NatalCare ST-LX

Intensive Care Incubator

TECHNICAL SERVICE MANUAL

Catalogue number: 72697J

natus newborn care

Natus Medical Incorporated
Corporate Headquarters
1501 Industrial Road
San Carlos, CA 94070
USA

Phone: +1 (650) 802-0400
+ 1(800) 255-3901 (Toll Free)
Fax: +1 (650) 802-0401
www.natus.com

Marcos Sastre 1675, El Talar, Tigre, B1618EWC, Buenos Aires, Argentina
Tel: +54-11-5354-3700, Fax: +54-11-5354-3721
medix@medix.com.ar
www.medix.com.ar

INTENSIVE CARE INCUBATOR	NatalCare ST- LX
VOLTAGE	230 V~ – 50-60 Hz 120 V~ – 50-60Hz
POWER	6 A (230V~) 12 A (120V~)

CLASSIFICATION ACCORDING TO IEC-60601-1 / IEC 60601-2-19	
ELECTRIC PROTECTION	**CLASS I**
PROTECTION AGAINST LIQUIDS PRESENCE	**IPX0**
APPLICABLE PART	**TYPE BF** 
EQUIPMENT IS NOT SUITABLE FOR USE IN THE PRESENCE OF FLAMMABLE ANESTHETIC MIXTURES WITH AIR, OXYGEN OR NITROUS OXIDE.	

About This Manual

The information contained in this document offers the user proper and detailed information for installation, use, maintenance and how to request spare parts for this equipment. This manual has been updated and its content is accurate as of the date of publishing or revision. Product specifications may change without prior notice.

Technical Assistance

During the warranty period MEDIX I.C.S.A. equipment repair must be performed by trained personnel either at the hospital or at an authorized service center. If the equipment needs repairing, contact your local dealer, MEDIX I.C.S.A. Technical Department or Natus Service Center. Before calling please have model and serial numbers at hand. If shipping is necessary, pack the equipment and all its accessories carefully, in order to avoid damage during transportation.

UL Mark *

MEDICAL EQUIPMENT WITH RESPECT TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL 60601-1, CAN/CSA-C22.2 No. 601.1, IEC 60601-2-19, CAN/CSA-C22.2 No. 601.2.19

4NL6

*Applicable only for 120v

TABLE OF CONTENTS

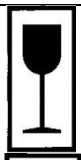
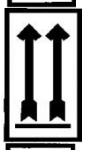
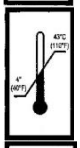
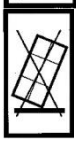
Symbols

The following table shows the symbols located on the equipment or in this manual and their meaning:

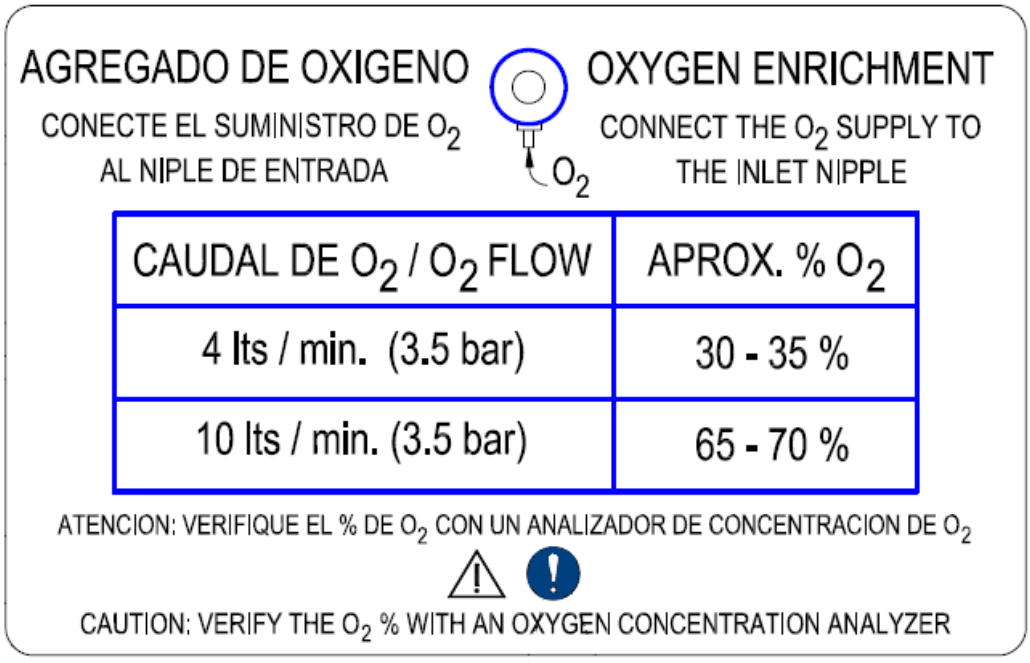
International Electrical Symbols:

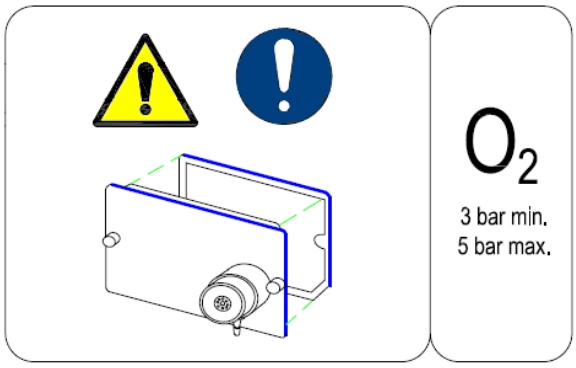
Symbol	Description
	ON / OFF
	CAUTION
	GENERAL WARNING SIGN
	GENERAL MANDATORY ACTION SIGN
	FOLLOW INSTRUCTIONS FOR USE
	WARNING: DANGEROUS VOLTAGE
	PROTECTIVE EARTH
	HOT SURFACE
	BATTERY
	TYPE BF APPLIED PART
	ESD (ELECTROSTATIC DISCHARGE) SENSITIVITY
	OPERATING INSTRUCTIONS
~	ALTERNATING CURRENT

Storing and packing symbols:

Símbolo	Description
	FRAGILE, HANDLE WITH CARE
	THIS SIDE UP
	KEEP DRY
	TEMPERATURE LIMITATION 4ºC (40ºF) – 43ºC(110ºF)
	DO NOT HANG
	DO NOT TILT

Warning labels fixed to the equipment

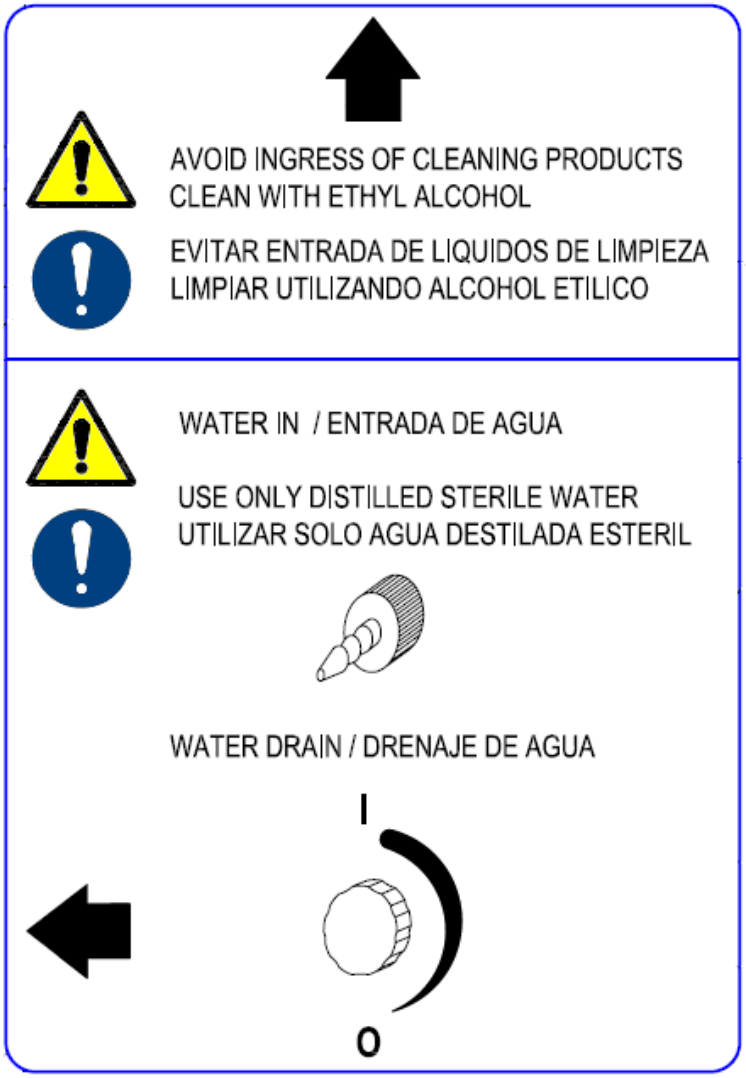




SUPPLY 100% O_2
DURING 60 s

SUMINISTRAR O_2 AL 100%
DURANTE 60 s

Continuous operation with Intermittent motor operation:
0.7 min ON , 30 min OFF



PACK BATERIA NIMH AAA 9.6 V / 650 mAh RECAMBIAR LA BATERIA A INTERVALOS DE TIEMPO NO MAYORES A 2 AÑOS	RECHARGEABLE BATTERY NIMH AAA 9.6 V / 650 mAh CHANGE THE BATTERY EVERY TWO YEARS OR LESS

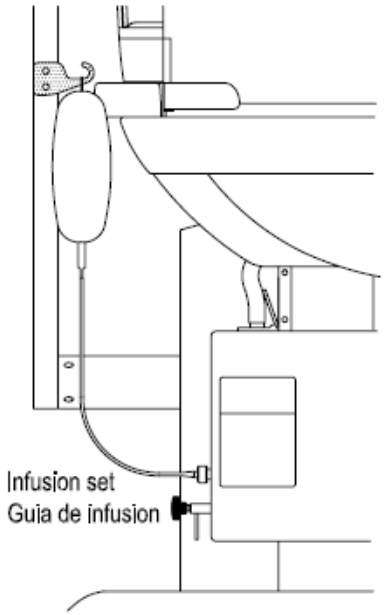
MODULE NCA -103
SERVOHUMIDITY

USE ONLY DISTILLED
STERILE WATER BAG

On the main screen,select

and enable module with

MORE INFORMATION
IN THE USER MANUAL



MODULO NCA -103
SERVOHUMEDAD

UTILIZAR SOLAMENTE SACHET
DE AGUA DESTILADA ESTERIL

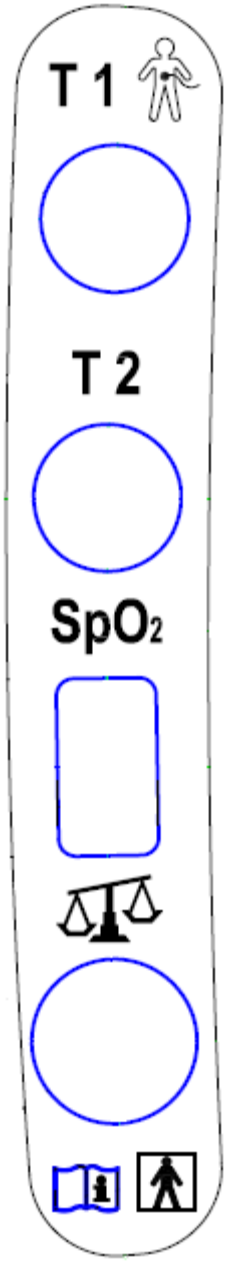
En la pantalla principal seleccionar

y habilitar el modulo con

MAS INFORMACION
EN EL MANUAL DE USO

WHEN HUMIDITY IS IN USE, WATER INSIDE THIS TANK IS SCALDING. DO NOT DISCONNECT TUBING UNTIL COMPLETELY COOL.

CON LA HUMEDAD EN USO, EL AGUA EN EL EVAPORADOR ESTA HIRVIENDO. NO DESCONECTAR LA GUIA HASTA QUE ESTE SE ENFRIE.



INCUBATOR - MEANING OF SYMBOLS

ON (I) OFF (O)

ALARM SILENCE

SKIN TEMPERATURE

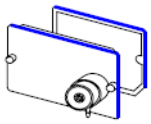
AIR TEMPERATURE

((TEST)) SOUND AND INDICATORS TESTING

MONITOR SHELF MAXIMUM LOAD 25 Kg.

SET CONTROL RANGE

HOT SURFACE



CHANGE AIR FILTER EVERY 3 MONTHS.
INCORRECT POSITIONING AND/OR THE LACK
OF ANY OF THE TWO PIECES IN THE FIGURE
WILL LEAD TO OPERATION FAILURE OF THE INCUBATOR.

WHEN THE INCUBATOR DOES NOT HAVE THE SERVO OXYGEN MODULE INSTALLED
AND OXYGEN IS DELIVERED TO THE INFANT COMPARTMENT
VERIFY THE O_2 % CONCENTRATION WITH AN OXYGEN MONITOR

RANGE 0 - 8000 g

THE SERIAL NUMBER OF THIS SCALE
MUST MATCH THE SERIAL NUMBER OF THE INCUBATOR.
THE SCALE SHOULD NOT BE USED ON OTHER INCUBATORS.

RANGO 0 - 8000 g

ESTA BALANZA POSEE UN NUMERO DE SERIE
QUE DEBE SER COINCIDENTE CON EL DE LA INCUBADORA.
NO ADMITE EL INTERCAMBIO DE BALANZAS CON OTRAS INCUBADORAS.

SN

F 1.5AL , 250V

F 3AL , 250V

MAX
345 VA

DIR- 30

natus newborn care

DISPOSABLE SKIN TEMP. PROBE/
SENSOR DE TEMPERATURA DE PIEL DESCARTABLE

medix I.C.S.A.

DIR- 34

natus newborn care

SKIN PROBE COVERS/
PROTECTORES DE SENSOR DE PIEL

medix I.C.S.A.

natus newborn care

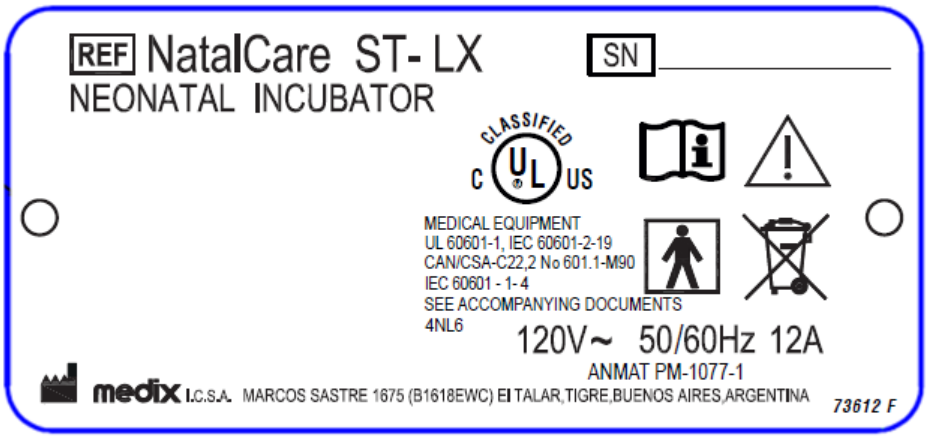
SENSOR PACIENTE DIR-10

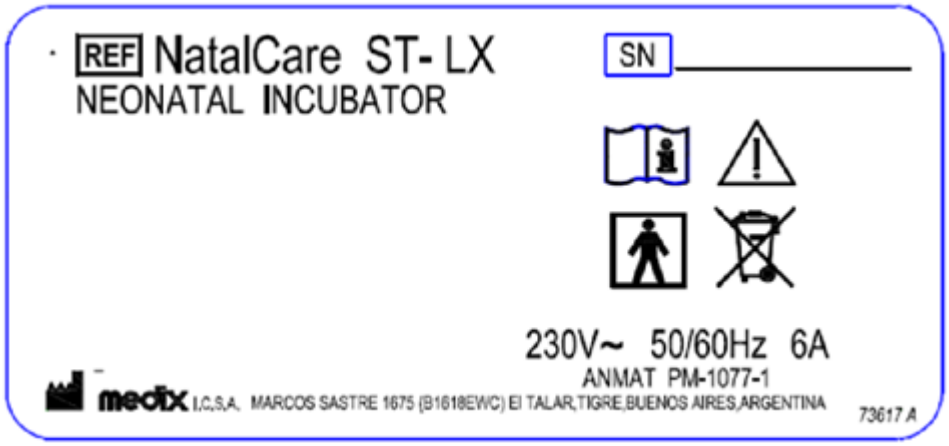
natus newborn care

Medix I.C.S.A

SKIN TEMP. PROBE DIR-10

Equipment Identification





1. INTRODUCTION

The **NATALCARE** incubator is intended for use for newborn babies who require additional thermal and humidity support. NATALCARE incubators can be used in neonatal and pediatric intensive care units.

Standard features of the intensive care incubator offers large displays of skin and air temperatures with their respective preset temperatures. A graphic LCD screen allows users to select a configuration option menu and also to check the modular optional accessories (servo-humidity, servo-oxygen and weighing scale).

Two skin temperature probes can be used with twins or for the monitoring of core and peripheral temperature of a newborn for the early detection of thermal stress of the infant.

1.1 Standard equipment

NATAL CARE ST LX	**INTENSIVE CARE INCUBATOR** Includes: A mobile command module with LCD (Liquid Crystal Display) graphic screen, air temperature sensor and two skin temperatures T1 and T2. Alarms, Trend Plots, Comfort Zone (CZ), Patient Identification (PID), Electronic Tilting Mechanism, Double walled dome. 4 access doors; two double walled, foldable 180º (2 intensive care and 2 auxiliary lateral doors), 5 oval ports; two on each intensive care door and one on the right auxiliary door, 1 MAX IV port on the left auxiliary door, 8 IV ports, X-ray cassette tray, two temperature probes (one reusable probe and one disposable probe). Pack of 4 air filters. User manual. Cabinet stand with 4 wheels (2 with brakes).

1.2 Optional parts

CATALOGUE	DESCRIPTION
NCA-102	Oxygen servo-control module
NCA-102C/1	Oxygen servo-control module without accessories.
NCA-103B/1	Humidity servo control module 120VAC
NCA-103B/2	Humidity servo control module 230VAC
-	Variable height adjustment system (lift)
NCA-105	Integrated electronic weighing scale module

CATALOGUE	DESCRIPTION
NCA-106	Drawer (mounted to the center)
NCA-106/1	Drawer (mounted to the right)
NCA-106/2	Drawer (mounted to the left)
NCA-107	IV Pole
NCA-108	Monitor shelf (maximum weight admitted: 25 kg)
NCA-109	Additional iris port for lateral right door
NCA-109/1	Additional iris port for lateral left door
NCA-110	Four Antistatic wheels
NCA-112	Short Pole for accessories
NCA-113	Gel Mattress
NCA-121	Type E Oxygen Cylinder Holder
NCA-126	Flexible holder for ventilator tubing
NCA-127	Water discharge tank set for NCA-103
NCA-128	Reusable water tank for NCA-103
NCA-131	Column for accesories
NCA-132/1	Auxiliary outputs 120VAC
NCA-132/2	Auxiliary outputs 230VAC
NCA-137	Additional insert for drawer
SMC-NC01	Resuscitation system

1.3 Accessories, consumables, and replacement parts

CATALOGUE	DESCRIPTION
TR-69	Air filter (4 pieces per pack)
13142	Mattress (without weighing scale module)
13147	Mattress (with weighing scale module)
13156	Complementary mattress (with weighing scale module)

23464	Port gasket
DIR-06	Iris port sleeves (100 pieces per pack)
DIR-10	Skin temperature probe (reusable)
R25266	IV Ports
R25270	MAX IV port
DIR-30	Disposable skin temperature probe (12 pieces per pack)
DIR-34	Skin temperature probe cover (120 pieces per pack)
DIR-36	Oval hand port sleeves (100 pieces per pack)
R18130	Servo-humidity hose set
18136	Oxygen supply hose set
R43690	Set of 2 Oxygen Sensors
R18130/10	Package of 10 humidity hoses

1.4 Technical and functional specifications

1.4.1 Essential performance

The essential performance of an Intensive Care Infant Incubator is to keep an adequate thermal environment for newborn during long term treatment and assure isolation of the patient.

1.4.2 Technical specifications

NOTE ENVIRONMENTAL CONDITIONS RECOMMENDED FOR NORMAL FUNCTIONING TEMPERATURE: 18 - 30 ºC / 64.4 -86 ºF

BAROMETRIC PRESSURE: 86-106 Kpa (648-795mmHg)

RELATIVE HUMIDITY: 50±5%

AIR SPEED: 6-8 m/min

Dimensions:

Baby's compartment (useful area)

Width	80 cm / 31.5 in
Height	40 cm / 15.7 in

Depth	48 cm / 18.9 in
External dimensions	
Height	135 cm / 53.1 in
Width	105 cm / 41.3 in
Depth	60 cm / 23.6 in
Variable height system incubator (optional)	
Mattress height range	+ 30 cm / 11.8 in
Mattress area	
Width	61 cm / 24 in
Depth	40 cm / 15.7 in
Access doors	
Front and back	
Width	72 cm / 28.3 in
Height	32 cm / 12.6 in
Lateral doors	
Width	31 cm / 12.2 in
Height	32 cm / 12.6 in

Gross weight (Basic equipment) 78 Kg / 172 lb

Electronic tilting mechanism Angle ± 15º

Access

Oval hand port, automatic and noiseless	5
Iris port	(2 optional)
MAX IV port	1
IV ports	8
Lateral doors	4

Oxygen enrichment capacity (volume controlled)
21% to 80% ±5%

Maximum CO_2 concentration: <<0.5%(according to IEC60601-2-19, clause 105.1)

Temperature controls

Air: 20 to 37 °C / 68 to 98.6 °F (0.1 °C/ºF) up to 39°C / 102.2 °F with override key

Skin 1 (T1): 34 to 37 °C / 93.2 to 98.6 °F (0.1 °C/ºF) up to 38°C / 100.4ºF with override key

Indicators (Displays)

- **Skin temperature (T1)**: (control/ real temperature)

Resolution: 0.1 °C/ºF
Measurement range: 10 to 45 °C / 50 to 113 °F
Accuracy: ±0.3 ºC /±0.6 ºF

- **Skin control temperature (T1)**

Control range: 34 to 37 ºC / 93.2 to 98.6 ºF (with override up to 38 ºC /100.4 ºF)

- **Air temperature**: (control/ real temperature)

Resolution: 0.1 °C/ºF
Measurement Range: 10 to 45 °C / 50 to 113 °F
Accuracy: ±0.3 ºC /±0.6 ºF

- **Air control temperature**

Control range: 20 to 37 ºC / 68 to 98.6 °F (with override up to 39ºC / 102.2 °F)

Graphic Screen LCD

Alarms (visual and audible)

- Alarm condition indicator.
- Skin temperatures: ± 1°C / ± 2ºF (adjustable)
- Air temperatures: + 1ºC, - 3°C / + 2ºF, - 5ºC (adjustable)
- Skin / air sensor failure.
- Air flow failure.
- Electronic circuit failure.
- Power supply failure.
- Air overheating alarm with independent circuit.
- Alarms test: activates all the indicators.
- Alarm reset: only silences the sound alarm during 15 minutes. A new alarm condition activates it again.
- Alarms are silenced during 45 minutes when the incubator is powered on, while the preset parameters are stabilized.
- MODULE ALARMS: SERVO-HUMIDITY, SERVO-OXYGEN, WEIGHING SCALE

OPTIONAL MODULES

NCA-102: SERVO-OXYGEN

Measurement range: 18-100%
Control range: 21-80%
Accuracy: ±3%
O_2 Supply Pressure: 300 to 500 kPa (normal: 350kPa)
Oxygen Monitor:
Measurement basis: electrochemical cells.
Oxygen sensors R-17MED.
Range: 0-100% O_2 (max), 0-1% O_2 (min).
Accuracy: within 1% at depth of scale with continuous temperature and pressure.
Response time: <6 seconds at 90% from the final value.
Functioning Humidity: 0-99 %(non-condensing).
Functioning Temperature: 0 – 40 ºC / 32 – 104 ºF
Expected service life: 48 months on air at 25 ºC / 77 ºF and 50 RH%

NCA-103: SERVO-HUMIDITY

Measurement range: 20-100%
Control range: 40-95%
Accuracy: ±7%

NCA-105: ELECTRONIC WEIGHING SCALE

Maximum weight admitted: 8000 g / 282.19 oz
Reading steps: 1 g / 0.01 oz
Accuracy: ±5 g / ±0.18 oz

Internal Battery Pack (control module)

Powers sound alarm in case of power supply failure and for parameters recording.

NiMH 9,6V-650mAh

Power Supply

230 V~ 50-60 Hz
120 V~ 50-60 Hz

Interchangeable skin temperature probes ± 0.1 °C/ºF.

Automatic Initialization

34° C / 93.2 °F for air temperature and 36 °C / 96.8 °F for skin temperature.
Memory for control settings and operational mode.

Packing and Storing

Medical equipment – Fragile – do not pile up
Environmental Conditions: keep in a dry place.

1.4.3 Functioning

Technical and operational specifications are referred to IEC 60601-2-19 standards: "Particular requirements for safety of baby incubators"

1. Warm-up time: 30 minutes. Heating rate approx. 10 °C / 50 °F every 30 minutes.
2. Temperature variation: ± 0.2 °C / ± 0.4ºF
3. Control temperature range:

   SKIN MODE (skin control) 34.0 to 37.0 °C / 93.2 to 98.6 °F with override key up to 38.0 °C / 100.4 °F in 0.1 ºC/ºF steps.

   AIR MODE (air control) 20.0 to 37.0 °C / 68 to 98.6 °F with override key up to 39.0 °C / 102.2 °F in 0.1 ºC/ºF steps.
4. Temperature overshoot: 0.3 °C / 0.6 ºF.
5. Temperature control System:

   SKIN MODE: Keeps a constant baby skin temperature, according to the preset value indicated by the clinician. (SKIN TEMPERATURE CONTROL).
   AIR MODE: Keeps a constant air temperature inside the incubator, according to the preset value indicated by the clinician. (AIR TEMPERATURE CONTROL).
   AIR MODE / TWINS: In case of having twins inside the incubator, two skin temperature probes (T1 and T2) are used as thermometers.
   AIR MODE / THERMAL MONITORING: Two skin temperature probes (T1 and T2) are used to monitor the core and peripheral difference of the same infant.

6. Correlation between the incubator temperature and the stabilized indicated temperature: < 0.3°C/0.6ºF.

7. Correlation between the Skin control temperature and the indicated skin temperature: < 0.1°C/0.2ºF.
8. Continuous autocalibration of the measurement electronic circuits.
9. Continuous circuit self-check.
10. Skin T1 and T2 temperature alarms activation range: ± 1°C / ± 2ºF from skin control temperature (factory default).

    Skin T1 and T2 temperature alarms preset limits:

    Low range: -1ºC, -0,5ºC (-2ºF,-1.5ºF, -1ºF); High range: +0,5ºC, +1ºC (+1ºF, +1.5ºF, +2ºF)

NOTE Alarm limits can be changed on CONFIGURATION screen.

11. Air temperature alarm activation range: +1°C, -3°C (+2ºF, -5ºF) from air control temperature (factory default). (After power on the unit, this alarm mutes during 45 minutes to allow the incubator reach the stabilized temperature).

    Air temperature alarm preset limits.
    Low range: -3ºC, -2.5ºC, -2ºC, -1.5ºC, -1ºC, -0.5ºC
    (-5.0ºF, -4.5ºF, -4.0 ºF, -3.5 ºF, -3.0 ºF, -2.5 ºF, -2.0 ºF, -1.5 ºF, -1.0 ºF)
    High range: +3ºC, +2.5ºC, +2ºC, +1.5ºC, +1ºC, +0.5ºC
    (+5.0ºF, +4.5ºF, +4.0 ºF, +3.5 ºF, +3.0 ºF, +2.5 ºF, +2.0 ºF, +1.5 ºF, +1.0 ºF)

12. Air speed range over mattress: 0.1 m/sec.
13. Air flow alarm activation time when a failure occurs: <45 seconds.
14. SKIN TEMPERATURE electronic thermometer resolution: 0.1°C/ºF
15. AIR TEMPERATURE electronic thermometer resolution: 0.1°C/ºF
16. Oxygen concentration (flow controlled)
    - 4 lts/min (3.5bar):30-35% O_2.
    - 10 lts/min (3.5bar): 65-70% O_2.
17. Humidity:

    Measurement range: 20 – 100%

    Control range: 40 - 95%, ± 5% (steps of 1%).
18. CO_2 maximum concentration: << 0,5%(according to IEC60601-2-19 standard, clause 105.1)
19. Maximum inner noise level in normal use conditions: < 50 dBa
20. Maximum inner noise level during alarm activation: < 80 dBa

21. Maximum noise level at 3 meters from the incubator during alarm activation: > 65 dBa
22. Maximum weight suggested for shelves and trays: 25 Kg / 55 lb.
23. Air filter: Filters particles bigger than 0.3 microns.
24. Oxygen filter: Filters particles bigger then 0.5 microns.

