

- Using an oxygen cylinder and a test pressure regulator (or use any oxygen flow meter from the wall supply), adjust an oxygen flow of 3 L/min to 5 L/min and feed it into the connector of the oxygen mount (the oxygen mount is located underneath the sensor module).
- Press the "Oxygen" button.
- Press the "Cal." button.

Test The message "slide out sens" is displayed.

Action

 Unlock the latch of the sensor module and pull the sensor module out of the hood and into the calibration position.

Test Oxygen calibration starts. The message "100% cal." is displayed. The "Cal Pass" is displayed at the end of the calibration phase.

Result Calibration (100 vol.%O₂)

OK1

Action

- Push the sensor module back into the hood, and latch the sensor module in the hood
- · Interrupt the oxygen flow to the oxygen mount, if used.

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Oxygen controller module

Prerequisites

The unit is connected to the mains power supply and is switched on. O_2 is available at pressure and flow compliant with the O₂ label on the rear of the incubator, has the correct hose to mate with the incubator, and is connected to the incubator and switched on.

Action

- · Place an external, calibrated oxygen analyzer inside the hood on the center of the mattress/mattress tray.
- Set oxygen to 40 vol.%O₂.

Within 5 minutes the display should indicate the set oxygen concentration with a tolerance of +/- 2 vol.% O₂.

Within 5 minutes the display of the incubator indicates the display of the external oxygen analyzer with the following tolerances:

- +/- 5 vol.% O₂ for calibration at 21 vol.% O₂
- +/-3 vol.% O₂ for calibration at 100 vol.% O₂.

Result Oxygen controller module

OK

Action • Set the "oxygen" concentration to 21 vol.% O2.

4.2.4 Humidity system (if present) and humidity low alarm

NOTE

Humidity and air temperature values were set above, in 4.1.4 "Pre-heating the unit". The settings are repeated here for clarity. The "Humidity Low" alarm is displayed approximately 30 minutes after any water in the system is evapo-

Prerequisites

The unit is connected to the mains power supply and is switched on.

Action

- · Remove the humidity reservoir from the unit.
- · Set the humidity to "75%".
- · Set the air temperature to "35 °C".

During the following tests the message "humidity low" will be displayed. The audible alarm sounds. The lamp on the sensor module is flashing.

Result **Humidity low alarm**

OK]

NOTE

Use keyboard unlock, next display, and display softkey to show humidity % trend. Observe this graphic display to confirm humidity trend. If there is water in the evaporator, the humidity will rise to the set point, and maintain humidity until the water is evaporated. At that time, the humidity graphic display will fall, and 30 minutes later the humidity low alarm will be activated.

NOTE

Keep the unit in operating mode during the following tests. If the unit is switched off in between, the humidity system must be switched on everytime!

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NOTE

Do not perform the humidity system test (below) until "Humidity low" alarm test is complete.

Prerequisites

The unit is connected to the mains power supply and is switched on. The oxygen supply is **not** active.

Action

- If the "Humidity low" alarm has occurred in the meantime (refer to the "Humidity low alarm" test), refill the humidity reservoir of the humidity system with distilled water.
- · Allow the unit to heat to "35 °C".
- Position the test humidity meter at the center of the mattress tray at a height of 10 cm from the surface.
- Press the "humidity" button.
- · Press the "ON" button.
- · Set the humidity to "65%".

Test Within 30 to 60 minutes the test humidity meter indicates 59% to 71%.

Result Humidity system

____OK]

4.2.5 Front and rear access panel open indicator

Prerequisites The unit is connected to the mains power supply and is switched on.

Action • Open the front access panel.

Test The display shows the "access panel open" icon, see "1" following figure.



Fig. 8 Detail view of the controller; "Front access panel open" icon

Action

- · Close the front access panel.
- · If available, open the rear access panel.

Test The display shows the "access panel open" icon.

Result Front and rear access panel open indicator

____OK]

2853

Action

· Close the rear access panel.

