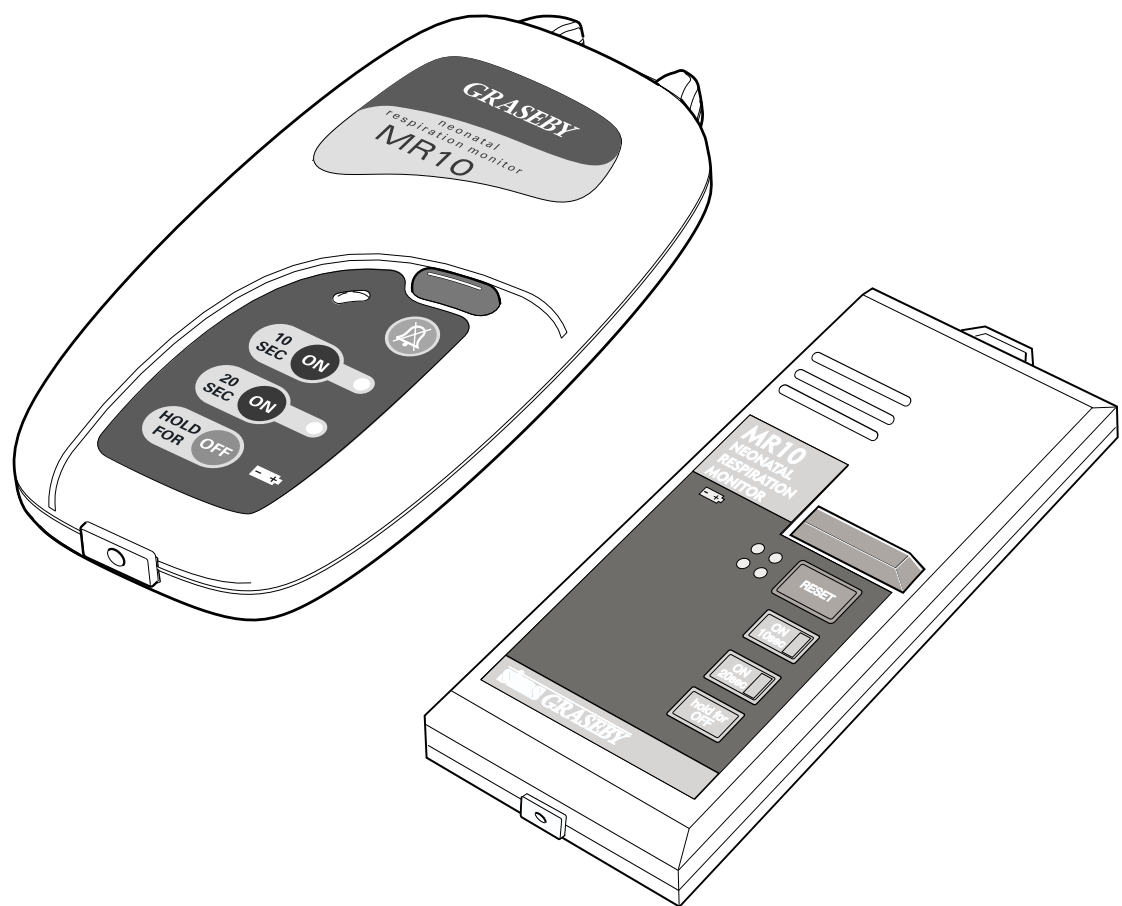


Graseby MR10 Neonatal Respiration Monitor



Technical Service Manual

Warnings

Warnings tell you about dangerous conditions, that could lead to death or serious injury to the user or infant, that can occur if you do not obey all of the instructions in this manual.

1. **WARNING:** The MR10 only informs of an apnoea attack, it cannot prevent an apnoea attack.
2. **WARNING:** If you suspect that the Monitor is not operating correctly, do not use and return to SIMS Graseby or a suitably qualified technician for testing.
3. **WARNING:** Only use the SIMS Graseby Respiration Sensor, REF 0108-0007. The performance of the Monitor can only be guaranteed with this Sensor.
4. **WARNING:** The Respiration Sensor should only be used on one infant. Using the same Sensor on more than one infant increases the risk of cross infection.
5. **WARNING:** Correct positioning of the Respiration Sensor tubing is important to avoid the tube becoming entangled around the infant's neck, resulting in infant injury or death.
6. **WARNING:** Mobile communication devices e.g. mobile phones, should not be used at a distance of less than one metre to the MR10 Monitor, as this could affect the safe operation of the Monitor. Even if these devices cause no obvious interference, possible interference can only be ruled out if this advice is strictly observed.
7. **WARNING:** The Monitor is not suitable for use with adults or children over the age of 18 months.
8. **WARNING:** The Monitor must not be covered by bedding or other objects so that the audible and visual alarms are impaired. Failure to observe this warning could result in infant injury or death.
9. **WARNING:** To prevent the Monitor being accidentally switched off, the Monitor must not be placed within reach of the infant. Failure to observe this warning could result in infant injury or death.
10. **WARNING:** The Monitor must not be pushed into confined spaces, so that pressure could be exerted upon the keypad buttons causing the Monitor to be switched off or the settings to be changed. Failure to observe this warning could result in infant injury or death.
11. **WARNING:** If the Monitor alarms, before doing anything else make sure that the infant is safe and comfortable and not in a dangerous situation.
12. **WARNING:** Use only type LR6 alkaline batteries. Rechargeable batteries are unsuitable and must not be used as they could affect safe operation of the Monitor.
13. **WARNING:** This equipment is not suitable for use in the presence of flammable anaesthetics oxygen-enriched or explosive atmospheres. The use of the device in such atmospheres can lead to explosion or fire.
14. **WARNING:** The Monitor must be operated within the specified parameters, see Technical specification page 1-11. Failure to do so could result in infant injury or death.
15. **WARNING:** With the monitor working correctly, if an alarm occurs frequently then medical advice must be sought to ensure that the infant's health is not in any danger.
16. **WARNING:** The monitor must not be used in the presence of, or in combination with Magnetic Resonance Imaging (MRI) machines. Induced current could cause burns to the infant or user injury and affect the functions of the monitor. The monitor may also affect the MRI image.
17. **WARNING:** To avoid possible malfunction of the monitor, do not expose the monitor to X-rays, gamma rays, ionising radiation, strong electric or magnetic fields such as diathermy or mobile telephones. Malfunction of the monitor can cause incorrect monitoring or loss of monitoring resulting in infant injury or death.