⚠ **WARNING!** Read the Operational Check Procedure, section 5.13 of this manual, before operating the incubator. If a problem is detected during any stage of the Functional Check Procedure the incubator should not be used. Contact the Authorized Service Center.

1.5 Access

Four intensive care doors foldable 180º with double locking mechanism

Five automatic hand ports

MAX IV port

Eight IV ports

1.5.1 Access through automatic hand ports

The hood has five automatic hand ports used for routine procedures with the infant. To avoid your hand contamination open the hand ports pressing the latch with your elbow.

⚠ **CAUTION** The hand port must be opened just by pushing the port latch (PUSH) as shown in the picture below to prevent breakages.

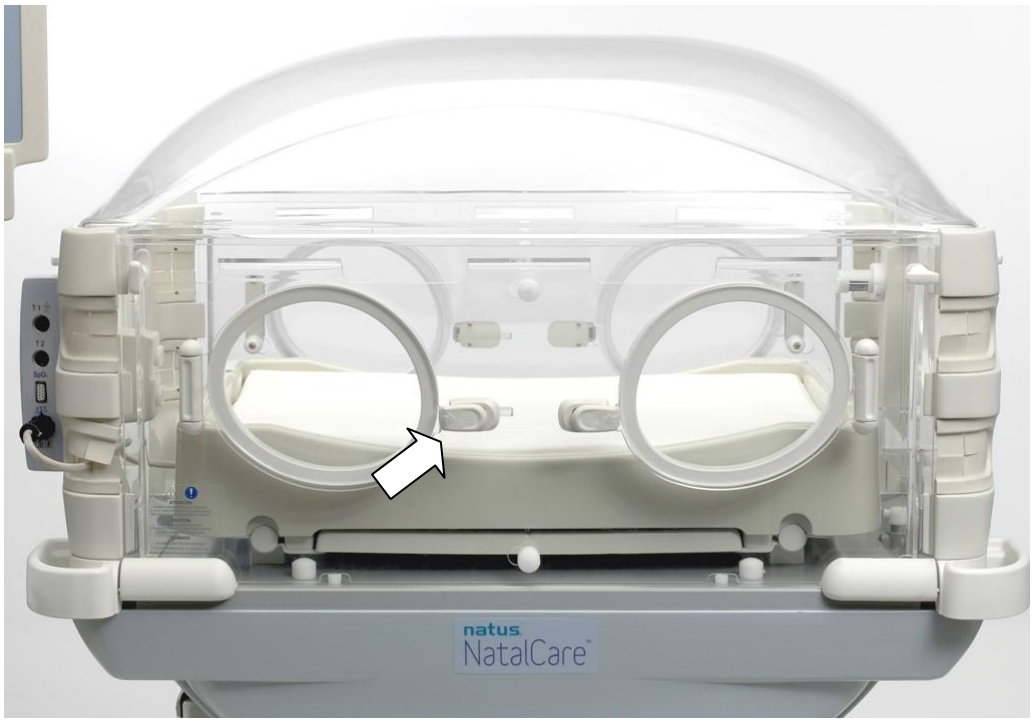
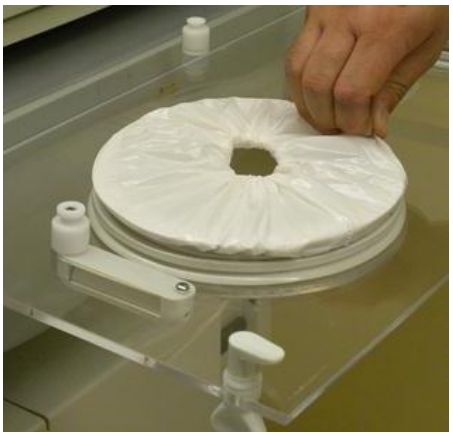


Figure 1: Automatic hand ports

⚠ **WARNING!** Use hand port sleeves and iris sleeves while the incubator is functioning to protect the infant's thermal environment.

⚠ **WARNING!** Do not move the incubator while a patient is under treatment.

1.6 Double wall



The double wall is incorporated in the front and back intensive care doors.

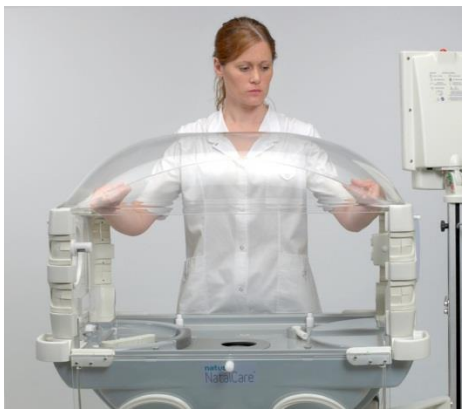
Open the double wall by moving the inner door to the right, releasing it from the door retaining pins.

⚠ **CAUTION** Once cleaning is finished, place the double wall in its place again.

PLACING THE OVAL HAND PORT SLEEVES

Unlatch the double wall to place the oval hand port sleeves.

1.7 Double Dome

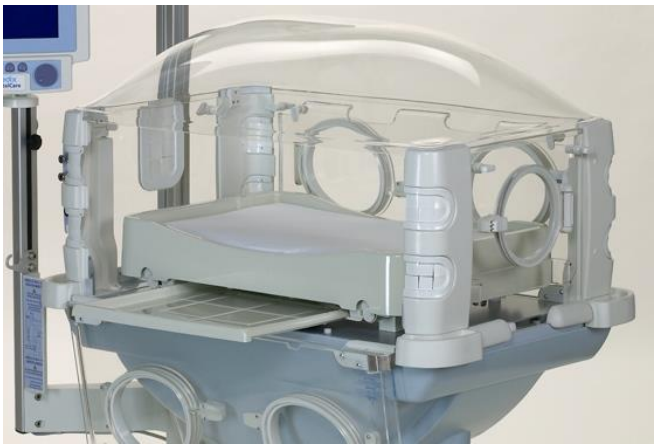


The double dome is removed by first gently pressing from one end towards the center of the incubator for it to unlock.

⚠**CAUTION** Once cleaning is finished, place the double dome in its place again and make sure it is positioned correctly.

1.8 X-ray cassette tray

The x-ray cassette is fully integrated to the mattress holder base. To access the tray open the front door and gently slide the tray out.



1.9 Command module positioning

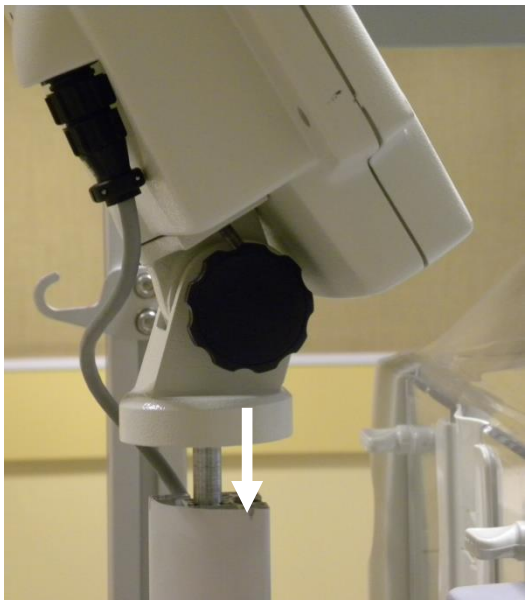
Manual knob **A** enables to modify the vertical position of the command module to give the user a better view angle. Adjust the knob to fix the position.

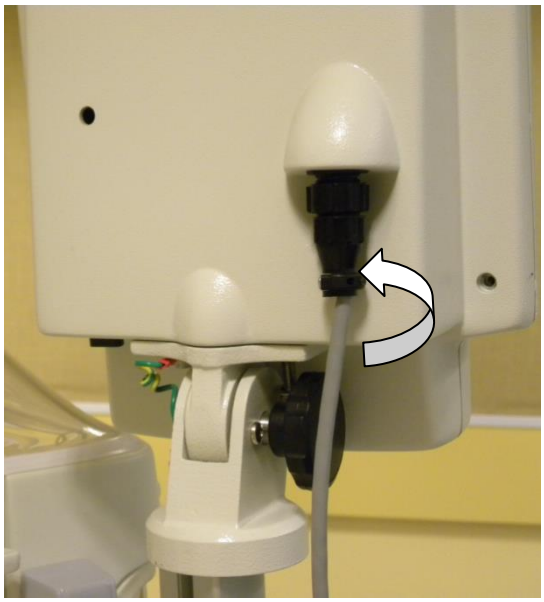
Manual knob **B** enables to rotate the command module to the laterals.

2. UNPACKING AND ASSEMBLY

2.1 Assembly instructions

- When unpacking the equipment, check that all parts are in good condition. Otherwise, contact your supplier or sales dealer to report any problems immediately.
- The command module is packed separately. When taking the equipment out of the boxes, be careful not to damage the surfaces. Place the module on the support and connect the communication cable to the back as shown in the pictures:





- Clean the equipment according to the instructions described in section 7 of the reference manual.
- Connect the power supply cable and the temperature probes according to the instructions described in section 4 of the reference manual.

NOTE Once the equipment is unpacked it must be plugged in at least 16 hours to ensure the charge of the internal batteries.

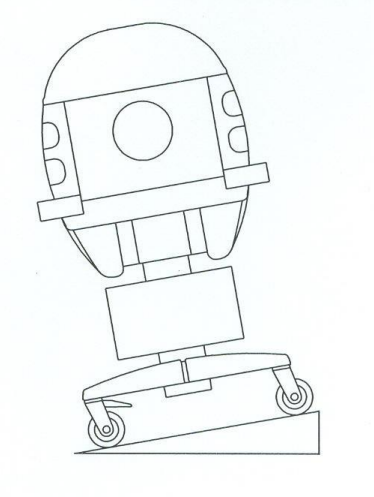
WARNING! The power supply cable must be connected to a medical grade power outlet with a grounded connection. Do not use adapter plugs or extension cables.

- The room temperature where the equipment will function must be between 18ºC and 30ºC (64.4 and 86ºF).

WARNING! This equipment is not suitable for use in the presence of flammable anesthetics. An explosion hazard exists under these conditions.

WARNING! Remove all the packing material, including the mattress protecting plastic cover before using the incubator on patients.

WARNING! To avoid the equipment slipping when it is on a slope, the front wheels of the rolling base must face to the slope and set the brakes, as shown in the picture.



WARNING! Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to EMC information provided in user and technical service manuals

WARNING! Do not place auxiliary equipment producing sparks in the incubator.

2.2 Starting up – software versions

Connect the equipment to 230V~ (120V~) grounded socket.

Check that the thermal breaker (located at the bottom and lateral part of the support) is on.

The green led shall light up and a “beep” sounds when the control module receives power supply.

Press  for approximately 2 seconds.

Upper digital displays will light up and the control software version is immediately indicated at the top part. Then a self-check routine runs automatically showing on the screen the optional modules incorporated and their current software versions. On the lower part of the screen it is shown the software version of the respective screen.

1. CONTROL SOFTWARE VERSION
2. SCREEN SOFTWARE VERSION
3. OPTIONAL MODULES SOFTWARE VERSIONS

The incubator is functioning in AIR MODE with a preset control temperature at 34 ºC.

2.3 Electromagnetic Compatibility Comments

Guidance and manufacturer's declaration – electromagnetic emissions		
The NATAL CARE ST is intended for use in the electromagnetic environment specified below. The customer or the user of the NATAL CARE ST should assure that it is used in such an environment		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The NATAL CARE ST uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF emissions CISPR 11	Class A	The NATAL CARE is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Table 201 (IEC 60601-1-2:2004)

Guidance and manufacturer's declaration – electromagnetic immunity			
The NATAL CARE ST is intended for the use in the electromagnetic environment specified below. The customer or the user of the NATAL CARE ST should assure that it is used in such an environment			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6kV contact +/- 8 kV air	+/- 6kV contact +/- 8 kV air	Floors should be wood, concrete or ceramit tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	+/- 2kV for power supply lines +/- 1 kV for input/output lines	+/- 2kV for power supply lines +/- 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	+/- 1kV line(s) to line(s) +/- 2kV line(s) to earth	+/- 1kV line(s) to line(s) +/- 2kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles	< 5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles	Mains power quality should b that of a typical commercial or hospital environment. If the user of the NATAL CARE ST requires continued operation during power mains interruptions, it is recommended that the NATAL

	70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	CARE ST be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
NOTE U_T is the a.c. mains voltage prior to application of the test level			

Table 202 (IEC 60601-1-2:2004)

Guidance and manufacturer´s declaration – electromagnetic immunity			
The NATAL CARE ST is intended for the use in the electromagnetic environment specified below. The customer or the user of the NATAL CARE ST should assure that it is used in such an environment			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no clorser to any part of the NATAL CARE ST, including cables, that the recommended separation distance calculated from the equuation aplicable to the freuency of the transmitter **Recommended separation distance** $d = 1,2\sqrt{P}$
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1,2\sqrt{P}$ 80 MHz to 800 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 2,3\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

[a] Field strengths from fixed transmitters, such as base stations fro radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the NATAL CARE ST is used exceeds the applicable RF compliance level above, the NATAL CARE ST should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the NATAL CARE ST.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m

Table 204 (IEC 60601-1-2:2004)

Recommended separation distances between portable and mobile RF communications equipment and the NATAL CARE ST

The NATAL CARE ST is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the NATAL CARE ST can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the NATAL CARE ST as recommended below, according to the maximum output power of the communications equipment

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1,2 \sqrt{P}$	80 MHz to 800 MHz $d = 1,2 \sqrt{P}$	800 MHz to 2,5 GHz $d = 2,3 \sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

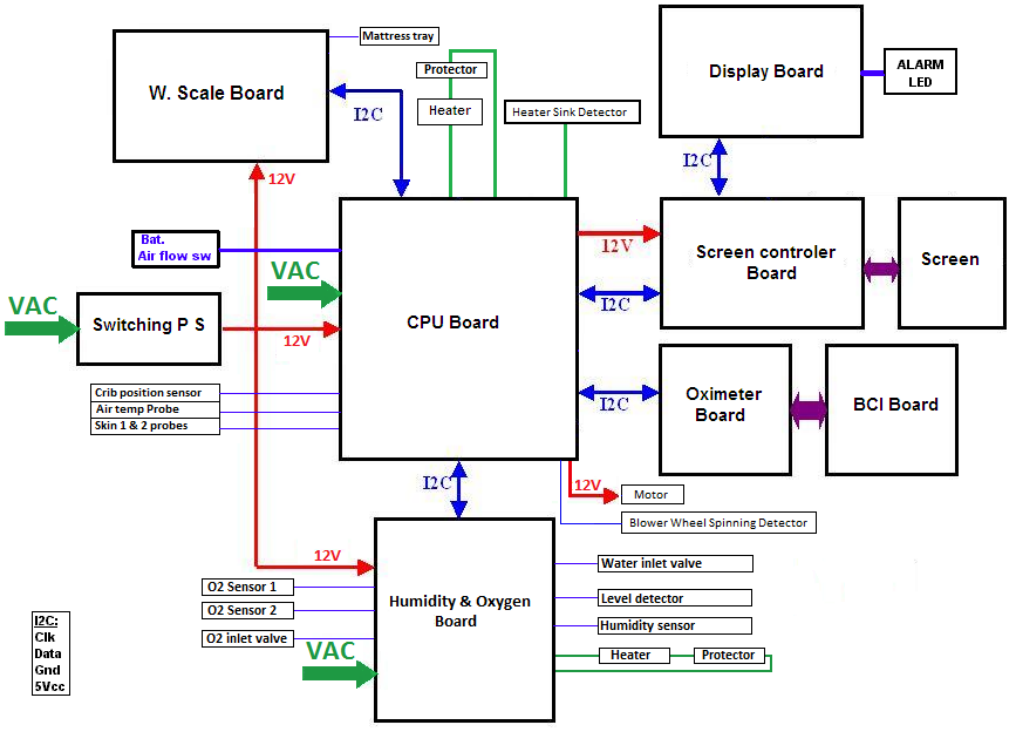
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Table 206 (IEC60601-1-2-:2004)

3. FUNCTIONING DESCRIPTION

The NATAL CARE neonatal intensive care incubator BASE version consists of three modules with i2c communication: Control Module, Screen Module, and 7 segments, keyboard and Display Module.
The **Control Module** manages the general control of the incubator, including the heater power control and the PID control (proportional, integrating and derivative), the power on and power off functions of the incubator, the thermistors, the audio of the different alarms, the bassinet movement and the engine.
The **Screen Module** manages the graphical screen and the optical encoder.
The **7 segment display module** manages the displays of 7 segments and keys.



3.1 Control module

This is the main control circuit of the incubator, which senses and controls the temperature, the alarms audio, power on and power off functions, the independent protection and control circuit and the bassinet movement.
This module is divided into areas based on their functionality. Each area has its own components which are identified in the PCB screen printing by their numbering:

Power source	X500
MCU (microcontroller)	X600
Power control	X700
Independent circuit	X800
Audio	X900
Temperature Measurement	X1000
Thermistors and EMI filter	

Regarding communication among modules and smart sensors, the **i^2c** standard is used. This solves the interconnection of different integrated elements very effectively with a simple two-way bus.

It consists of 2 wires, the data series (SDA) and the Clock series (SCL), and carries information between the devices connected to the Bus. Each device is recognized by a single address (microcontroller, LCD driver, memory interphase, etc.) and can operate both as a transmissor or receiver, depending on the function of the device.

3.1.1 Power source

A power on and power off system is used through a membrane key on the board with 7 segments and keys. This is due to the need to save all incubator parameters in operation, including all trend charts. In this system, the control microcontroller is never turned off, even in case of a power cut. If a user intends to completely turn off the incubator, the user must press the on/off key for 2 seconds and then cut the power (unplug), which disables the power supply, including the battery.
The circuit is powered by an external 12 V DC external source. This is regulated by the 5 V and 3 A switching source for all the digital circuits of the incubator. The switching source has an additional inlet for the back-up battery. As long as the 12 V of the power line are received, the battery current will not circulate. In turn, the battery is being charged by a C/16 mA continuous current source. The source continuously indicates the microcontroller if it is being powered normally or through the battery.

3.1.2 MCU (Microcontroller)

The microcontroller is the core of this board. It is an **ATMEL, Atmega 64,** 8-bit, AVR microcontroller with an RISC architecture and 128 Kb programmable flash memory, 4 Kb of EEPROM, 4 Kb of SRAM.

The general data and code are saved in the internal flash memory of the microcontroller, while the EEPROM saves some of the reference values.
The control board uses the internal RAM memory of the 128 ATmega. The 4 timers of the micro are used. It has an 8-bit timer for the heater control PWM, a 16-bit timer for the audio outlet generation, a 16-bit timer to capture the temperature measurement circuit frequency, and an internal timer to control time settings.
It has an RS232 serial port, a programming port and the graphical display module.
It has a 16 MHz external crystal and 4 LEDs for internal controls.

3.1.3 Power control

The power control complies with the standard for the physical separation of the power circuits (220VCA) and the control circuits (5 VCC). Therefore, all interactions are optocoupled or through a relay.
It has two circuits: one with zero-crossing thyristors for the heater power supply and another one for the relay, acting as a redundant shut-off in case of emergency.
There is an integrated TPIC01008B (H bridge) to manage the bassinet movement engine and a connector for the optical centering and movement sensors.

3.1.4 Independent circuit

The overheating circuit is an independent circuit that compares the air temperature with a reference level. When this reference level is reached, it shuts off the heater power source, overriding the microcontroller. When the equipment shows regular values again, the microcontroller resumes control. It has a self-calibration system that calibrates the independent circuit at 37.8 ºC (100.04 ºF) in regular mode and at 39.8 ºC (103.64 ºF) in extended range.
The shut-off threshold can be adjusted automatically through an electronic potentiometer regulated by the microcontroller. A logic was designed for the relay to cut-off after the thyristors and to get activated before them every time, to prevent excessive sparks.

An audio frequency is generated for the circuit failure alarm (external watchdog), since in that case the micro would not be able to control audio outlet.
There are two safety mechanisms. First, a microcontroller internal watchdog system that continuously verifies the normal software flow. Second, a system made up of a circuit that is independent from the microcontroller for the watchdog function, which acts when the system cannot recover.

3.1.5 Temperature measurement

Temperature is measured with a voltage to frequency converter to increase sensitivity.
One of the most important requirements is electrical isolation between the patient sensor (thermistor) and the measurement circuit in case of a possible leakage current. To meet this requirement, the whole thermistor circuit operates with a totally floating power supply, and the uC interphase is optocoupled. A specially designed DC-DC converter is used to achieve the galvanic isolation of the power source.
Temperature is measured with two multiplexers, by alternatively circulating a constant current through the 10 K and 5 K pattern resistances and the different thermistors.

3.1.6 Audio

This module uses an audio amplifier, TPA701, and a digital potentiometer to regulate alarm module through the microcontroller.
It has 2 inlets, a regular one and another one for the independent circuit in case of circuit failure.

3.1.7 Thermistors

The thermistors are placed at a certain physical distance from the control module and they are linked with a copper wire. This means that possible electromagnetic interferences (EMI) must be considered, because this long wire acts as an antenna with certain frequency emissions, generating a noise that causes unacceptable dispersion and error in measurement. A set of special coils and capacitors where used to correct this, acting over the possible regular and differential mode EMI.

3.2 Screen module

This board is basically in charge of the graphical display and the user interphase. It consists of a microcontroller and a graphical display controller.
This PCB is divided into areas based on their functionality. Each area has its own components which are identified in the screen printing by their numbering:

MCU (Microcontroller)	X200
LCD	X300

3.2.1 Microcontroller

This PCB contains an **ATMEL Atmega 128** microcontroller, and the additional 32 Kb external RAM. Its main function is to handle the LCD graphical display and intercommunication with users.
It also contains a display controller.

3.2.2 Graphical display controller

The display controller used is RAIO RA8835AP3N, which stores text data, character codes and graphs in bit maps in an external memory buffer. Its functions include transferring data from the control microprocessor to the memory buffer, reading memory data, converting data to display

pixels and generating time signals for the LCD panel memory buffer. It also has an internal character generator with 160 5 x 7 pixel characters in an internal ROM.

3.3 Keyboard and 7 segment display module

This board contains the 7 segments that are located beside the graphical display screen. It controls 14 high luminosity SC08-11 and SC39-11 displays and it reads the keys pressed on the keyboard. This module communicates with the control module through i2c.

3.4 Technical service screen

With the incubator off, connected to mains and with its thermal breaker on, verify the green LED on the ON/OFF key is lit on.

Press the key 

for 5 seconds. While you keep pressing this key, press the key labeled 
A beep will be heard and you will be directed to the Technical Service Screen.

	On the air temperature display the control software version will be shown. The screen shows internal software information, reserved to the manufacturer.  Scale calibration  Exit Technical Service Screen

3.5 Error codes

ERR001 Reference resistor error 25.0°C/77ºF (10K) out of nominal value.
ERR002 Reference resistor error 41.6°C/107ºF (5K) out of nominal value.
ERR003 Flash checking error.
ERR004 Ram checking error.
ERR005 Keyboard error.
ERR006 Reference resistor error 25.0°C/77ºF (10K) (short circuit).
ERR007 Reference resistor error 25.0°C/77ºF (10K) (open).
ERR008 Reference resistor error 41.6°C/107ºF (5K) (short circuit).
ERR009 Reference resistor error 41.6°C/107ºF (5K) (open).
ERR010 Digits front board error.
ERR011 Screen board error.
ERR012 Calibration error.

When the equipment is powered on, it performs a self-check function where it verifies the keyboard condition. If there is any key with a shortcut, an error message will appear on the 7 segment display to show error 5 and 5 bip sounds will be produced. Then, it will be turned on regularly, but any key with a shortcut will be disabled.
The other error messages arise from a continuous self-check, based on the following characteristics:

7 segment board error: no error message is shown, but 10 bip sounds are produced.

LCD module error: the 11 error message is shown on the 7 segment display and 11 bip sounds are produced.

4. PREVENTIVE MAINTENANCE

4.1 Technical service functional check procedure

It is suggested to make the following check at least once a year or after any equipment repair:

Overtemperature alarm adjustment

With the incubator off, connected to mains, and with its thermal breaker on, press  for 3 seconds and then simultaneously press  until an alarm beep sound is heard.
The incubator will enter the overtemperature alarm adjustment automatic mode.
In the Skin control display, under “CAL” verify there is a number ranged between 5 and 95. If this value is out of the mentioned range, proceed to perform the overtemperature alarm adjustment described in section 5.6.

Heater radiator lack alarm
Turn off the incubator and take out the mattress tray, lower tray and spiral cover assy to access the heater.
Take out the heater radiator and turn on the incubator. Verify the corresponding alarm activates immediately. Place the heater radiator in its place.

Air flow
With the incubator off, take out the fan wheel.
Turn on the device and verify that within 30 seconds, the air flow alarm activates.

Energy failure alarm and memory in energy failure
With the equipment functioning in skin mode, turn off the thermal breaker and verify the energy failure alarm activates (visual and audible alarm).
Turn on the thermal breaker and verify that the control temperature and functioning mode were maintained in their previously selected values.

Keyboard and alarm test
Press ALARM TEST and verify all LEDs turn on, the general alarm indicator flashes and an audible alarm sounds.

Tilting mechanism
Press the corresponding key and move the bassinet to one side. Then proceed to autocentrate it.
Move it to the other side and then press the autocentering key.

Environmental temperature, alarms volume and clock
Enter the T2 screen and verify the environmental temperature is displayed.
Enter the configuration screen and modify the alarm’s volume. Verify it by pressing the ALARM TEST key.

Enter the configuration screen and change the date and time. Turn off completely the incubator (including the thermal breaker). Wait 1 minute and then turn it on. Verify the date and time was maintained.

Accessories:

Check the optional lift functioning by increasing and decreasing the incubator's height.

Perform oxygen 21% calibration.

40% Oxygen concentration
Set the oxygen concentration in 40%.
Once the system is stable, verify the measured oxygen concentration is ranged between 38 and 42%

Weighing scale
Using a known weight, verify the scale weighs ± 5gr/0.18oz.
If the measured weight is not within this range, calibrate the weighing scale as described in section 5.13.3 and repeat the procedure making sure the mattress tray is properly placed (not touching the doors or double wall).

Humidity system
Set the incubator in 36.0ºC / 96.8°F functioning in air mode.
Connect the water supply.
Turn on the system and set the humidity in 80%.
After two hours, once the system is stable, verify the measured humidity is ranged between 77% and 83%.

