DELTA RM15 Respiration Monitor Instruction Manual

Respiration Monitor for Apnoea Detection
Model: RM15
Service Manual
Revision 1.14

Contents

RM15 Respiration Monitor

All possible care has been taken in the preparation of this manual, but Delta Medical International accepts no liability for any inaccuracies that may be found and reserves the right to make changes without notice to this publication and to the product.

Introduction:

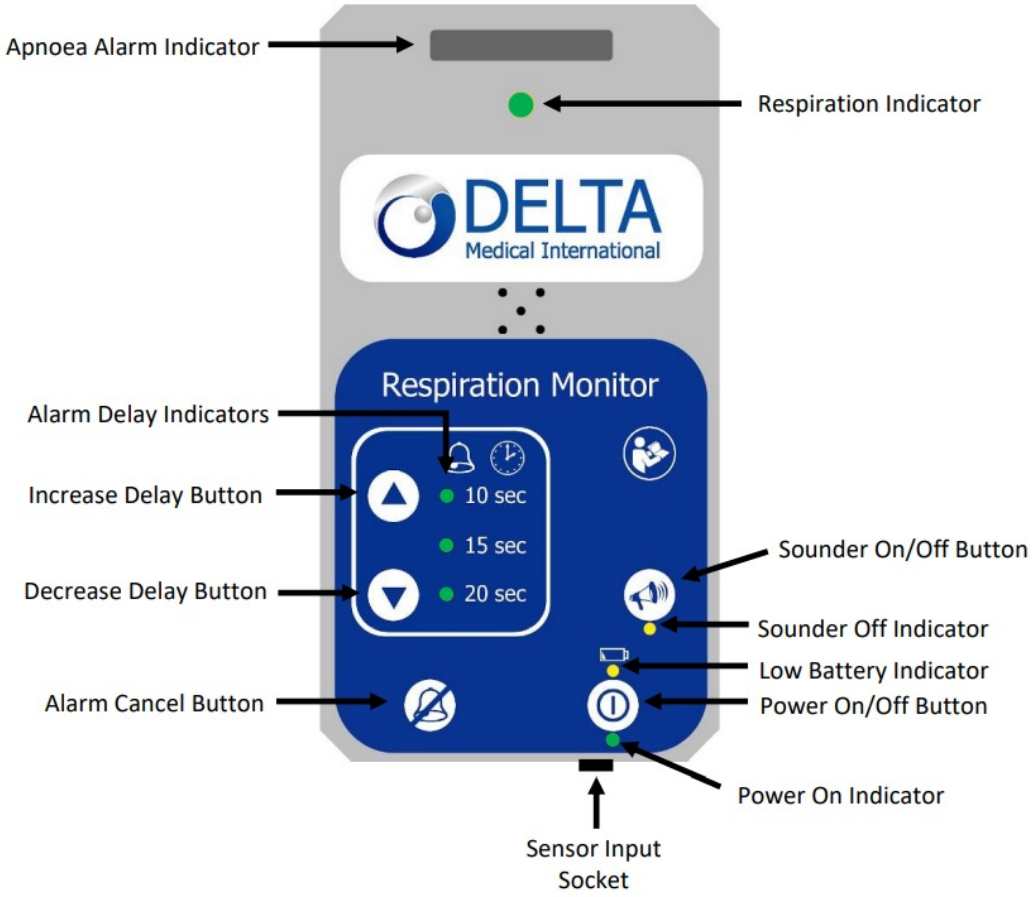
 **CAUTION:** Service and maintenance must only be undertaken by a suitably qualified engineer or technician. If in doubt refer to Delta Medical International or your local supplier.

The Respiration Monitor is used to continuously monitor the respiration of infants up to the age of 18 months. The Monitor will give audio and visual alarms if the infant stops breathing for more than a user-selected time.
The respiration signal is picked up by a disposable pneumatic sensor which is attached to the infant's abdomen. During breathing, expansion of the abdominal wall displaces a small amount of air in the sensor which is transmitted through an integral tube to the monitor. Each breath is detected by the monitor and triggers a visual indication and an audible click if enabled.
The Respiration Monitor only gives an indication of an apnoea event and cannot prevent it. The user must ensure all reasonable precautions and actions are taken.
The unit consists of one printed circuit assembly mounted in a molded plastic box with two sounders mounted internally to the case front panel and rear panel. The case has an externally accessible battery compartment designed to hold 3 off AA-size alkaline batteries, each with a 1.5Vdc output, connected in series to give a total output of 4.5Vdc.
The unit is an approved medical device and must only be serviced by competent authorized staff.
The instrument case is sealed so it is important to ensure correct reassembly after any service to maintain this level of protection.
This Manual should be read in conjunction with the Instruction Manual for the product.