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Isolette 8000 plus Function and condition test 4.2.6 Sensor module position alarm Prerequisites The unit is connected to the mains power supply and is switched on. Action • Pull the sensor module to the calibration position. The unit generates a visual and an audible alarm. The alarm lamp mounted Test on the sensor module lights up. Result Sensor module position alarm OK] Action Insert the sensor module into the hood. 4.2.7 Air temperature setting and air temperature low alarm Prerequisites The unit is connected to the mains power supply and is switched on. · Close all access doors and, if fitted, IRIS access ports. Action Using the "air" button, set the air temperature to "35 °C", and allow the unit to warm up (Note: The warm-up time is less than 1 hour). Place a test thermometer at the center of the mattress tray at a height of 10 cm from the surface. Connect both skin-temperature sensors into the respective sockets "Central" and "Peripheral" on the sensor module. As soon as the air temperature has stabilized as indicated on the display (no Test value changes visible within 15 minutes), the display shows the set air temperature with a tolerance of +/-0.7 °C. The test thermometer is within +/-0.8 °C of the controller air display. The skin-temperature displays (Central and Peripheral) indicate the test thermometer value with a tolerance of +/-0.2 °C. Result Air temperature setting OK] Air temperature low alarm Action · Set the incubator to Air mode. · Set the air temperature to "36 °C". · Open the front access panel and, if applicable, also the rear access panel. Test Within approx. 5 minutes the unit should display the "air-temperature low" message. The audible alarm sounds. The alarm lamp flashes. Air temperature low message/Audible alarm sounds/Alarm lamp flashes Result OK] Action · Close all access panels and, if fitted, the IRIS ports. The unit returns to normal operating mode. The audible alarm is off and the Test error message is no longer displayed. No.1507_0000010139 38 / 43 Test Instructions / Service Card IPM | Revision 1.0 |

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4.2.8 Skin-temperature monitoring

Prerequisites The unit is connected to the mains power supply and is switched on.

Action

- Connect the Central and Peripheral skin-temperature sensors to the Sensor Module.
- Position both skin-temperature sensors and the test thermometer 10 cm above the center of the mattress.
- Set the skin-temperature to "35 °C" using the "skin" button.

Test Once the temperature has stabilized, the display should indicate the set skin temperature with a tolerance of +/-1.0 °C.

Action • Open one access door.

 Insert both skin-temperature sensors through the open access door and allow them to be cooled down by the ambient air.

Test Within approx. 5 minutes the unit should display a "skin-temperature low" message. The audible alarm sounds. The remote indicator lamp flashes.

Result Skin-temperature monitoring

OK]

 Place the skin-temperature sensors back into the incubator and close the access door.

4.2.9 Central Skin-temperature Alarm

Prerequisites

The unit is connected to the mains power supply and is switched on. Central and Peripheral Skin-temperature sensors are connected.

Action

- Select the "skin-temperature" mode.
- · Disconnect the Peripheral skin-temperature sensor.
- · Wait 10 seconds.
- · Disconnect the Central skin-temperature sensor.

The audible alarm does not sound until the Central skin-temperature sensor is disconnected. No measured value is shown on the display. The message "Skin Temp probe disconn" is displayed. The remote indicator lamp on the sensor module lights up.

Action • Press the "alarm silence" button.

Test The audible alarm is silenced.

Action • Plug the Central skin-temperature sensor into the sensor module.

Test The unit returns to normal operating mode. The audible alarm is off and the error message is no longer displayed.

Result Central skin-temperature Alarm

[____OK]

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4.2.10 High-temperature limit/switch-off

NOTE

When using the temperature and humidity meter set 7910980 (meter 7910989), use the combination temperature and humidity probe 7910982, not the surface temperature probe to make air temperature measurements.

Prerequisites The unit is connected to the mains power supply and is switched on.