4.2 Preventive maintenance plan

PARTS	When necessary	Between Patients	Daily	Every 3(three) months	Every 6 months	Once a year	Every 2(two) years	Required Personnel	Observations
Air filter				X				N	User Manual Chap.4
IV ports / gaskets	X							N	Replace if material becomes brittle
Iris port sleeves		X						N	Disposable
Port sleeves		X						N	Disposable
Reusable skin temperature probe	X							N	User Manual Chap.6 (6.1) User Manual Chap.7 (7.4)
Mattress	X							N	User Manual Chap.7 (7.2.2)
Humidity hose							X	N	User Manual Chap.7 (7.3)
Battery pack							X	BT	Technical Service Manual Chap. 5 (5.14)
Clock battery replacement							X	BT	Technical Service Manual Chap. 5 (5.13)

N: Nurse
BT: Biomedical Technician
DP: Distributor Partner

PROCEDURES	When necessary	Between Patients	Daily	Every 3(three) months	Every 6 months	Once a year	Every 2(two) years	Required Personnel	Observations
Cleaning and disinfection		X (*)						N	User Manual Chap.7
User Functional check procedure		X						N	User Manual Chap.5 (5.13)
Technical Service check procedure						X		BT	Technical Service Manual Chap.4 (4.1)
Electrical Safety						X		BT	Appendix 1
Check battery pack					X			BT	Technical Service Manual Chap. 5 (5.14.1)
Servo-humidity module									
Servo-humidity Module evaporator system cleaning						X		DP	Technical Service Manual Chap.5 (5.19.2)
O'ring replacement						X		DP	Technical Service Manual Chap. 5 (5.19.1)
Servo-humidity hose sterilization		X						N	User Manual Chap.7 (7.2)
Optional NCA-128 (water tank with cap and internal connection hose) sterilization		X						N	User Manual Chap.7 (7.2)
Servo-oxygen module									
O_2 sensor calibration			X					N	User Manual Appendix 2

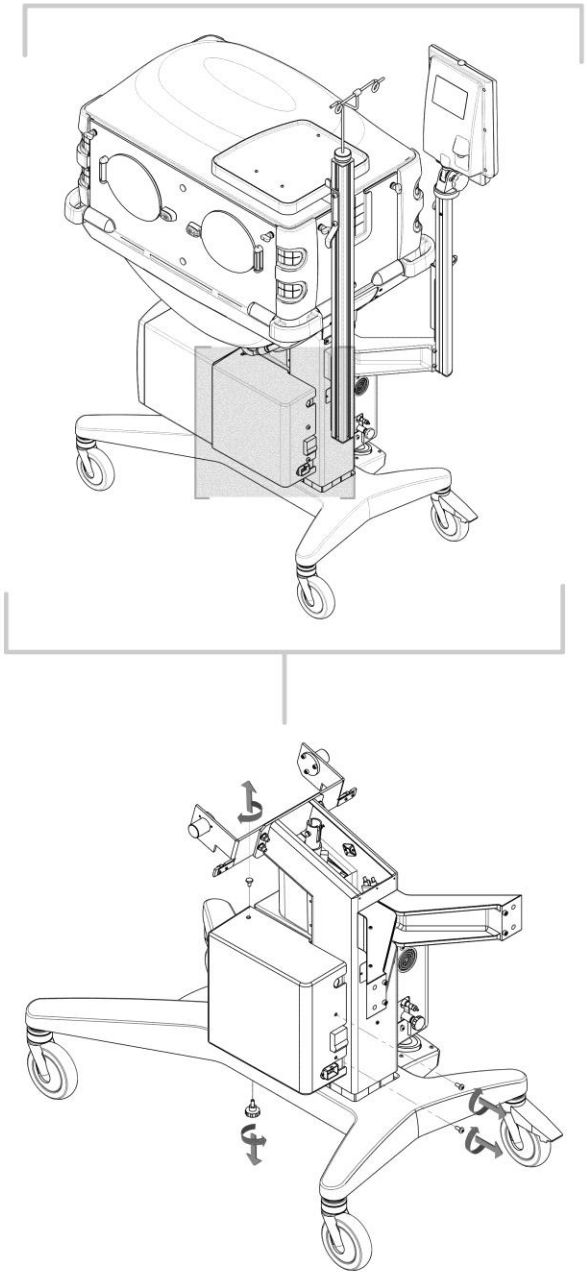
(*) According to Hospital procedure
N: Nurse
BT: Biomedical Technician
DP: Distributor Partner

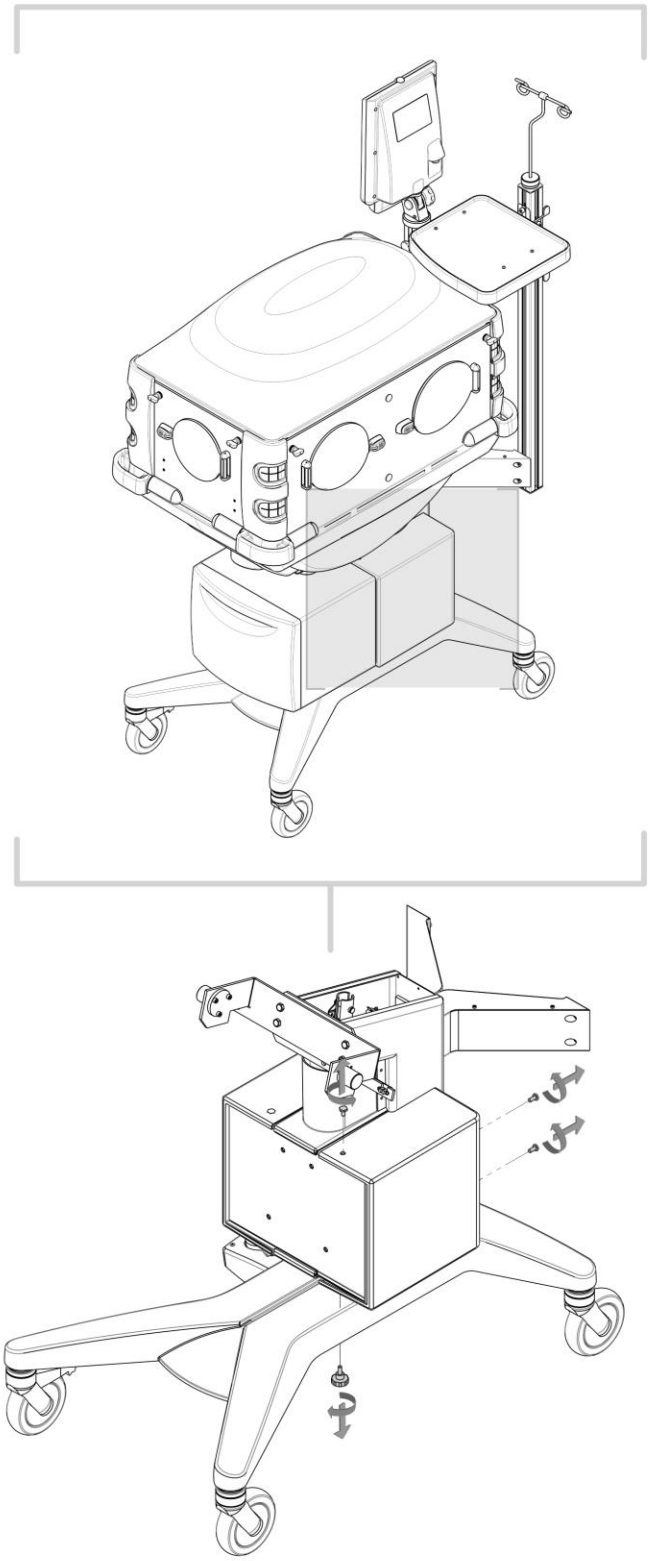
NOTE After performing the Preventive Maintenance Plan, please remember to complete the Performance and Safety Check Report that is in Appendix 2.

5. TECHNICAL SERVICE PROCEDURES

5.1 Accessing the control module

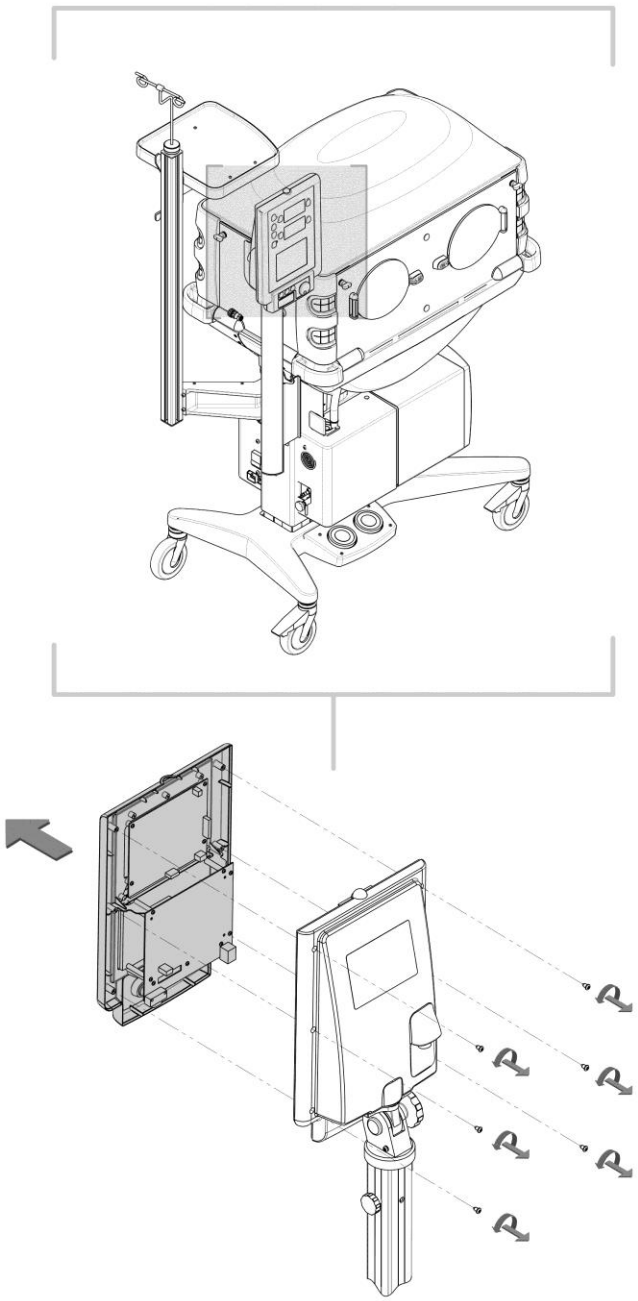
1. Turn the incubator off and disconnect it from mains.
2. Use a grounded antistatic wristband to perform technical service procedures.
3. Remove the electronic cover lid (next to the thermal breaker) taking the indicated screws away, as shown below.





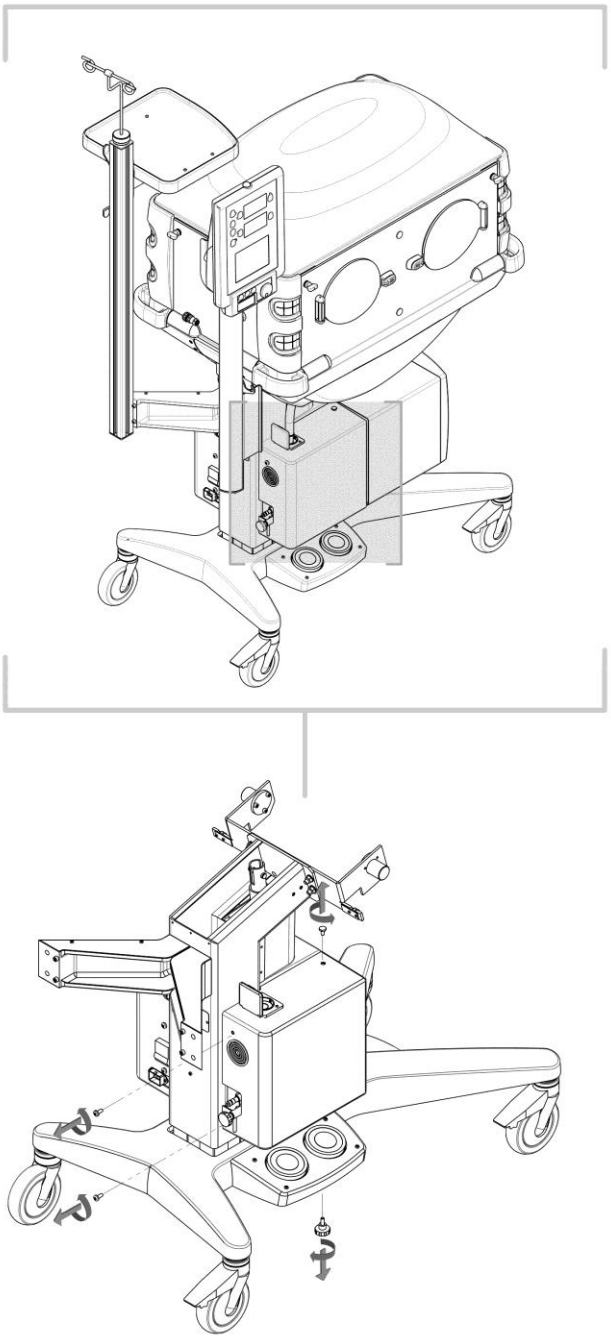
5.2 Accessing the command module

1. Turn the incubator off and disconnect it from mains
2. Use a grounded antistatic wristband to perform technical service procedures.
3. Identify the command module, remove the front panel taking the indicated screws away and disconnect all the connectors.



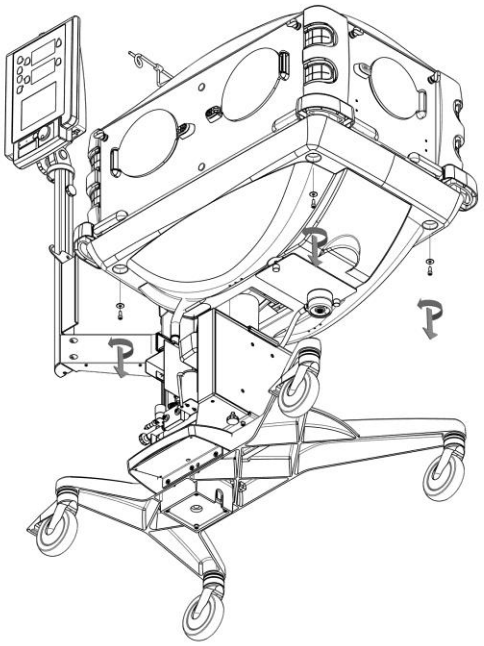
5.3 Accessing the humidity and oxygen modules

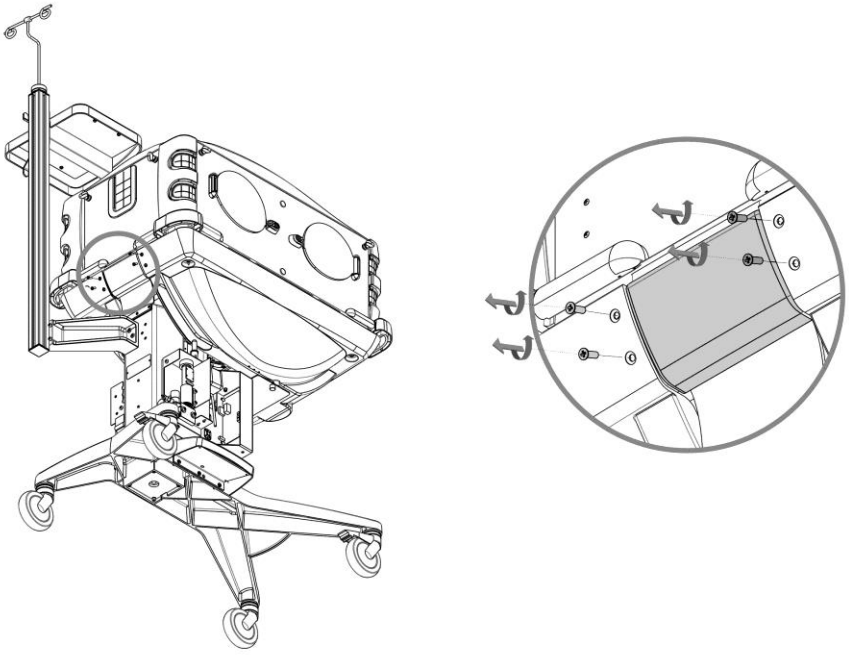
1. Turn the incubator off and disconnect it from mains.
2. Use a grounded antistatic wristband to perform technical service procedures.
3. Remove the electronic cover lid (next to the water inlet connector) desconecting the humidity hose and taking the indicated screws away.

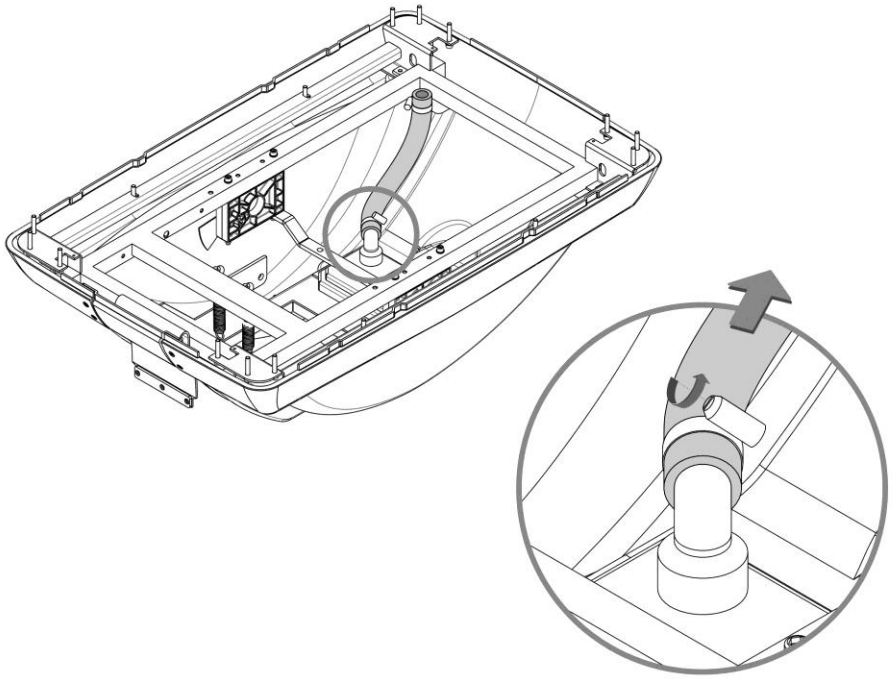


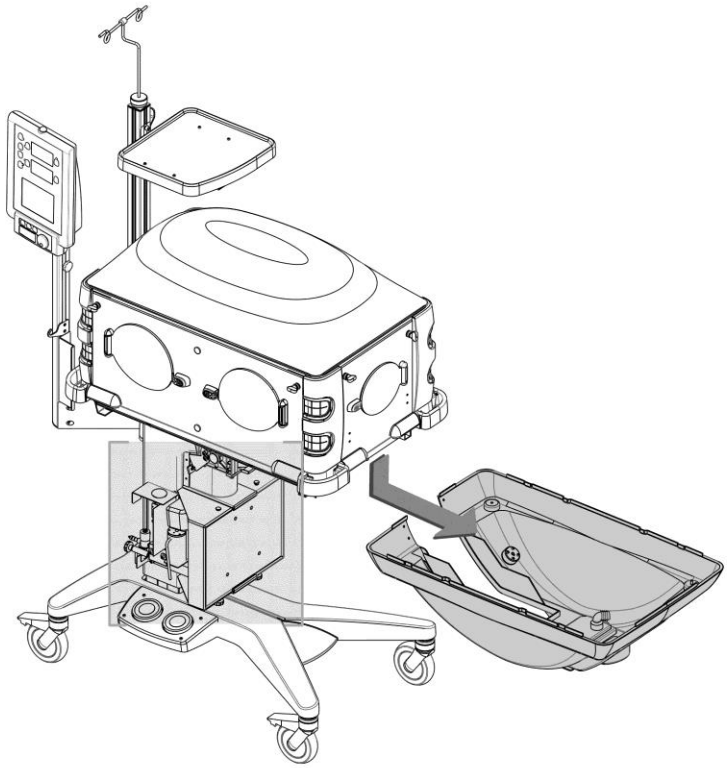
5.4 Lowering the crib base

1. Turn the incubator off and disconnect it from mains.
2. Use a grounded antistatic wristband to perform technical service procedures.
3. Remove the four Allen screws that fix the crib base to the incubator, disconnect the air filter hose and remove the crib base lock supplement (4 screws with nut).



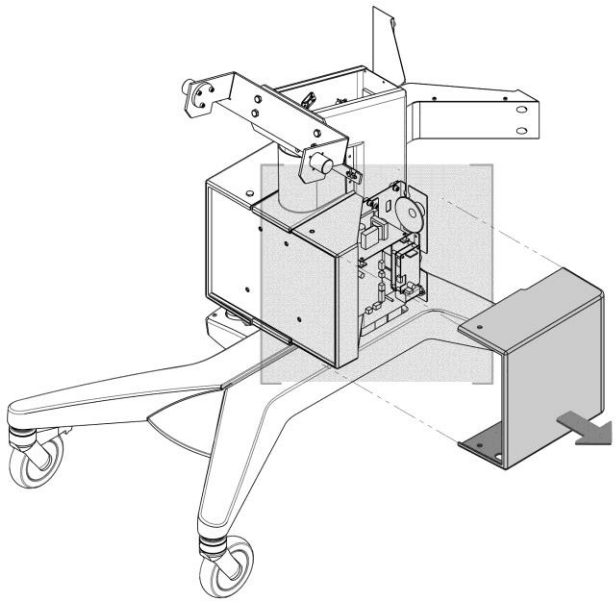


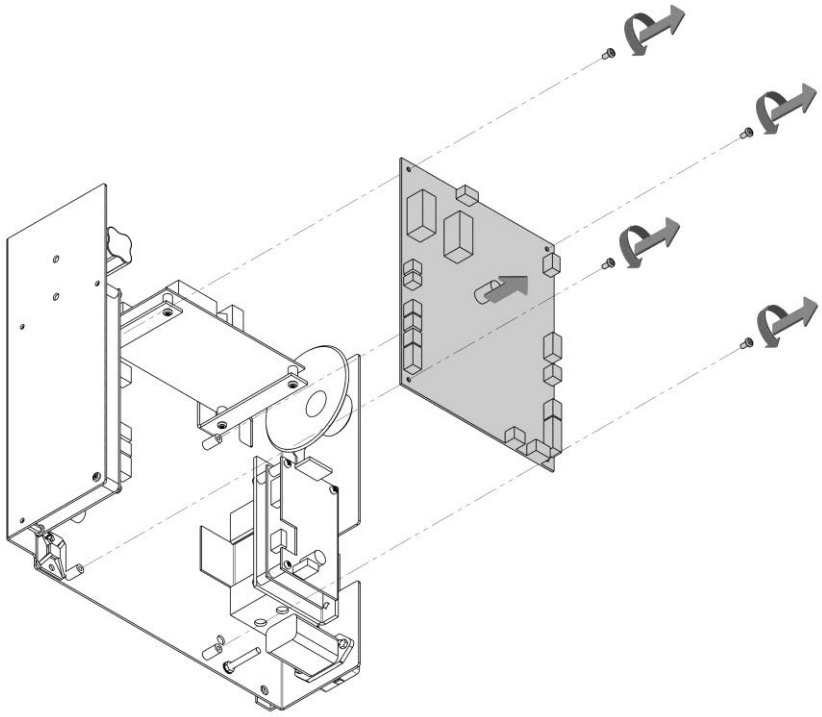




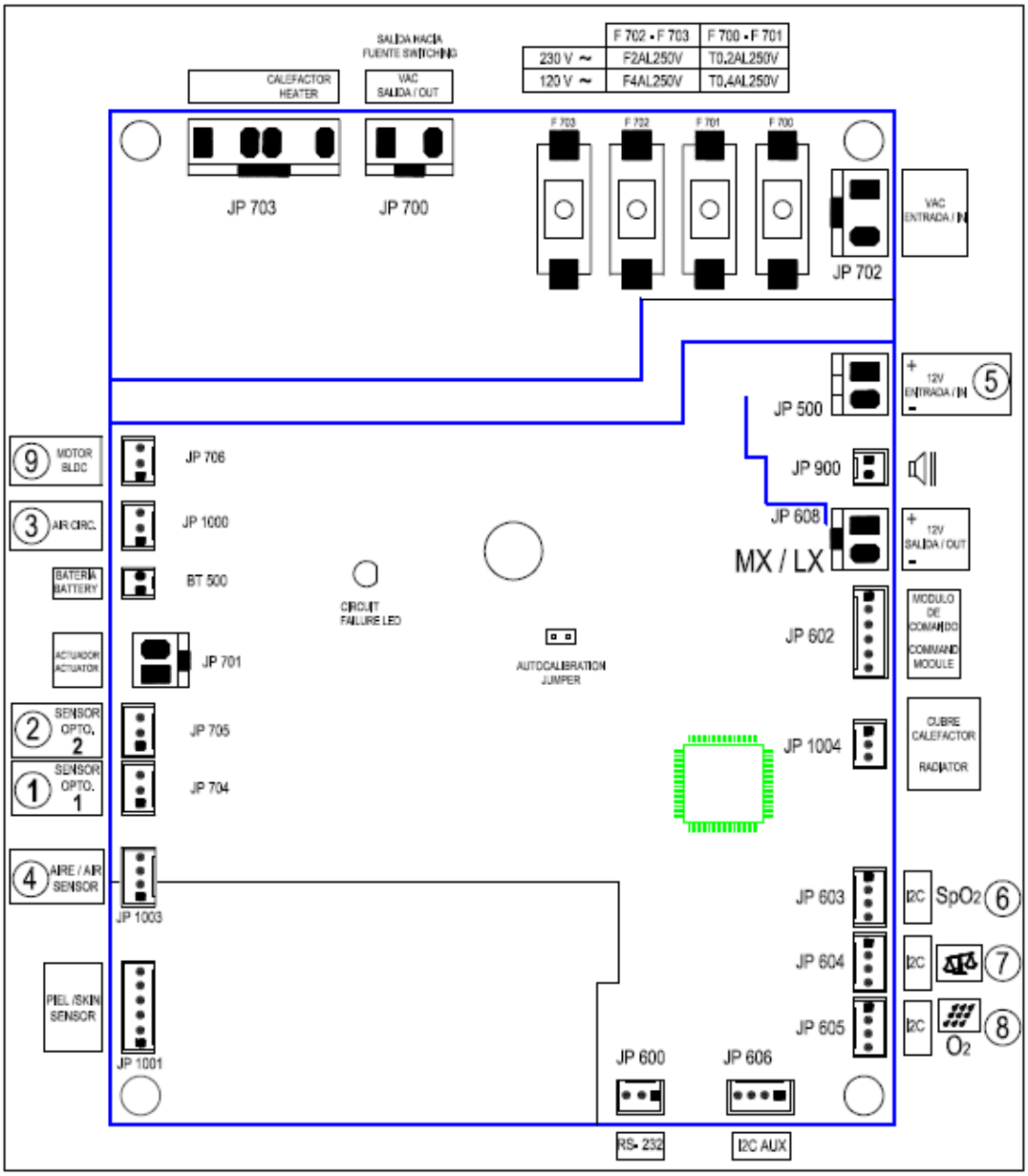
5.5 Control board replacement

1. Access the control module as described in section 5.1.
2. Identify the control board. Disconnect all the connectors and unscrew the four screws to remove the board.





3. Replace the control board by the new one. Fix it again with the four fixing screws. Reconnect all the connectors as indicated in the following image.



5.6 39 ºC alarm autocalibration

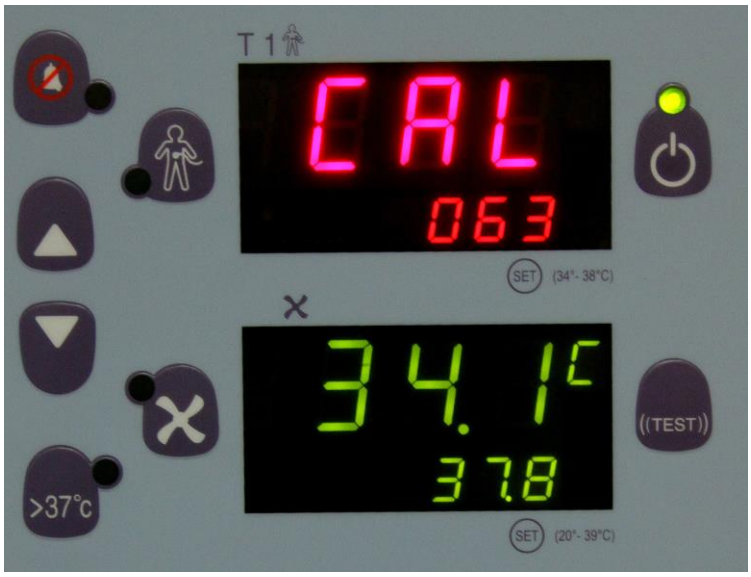
This adjustment will be made automatically by software.
With the incubator connected to mains, but with its thermal breaker down, a jumper must be placed in the “W800” position on the control board.

NOTE: A grounded antistatic wristband connected to earth must be used.

Turn on the thermal breaker and press the silencing key for 3 seconds and then simultaneously press the air mode key until an alarm beep sound is heard.

The incubator will enter an automatic mode in which the Overtemperature alarm will be adjusted both in override range and not override range.

Once this process is finished, the electronic potentiometer value will be shown in the skin temperature control display. The temperature value at which the alarm will activate in not override range will be shown in the air temperature display.

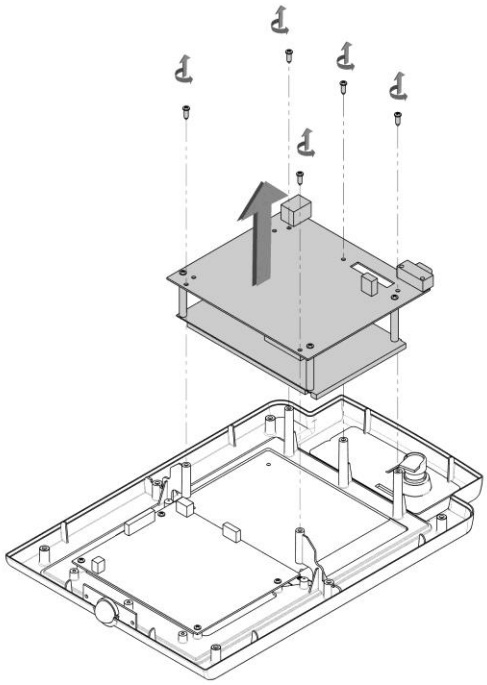


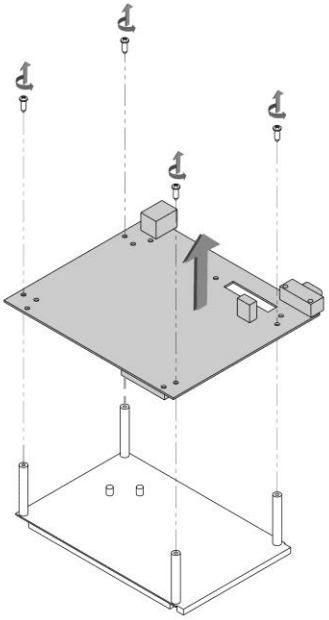
The electronic potentiometer value (Skin control display) should be ranged between 5 and 95. If this value is out of the mentioned range, the incubator’s control board must be replaced (as described in section 5.5).
The overtemperature alarm value must be ranged between 37.6 ºC and 37.8ºC (98.6 ºF and 100.0 ºF).