Warnings & Cautions

Service and maintenance must only be undertaken by a suitably qualified engineer or technician.
If in doubt refer to Delta Medical International or your local supplier.
Ensure work areas are clear, clean, and free from any dirt before starting any service work.
Always use the correct type and size of a screwdriver when removing and fitting screws.
Only AA size 1.5V alkaline batteries must be used.
Check case is correctly reassembled to preserve IP rating.
If replacing the case ensure the serial number is correctly transferred.
Verify correct performance after any service or repair work using the designated test procedure.
Do not autoclave, steam sterilise, ETO sterilise, immerse in fluids or expose the Monitor to high temperatures, in excess of 45°C.
The screwdriver and batteries supplied with this product could be a choking hazard. Keep them away from small children.

Controls & Indicators:



NOTE:
On older devices (SN up to 20:00116) the Low Battery Indicator is combined with the Power On Indicator

Symbols:

Warning or Caution that could cause harm to the user or patient or damage to the product	
Power On/Off (standby)	Refer to operating instructions
Respiration Sounder silence/enable	Alarm Cancel button
Alarm Delay	Alarm Delay increase/decrease
Sensor input connector	Type B applied part
Negative Battery Polarity Positive	Battery compartment 3 x AA 1.5V cover
CE Mark, European MDD 93/42/EEC	Manufacturer details
Dispose according to EU WEEE Directive	**S**/**N** Product Serial Number
Low Battery indicator	

Spare Parts List:

Part No.	Description
NMA021	Strap, blue, RM15
NMA025	Screwdriver, Miniature
RM-120006	Front Label, RM15
RM-120003	Handle, RM15, for strap, supplied with screws and washers
RM-1200013	Main PCB Assembly, RM15, with input tubing fitted
RM-1200014	Case front panel, with label and sounder, fitted
RM-1200015	Case rear, RM15, with input connector, handle, sounder and labels fitted
RM-UM-001	User Manual, RM15

Routine Maintenance:

The following routine maintenance should be carried out at the intervals shown.
Before each use:

- Check there is no sign of damage or contamination to the monitor.
- Check there is no sign of damage or contamination to the hanging strap if fitted.
- Check the condition of the batteries.

- Check alarm sounds after delay period if no sensor is connected.
- Check the unit has been decontaminated in accordance to local infection control guidelines.
- Check the unit registers breathing once connected to patient.

Daily:

- Check there is no sign of damage or contamination to the monitor.
- Check there is no sign of damage or contamination to the hanging strap if fitted.
- Check the condition of the batteries.
- Check the unit is registering patient's breathing.
- Check alarm sounds after delay period if no sensor is connected.

Annually (or at interval dictated by local guidelines if different):

- Check there is no sign of damage or contamination to the monitor.
- Check there is no sign of damage or contamination to the hanging strap if fitted.
- Check the condition of the batteries.
- Check the condition of the battery compartment screw and replace it if necessary.
- Check there is no sign of corrosion to the battery compartment terminals.
- Check the condition of the battery compartment seal and replace it if necessary.
- Carry out Test Procedure as specified in Appendix A.

Fault Finding:

The following table gives a guide to the diagnosis of the cause of any fault. Ensure that the suggested causes/actions are carried out in the order shown.