Action

- · Connect the Central skin-temperature sensor to the sensor module.
- Select the "skin-temperature monitoring" mode.
- Set the skin temperature to "38 °C".
- · Open one access door.
- Expose the Central skin-temperature sensor to room air through the open access door.
- · Close the access door.
- Place the test thermometer about 10 cm above the center of the mattress tray.
- Allow the device to warm up until the heating capacity just begins to decrease (read the heating capacity off from the trend display).

Test The "skin-temperature low" alarm will possibly be triggered.

Action

- As soon as the heating capacity has decreased to approx. 50%, switch to AIR mode and check that the maximum temperature on the test thermometer does not exceed 40 °C. Read the heating capacity off from the trend display.
- If necessary, press the "alarm silence" button, then switch over to "air-temperature monitoring" mode.

Test The "over temperature cutout" alarm occurs within 1 minute.

Result High-temperature limit/switch-off

OK]

Action • Close all access panels and, if fitted, the IRIS ports.

Test The unit returns to normal operating mode. The audible alarm is off and the error message is no longer displayed.

Action • Switch off the unit.

4.2.11 Option VHA Trolley height adjustment

Prerequisites The unit is connected to the mains power supply and is switched on.

 Press and hold the right-hand pedal of the "Up/down" switch on the front until the incubator is in the highest position.

Test The incubator moves evenly and smoothly to the highest position.

Action • Press and hold the left-hand pedal of the "Up/down" switch until the incubator is in the lowest position.

Test The incubator moves evenly and smoothly to the lowest position.

Result Variable height stand (VHA)

____OK]

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	Function	Isolette 8000 p and condition t
Action	Repeat the tests with the pedals on the rear.	
4.2.12 Metrolog	gical check (Germany, Austria, and Switzerland only, every 2 years)	
	NOTE	
	Perform the "metrological check" (Germany only) every two years.	
Action	 Perform the metrological check according to the test instructions "Metrological Check". 	
Result	Metrological check	
		[(
Action	,	
Result	Date of the next metrological check	[(
		`
4.2.13 Option,	Safety check (Germany only, yearly)	
	NOTE	
	Perform the "safety check" (Germany only) every year.	
Action	Perform the safety check according to the test instructions "Safety Tests measurement tests".	
Result	Safety check	[(
Action	Entry date of the next Safety check.	
Result	Date of the next "Safety check"	
4.2.14 Final pro	ocedures	
Prerequisites	 The test instructions have been performed as specified. 	
	 All tests performed were passed successfully. 	
4.2.14.1 Test labe	el and device handover	
Action	Attach a test label to the device.	
	Supply the user/owner with a fully functioning device.	
Result	Test label and device handover	г (
		[(

Isolette 8000 plus Test Equipment

5 Test Equipment

This chapter lists the service equipment required to perform the tests specified in these test instructions.

5.1 Test equipment subject and not subject to mandatory calibration

NOTE

Use the following test equipment or equivalent aids.

5.1.1 Test equipment subject to mandatory calibration

Designation	Order number	Remark
Tester for electrical safety	7910594	B AS
Temperature / humidity meter	7910980	
Spring balance with pressure kit	7911370	
Flowmeter	7901161	
Decade resistor	7910120	*******
Flowmeter	2M86553	A

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Designation	Order number	Remark
Pressure regulator O ₂	7901482	'
or		
Pressure regulator, Pin index	7910342	
or		
Pressure regulator CS, Air/O ₂	7910487	

Result Test equipment calibrated in a valid manner used.