IMPORTANT: Remove the jumper from the control board.

5.7 Screen board replacement

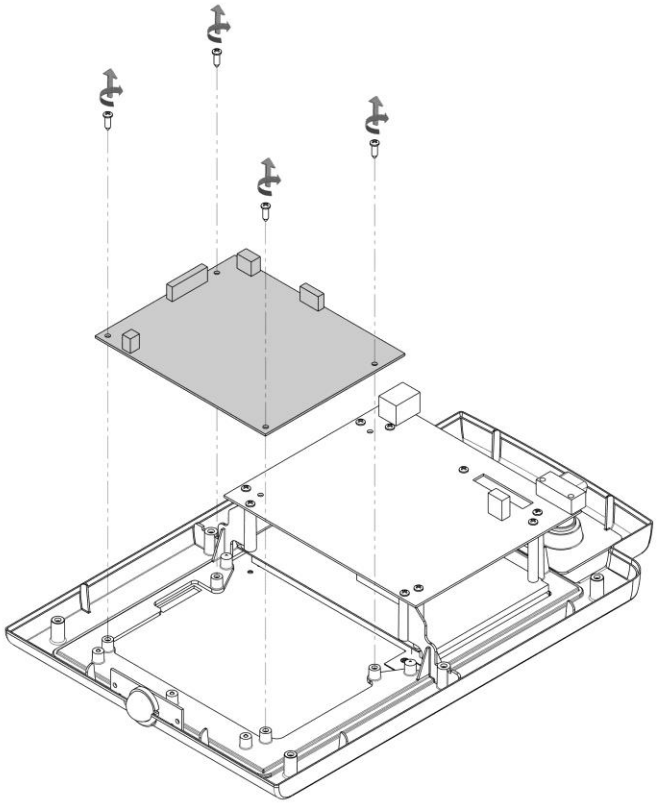
Access the command module as described in section 5.2.
Identify the Screen Board. Disconnect all the connectors. Unscrew the four screws to remove the board and the LCD Screen set and then unscrews the four screws to remove the Screen Board.
Replace the Screen Board by the new one. Fix it again with the four fixing screws to the LCD Screen and then fix the set to the front cover with the four screws. Reconnect all the connectors and reassemble the command module.





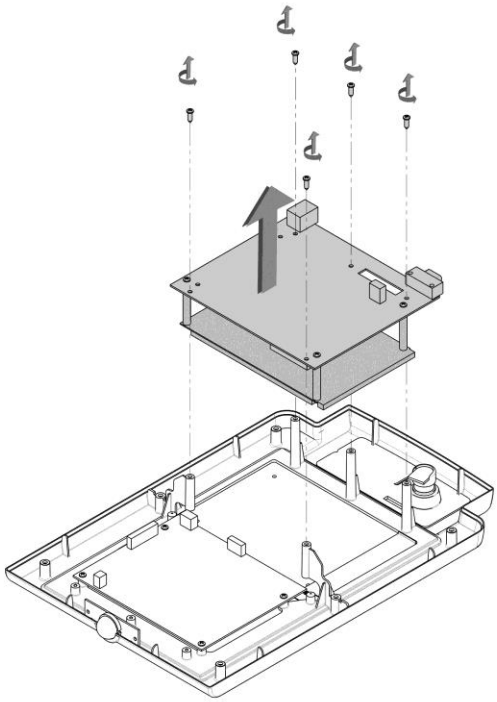
5.8 Display board replacement

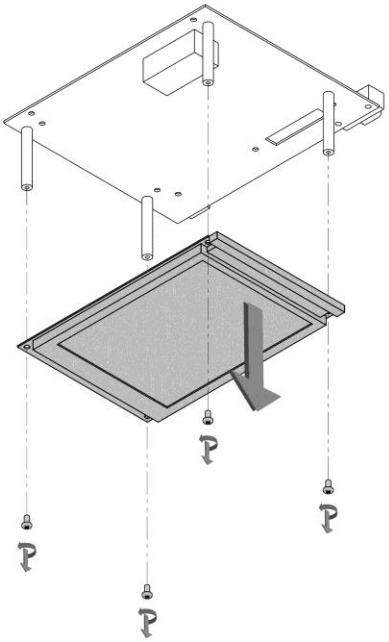
Access the command module as described in section 5.2.
Identify the Display Board. Disconnect all the connectors and unscrew the four screws to remove the Display board.
Replace the Display Board by the new one and fix it again with the four fixing screws to the front cover. Reconnect all the connectors and reassemble the command module.



5.9 LCD screen replacement

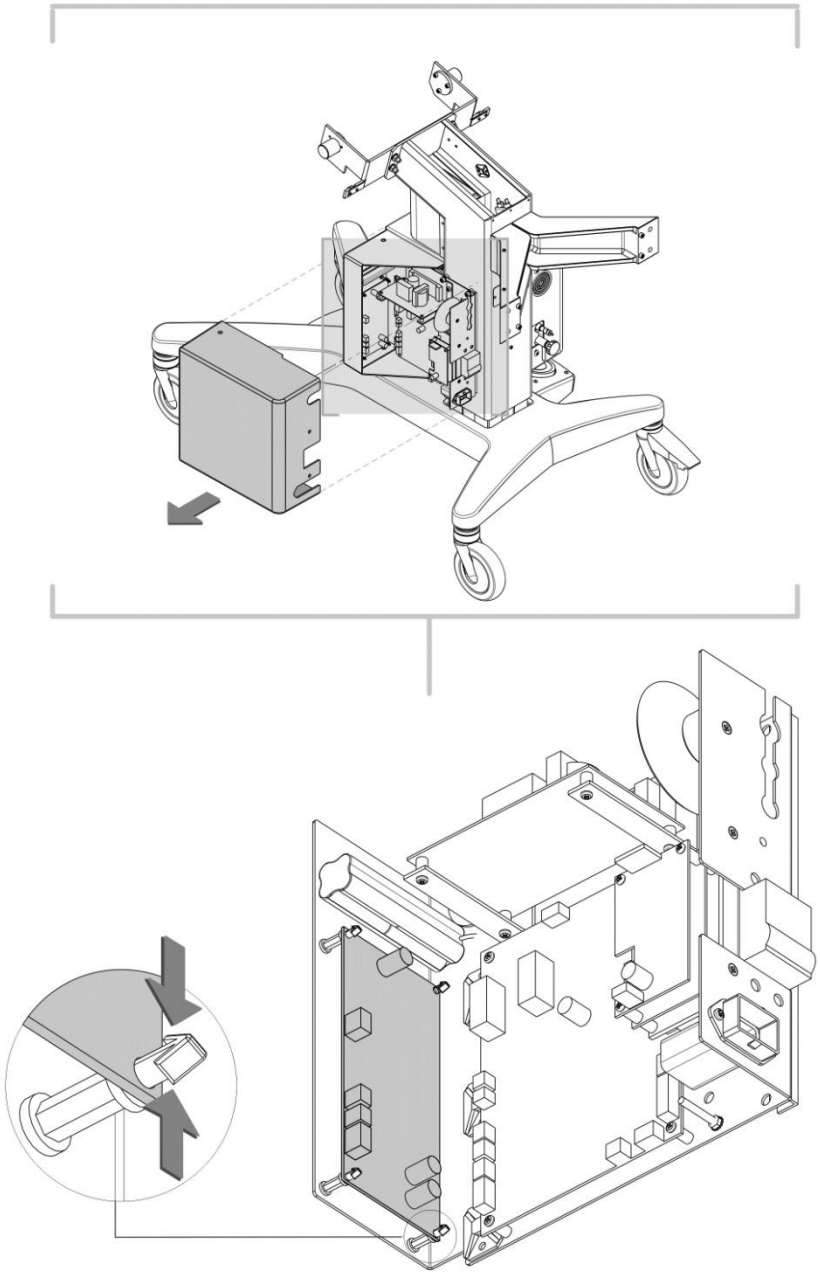
Access the command module as described in section 5.2.
Identify the LCD Screen. Disconnect all the connectors. Unscrew the four screws to remove the Screen Board and the LCD Screen set and then unscrews the four screws to remove the LCD Screen.
Replace the LCD Screen by the new one. Fix it again with the four fixing screws to the Screen Board and then fix the set to the fron cover with the four screws. Reconnect all the connectors and reassemble the command module.





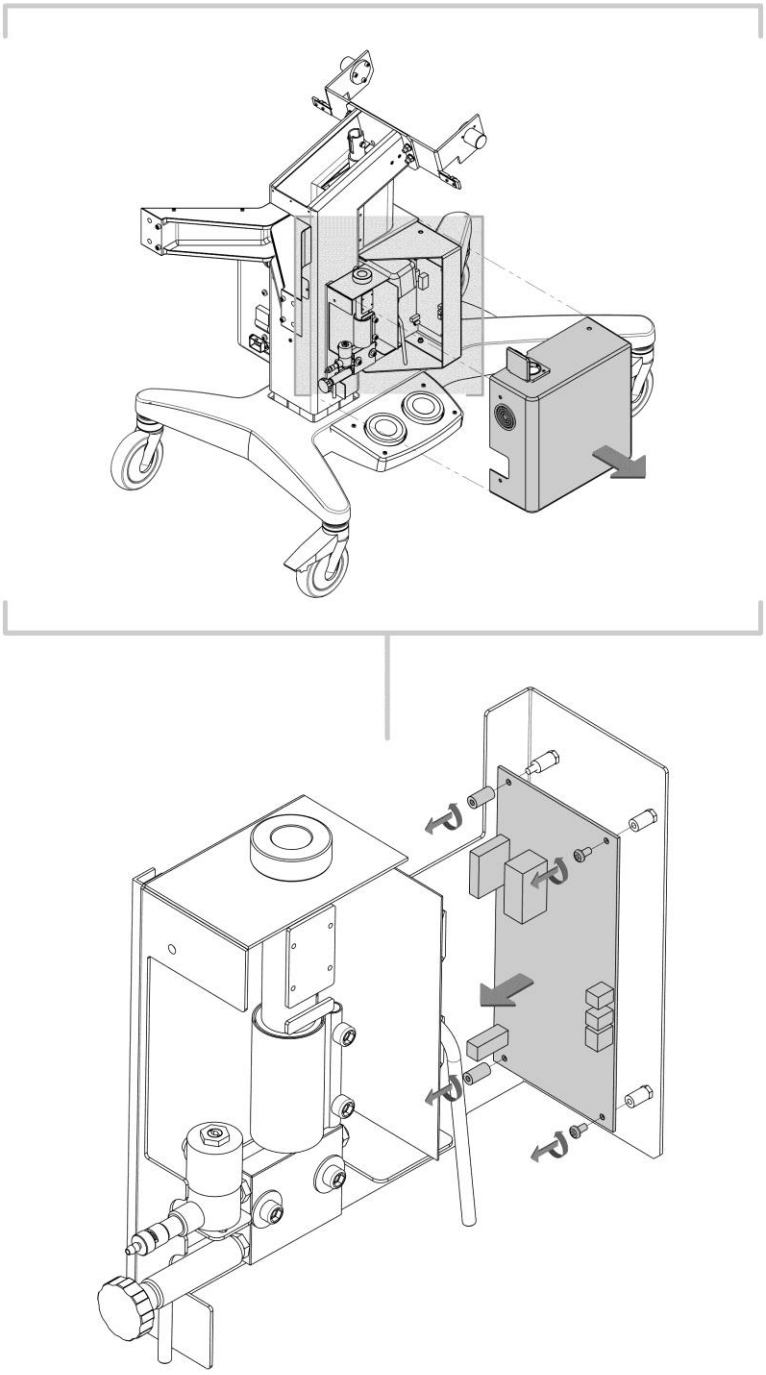
5.10 Weighing scale board replacement

Access the control module as described in section 5.1.
Identify the Weighing Scale Board. Disconnect all the connectors and release the four locks to remove the board.
Replace the Weighing Scale Board by the new one and fix it again engaging the locks. Reconnect all the connectors and reassemble the control module.

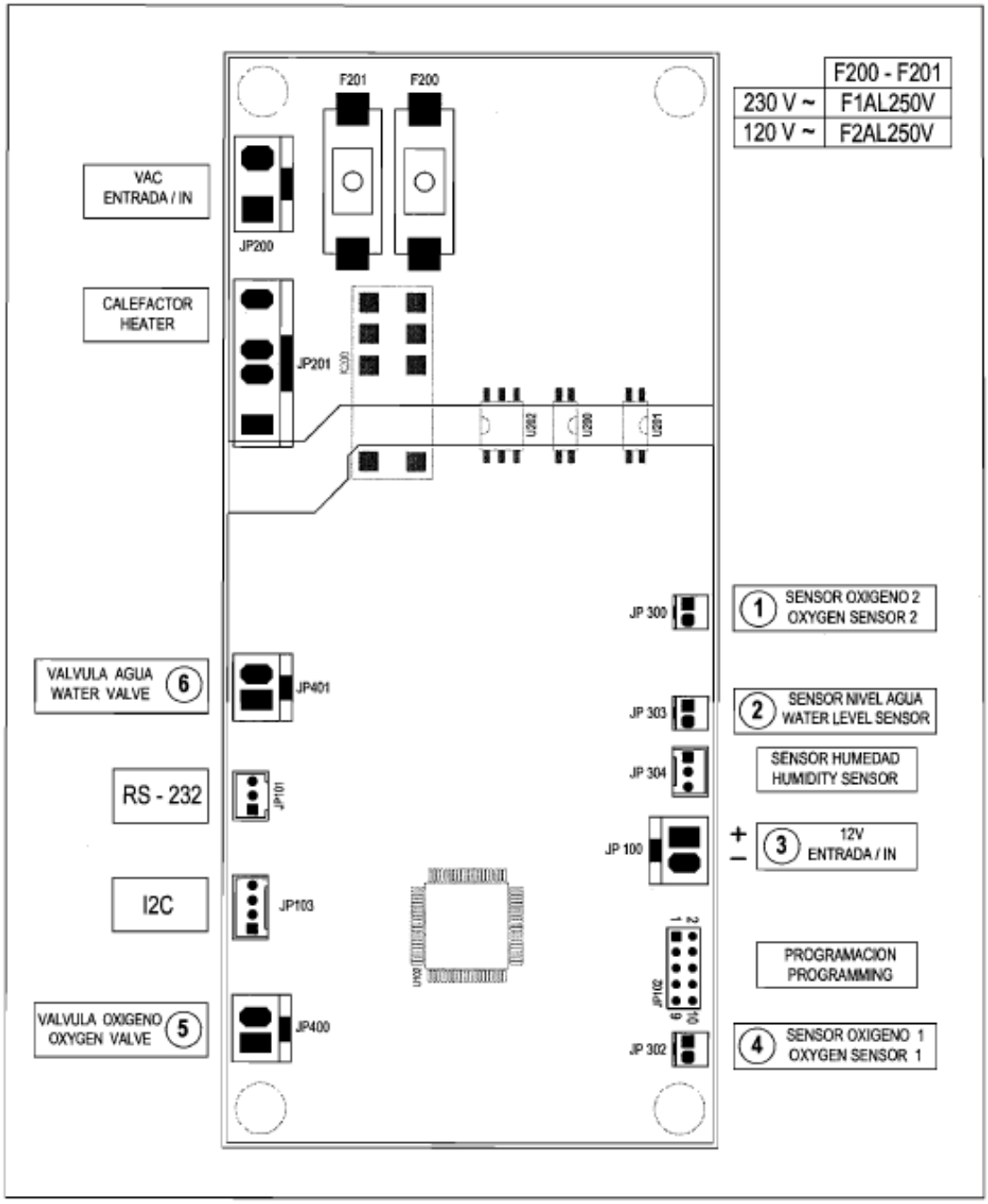


5.11 Humidity and oxygen board replacement

Access the humidity and oxygen modules as described in section 5.3
Identify the Humidity and Oxygen Board. Disconnect all the connectors and unscrew the four screws to remove the board.
Replace the Humidity and Oxygen Board by the new one and fix it again with the four fixing screws.

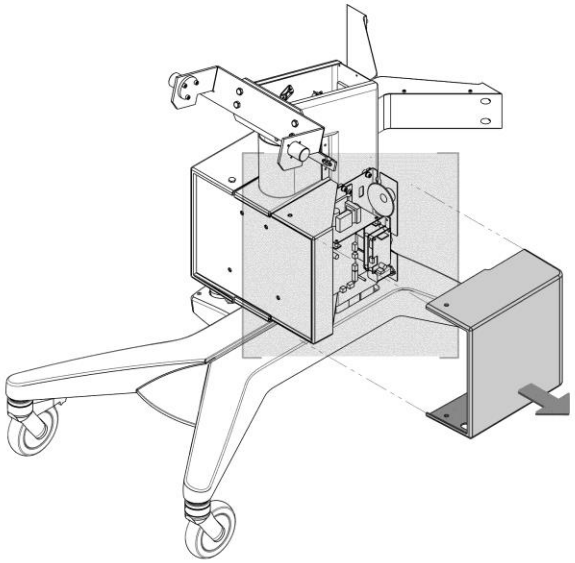


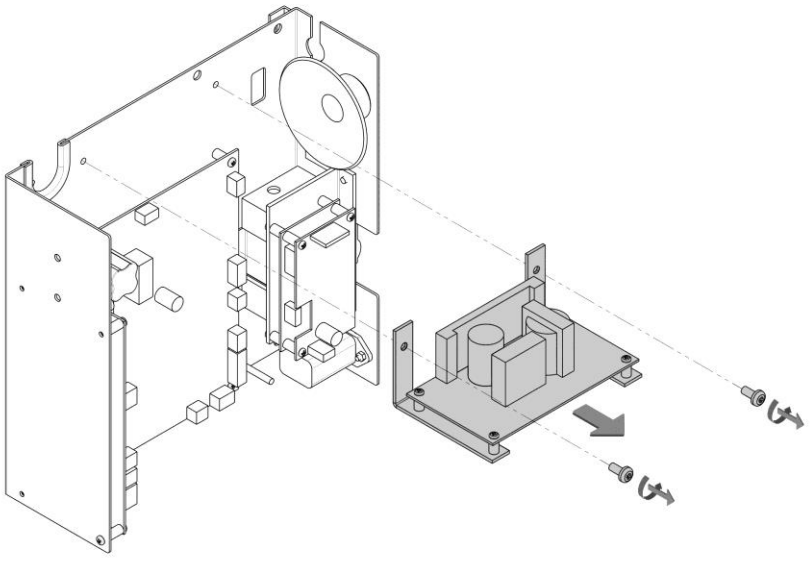
Reconnect all the connectors as indicated on the following image.



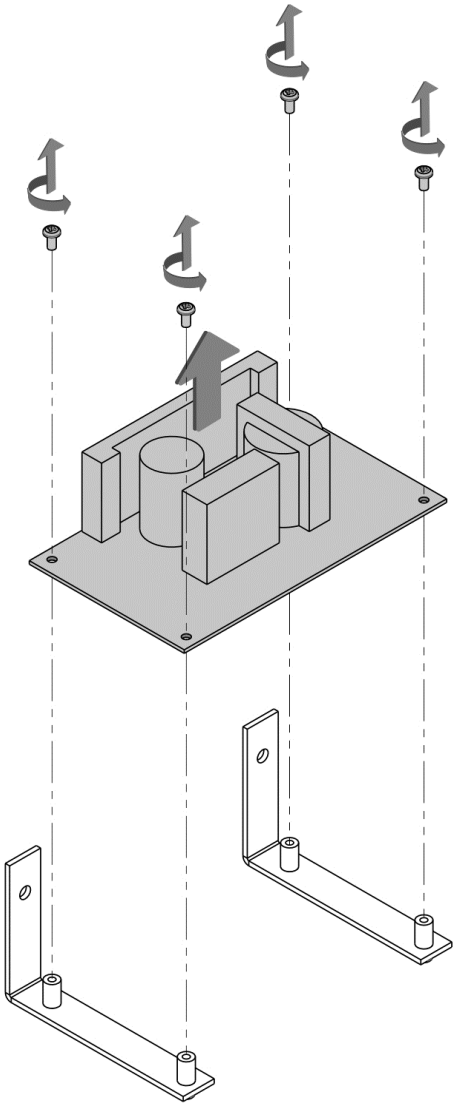
5.12 Switching power supply replacement

Access the control module as described in section 5.1.
Identify the switching power supply. Disconnect all the connectors (the 12V power supply wirings from the CN2 connector, the control source-board power supply wiring from the CN1 connector, and the SW source ground cable from the JP1 connector). Unscrew the two screws to separate the board with the fixing elements.





Unscrew the four screws to remove the board. Replace the switching power supply by the new one and reassemble the unit.



5.13 Clock battery replacement

Acces the command module as described in section 5.2.
Identify the battery holder (BT200) in the screen board and remove it.
Replace the battery by the new one (Type CR2032 with UL certification) and reassemble the unit.

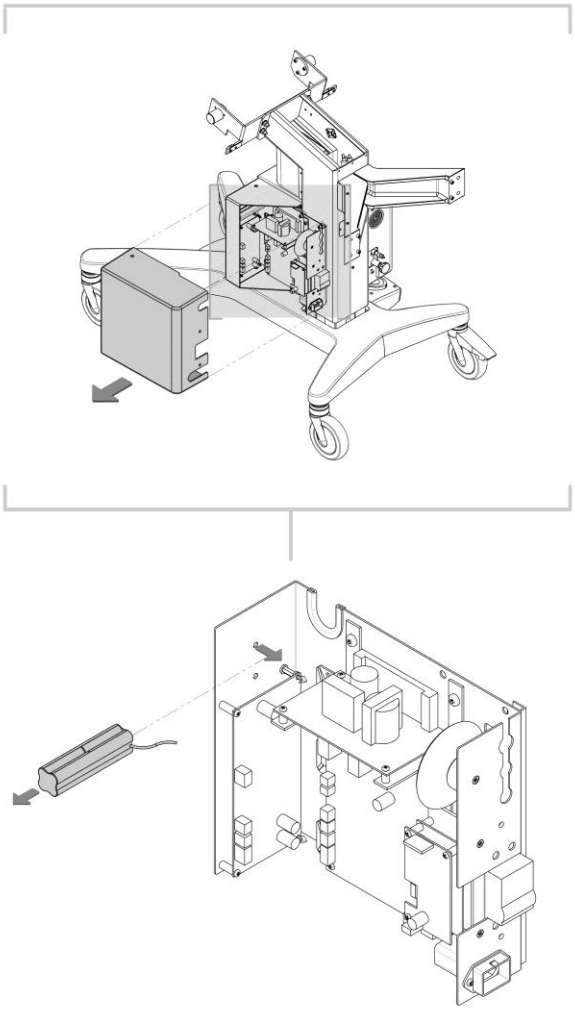
5.14 Internal battery pack

5.14.1 Check battery pack

Turn on the equipment, change the default set point of air temperature and verify the operation of the battery by turning off the thermal circuit breaker. The power supply failure alarm must turn on. Turn on the thermal circuit breaker and check that the equipment maintains the previously selected set air temperature value.
If the test does not work, leave the incubator on for about an hour to get a minimum charge on the battery pack, and repeat the test.

5.14.2 Battery pack replacement

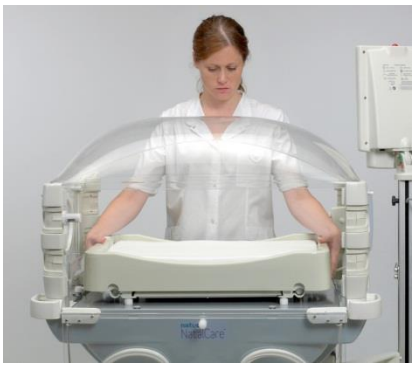
Access the control module as described in section 5.1.
Identify the battery pack.
Disconnect the battery connector (BT500) from the control board.
Cut the ties of the wiring and the battery pack.
Remove the battery pack.



Place the new battery pack, removing the double-sided tape protection to attach it to the frame.
Press firmly on the battery pack to achieve good adherence and place the ties on the wiring again.
Connect the battery pack to the BT500 connector on the control board.
Check the battery pack as described in section 5.14.1 and the proceed to reassemble the unit.

5.15 Weighing scale

5.15.1 Cells replacement

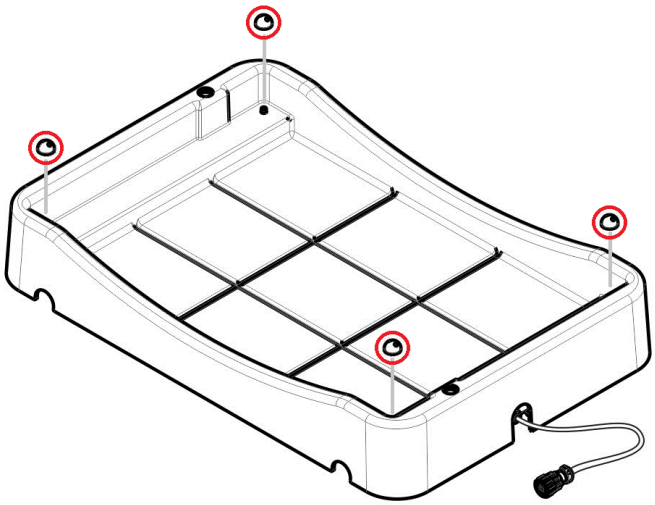


Disconnect the weighing scale cable from the sensor box.

Pull out the mattress holder from the incubator.

Note:
To take out the mattress holder, push the tray toward the back and gently lift it to unlock it from the lower tray guides.

Unscrew the four plastic nuts shown in the following figure. A needle nose pliers may help to unscrew the nuts.

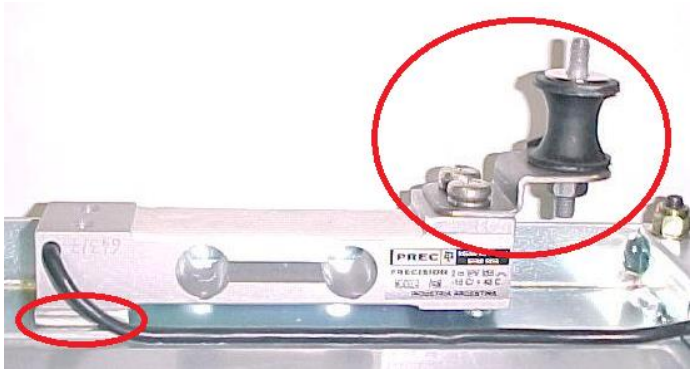


Separate the mattress holder from the weighing scale mechanism, uncovering the four cells .

Unweld the cell to be replaced from the PCB and remove the corresponding cables. If looked from below, there are two black caps covering two screws that hold the cell to the tray. Remove these two black caps and using an M6 allen wrench unscrew the corresponding screws.The cell will now be free.

Remove the two screws to separate the silent block which must be used on the new cell.

Place the silent block with its corresponding screws on the new cell.
Be carefull not to lose any of the following parts which have to be reused with the new cell.



Mount the new cell in its place following the previous steps backwards.

NOTE: Do not cut the cables until they have to be welded.

Take into account that the cell must have the 10Kg legend and its serial number upwards.

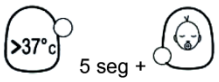
Proceed to perform the cells equalization procedure described in section 5.12.2.

5.15.2 Cells equalization

IMPORTANT: To perform this procedure, the mattress holder must be placed in a horizontal plane surface and must remain connected to the incubator. At the bottom of the mattress holder, there are four little holes aligned which must be accessible while equalizing the cells.

Pull out the mattress holder from the incubator and place it in a horizontal plane surface while still connected to the incubator. Make sure the four holes at the bottom are accessible in order to adjust the cells' potentiometers.