Symptom	Suggested Cause / Action
Strap comes loose	Check strap is passed through the buckle in the correct orientation
Unit will not turn on	Check the On/Off button pressed for at least 2 sec. Check batteries ar e the correct type and correctly fitted Fit new batteries Check PCB is n ot loose inside the case Check internal PCB connection to battery ter minals Check supply voltage to PCB If no supply voltage replace the case (battery compartment) If voltage i s present and still not working replace PCB
Unit will not turn off	Check the On/Off button pressed for at least 3 sec. Check PCB is not l oose inside the case If still not working replace PCB
Audio output volume low / No audio ou tput	Check holes in the front label are not blocked Check connections to both internal sounders are intact If only one sounder not working, replace the sounder If both sounders not working replace PCB
Breath Sounder not working	Check breath silence button is not pressed or stuck Remove the sensor and check alarm sounds after the delay period If t he alarm also not working check audio output as above If still not work ing replace PCB
Unit does not register breathing	Check sensor is correctly attached to a baby Change the sensor and see if the problem resolved Check input connector is not obstructed Check internal input tubing is not kinked or obstructed Check internal i nput tubing is not detached or loose Check patient is no more than 18 months old Check sensitivity is in the correct range (see Section 11) Increase sen sitivity so breaths are detected at a lower level If still not working repla ce PCB
Breath silence not working	Check PCB is not loose inside the case If still not working replace PC B
Breath LED not working	Check breath sounder is working If sounder is working replace PCB If the sounder not working check as “unit does not register to breathe” above
Delay adjust not working	Check buttons pressed for at least 2 sec. Check PCB is not loose insi de the case If still not working replace PCB

Symptom	Suggested Cause / Action
Alarm not working (both audio and visual)	Check lack of signal lasts longer than Delay setting Check movement not creating artificial signal Check vibration not creating an artificial sig nal Put tape over the input connector and check alarm sounds If still not w orking replace PCB
Alarm LEDs not working	If sounder not working check “alarm not working” as above If the alar m sounder is working replace PCB
Alarm audio not working	If breath sound not working check the audio output as above If still not working replace PCB
Alarm silence not working	Check PCB is not loose inside case Replace PCB
Device generates frequent false alarm s	Check sensitivity is in the correct range as described in Section 11. & Appendix A Increase sensitivity so breaths are detected at lower level See also “u nit does not register breathing” above

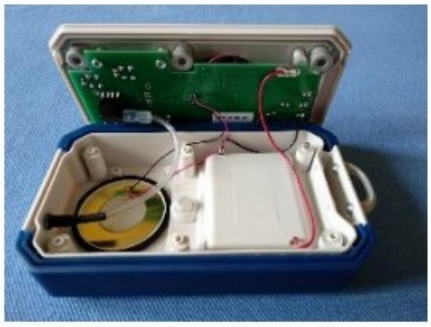
If it is not possible to diagnose the fault using above guide please return the unit to Delta Medical International or your local supplier for investigation, including as much detail about the fault as possible.

Batteries:

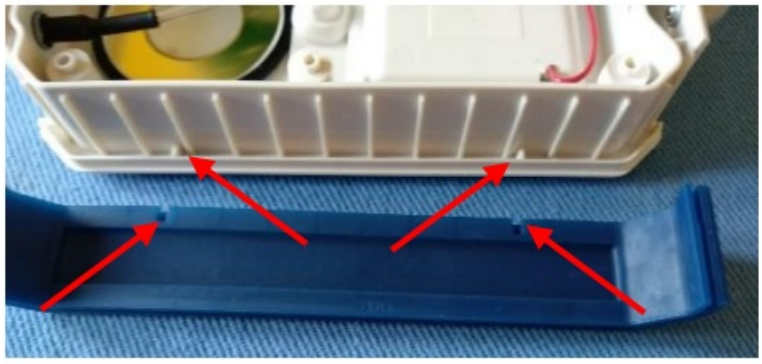
Always check batteries used are of the type specified in the Operating Instructions.
Always check batteries are fitted with correct polarity as shown inside the battery compartment.
To change batteries open the compartment at the rear of the unit using a suitable-sized screwdriver.
Ensure the compartment is closed securely after replacing batteries to maintain seal.

Opening & Closing the Case:

Opening the case:
Remove the battery compartment cover and remove batteries. Remove 6 off crosshead screws holding the two case halves together.
Note that the sounder connecting wires are short and fragile so ensure they are not stressed when opening the case.
Carefully prise the case front panel from the case rear and place the front panel so that the sounder wires are not pulling. Remove the blue side pieces so they are not damaged.