[____OK]

5.1.2 Test equipment not subject to mandatory calibration

Designation	Order number	Remark
O ₂ oxygen analyzer (MX 300-i), complete with sensor	7911955	
VDE adapter 8000	7910808	
Central Skin-temperature sensor (pack of 10)	MU26041	
Peripheral Skin-temperature sensor (pack of 10)	MU26042	

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5.2 Result Sheet Test instructions / Service Card IPM



Result Sheet Test Instructions / Service Card IPM Isolette 8000 plus

Order number:

Location:	Serial no. (basic unit):	
Department:	Cust. invent. no.:	
Maintenance interval:	Other / Delivery date:	

Applies to Test Instructions / Service Card IPM Revision 1.0

Key

√/OK = OK

+ = Spare part used
! = Error / Report
/ = Accessory not available
- Not applicable

Tes	t		Result
1 [Device c	onfiguration	
1.1	Devic	e configuration Isolette 8000 plus	
1.1.	.1 Ser	ial numbers (SN)	
	1.1.1.1	Isolette 8000 plus	tx
	1.1.1.2	Controller	tx
	1.1.1.3	Variable Height Stand (VHA)	tx
	1.1.1.4	Sensor module	tx
	1.1.1.5	Option Scale	tx
	1.1.1.6	Option Servo-controlled Oxygen module	tx
	1.1.2	Software version	tx
	1.1.3	Sensor module firmware	tx
	1.1.4	Heater thermocouple	Oł
2 N	Maintena	ance parts	
2.1	Mainte	enance intervals, overview	
2.2	Mainte	enance parts by specified interval	
	2.2.1	(Option) Oxygen sensors	da
	2.2.2	Heat shield latches	da
	2.2.3	(Option) O ₂ solenoid valve	da
	2.2.4	Impeller motor spare parts kit	da
	2.2.5	Vibration dampening rubbers for impeller motor	da
	2.2.6	Fan assembly (Sensor module)	da
	2.2.7	Fan assembly (Controller)	da
	2.2.8	Fresh Air Valve	da
	2.2.9	Tilt Bar O-Rings	da
	2.2.10	(Option) O ₂ Pressure regulator	da
2.3	Mainte	enance parts as required	
	2.3.1	Air Filter	da
	2.3.2	Drain plug with O-ring (Isolette 8000 plus without humidity system)	da
	2.3.3	Manifold (Isolette 8000 plus without humidity system)	da
	2.3.4	Reservoir and Cover (Isolette 8000 plus with humidity system)	da
	2.3.5	Heater Cover and Duct (Isolette 8000 plus with humidity system)	da
	2.3.6	Humidity evaporator (100 VAC) (Isolette 8000 plus with humidity system)	da
	2.3.7	Humidity evaporator (120 VAC) (Isolette 8000 plus with humidity system)	da
	2.3.8	Humidity evaporator (230 VAC) (Isolette 8000 plus with humidity system)	da
3 E	Electrica	l safety	
3.1	Electr	ical safety according to IEC 62353	
	3.1.1	Visual check	Oł
3.1.	.2 Pro	tective earth conductor resistance	
	3.1.2.1	Maximum measured value of device with pow- er cable	2

Tes	it		Result		
	3.1.2.2	Maximum measured value of optional power cable	Ω		
	3.1.3	Protective earth conductor resistance measurement points	ОК		
3.1	.4 Equ	ipment leakage current			
	3.1.4.1	Initial value	μA		
	3.1.4.2	Recurrent value	μA		
3.1		olied part leakage current, mains on applied t, type BF			
	3.1.5.1	Reference value	μA		
	3.1.5.2	Recurrent test	μA		
3.2	Electri	ical safety according to IEC 60601-1			
	3.2.1	Visual check	OK		
	3.2.2	Protective earth conductor resistance	Ω		
3.2		th leakage current			
	3.2.3.1	Normal condition (N.C.)	μA		
	3.2.3.2	Single fault condition (S.F.C.)	μA		
	3.2.3.3	Normal condition (N.C.)	μA		
	3.2.3.4	Single fault condition (S.F.C.) (The power conductor is interrupted.)	μA		
3.2	.4 Pati	ent leakage current			
	3.2.4.1	Normal condition (N.C.) DC	μA		
	3.2.4.2	Normal condition (N.C.) AC	μA		
	3.2.4.3	Single fault condition (S.F.C.) (The power conductor is interrupted.) DC	μA		
	3.2.4.4	Single fault condition (S.F.C.) (The power conductor is interrupted.) AC	μА		
3.2	.5 Tou	ch current			
	3.2.5.1	Normal condition (N.C.)	μA		
	3.2.5.2	Single fault condition (S.F.C.) The Protective Earth wire is interrupted.	μA		
	3.2.5.3	Single fault condition (S.F.C.) The Neutral wire is interrupted.	μA		
	3.2.6	Touch current measurement point pairs	OK		
_		and condition test			
4.1 Condition tests					
	4.1.1	Accompanying documents	OK		
	4.1.2	Power-on self test	OK		
	4.1.3	Secure attachment of trolley to basic unit	OK		
	4.1.4	Pre-heating the unit	OK		
	4.1.5	General condition	OK		
	4.1.6	Impeller, fan shaft and detector seal	OK		
	4.1.7	Labeling	OK		
	4.1.8	Hood and locking pivot	OK		
	4.1.9	Grommets/tubing ports	ОК		
	4.1.10	Front and rear access panels	ОК		
	4.1.11	Access doors	ОК		