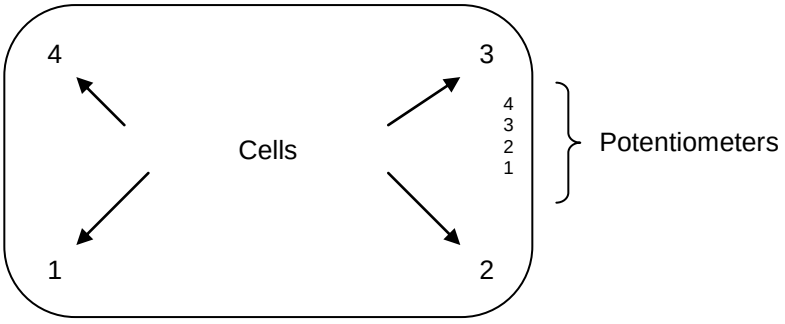
With the incubator off but with its thermal breaker on, enter the technical service screen by pressing the following combination of keys.



Once in the technical service screen, press the scale key  .

At the center of the screen there will be a number we call “counts”.

1. Turn the potentiometers to its maximum value, by turning them fully counterclockwise until a “click” sound is heared, or 25 turns are reached.



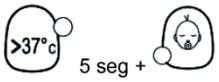
Upper view of the scale system

2. Place a 2kg known weight over one of the four cells and write down the “count” number. Place the weight in the other cells and compare the “count” values to determine the lower and higher count readings.
3. In case of having a known weight different to 2kg, select the corresponding value by pressing the  key.
4. Place the weight over the lower count cell and turn clockwise the corresponding potentiometer to read 200 counts less than the original lower value. Write down this new count value and place the weight over the other cells and adjust the potentiometers to achieve this value.
5. Continue to adjust each potentiometer until the count readings differ in less than 5 counts one of another.

Once completed the equalization a 0Kg and 2Kg calibration must be performed as described in section 5.13.3

5.15.3 Scale calibration

With the incubator off but with its thermal breaker on, enter the technical service screen by pressing the following combination of keys.



Once in the technical service screen, press the scale key  .

Take out the mattress and make sure there is nothing on the mattress tray which could alter the scale calibration.

At the center of the screen there will be a number we call “counts”.

Once the count reading is stable and ranged between 15000 and 20000, proceed to press the “0.000” key.

Place a 2kg known weight at the center of the mattress holder and wait for the “count” number to be stable. Then press the  key and wait a few seconds. Take away the weight and exit the technical service screen.

In case of having a known weight different to 2kg, select the corresponding value by pressing the  key.

5.16 Air sensor

5.16.1 Air sensor replacement

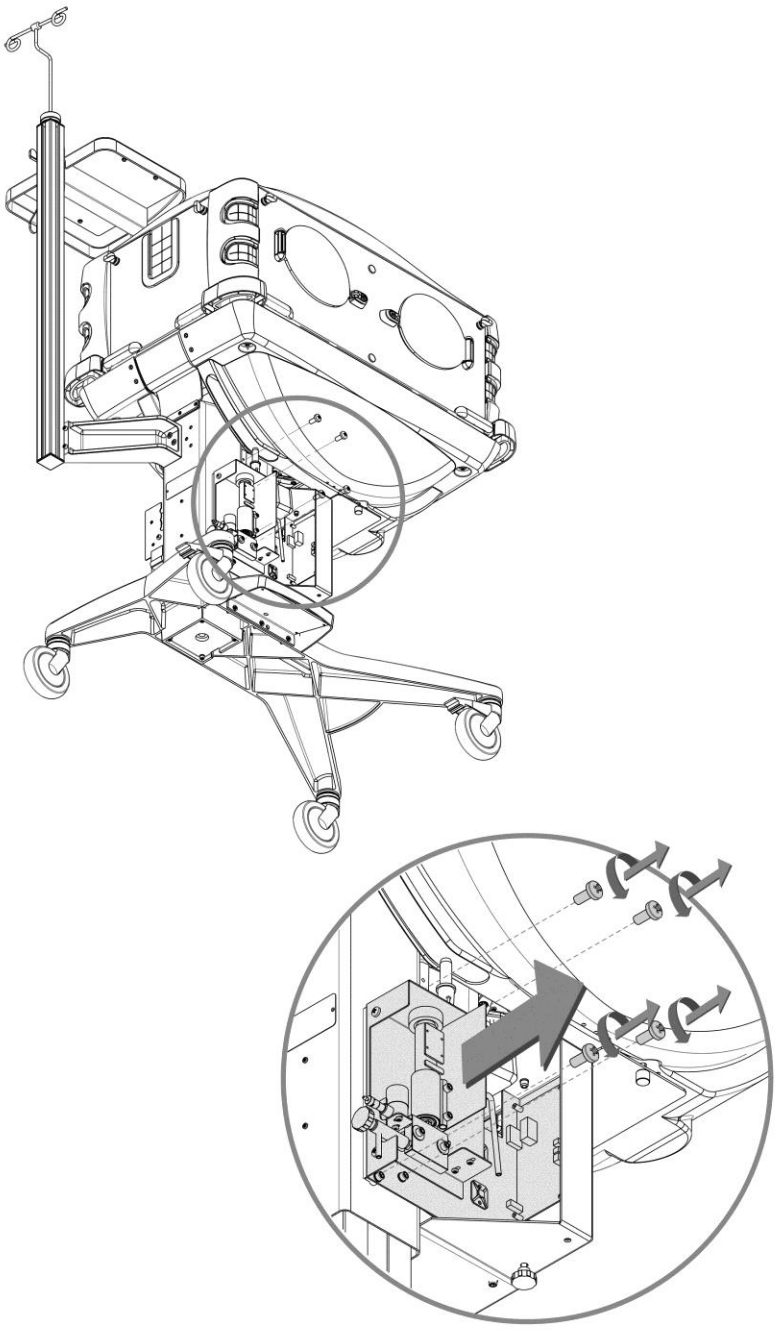
Preparing the unit

Acces the control module as described in section 5.1.

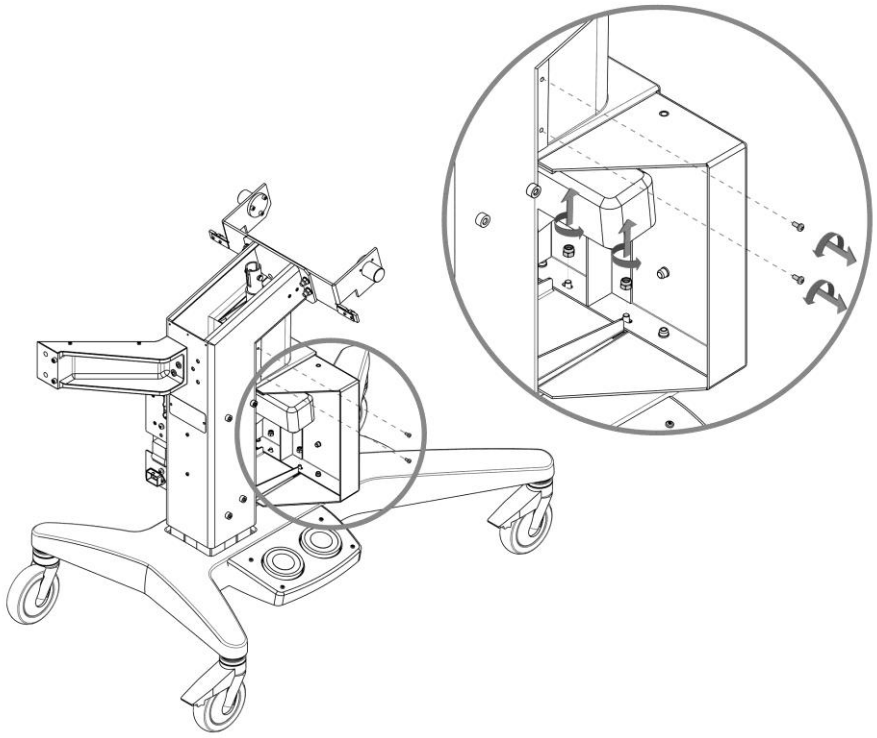
Lower the crib base as described in section 5.4.

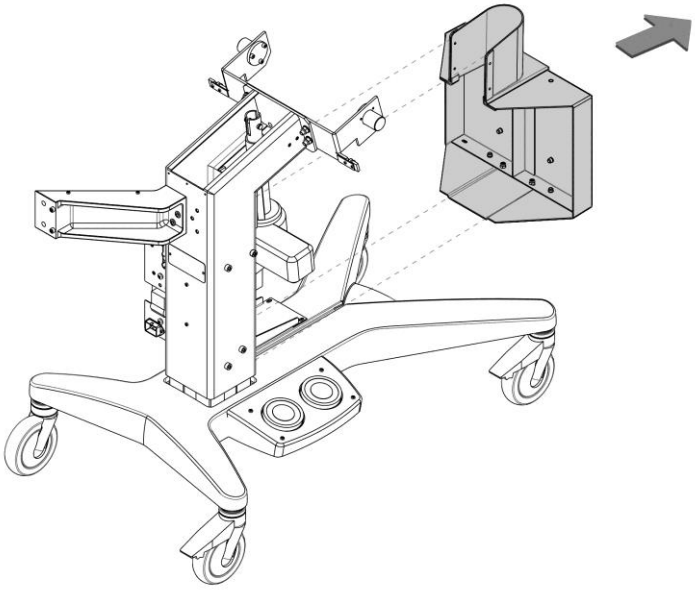
Access the humidity and oxygen modules as described in section 5.3

If the humidity and/or oxygen modules are present, disconnect all the cables and remove the complete chassis (4 allen screws must be removed).



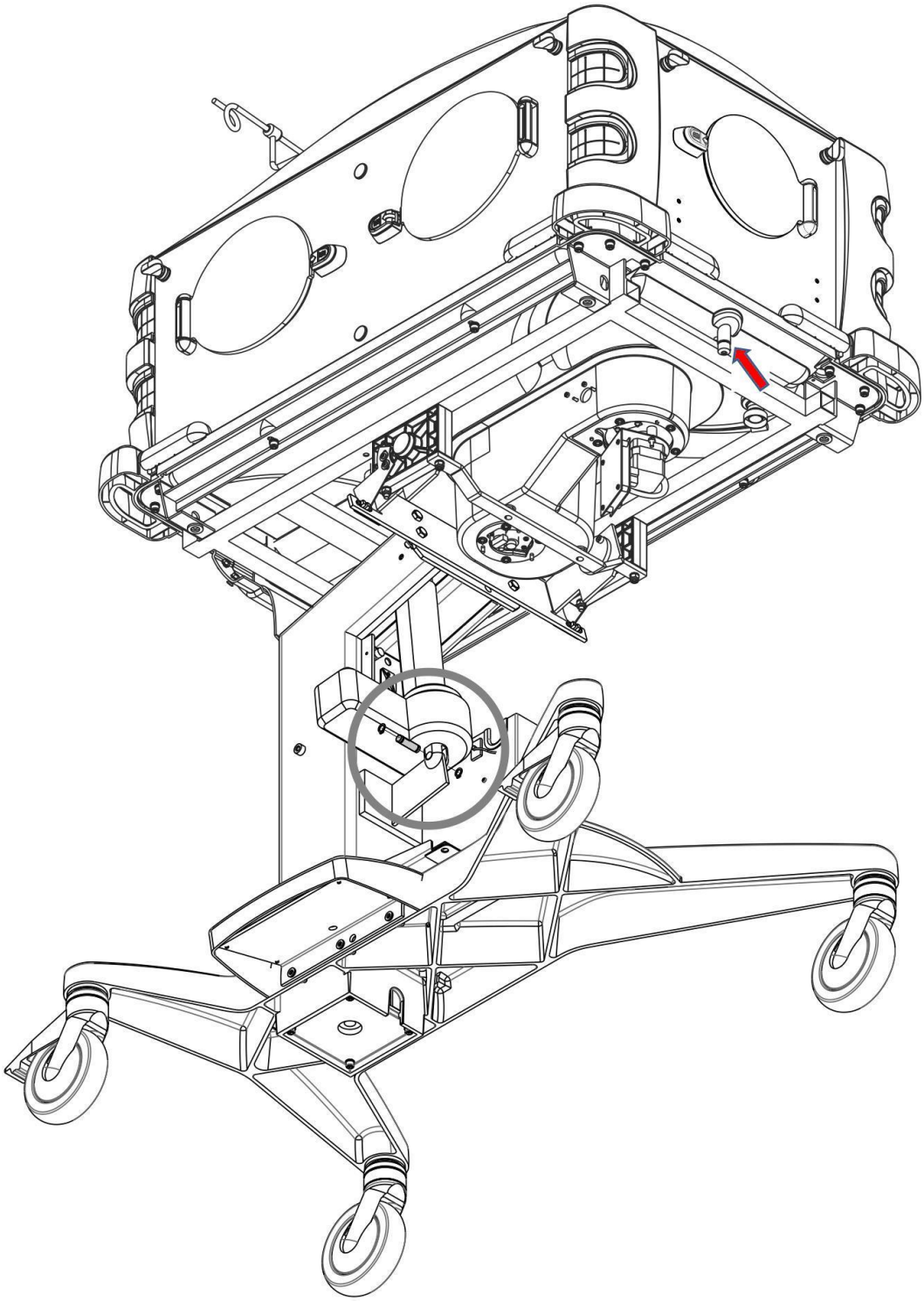
The drawer accesory must also be removed. In case it is installed, take out the drawer and remove the four screws inside it.
Remove 2 screws that hold the front lower cover and 4 screws at the top of the cover in order to remove such cover.





Removing and replacing the air temperature sensor

1. Disconnect the defective air temperature sensor from the control board, cut all the cable ties that fix the air temperature harness to the chassis and loose the allen screw to release it from the incubator.



2. Replace the air temperature sensor for the new one and reassemble the unit.

5.16.2 Air sensor calibration

1. First loose the allen fixation on the air temperature sensor to move up or down its position.
2. Place a skin temperature probe at the center of the mattress at 10 cm height.
3. Turn on the incubator and set 34ºC / 93.2ºF on air control mode.
4. At steady air temperature (34 ± 0.1º C / 93.2 ±0.2 ºF) connect the skin temperature probe to the incubator on Skin Temp 1. The skin temperature reading should be 34ºC ± 0.3ºC / 93.2 ±0.6 ºF.
5. If the skin temperature is out of this range, change the position of the air temperature sensor (up or down) slightly and repeat the operation until it is achieved.
6. Set 36ºC on air control mode.
7. At steady air temperature (36 ± 0.1º C / 96.8 ±0.2 ºF) the skin temperature reading should be 36ºC ± 0.3ºC / 96.8 ±0.6 ºF.
8. Set 38ºC on air control mode.
9. At steady air temperature (38 ± 0.1º C / 100.4 ±0.2 ºF) the skin temperature reading should be 36ºC ± 0.3ºC / 100.4 ±0.6 ºF.
10. Screw the allen of the air temperature sensor to fix it to the incubator.

NOTE: If to meet points 7 and 9 it is absolutely necessary to modify the air temperature sensor position, be advised that the previous verifications should be repeated until the reading differences of ±0.3ºC/0.6ºF at the three test points (34ºC, 36ºC and 38ºC / 93.2ºF, 96.8ºF and 100.4ºF) are met with the air temperature probe located in the same position.

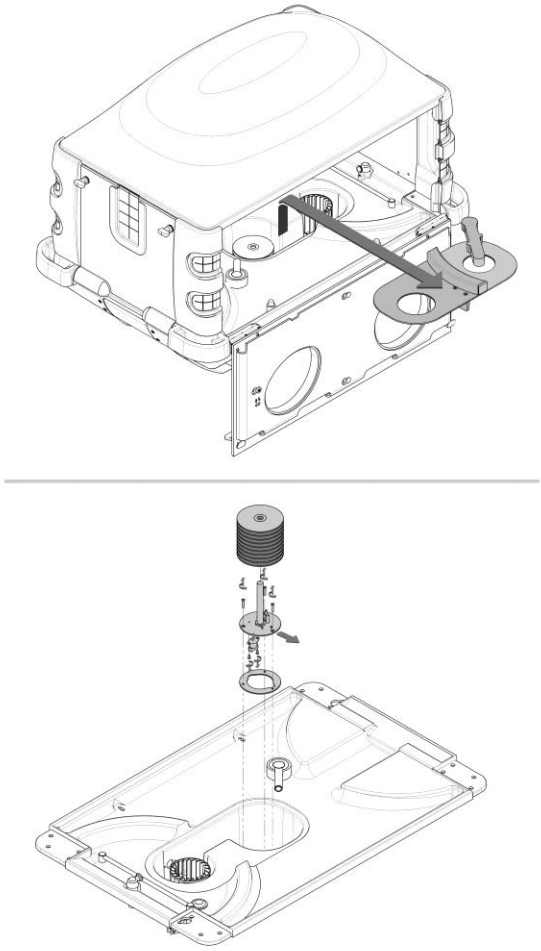
5.17 Heater replacement

NOTE: The equipment must be off and cold in order to perform this procedure. You may have to wait for 20 minutes until the heater cools down before removing it, to prevent any burning.

Turn the incubator off and disconnect it from mains.
Use a grounded antistatic wristband to perform technical service procedures.

Open the doors and remove the following:
- Mattress holder
- Lower tray
- Heater compartment cover
- Heat sink

Remove the heater that will be replaced by unscrewing the three screws of the base of the heater and disconnecting it from the cable harness.
Remove the siliconized joint and the screws from the heater to use them in the new heater.



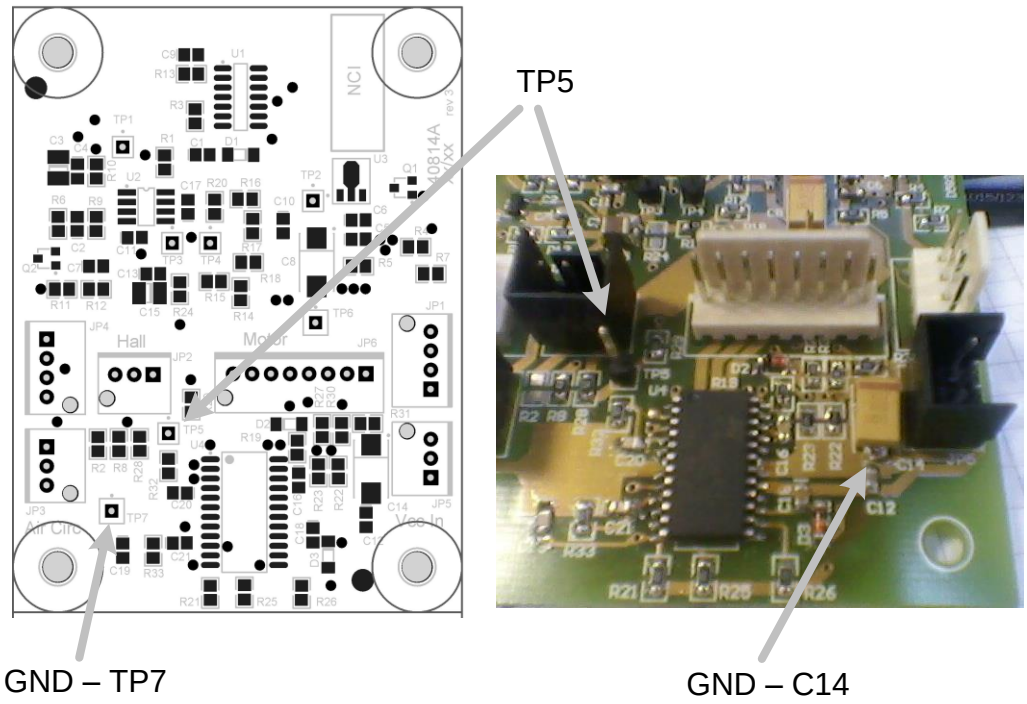
Place the siliconized joint and the screws on the new heater.
Use “Loctite 242” on the screws. Place the siliconized joint and the heater on the base, making sure that the threaded holes match their screws.
Adjust the screws and clean any Loctite excess.
Place the heat sink. Turn on the equipment and make sure that the heater warms up.
Reassemble the unit.

5.18 Motor

Use a grounded antistatic wristband to perform technical service procedures.

5.18.1 Checking motor speed

The brushless direct current (BLDC) motor speed will be measured indirectly by reading the *TACHO* output frequency signal from de BLDC control board.
Lower the crib base as described in section 5.4.
An appropriate multimeter in frequency mode or a frequencimeter must be connected to the test point 5 (TP5) and ground reference. Ground (GND) is available on test point 7 (TP7) or on capacitor C14 lower pad as is it shown in the following figure.



Test points and ground reference positions on BLDC control board

The incubator must be powered (ON) and without alarms.
Read the frequency at least over one minute to verify stability.
The normal values and ranges are shown in the following table.

	MIN [Hz]	MAX [Hz]
TP5 (TACHO) 1 minute stability	0	1.3
TP5 (TACHO) frequency	80	100

BLDC Motor normal operating ranges

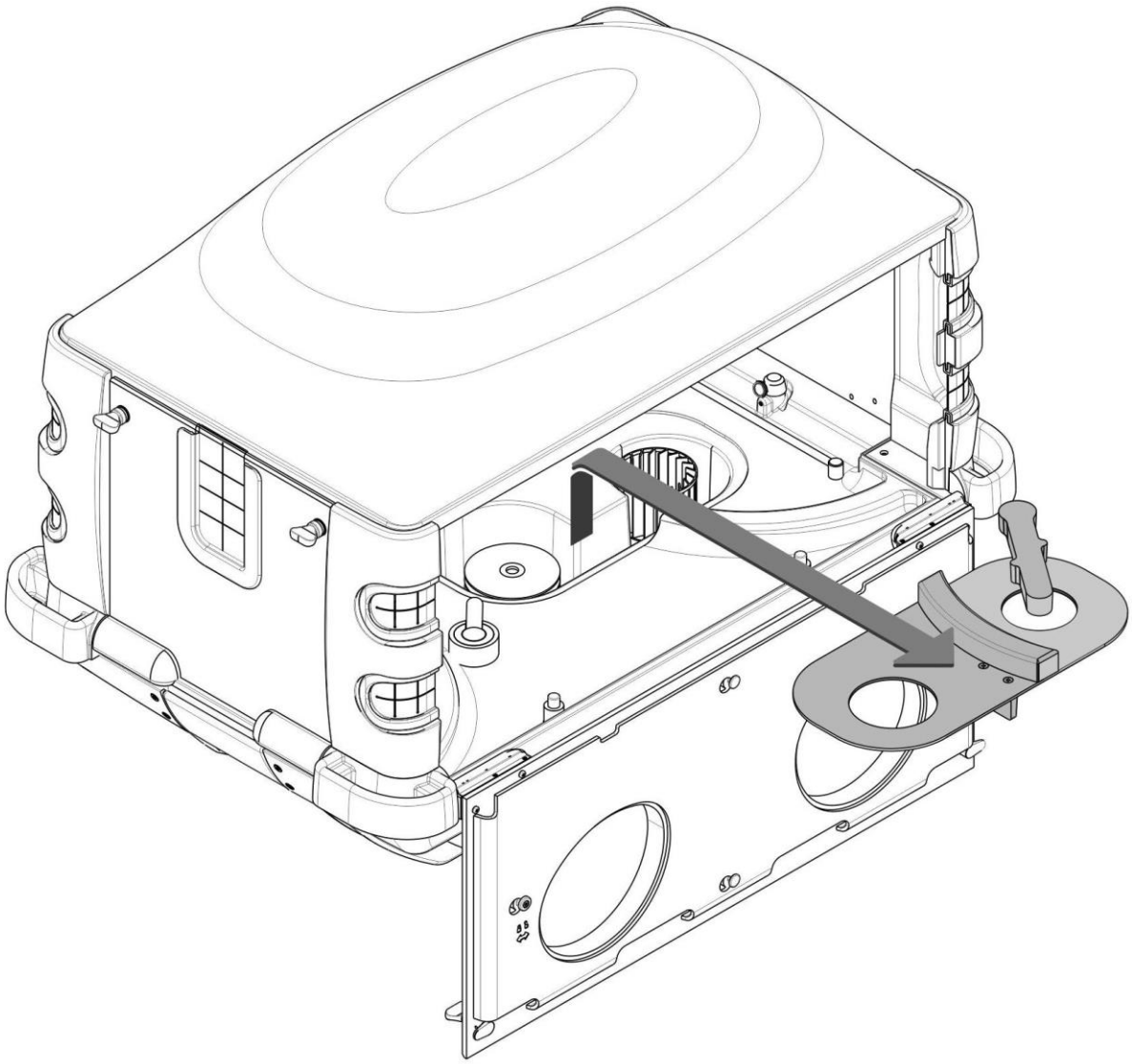
The real frequency is calculated by:
$F_{MOTOR}[rpm]=F_{TACHO}[Hz] \times 15$

The BLDC motor is considered under specifications if it fulfills these requirements.

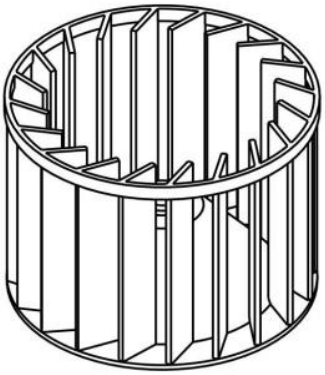
5.18.2 Motor replacement

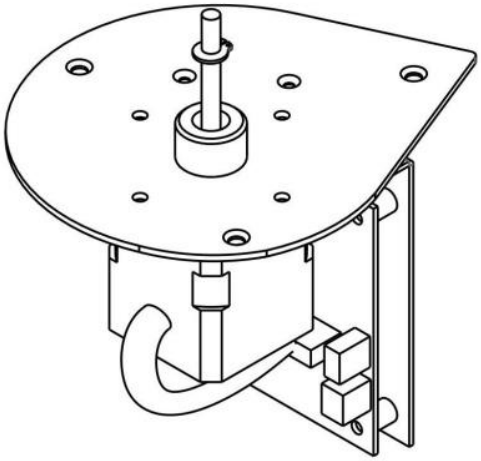
Lower the crib base as described in section 5.4.

As showed below, the motor is located under the mattress holder and the metallic cover plate. If the equipment has a weighing scale, the first step is to disconnect it from the incubator. After that, the mattress holder must be removed. Metallic plate will be accessible and it must be removed also.



Inside the hole of the base, appears the fan wheel: it must be extracted by pulling it up. The four screws that fix the motor must be unscrewed (motor must be holded during this process to avoid the fall of the unit).





Disconnect the cable connected to JP5 (Vcc In) and the cable connected to JP3 (Air Circ) on the *BLDC control board*. Motor can now be extracted and replaced.
Screw the new motor to the base (during this process the motor must be holded to avoid the fall).
Reassemble the unit following the previous described steps backwards.
Make sure the fan wheel can turn freely.

5.19 Servo-humidity system

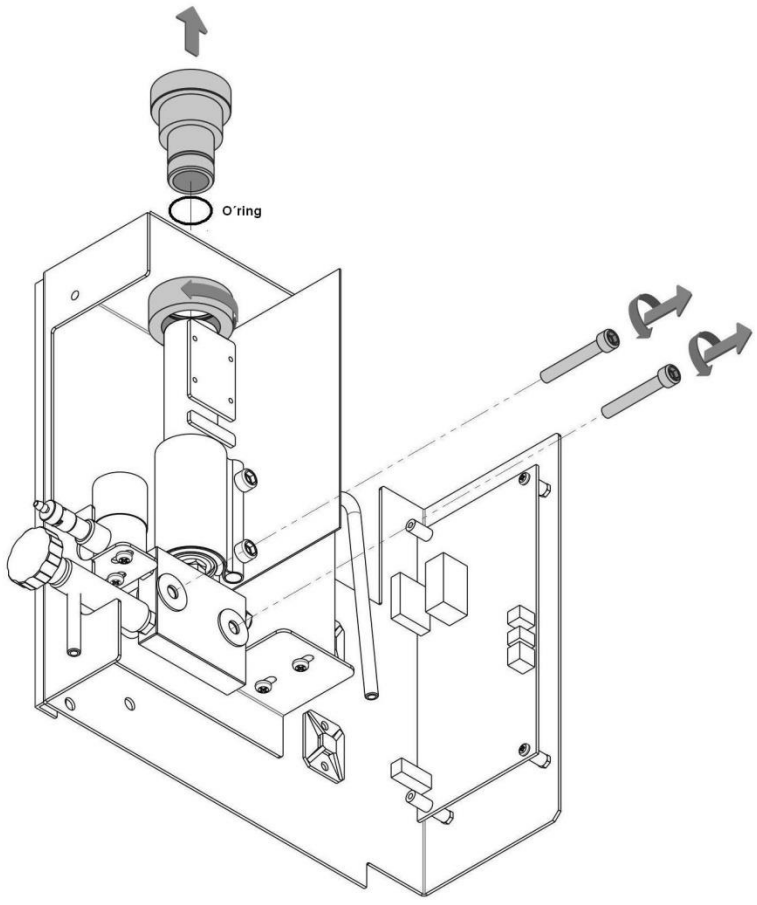
5.19.1 Water level sensor, Heater and O'ring replacement

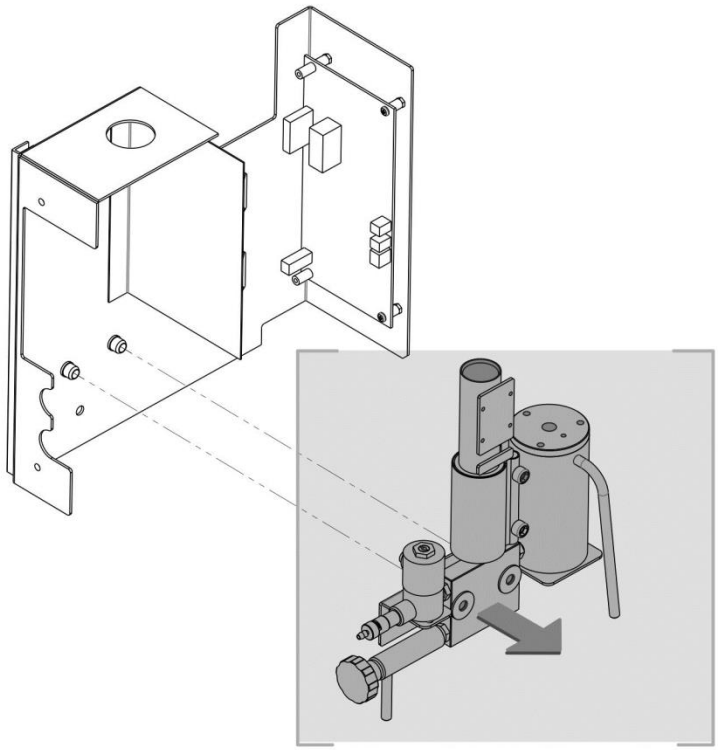
Access the humidity and oxygen modules as described in section 5.3.