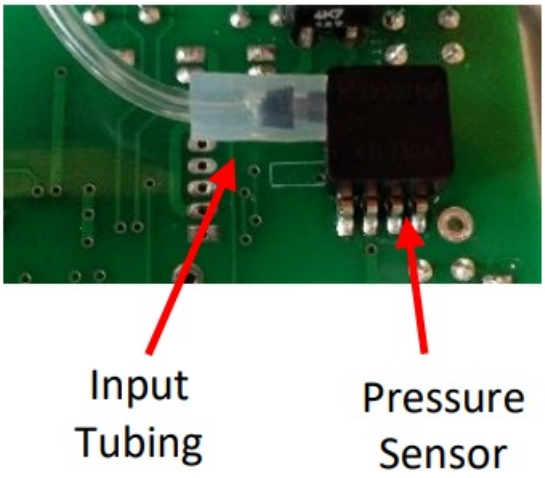


Closing the case:
To close the case replace the blue side pieces, noting that they each need to be orientated so that the two notches fit over the corresponding spars in the case. Ensure that the grooves on each edge of the side pieces fit over the corresponding edges of the case and carefully push the two halves together so that the seal is made and the side pieces fit correctly and are not distorted. Replace the 6 screws, checking that they are all fully tightened. Then replace the batteries and battery compartment cover, checking the retaining screw is fully tightened.

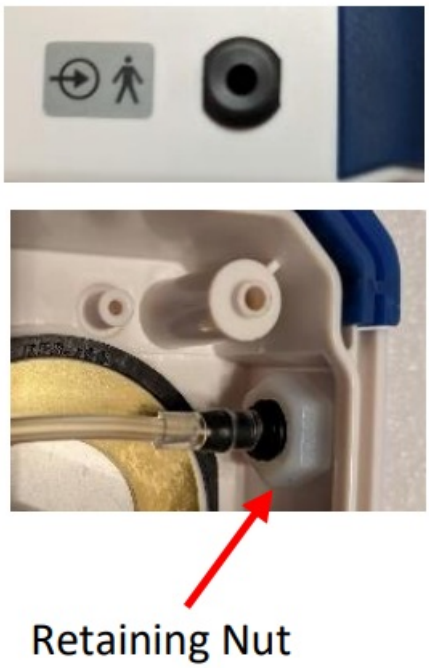


Replacing the Input Connector Assembly:

Open the case as described earlier. Determine whether the connector is attached to the case by a nut on the inside or if it is glued in place.
Disconnect the input tubing from the pressure sensor as shown on the PCB by carefully pulling it away.
If the connector is secured using a nut, then unscrew the nut and remove it. If the connector is glued in place then gently rock the connector from the rear to break the glue seal.
When the connector is free remove it by pulling from the outside of the case, easing the tubing through the hole.



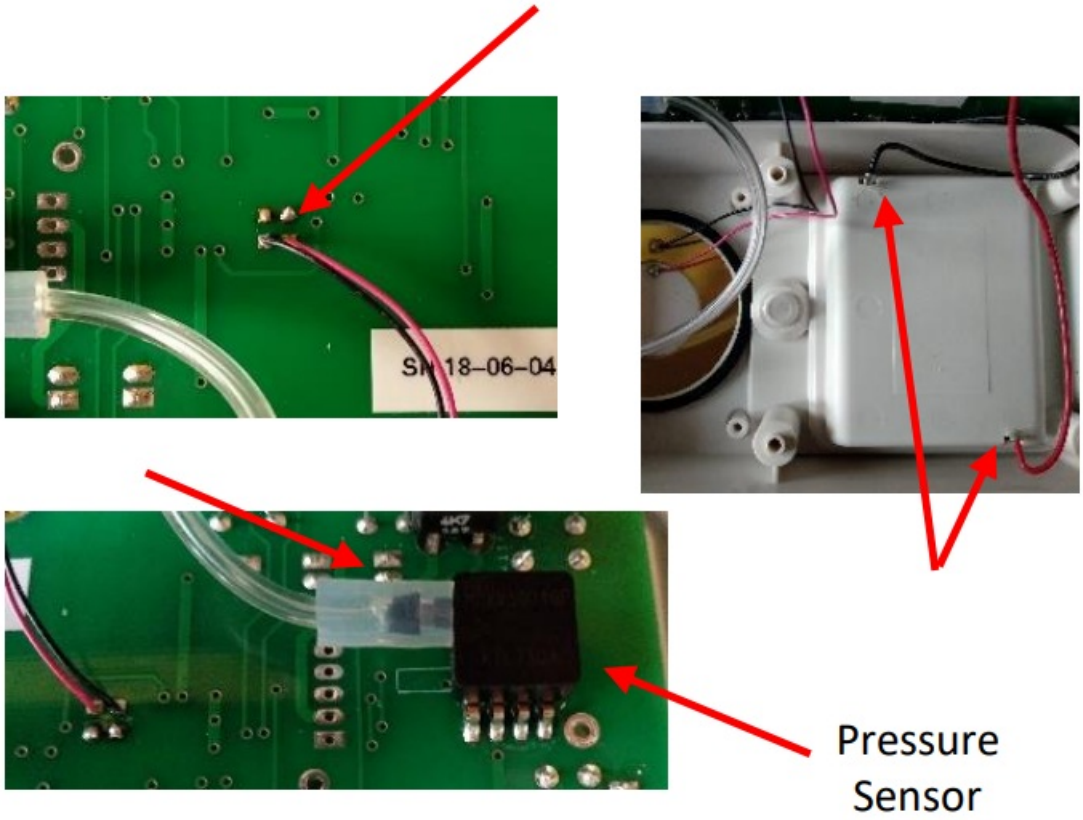
To fit the new connector assembly, first, remove the retaining nut which is attached to the rear of the connector. Then insert the connector through the case opening from the outside, easing the tubing through first. Pass the retaining nut over the tubing inside the case and screw it by hand onto the rear of the connector, taking care not to cross-thread it. Hold the connector on the outside with a suitable spanner, using the flat edges, and tighten the nut from the inside with a suitable spanner. Ensure that the connector is firmly attached and cannot rotate.