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			I =	
Tes			Result	
	4.1.12	IRIS ports cuffs	OK	
	4.1.13	Sensor module with cable and clamp	OK	
	4.1.14	Mattress tray	OK	
	4.1.15	X-ray tray	OK	
	4.1.16	Mattress tray tilt mechanism	OK	
	4.1.17	Control unit and power switch	OK	
	4.1.18	Power failure alarm test	OK	
	4.1.19	Castors	OK	
	4.1.20	Pedals	OK	
	4.1.21	Air filter (air inlet) on the incubator	OK	
	4.1.22	Blanking plug on basic housing (if no humidity is installed)	OK	
	4.1.23	Blank manifold (if no humidity is installed)	OK	
4.2	Functi	ional Tests		
	4.2.1	Low air flow alarm	OK	
	4.2.2	Flow controlled External O ₂ (if present)	OK	
4.2	.3 Ser	vo-controlled oxygen module (if present)		
	4.2.3.1	Calibration (21 vol.%O ₂)	ОК	
	4.2.3.2	Calibration (100 vol.%O ₂)	OK	
	4.2.3.3	Oxygen controller module	OK	
4.2	4.2.4 Humidity system (if present) and humidity low alarm			
	4.2.4.1	Humidity low alarm	OK	
	4.2.4.2	Humidity system	OK	
	4.2.5	Front and rear access panel open indicator	ОК	
	4.2.6	Sensor module position alarm	OK	
4.2				
	4.2.7.1	Air temperature setting	OK	
	4.2.7.2	Air temperature low message/Audible alarm sounds/Alarm lamp flashes	OK	
	4.2.8	Skin-temperature monitoring	OK	
	4.2.9	Central Skin-temperature Alarm	OK	
	4.2.10	High-temperature limit/switch-off	OK	
	4.2.11	Option VHA Trolley height adjustment	OK	
4.2		rological check (Germany, Austria, and Switand only, every 2 years)		
	4.2.12.	1 Metrological check	OK	
	4.2.12.2	2 Date of the next metrological check	dat	
4.2	.13 Opt	ion, Safety check (Germany only, yearly)		
	4.2.13.	1 Safety check	OK	
	4.2.13.2	2 Date of the next "Safety check"	dat	
4.2	.14 Fin	al procedures		
	4.2.14.	1 Test label and device handover	OK	
5 1	Test Equ	ipment		
5.1		quipment subject and not subject to mandato- bration		
	5.1.1	Test equipment subject to mandatory calibration	ОК	
5.1.	.2 Tes	t equipment not subject to mandatory calibra-		

		
Domonto		
Report:		
Test has been performed a	according to the test instructions.	
rest has been penomied a	iccording to the test instructions.	
		_
Name::		
		_
		_
		_
		3/3



Directive 93/42/EEC concerning medical

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