Disconnect the heater/thermal protector, water level sensor and water valve cables from the humitidiy/oxygen board.

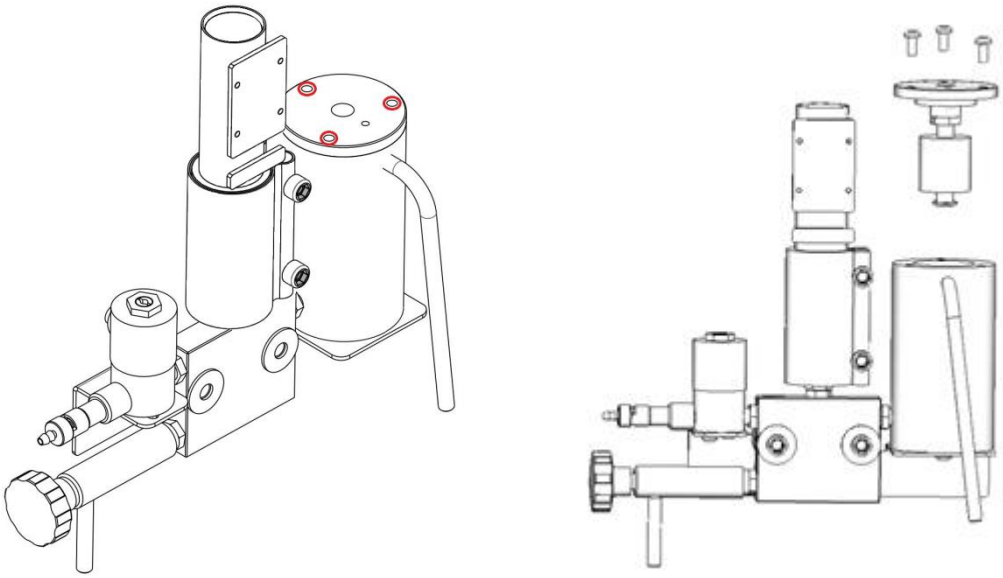
Unscrew the nut to remove the steam outlet piece from the evaporator system. Take out the O´ring from it and replace for a new one when the evaporator system is installed again.

Remove the two Allen screws and take out the evaporator system from the chassis, as shown below.



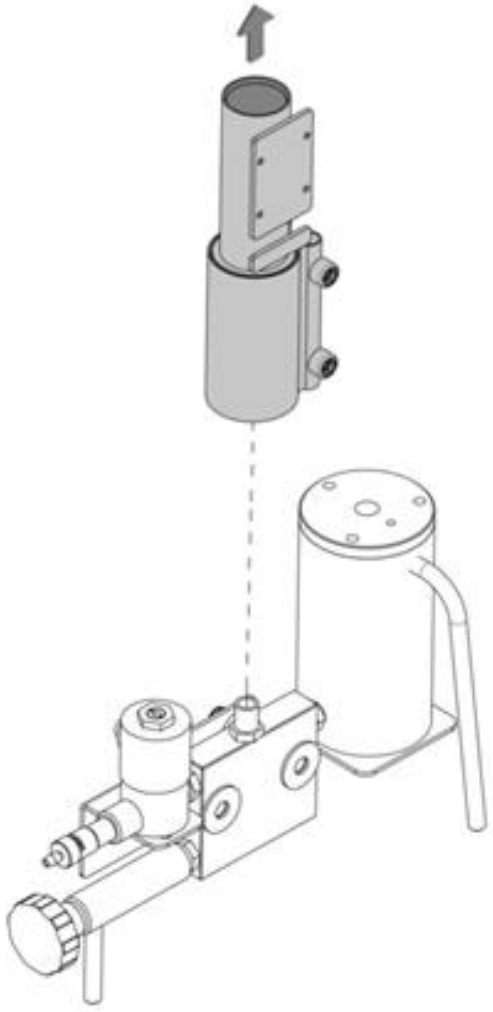


Water level sensor replacement:
Remove the three screws indicated in the following figure and replace the water level sensor.



Reassemble the system following the above described steps backwards.

Heater replacement:
Unscrew the stainless steel pipe with the heater from the evaporator. Remove the heater by loosening the two allen screws on it and disconnecting the faston terminals on the thermal protector.



Install the new heater on the stainless steel pipe in the same position and connect the faston terminals on the thermal protector. Screw the heater to the evaporator using Loctite 242 to assure a complete seal.

Reassemble the system following the above described steps backwards.

5.19.2 Cleaning

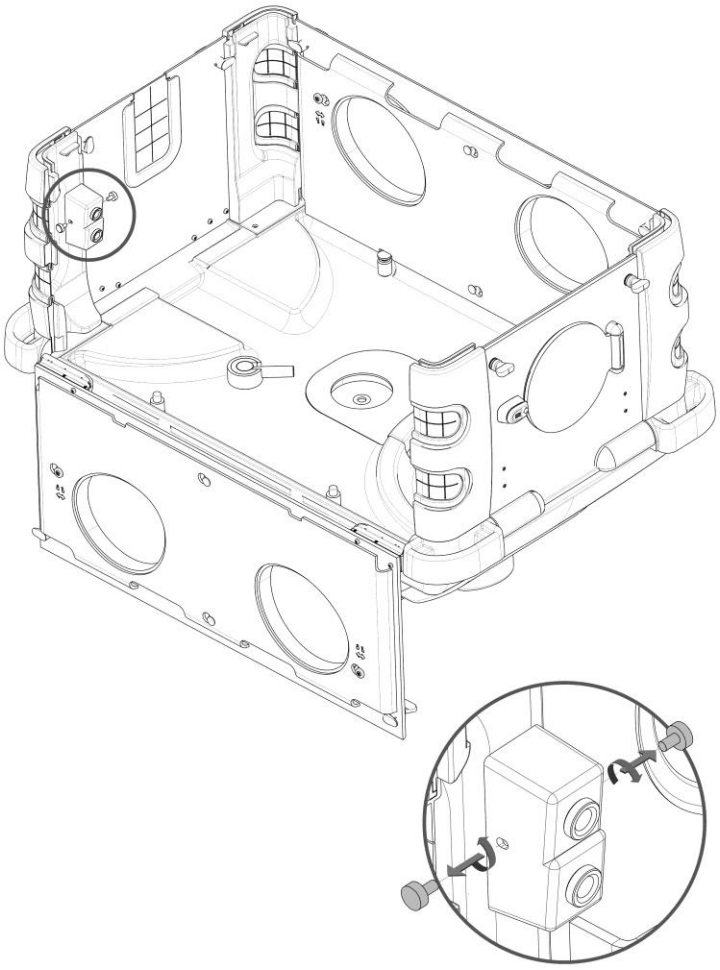
Acces the humidity and oxygen modules as described in section 5.3.
Follow the steps in section 5.19.1 to remove the heater and stainless steel pipe. Wash them with brush and disinfectant and then rinse them with abundant water
Check the water hose to evaluate its replacement.

5.20 Servo-oxygen system

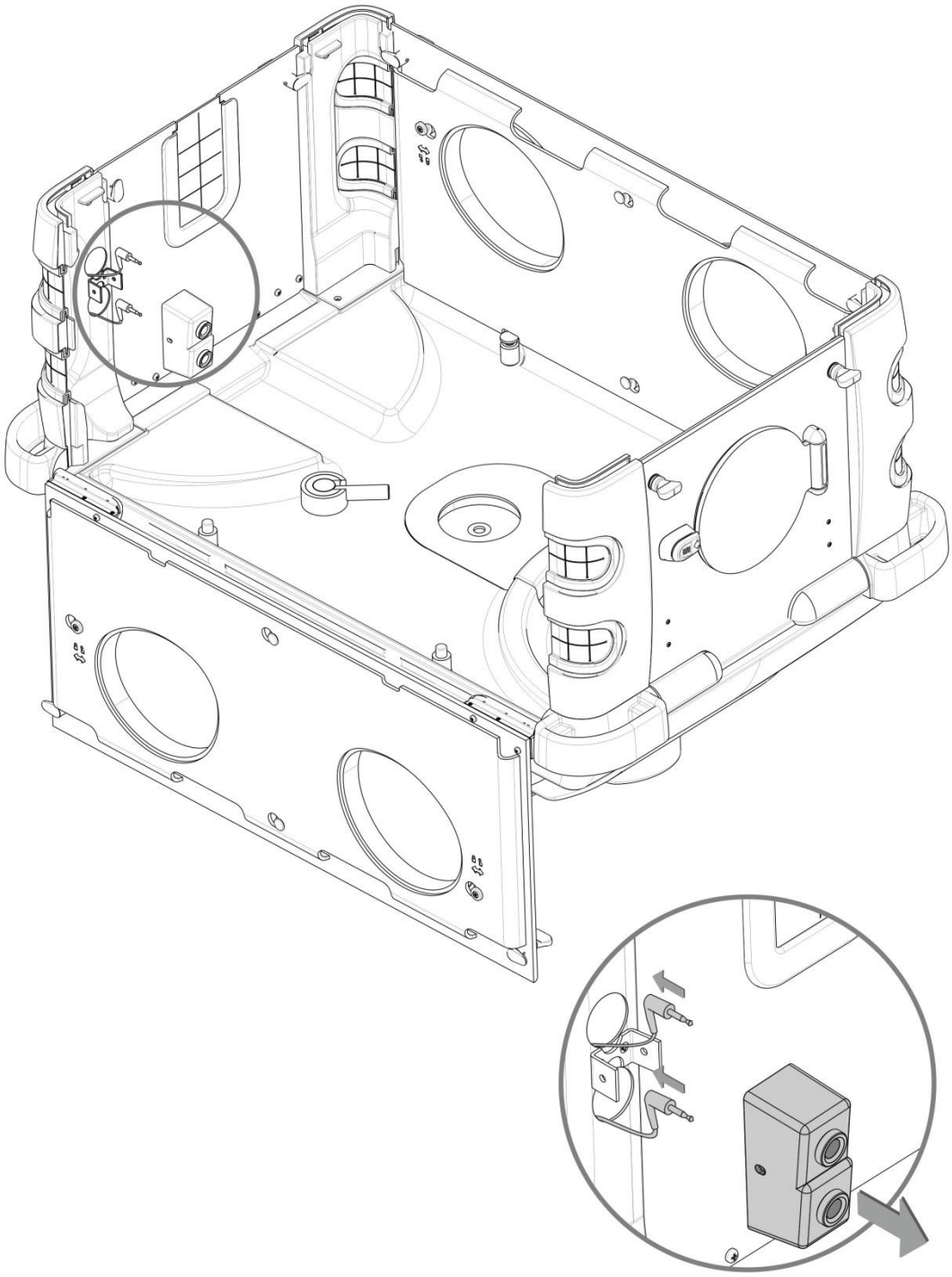
5.20.1 Cells replacement

NOTE: During the calibration procedure the defective cell number is indicated on the screen. The upper cell is the number 1 and the lower cell is the number 2.
NOTE: It is not necessary to turn off the equipment to change the cells.
NOTE: Use an antistatic wristband when performing this procedure.

Open the incubator doors and loosen the cells box by unscrewing the plastic knobs in order to remove it from the column.

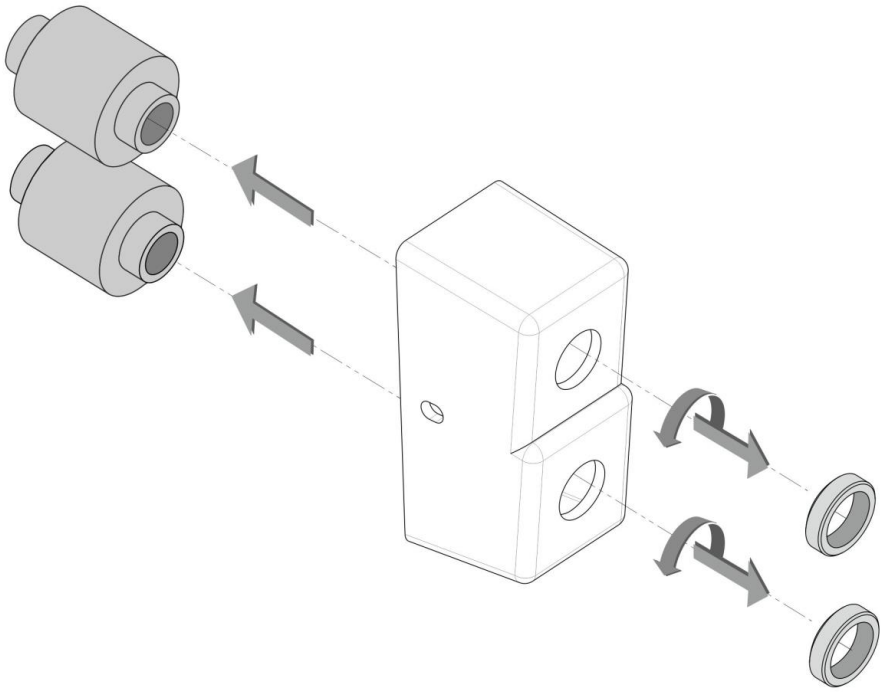


Once the cells box has been loosened, disconnect the cells from Plug 1 and 2.

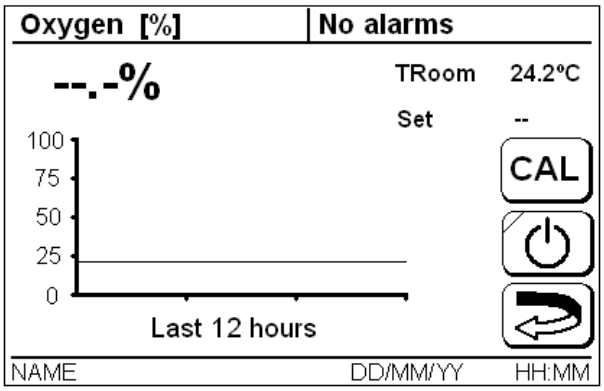


Disassemble the box by loosening the cells, unscrewing the threaded rings in anticlockwise direction.

Get the new cells out of their packs. Discard all the accessories inside the pack, including the O-ring that is delivered with the cells. Only the cells must be used.
Reassemble the cells box by screwing the new cells with the threaded rings.
Respect the position of the cells box as shown in the following figure. Connect the top cell to Plug 1 and the bottom cell to Plug 2.
Adjust the cells box to the incubator column with the plastic knobs.
Perform the oxygen calibration procedure described in section 5.20.2.



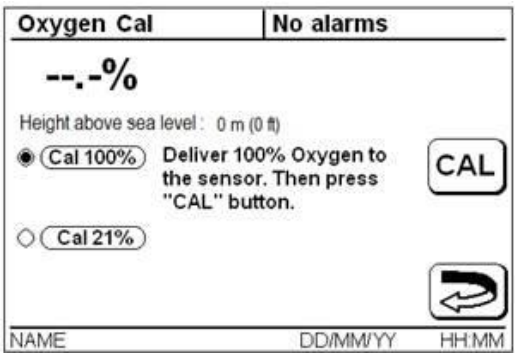
5.20.2 Cells calibration



The O_2 module must be TURNED OFF for the oxygen cells calibration procedure.

Select with the OPTIONS SELECTION DIAL the CAL key on O_2 screen.

Oxygen cells can be calibrated either 100% or 21% according to required reading accuracy.



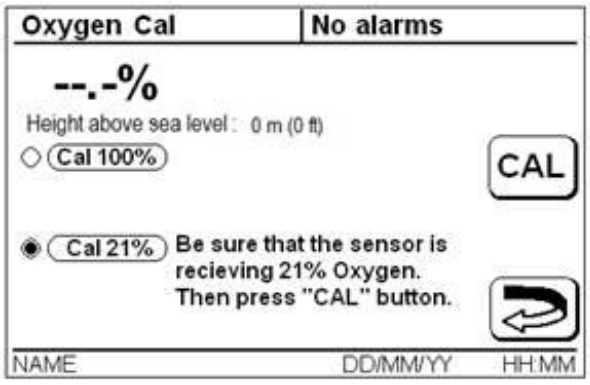
CALIBRATION 100%

To increase the readings accuracy, select calibrate at 100% whenever O_2 percentage >40%.

Place the CALIBRATION accessory supplied with the equipment on the respective sensors.
Open the O_2 supply at 100% (with low flow <3lpm) and let it stabilize for 60 seconds before beginning the procedure.

Select option CAL on the screen to begin the procedure it is completely automatic.

Once the operation is finished, a message of CALIBRATION SUCCESSFUL will appear on screen or if not, it will require repeating the process. To check calibration, return to main screen and verify 21% reading for environmental oxygen concentration.

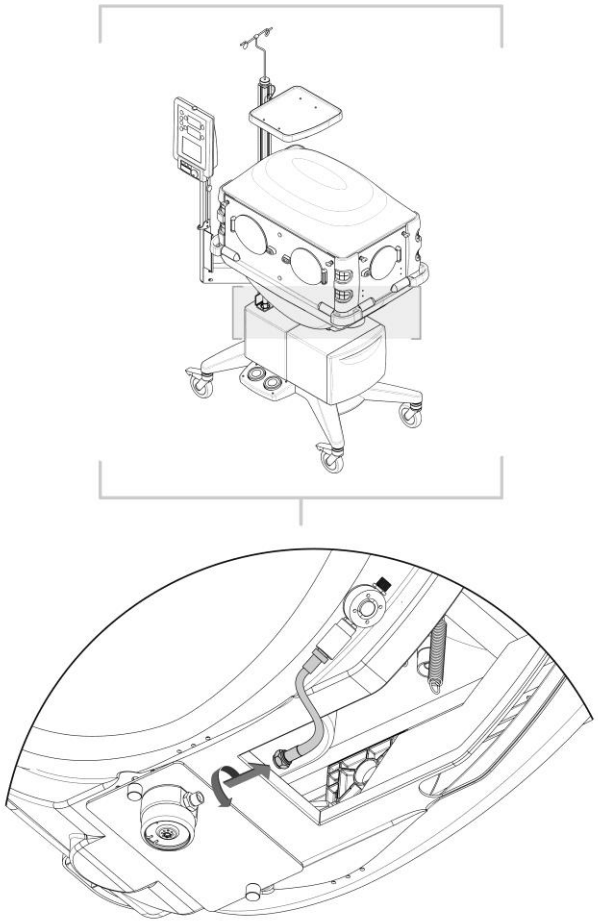


CALIBRATION 21%
This calibration can be made when O_2 values used for the control are lower than 40%.

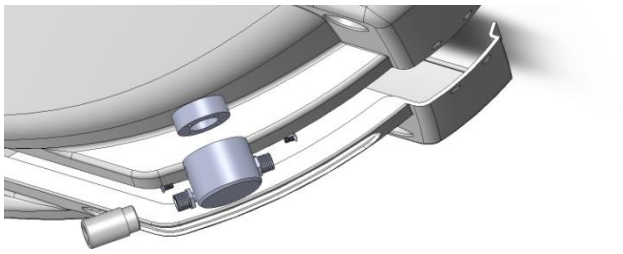
In this case it is not necessary to use accessory to cover the sensors.
IT IS RECOMMENDED TO OPEN THE DOORS AND LET THE SENSORS STABILIZE WITH ENVIRONMENTS OXYGEN FOR AT LEAST 5 MINUTES BEFORE TRYING THIS CALIBRATION.

5.20.3 Valve replacement

Disconnect the reinforced hose from the mixing valve on theair filter cover as shown below.



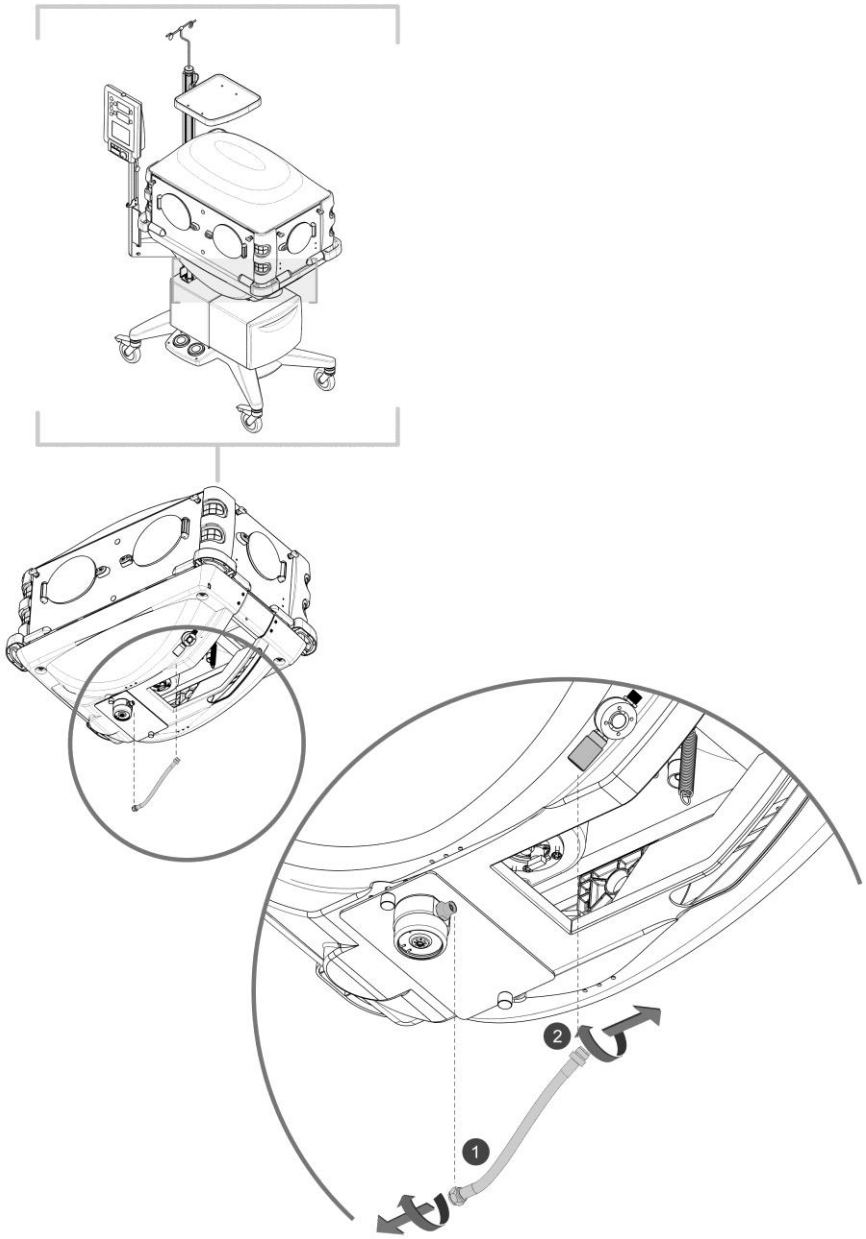
Disconnect the reinforced hose from the oxygen valve assy and then remove the two screws to release the oxygen valve assy from the crib base. Unplug the oxygen valve cable from the connector.



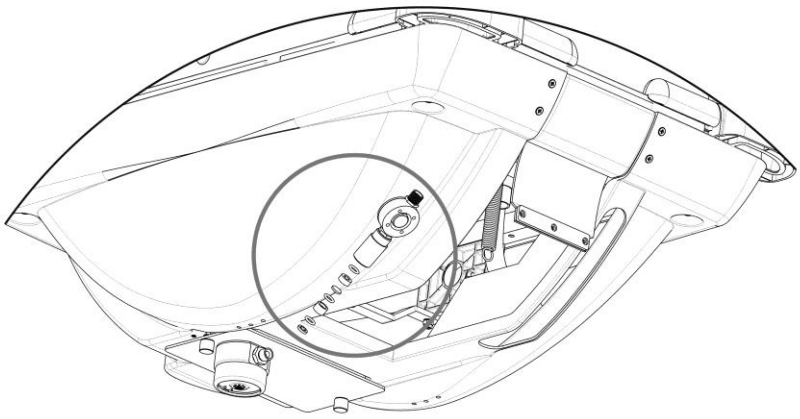
Reassemble the system following the above described steps backwards.

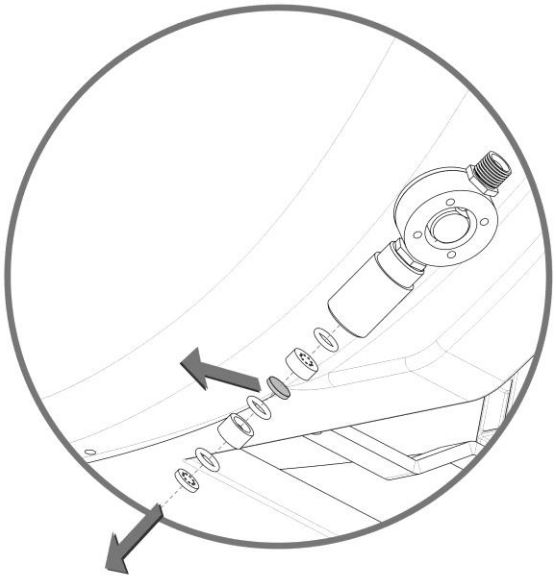
5.20.4 Filter replacement

1) Remove the assembled filter cover from the base of the bassinet by unscrewing the clamping knobs in anticlockwise direction.
2) Separate the assembled filter cover from the hose of the noise absorption device with a No. 19 wrench.
3) Holding the chrome hose joint nipple with a fix 5/8 wrench, unscrew the O_2 diffuser with a parrot-beak clamp. Be careful to hold the nipple tightly to prevent it from detaching from the base of the bassinet.
4) Separate the O_2 diffuser from the hose assembly of the noise absorption device. Be careful not no lose the closing disk, which is inserted inside the nipple.



5) Disassemble the O_2 diffuser. Be careful not to damage or lose any of the diffuser pieces.
6) Replace the oxygen filter and assemble the diffuser again, making sure that no pieces are missing.
7) Reassemble the unit following the previous described steps backwards.