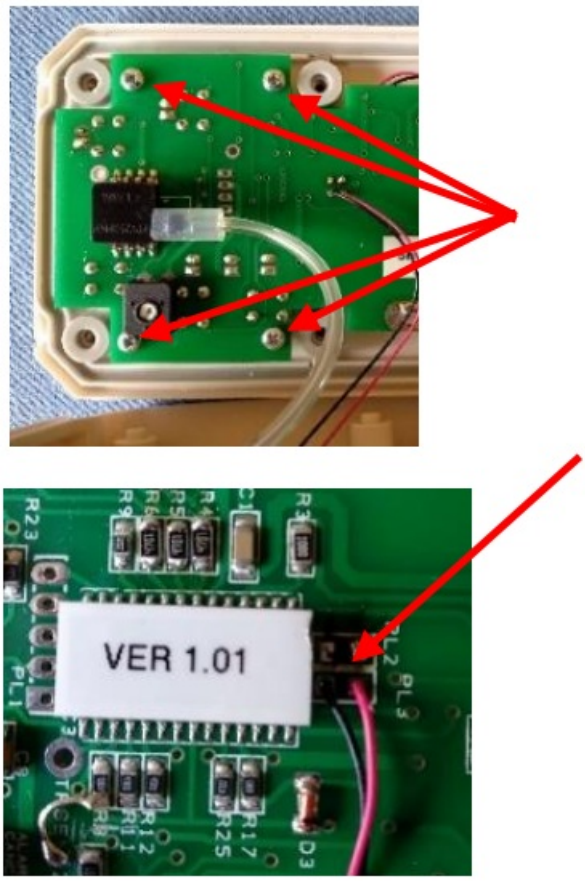
Connect the open end of the input tubing onto the pressure sensor on the PCB by pushing the tube firmly over the barbed inlet on the pressure sensor and ensuring it butts right up to the wall of the component. Carry out Test Procedure as specified in Appendix A.

Replacing the Circuit Board:

Open the case as described earlier.
Note the points on the PCB where the wires from the rear panel sounder are connected, as shown, and de-solder them so the sounder is disconnected.
Disconnect the power input connection wires from the battery pack terminals as shown.
Carefully disconnect the sensor tubing from the input to the pressure sensor on the PCB where shown.



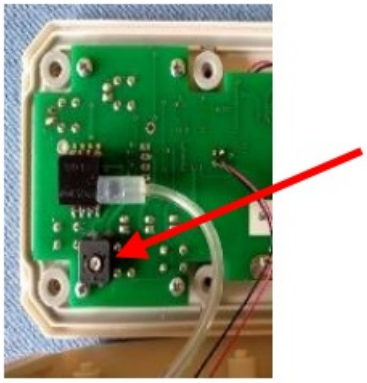
Remove the 4 screws securing the PCB to the case front panel, store them safely, and carefully lift the PCB to allow access to the wires connecting the front panel sounder. Note the points on the PCB where the wires are connected and de-solder them so the sounder is disconnected.
The PCB can now be removed. As the board uses surface-mount components there are no parts that are user serviceable and the complete assembly needs to be replaced.



Re-solder the front panel sounder wires to the new PCB, ensuring the correct polarity as shown. Seat the PCB on the pillars on the front panel and secure using the 4 screws removed from the old board. Check the PCB is held securely and that the buttons can be operated. Reconnect the power input wires to the battery pack terminals. Re-solder the rear panel sounder wires to the new PCB, ensuring the correct polarity as noted when removing. Reconnect the sensor tubing by pushing the tube firmly over the barbed inlet on the pressure sensor and ensure it butts right up to the wall of the component. Close the case as described above. Carry out Test Procedure as specified in Appendix A.

Adjusting Sensitivity:

If the sensitivity test criteria cannot be met as described in the Test Procedure below, then adjust the sensitivity by adjusting the potentiometer shown until the unit meets the necessary performance characteristics specified. Sensitivity setting must be in the range 0.23µl to 0.37µl and must be adjusted using a Sensitivity Test Rig operated in accordance with its instructions for use.

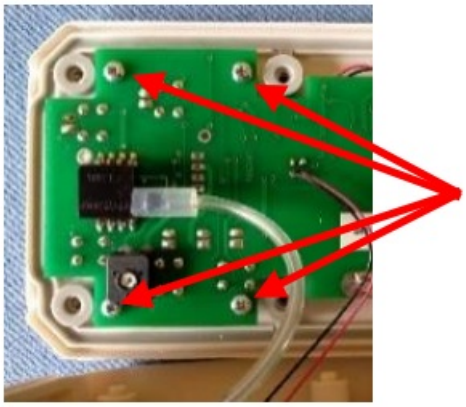


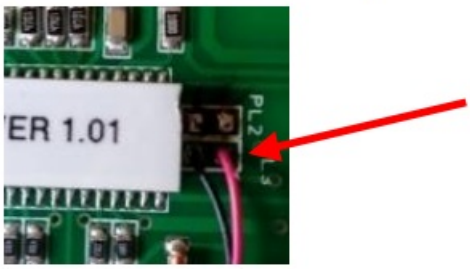
Replacing a Sounder:

Open the case as described earlier and determine which sounder needs replacing. It is prudent first to check that the problem is not due to any break in the connection wires or solder joints. As the sounders are glued to the case moldings it is necessary to replace either the front panel or the case rear depending on which sounder has failed. Refer to the instructions below for these.

Replacing Front Panel:

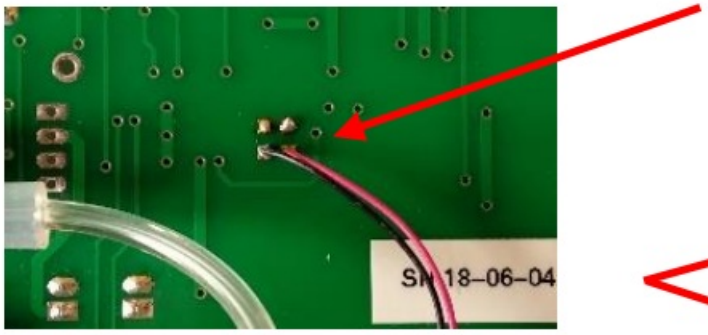
Open the case as described earlier. Remove the 4 screws securing the PCB to the case, store them safely, and carefully lift the PCB to allow access to the wires connecting the front panel sounder. Note the points on the PCB where the wires are connected and de-solder them so the sounder is disconnected. Solder the front panel sounder wires to the PCB, ensuring the correct polarity. Seat the PCB on the pillars on the front panel and secure using the 4 screws removed from the old board. Check the PCB is held securely and
that the buttons can be operated. Close the case as described above. Carry out Test Procedure as specified in Appendix A.