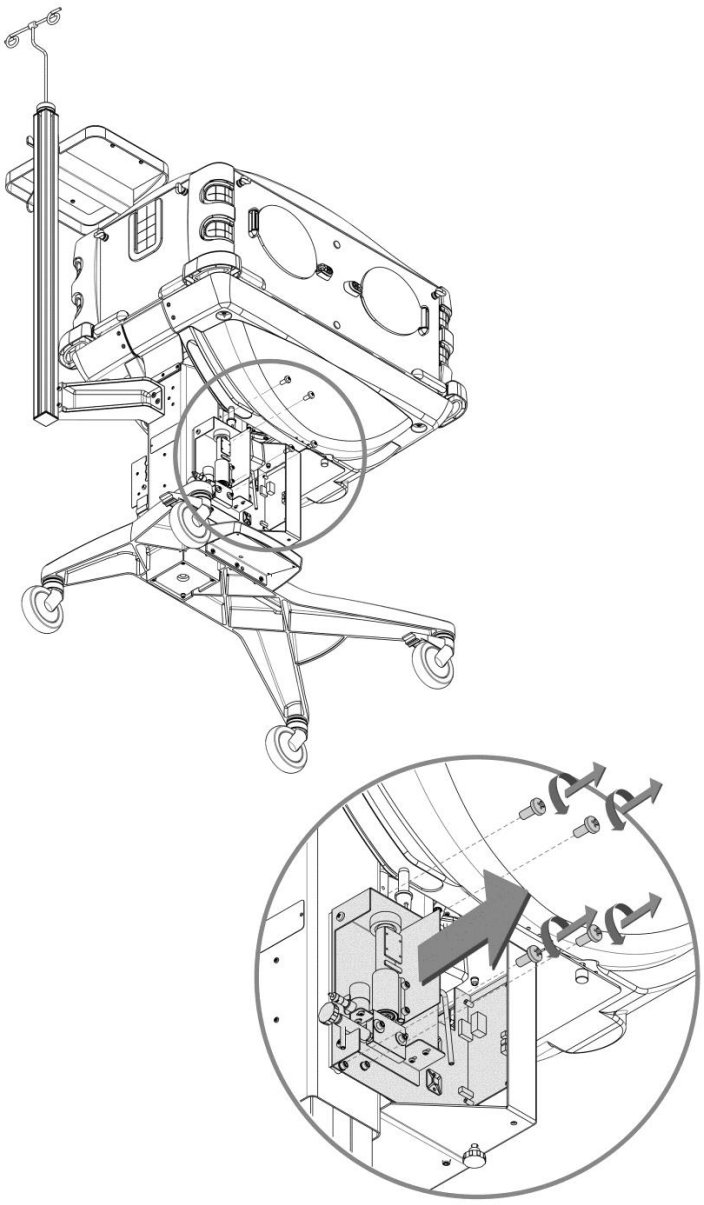




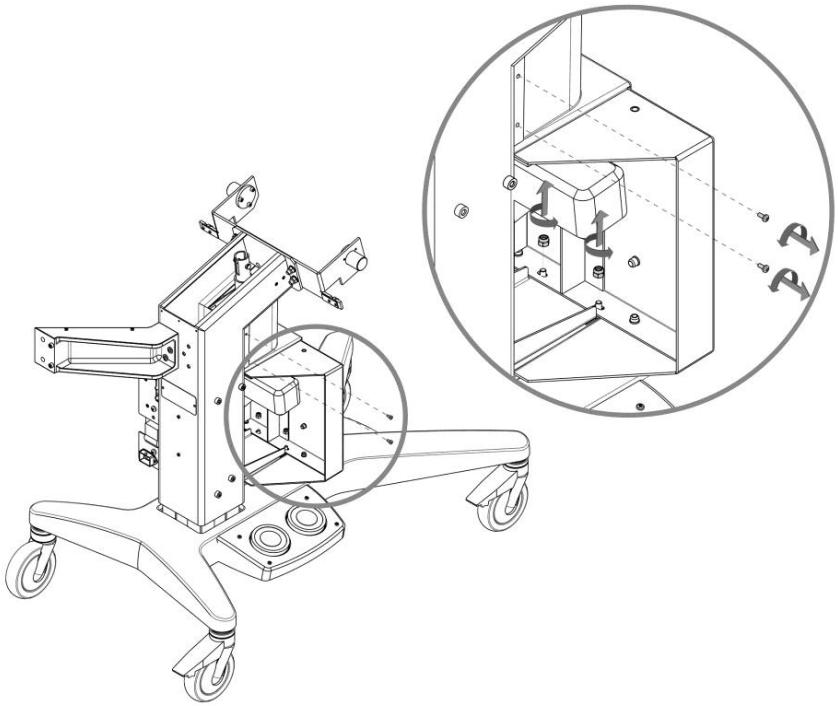
5.21 Tilting mechanism motor replacement

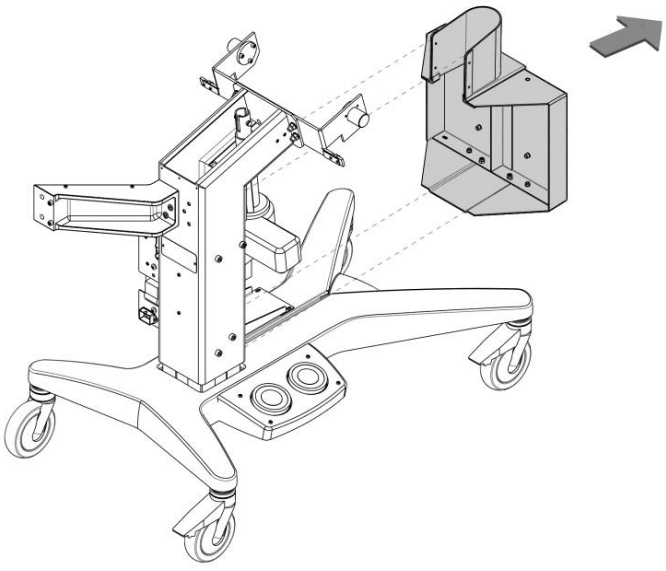
Preparing the unit

1. Access the control module as described in section 5.1
2. Access the humidity and oxygen modules as described in section 5.3.
3. Lower the crib base as described in section 5.4.
4. Take out the humidity system as described below.



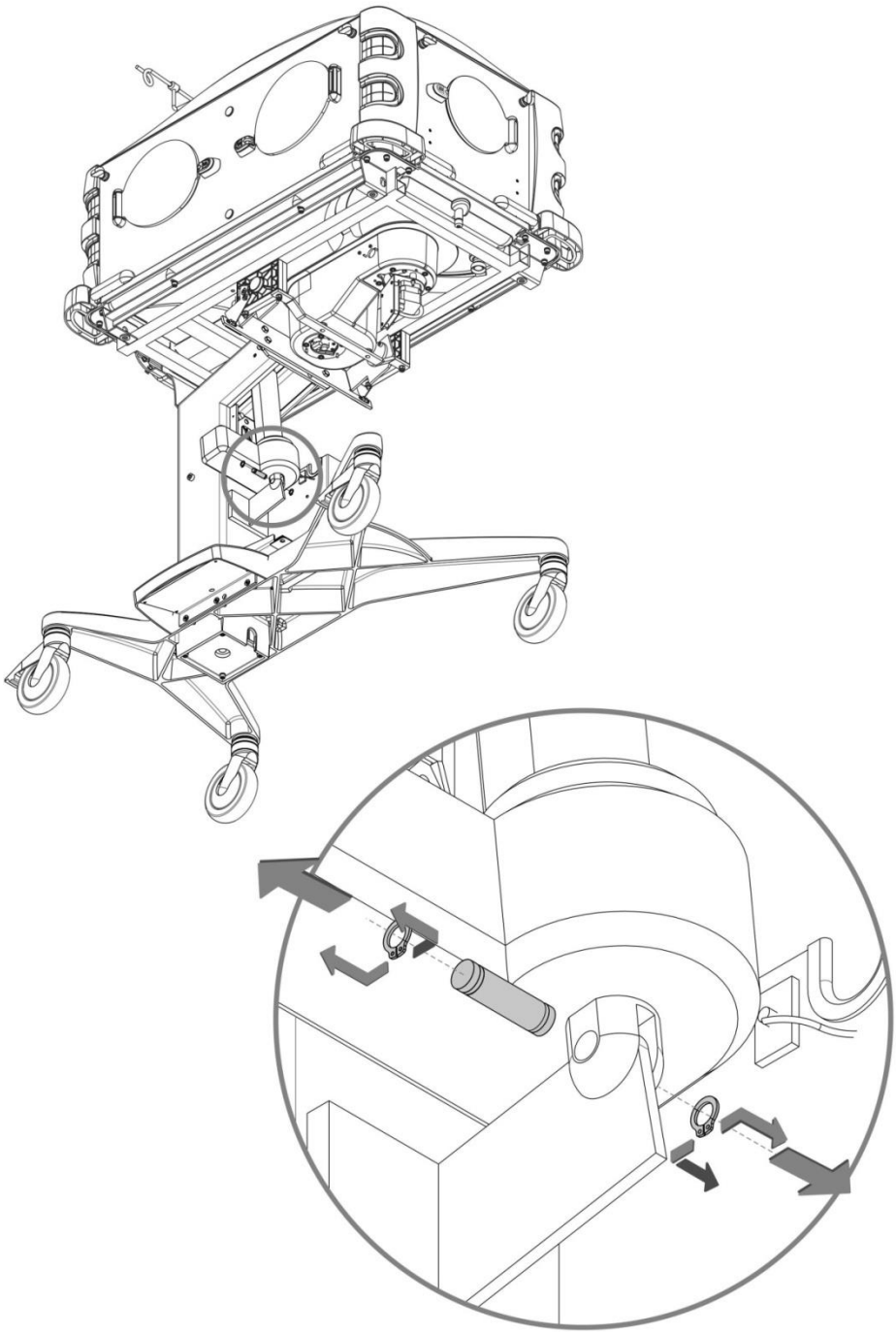
5. The drawer accesory must also be removed, in case it is intalled, first take out the drawer and remove the four screws inside it.
6. Remove 2 screws that hold the front lower cover and 4 screws at the top of the cover and remove it.

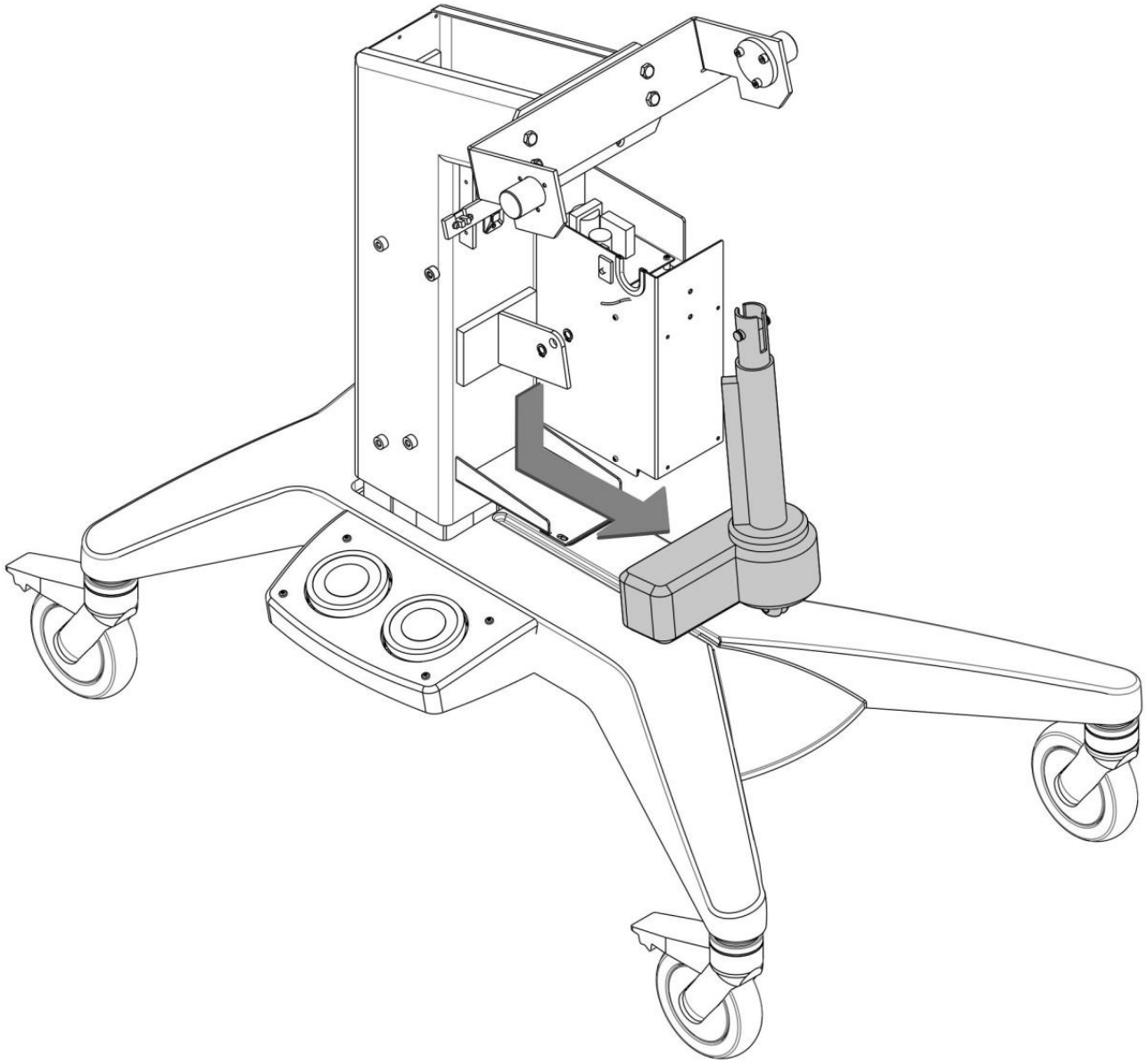




Removing and replacing the motor

7. Disconnect the motor from control board.
8. Remove the seeger locks that secure the motor´s support at both ends, then remove the spikes and the motor.

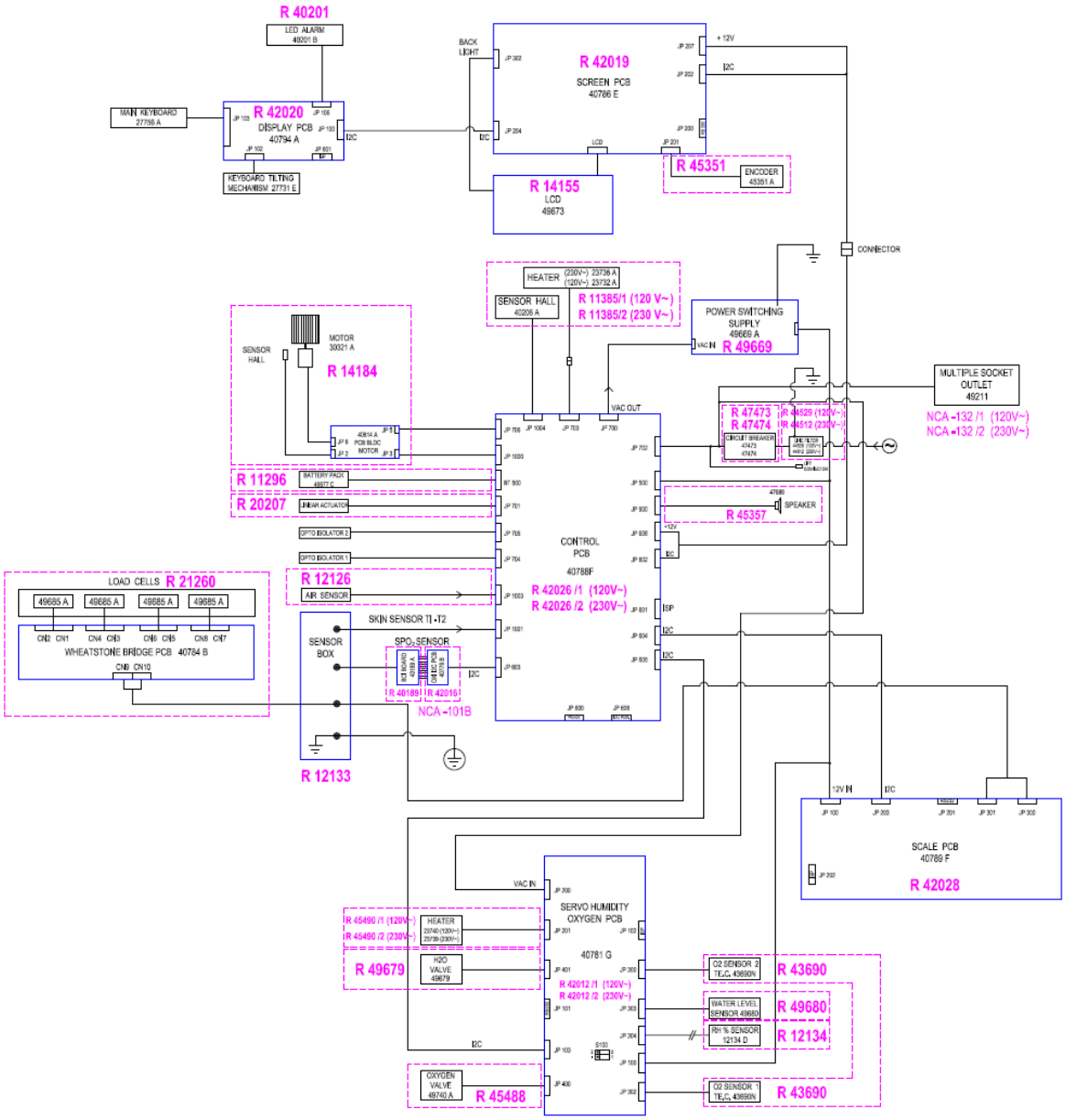




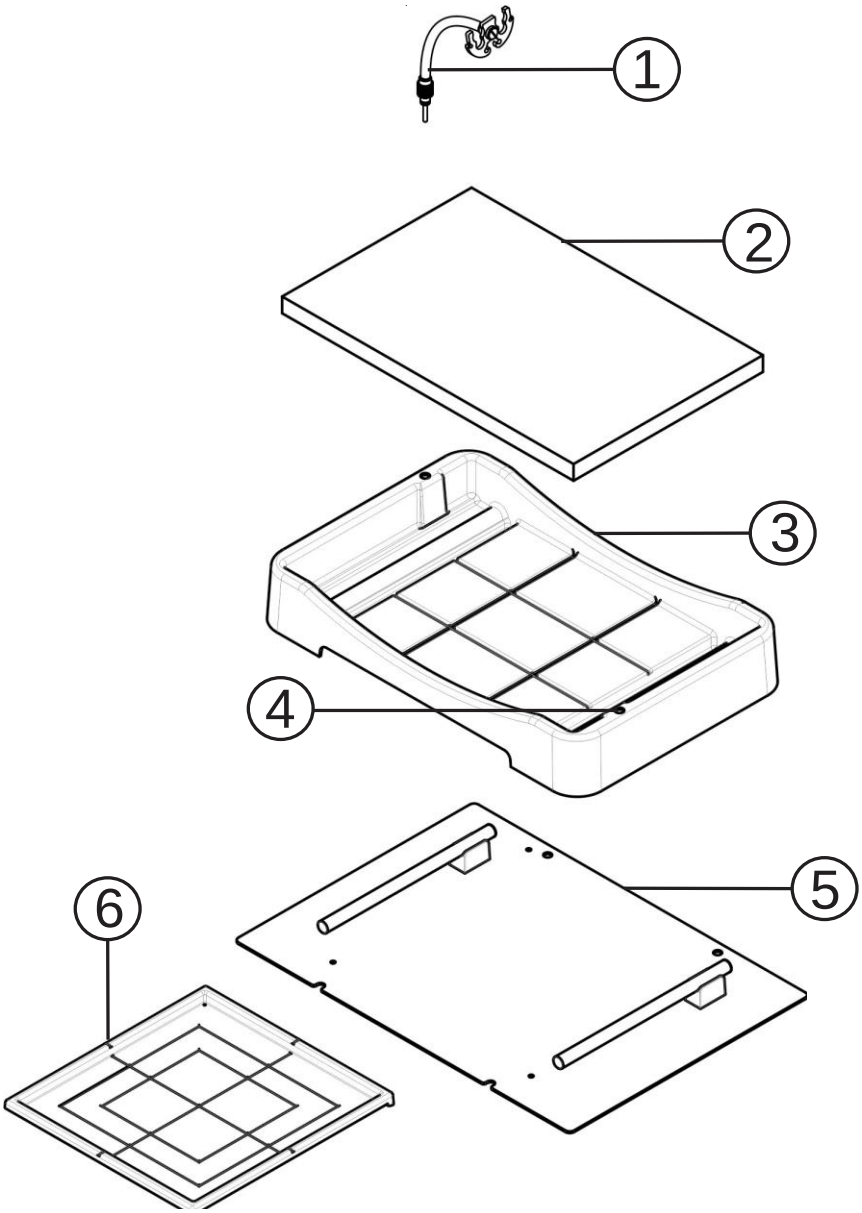
9. Replace the motor and reassemble the unit.

NOTE After performing the Technical Service Procedures, please remember to complete the Performance and Safety Check Report that is in Appendix 2.

6.1 Connection Diagram & Spare Parts

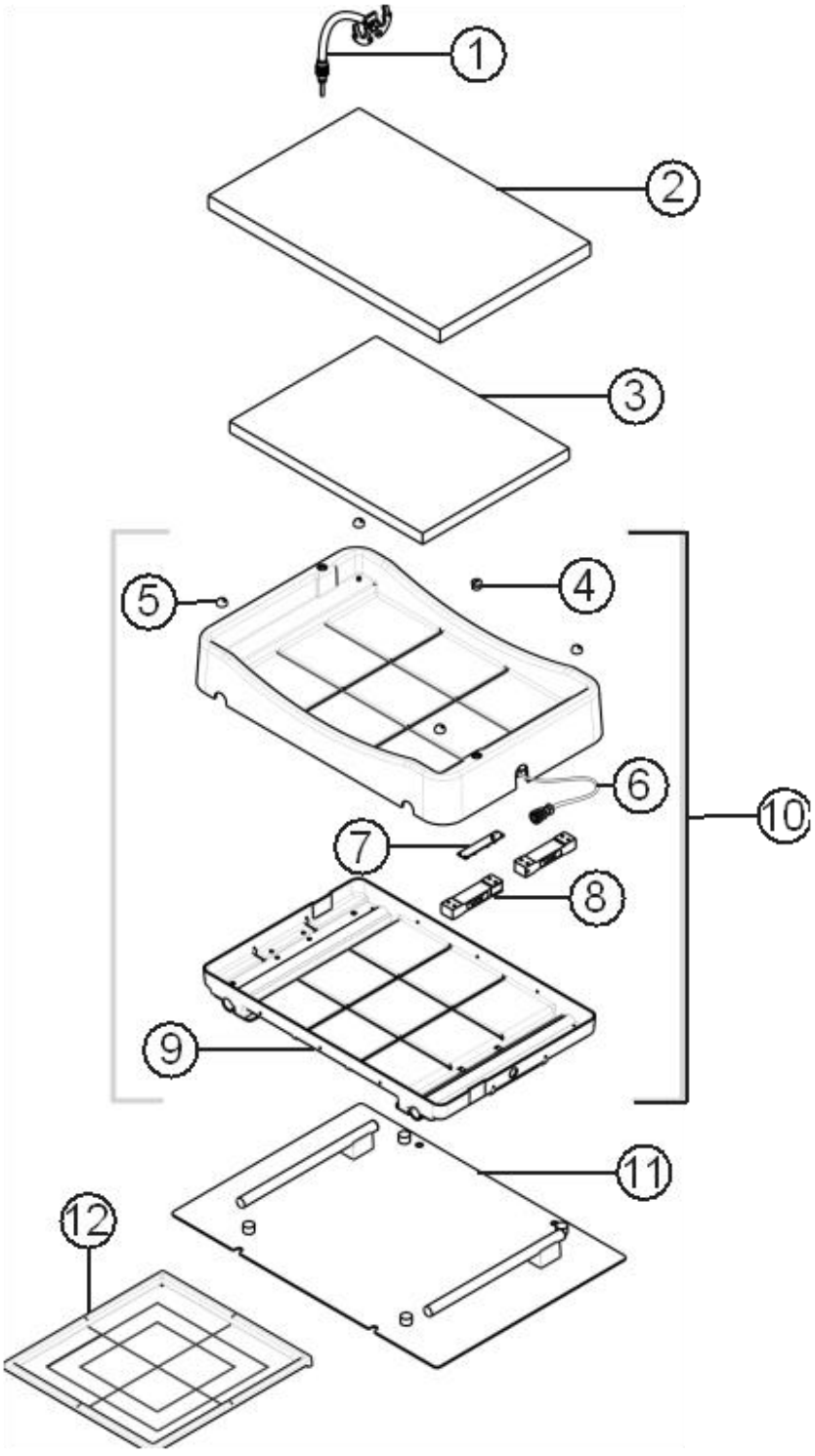


6.2 Mattress tray (without weighing scale)



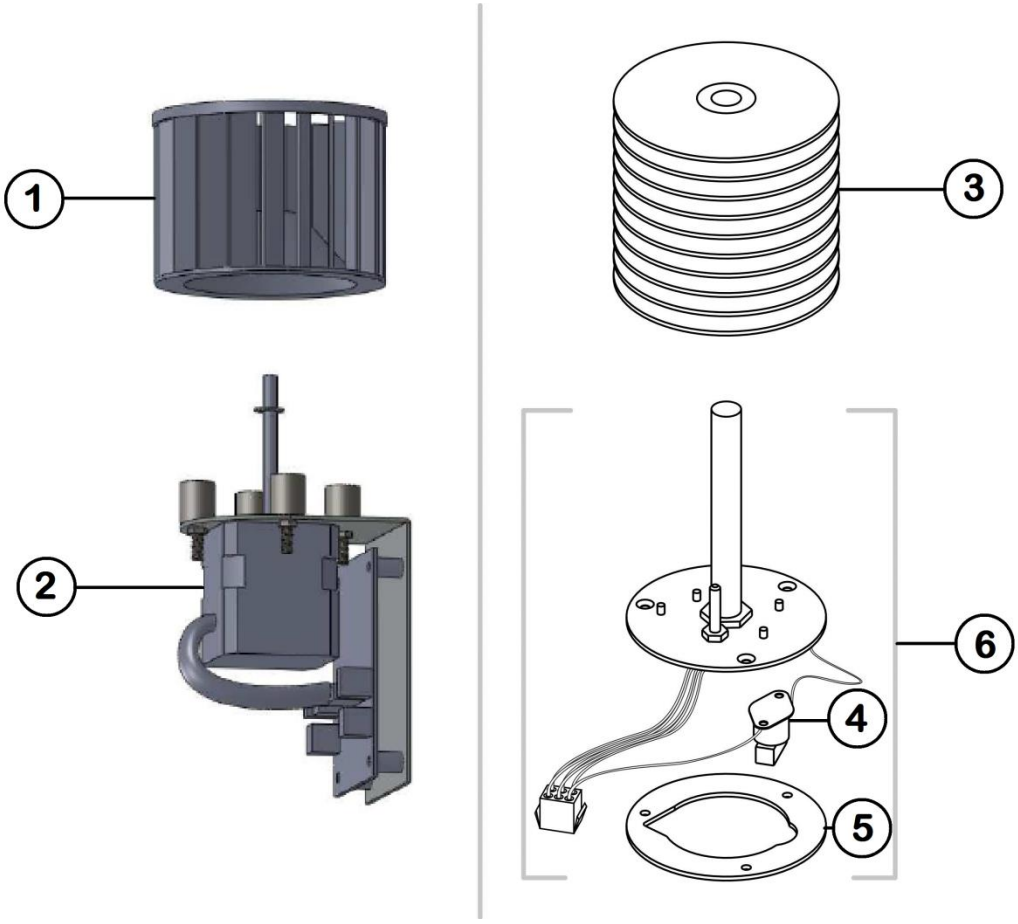
Item	Part Number	Description
1	NCA-126	Flexible holder for ventilator tubings
2	13142	Mattress
3	R21253	Mattress tray
4	33890	Threaded stopper
5	R19061	Lower tray
6	21261	X-ray chassis tray