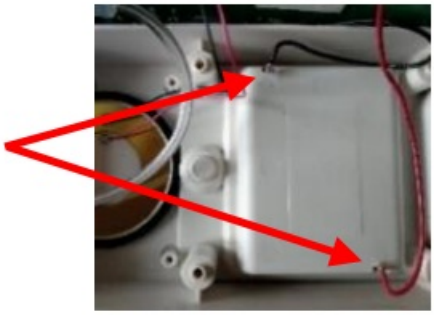


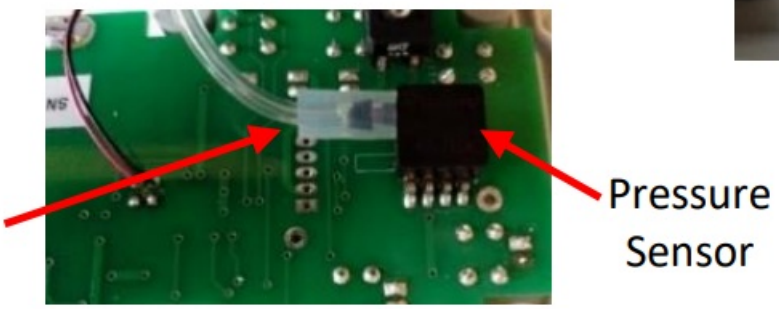


Replacing Case Rear:

Open the case as described earlier.
Note the points on the PCB where the wires from the rear panel sounder are connected, as shown, and de-solder them so the sounder is disconnected.
Disconnect the power input connection wires from the battery pack terminals as shown. Carefully disconnect the sensor tubing from the input to the pressure sensor on the PCB where shown.







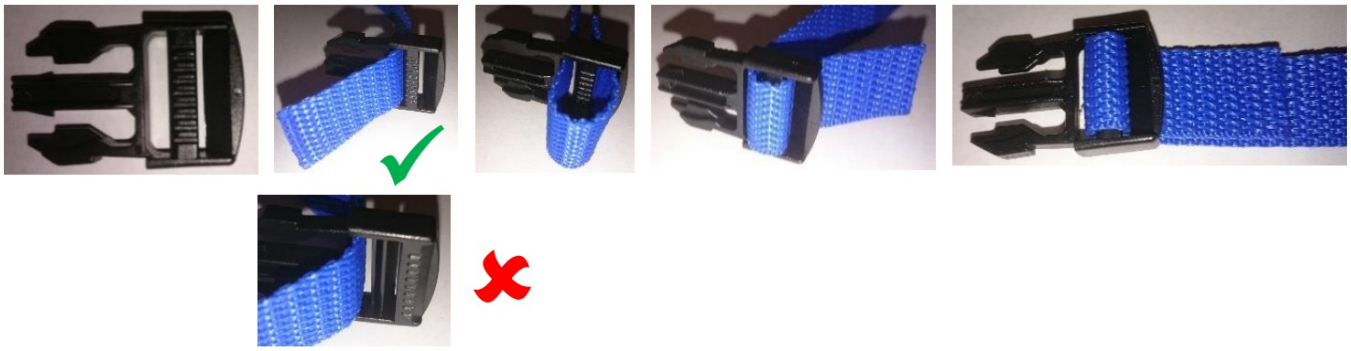
The rear case is now removed and the new part can be fitted by reconnecting the sensor tubing. Push the tube firmly over the barbed inlet on the pressure sensor and ensure it butts right up to the wall of the component. Then reattach the speaker and power input wires, ensuring the correct polarity in both cases as noted above. Close the case as described above. Ensure that the serial number from the old case rear is transferred to the new rear serial number label. This is very important for Medical Device compliance.
Carry out Test Procedure as specified in Appendix A.

Replacing the Strap Handle:

The handle should be fitted to the case with two self-tapping screws and washers supplied with the handle, using screwdriver access holes in the case.
Open the case and remove the PCB as described above, although if careful it may not be necessary to de-solder the sounder wires. If there is silicone sealant in the two access holes carefully remove it (this was only fitted to early units and should not be replaced). Using the access holes, remove the two screws securing the handle to the case and the associated washers thus releasing the handle. Fit a new handle using the screws and washers provided by reversing the above process, ensuring the screws are tightened so the handle is fitted securely. After fitting check handle is securely attached.

Attaching the Strap:

Attach the strap to the monitor, if required, by unclipping the buckles and passing the strap through the attachment loop at the top of the unit, then reattaching the loose clip as shown below. Check if the orientation of the clip is correct or if the strap will not be secure.



The length of the strap can be adjusted by feeding the strap through the adjustment cleat in the appropriate direction.

Technical Specifications:

Parameter	Specification
Power Input	4.5V – 3 x AA (LR6) Alkaline Batteries
Power Consumption	32mW (typ.)
Power Input	4.5Vdc, 7mA (typ.)
Apnoea Alarm Interval	10, 15 or 20 sec (user selected)
Size	8.8 x 14.6 x 3.3cm (W x H x D)
Weight	0.3kg (including batteries)
Operating Temperature	+10°C to +40°C
Storage Temperature	-10°C to +55°C
Compliance	EN 60601-1, EN 60601-1-2, MDD 93/42/EEC

These specifications may change without notice due to continuous product improvement

Appendix A – Test Procedure
(Requires the use of a Sensitivity Test Rig)

Check the unit serial number and enter it on the Test Record (see Appendix 8)
Set simulator and leave for 1 hour running before use, adjust Supply Voltage to give 60 breaths/minute
Fit batteries
Attach the respiration simulator to the device and set a respiration volume 0.030 below the required threshold a s defined in Section 12 above.
Adjust the potentiometer on the rear face of the PC8 so that breaths are just not detected.
Increase simulator output to the required threshold and check at least 10 breaths are detected and no breaths a re missed.
If tests 4 & 6 are not passed then adjust the potentiometer until both criteria are met and leave the simulator out put set to the required threshold for the next steps.
Check the unit has no sign of any damage
Power up the unit using the Power Button and check the Power On/Off indicator illuminate
Press Power Button for 1 second and release. Ensure the unit does not tum off
Press Power Button for 3 seconds and release. Ensure the unit turns off.
Power up the unit again using the Power Button
Press up or down buttons to set the delay to 10,15 and 20 seconds and ensure that the indicators for each resp ective delay illuminate. Leave set on 20 seconds
Restart devise by turning it off and on
Check the delay is stilt set to the last setting
Set delay to 10 seconds. Restart devise and check delay is still set to 10 seconds
Check the green LED aluminates at each breath detected
Check an audible click is heard at each breath detected
Press Sounder On/Off button and check the indicator illuminates
Check the green LED illuminates at each breath but the audible click is off
Press Sounder On/Off button and check the indicator LED is off

Check both the visual and audible breath indication is present
Turn off the respiration simulator, check the audible and visual alarm starts after the selected delay time (t2 sec.
Press Alarm Cancel and check audible and visual alarm stops and re-starts after 60 seconds ±5 secs
Press Alarm Cancel and re-start the simulator
Check alarm does not rear after 60 seconds
Change delay to 15 seconds and repeat Steps 24 to 27
Change delay to 20 seconds and repeat Steps 24 to 27
Set delay to 10 seconds
Disconnect the simulator from the device and check the audible and visual alarm starts after 10 seconds
Turn off the unit and remove the batteries
Attach DC Voltage Supply set to 4.5 V
Turn on the device and slowly tum down the Variable CPC Voltage from 4.5 V to 3.5 V
Check the low battery indicator flashes to indicate low battery, check an audible beep sounds every 30 seconds t5 sec
Replace batteries and tum on to ensure low battery indication has ceased
Complete and sign the Test Record

Appendix B – Test Record

Unit Serial No.:	Test Date:

Test Action	Result	Value
Check calibration & adjust if necessary	Pass / Fail	p1
Check the unit has no sign of any damage	Pass / Fail	N/A
Power on/off light illuminates	Pass / Fail	N/A
Power off functions correctly with delay	Pass / Fail	N/A
Delay Set lights illuminate	Pass / Fail	N/A
Last delay setting stored	Pass / Fail	N/A
Respiration monitor function (Light & Sound)	Pass / Fail	N/A
Respiration monitor silence function	Pass / Fail	N/A
Alarm function (10s) and delay time	Pass / Fail	sec
Alarm function (15s) and delay time	Pass / Fail	sec
Alarm function (20s) and delay time	Pass / Fail	sec
Alarm Cancel function (10s) and time silenced	Pass / Fail	sec
Alarm Cancel function (15s) and time silenced	Pass / Fail	sec
Alarm Cancel function (20s) and time silenced	Pass / Fail	sec
Sensor removed alarm	Pass / Fail	N/A
Battery low detection and alert	Pass / Fail	sec

Tested by:……..
(Print Name)
Signed:……..
Date:……

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Documents / Resources

	**DELTA RM15 Respiration Monitor** [pdf] Instruction Manual RM15 Respiration Monitor, RM15, Respiration Monitor, Monitor

References

- Delta Medical International | Healthcare & Medical Products