6.3 Mattress tray with weighing scale



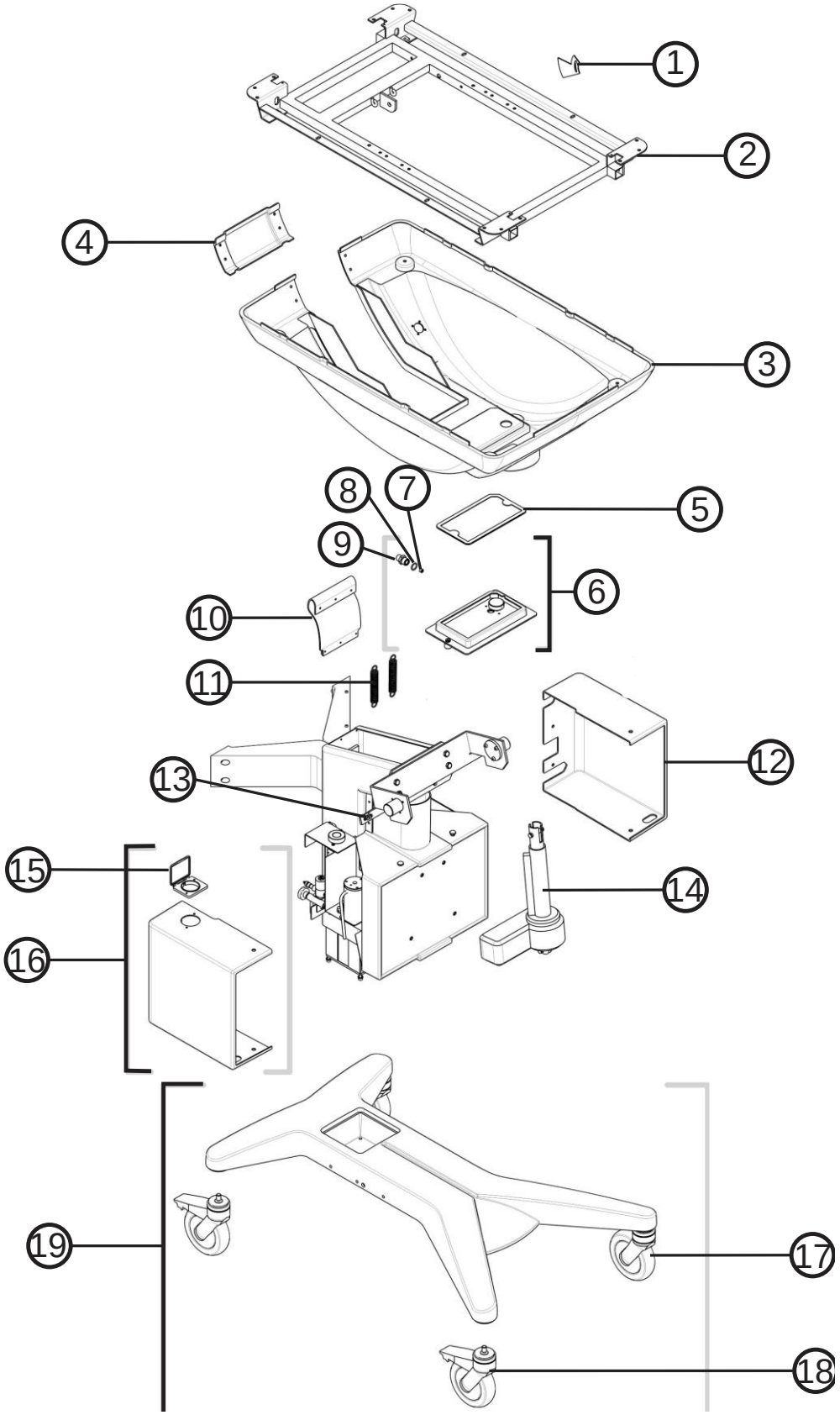
Item	Part number	Description
1	NCA-126	Flexible holder for ventilator tubings
2	13147	Mattress
3	13156	Complementary Mattress
4	33890	Threaded stopper
5	63939	Plastic Nut
6	R41594	AMP Plastic connector Male (in weighing scale cable)
	R41595	AMP Plastic Conector Female (in sensor box)
7	R40211	Equalizer Board
8	49685	Load Cell
9	24470	Weighing scale lower plastic cover
10	R21260	Weighing scale Platform assembly (includes item 4 and the four load cells)
11	R19061	Lower tray
12	21261	X-ray chassis tray
	R42018	Weighing Scale control Board
	R45387	Weighing scale wiring

6.4 Heater and motor



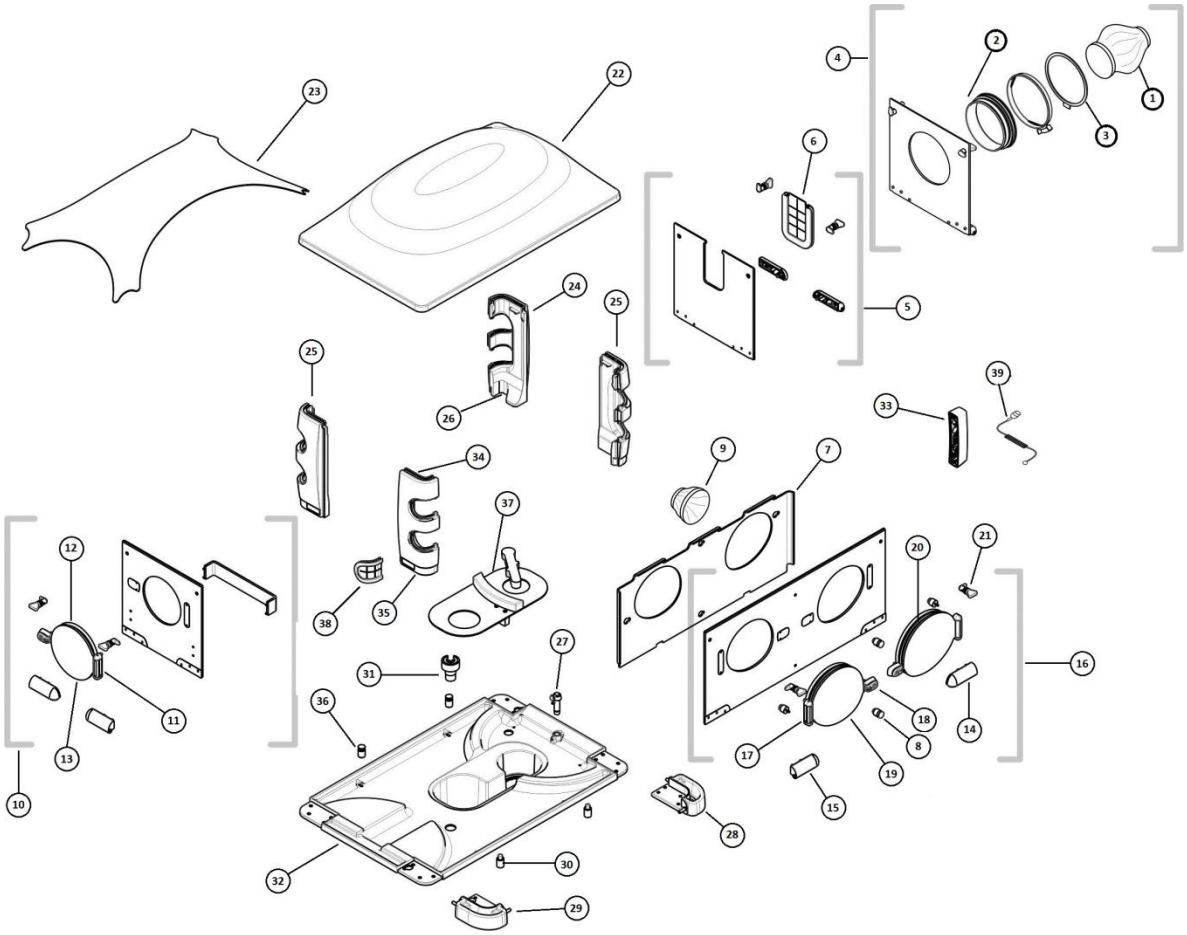
Item	Part number	Description
1	R11391	Fan wheel
2	R14184	Motor Assy
3	R26416	Heater plate
4	44408	Thermal Protector 85°C
5	21022	Heater silicon Insulator
6	R11385/1	Heater assy 120VAC
6	R11385/2	Heater assy 230VAC

6.5 Lower cabinet



Item	Part number	Description
1	25788	Centering guide plate
2	11163	Base frame
3	R24462/1	Crib base
4	R36044	Cib base lock supplement
5	TR-69	Air filter (Pack of 4 units)
6	R11368/1	Air filter cover Assy (includes items 8, 9 and 10)
6	R11368/2	Air filter cover Assy (For units w/ O2 Servocontrol)
7	R27200	Oxygen filter
8	20815	O´Ring
9	R30401	Oxygen valve connector (units without Servo-Oxygen module) (includes item 9)
10	R19044	Rubber cover
11	34243	Compensation spring
12	R33911	Rear column case
13	R40779	Crib Position sensor
14	R20207	12 V Actuator
15	R49210	Humidity output cap
16	R33912	Front column case (Units without Servo-Humidity module)
16	R33923	Front column case (Units with Servo-Humidity module)
17/18	R11394	Four wheels (two lockable and two unlockable)
18	R34622	Antistatic lockable wheel
19	R19050	Rolling base w/wheels (two lockable and two unlockable)

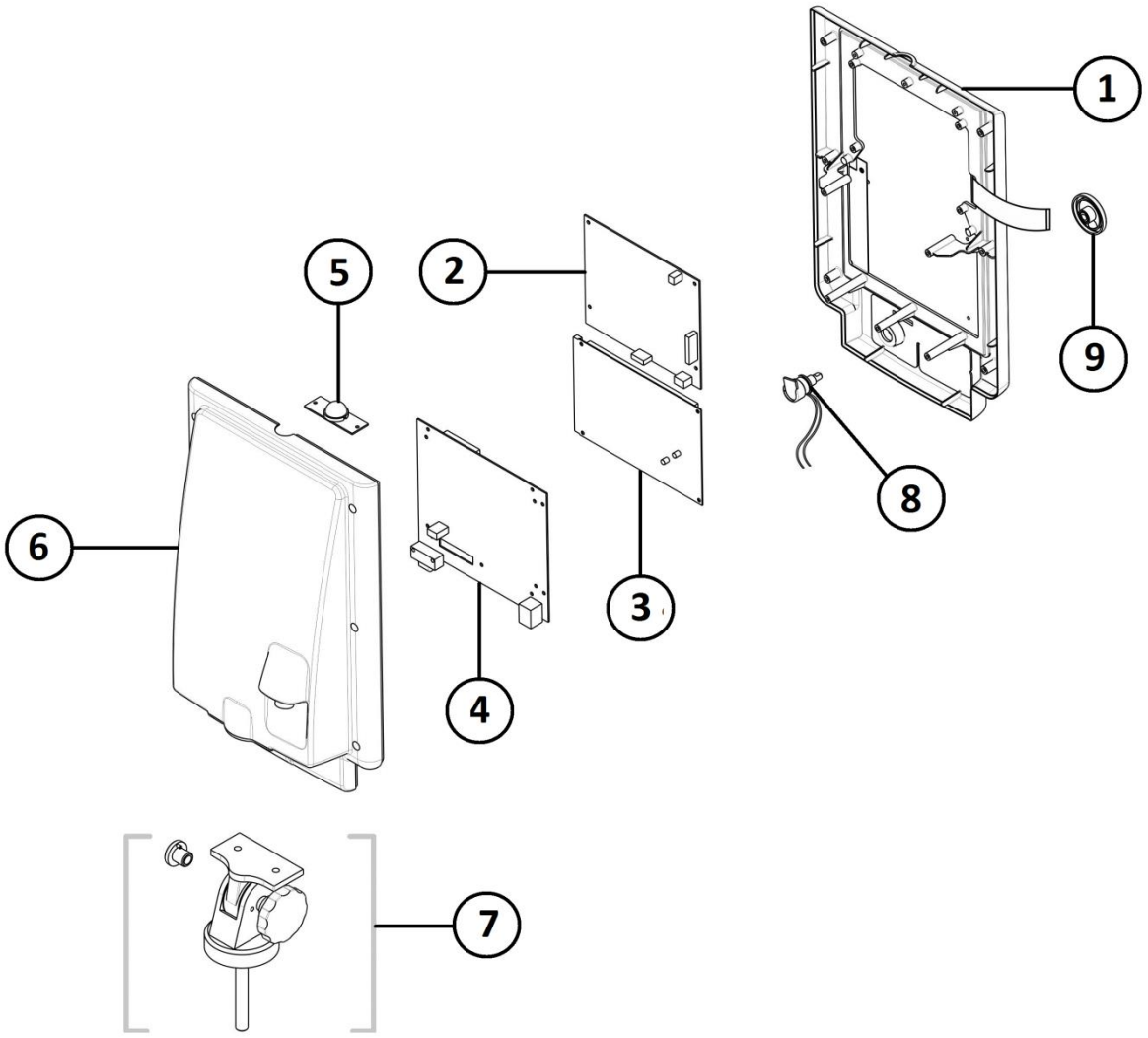
6.6 Hood Assy



Item	Part number	Description
1	DIR-06	Iris port sleeve (100 pieces per pack)
2	R25407	Iris port assy (includes item 2, 3 and 4)
3	R21002	Iris port gasket
4	R12131	Lateral door assy (Iris port)
5	R12145	Lateral door w/ Max IV port
6	R25270	Max IV port
7	R24122	Double wall
8	R37053	Double wall support assy (4 units)
9	DIR-36	Oval hand port sleeve (100 pieces per pack)
10	R12132	Lateral door assy (Round port)

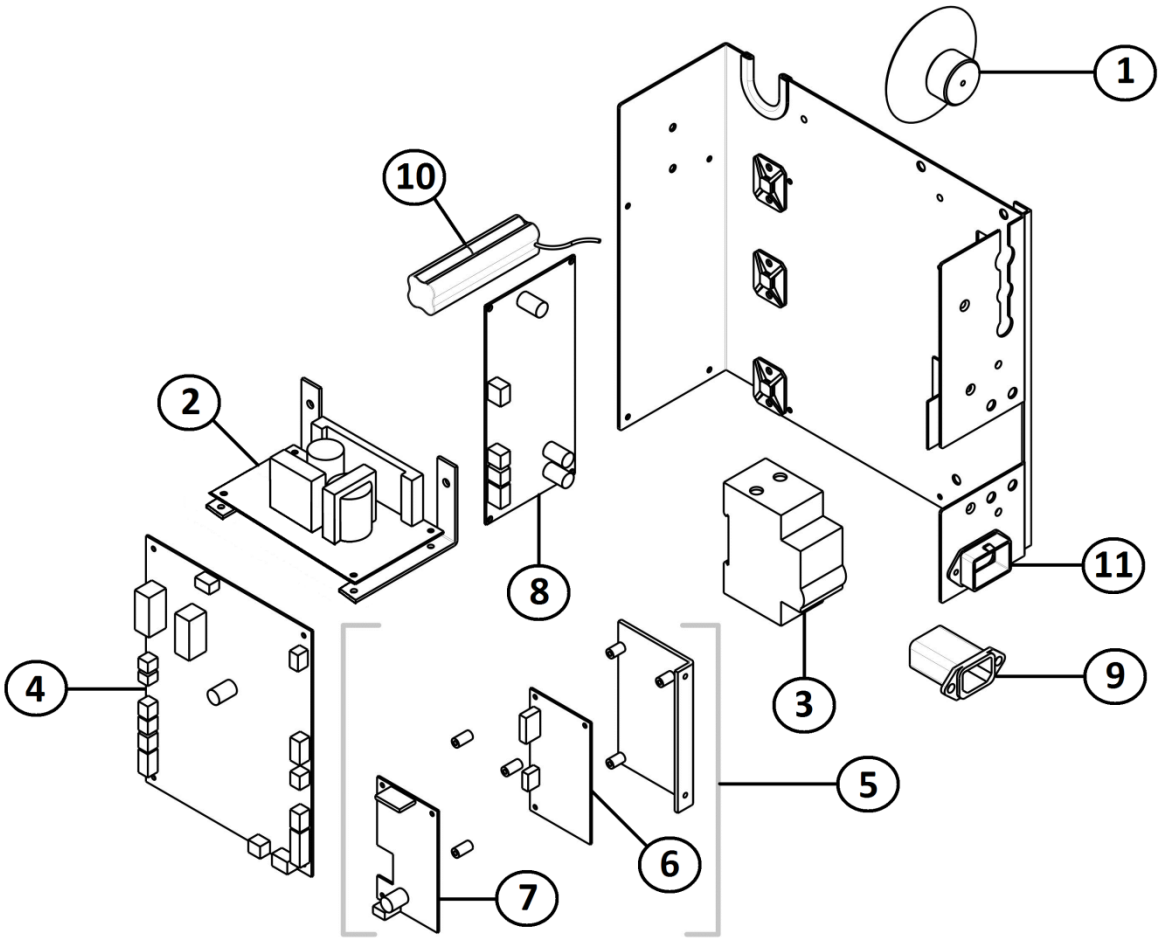
11	R12114	Port Hinge
12	23465	Lateral hand door gasket
13	R32835	Lateral door port
14	R12135	ICD right hinge
15	R12136	ICD left hinge
16	R12147	Intensive Care Door Assy
16	R32839	Intensive Care Door (Acrylic part only)
17	R12116	Port hinge assy
18	R12146	Port lock Assy.
19	R32833	Port (acrylic part only)
20	23464	Port gasket
21	R12122	ICD Latch
22	R25267	Hood top
23	R24121	Removable double hood top
24	R31401/2	Left (rear) hood support
26	R24464/1	Sensor box (for servo humidity)
25	R31400	Right hood support
27	R12126	Air temperature probe
28	R30032	Right handle
29	R30033	Left handle
30	32089	Tray guide pin
31	R30600	Humidity hose housing
32	R21650	Main Base assy
33	R12133	Sensor connection box Assy
34	R24464	Sensor box
34	R24464/2	Sensor box (for servo Oxygen)
35	R31401/1	Left (front) hood support
36	22407	Tray lock pin
37	R11146	Spiral cover assy
38	R25266	IV port
39	DIR-10	Reusable skin temperature probe
39	DIR-30	Disposable skin temperature probe (12 pieces per pack)
	DIR-34	Skin probe protectors (120 pieces per pack)
	R12134	Humidity sensor

6.7 Command module



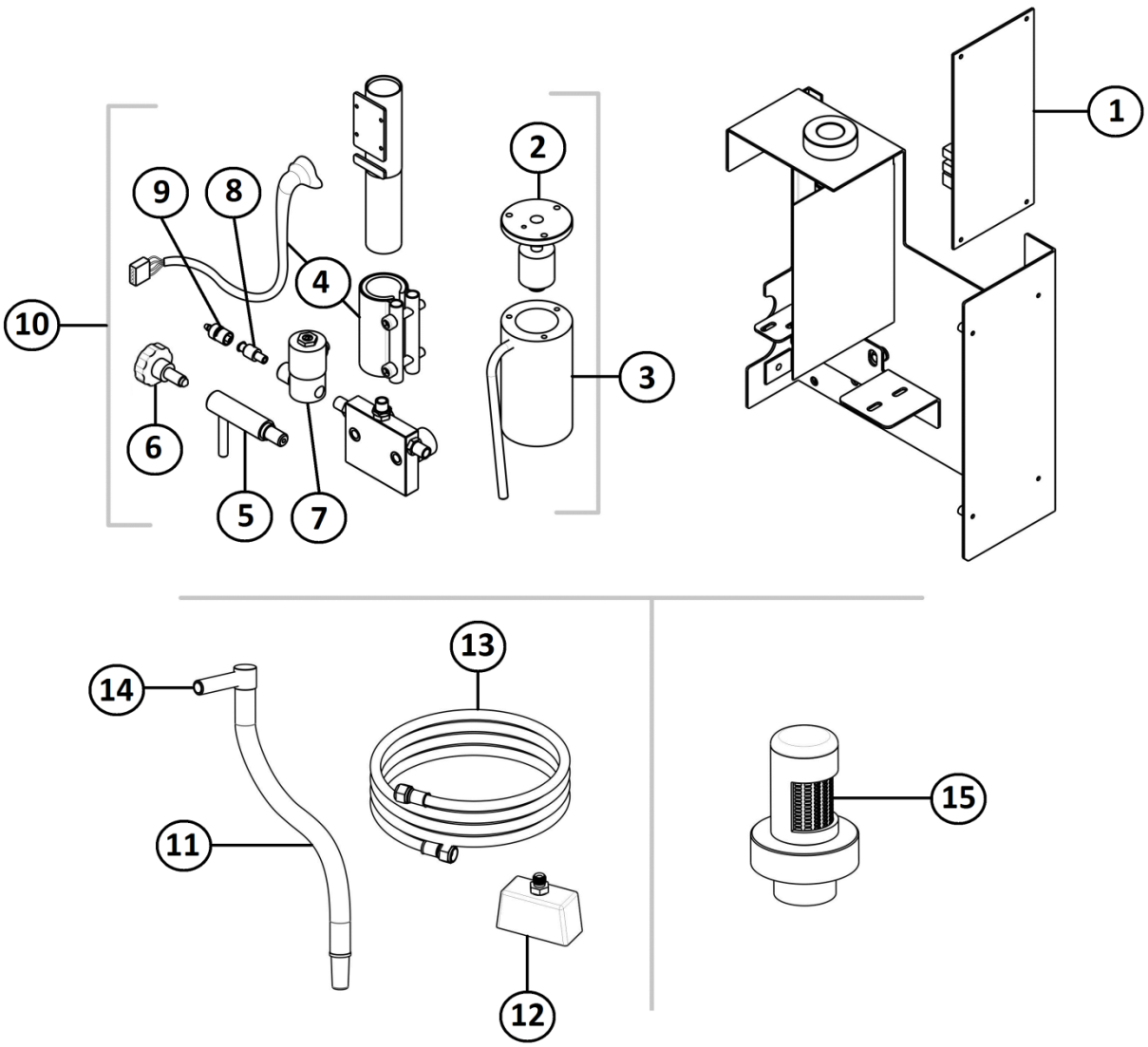
Item	Part number	Description
	R10306	LX Command Module
	27731+1	Crib movement keyboard
	27756	Keyboard
1	R27730	Front case (Keyboards included)
2	R42011	Display board
3	R14155	LCD Screen
4	R42036	Screen controller board
5	R40201	Alarm Board
6	R33900	Rear case
7	R19056	Tilt & pan Assy
8	R45351	Optical encoder
9	31858	Optical encoder knob
	R45401	Module/control wiring

6.8 Control module



Item	Part number	Description
	R47258	120 VCA set of fuses
	R47259	230 VCA set of fuses
1	R45357	Speaker, 8 ohm
2	R49669	Switching power supply
3	R47473	Thermal breaker 16A
3	R47474	Thermal breaker 10A
4	R42026/1	Control board 120 VCA
4	R42026/2	Control board 230 VCA
5	NCA-101	SpO_2 Module
6	R40189	BCI SpO_2 Board
7	R42016	SpO_2 Control board
8	R42018	Weighing Scale control Board
9	R44512	Line Filter 230VCA
9	R44529	Line Filter 120VCA
10	R11296	Battery pack
11	49702	Safe lock
	R46748	Power cord 220 VCA Argentinean plug
	R46756	Power cord 230 VCA Australia
	R46752	Power Cord 120 VCA USA Hospital Grade Connector
	R46754	Power Cord 230 VCA United Kingdom
	R46753	Power cord 230 VCA SCHUKO
	46757	Universal power cord for NCA-111 socket outlets

6.9 Servo-humidity and servo-oxygen



Ítem	Part number	Description
1	R42013/1	Humidity/Oxygen Board 120VAC
1	R42013/2	Humidity/Oxygen Board 230VAC
2	R49680	Water level sensor
3	R25291	Water level detector bowl (does not include item 2)
4	R45490/1	Humidity Heater Assy 120VAC
4	R45490/2	Humidity Heater Assy 230VAC
5	R24814	Drainage assy
6	R19045	Drain knob
7	R49679	Water inlet valve assembly (incluyes items 8 and 9)
8	18141	Water inlet conector
9	39243	Luer Lock/hose adaptor
10	R25274/1	Boiler assy 120VAC
10	R25274/2	Boiler assy 230VAC
11	R18130	Servohumidity hose assy
11	R18130/10	Set x10 Servohumidity hose assy
12	R19048	O_2 calibration cap
13	18136	Oxygen inlet hose
14	R36031	Humidity hose connector
15	R12134	Humidity sensor
	44409	Thermal Protector 165ºC
	R43690	Set of 2 Oxygen Sensors
	R15105	Servo O_2 inlet valve assy
	R45488	Servo O_2 inlet valve

7. SPARE PARTS AND TECHNICAL SERVICE REQUEST INSTRUCTIONS

In order to avoid spare parts supply problems with our customers and dealers, the three basic items described below must be followed for their correct request:

A) Locate the equipment serial number on the respective metallic label.

B) Locate the spare part requested in its respective group or any other sub-group into which this SPARE PARTS CATALOG is divided. After the part has been found on the parts list schematics, write down the respective item number and its part number on the list of spare parts.

Check the number of pieces to be requested.

With the data above mentioned, i.e.: Serial Number, Item number, Part Number, and Number of Pieces, contact our factory or dealer.

APPENDIX 1: ELECTRICAL SAFETY CHECK

The Natal Care ST-LX has been developed to comply with the standards IEC/UL 60601-1 and CAN/CSA-C22.2 No.601.1-M90. To ensure electrical safety of the equipment it is recommended that qualified service personnel performs the electrical safety check at regular intervals (at least every 12 months or in accordance with the local and governmental regulations) and after every repair procedure, which involves the opening of the Natal Care ST-LX housing.
The electrical safety tests for the Natal Care ST-LX have to be performed in accordance with the standards IEC/UL 60601-1 and CAN/CSA-C22.2 No.601.1-M90 for instruments classified as Class 1 and Type BF. Technicians must be familiar with these standards applicable to the institution and the country. Test equipment and its application must comply with the applicable standard.

Safety test according to IEC/UL 60601-1

Tools: Safety analyzer for tests according to IEC/UL 60601-1 (e.g. 601PROXL International Safety Analyzer from BIO-TEK)

 Before performing the safety test read the operating instructions of your safety analyzer.

 Never touch the equipment under test or anything connected to it while high voltage is applied during the high potential test. High voltage can lead to injury or death.

The sensor is an applied part of Type BF.

The safety test is performed according to IEC/UL 60601-1. The following connections must be tested (while the Natal Care ST-LX is switched on):

- Protective Earth Resistance test: Earth wire of the AC power cord, equipotential terminal (ground), and heater. The resistance between two of these must be less tan 0.2 Ω. Minimum current: USA= 1 A, Europe= 5 A.
- Earth Leakage Current: The current must be below 500 µA.

If the above requirements are not fulfilled, the Natal Care ST-LX needs to be repaired. Refer to troubleshooting specific section to further evaluate the problem.

Check the AC power cord for breaks or damages of the isolation. Check the connectors for damages.

The AC power cord must be tested when connected to the AC power outlet. Thereby the cable must be swayed to detect potential cable breaks or loose contacts. The AC power cord must be tested together with the Ground Integrity.
If the above specifications are not met, then the AC power cord needs to be replaced by a new AC power cord.

High potential test according to IEC/UL 60601-1

Tools: AC High potential tester (e.g. CE Multitester from METREL).

 Before performing the safety test read the operating instructions of your safety analyzer.

Never touch the equipment under test or anything connected to it while high voltage is applied during the high potential test. High voltage can lead to injury or death.

The sensor is an applied part of Type BF. The interface ports of the Natal Care ST-LX meet the same requirements as the sensor port and are tested in an analogous manner.

The high potential test for accessible parts is performed with a voltage of 1760Vac during 1 second for units of 230 Vac and with a voltage of 1200 Vac for units of 120 Vac, between the following connections of the Natal Care ST-LX:

HIGH POTENTIAL TEST, ACCESSIBLE PARTS (AP)		
	CONNECTION 1	**CONNECTION 2**
1. MEASUREMENT	**PHASE CONNECTED TO NEUTRAL OF THE AC POWER CORD**	**PROTECTIVE EARTH TERMINAL**

If a disruptive discharge occurs refer to troubleshooting specific section to further evaluate the problem.

APPENDIX 2: NATAL CARE PERFORMANCE AND SAFETY CHECK REPORT

Product identification:					
Natal Care ST LX S/Nº					
Optional Modules					
Servo Oxygen		Servo Humidity			
Weighing scale					
Organization name				Place	
Service Rep Name				Date	
Signature					

a- Operational Check

Test (Item in User Manual)	Results	Passed
Air filter integrity (1)		
Alarm test (6,7&8)		
Visual inspection (9)		
Power failure alarm (10)		
Air temperature at 32ºC (11)		
Skin mode (12)		
Override (13)		
T2 display (14)		
Sensor failure alarm (15)		
Tilting mechanism (16)		
Lift (17)		
Oxygen cells calibration (18)		
Low water alarm (20)		
Weighing scale (21)		

b- Technical Check

Test	Results	Passed
Over temperature alarm		
Heater radiator alarm		
Air flow		
Power failure alarm		
Keyboard		
Environmental sensor		
Oxygen at 40%		

b- Technical Check (Cont)		
Test	**Results**	**Passed**
Scale calibration		
Humidity at 80% RH		

c- Safety test IEC/UL 60601-1			
Safety analyzer Brand		Model	
Serial Number		Next calibration date	

Test	Results		Passed
Ground integrity, cable power incl.	Value	Ω	
Earth leakage current, max 500 µA	Value	µA	
Dielectric Strenght Test, IEC/UL 60601-1 Accessible parts 1200 VAC 1 sec (For 120 VAC units); 1760 VAC 1 sec (for 230 VAC units)	**No disruptive discharge** Measurement	µA	

Due to MEDIX' and Natus' commitment to continually improve its products, the manufacturer reserves the right to make changes without prior notice.

Natus Medical Incorporated
Corporate Headquarters
1501 Industrial Road
San Carlos, CA 94070
USA

Phone: +1 (650) 802-0400
+ 1(800) 255-3901 (Toll Free)
Fax: +1 (650) 802-0401

, www.natus.com

a division of natus

Marcos Sastre 1675, El Talar, Tigre, B1618EWC, Buenos Aires, Argentina
Tel: +54-11-5354-3700, Fax: +54-11-5354-3721
medix@medix.com.ar
www.medix.com.ar