Cautions

Cautions tell you about dangerous conditions that can occur and cause damage to the Monitor if you do not obey all of the instructions in this manual.

1. **CAUTION: Refer all service, repair and calibrations only to qualified technical personnel. Unauthorised modifications to the Monitor must not be carried out.**
2. **CAUTION: Failure to observe the following cautions may cause internal damage to the monitor.**
 - **Do not autoclave, steam sterilise, pressure sterilise or gas sterilise this monitor.**
 - **Do not expose this monitor to temperatures in excess of 40°C (104° F).**
 - **Cleaning Do not immerse the monitor in any liquid.**
 - **Wipe off any liquid spills immediately, do not allow any fluid or residues to remain on the monitor.**
 - **Do not use abrasive agents or strong organic solvents.**
3. **CAUTION: The Printed Circuit Board (PCB) contained in the monitor is electrostatically sensitive. Always use an earthing strap when handling the PCB to avoid electrostatic damage to the components. Ensure that replacement PCB are stored in anti-static containers.**

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Abbreviations

The following list shows the abbreviations that have been used within this Manual.

Abbrev.	Item
ABS	Acrylonitrile butadiene styrene
C	Capacitor
D	Diode
dB	Decibel
DSP	Digital switching processor
Hz	Hertz
IC	Integrated circuit
kHz	Kilo Hertz
µL	Microlitres
LED	Light emitting diode
PC	Polycarbonate
PCB	Printed circuit board
Pf	Picofarad
Pl	Plug
R	Resistor
Sec	Second
Sk	Socket
V	Volts

Chapter 1

Introduction

The MR10 Neonatal Respiration Monitor is capable of continuously monitoring the respiration of infants up to the age of 18 months, and will give audible warnings and visual alarms if the infant stops breathing for more than the pre-set selected time.

The Respiration Sensor consists of an encapsulated foam pad connected to a plastic tube. Expansion of the baby's abdomen (with each breath) produces a change in pressure in the tube; this change is detected by the Monitor which shows the following:

- a flashing green light if the **ON 10 sec** alarm delay button is selected or an orange light **ON 20 sec** alarm delay button is selected
- an audible clicking sound.

If the baby stops breathing the condition is called apnoea. After a programmable preset delay (10 or 20 seconds depending on which alarm delay was selected) an apnoea is indicated by both audible and visual alarms.

Case design

The MR10 Neonatal Respiration Monitor has two different types of case design, although the actual monitor operates exactly the same. This manual covers both versions of the MR10 case design, where differences occur within the manual they are referred to as the *old case* or *new case* design. The 2 types of design are shown on the next page.

- the old case design covers monitors with serial numbers from 30,000 to 80,000 see Figure 1-1.
- the new case design covers monitors with serial numbers from 80,000, see Figure 1-2.

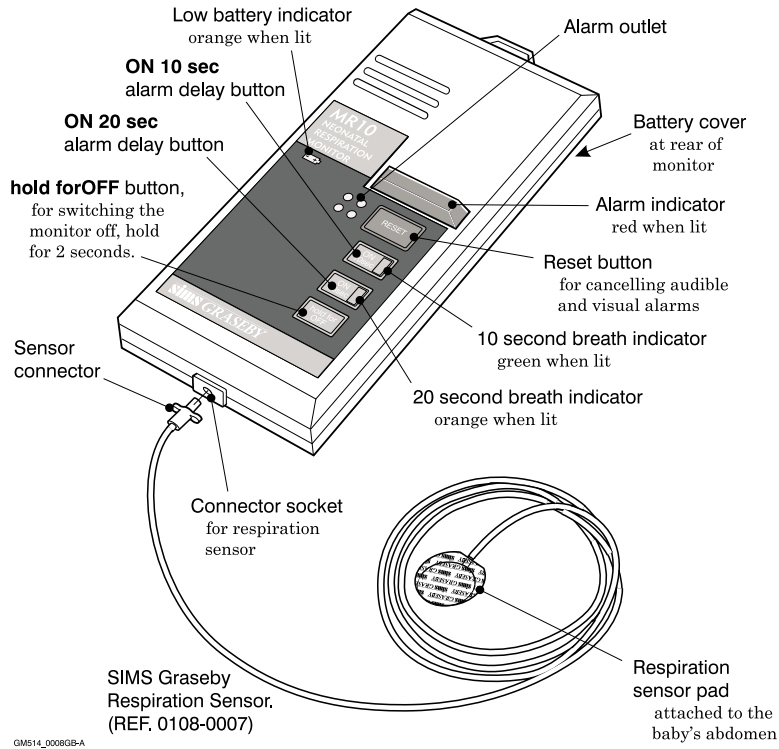


Figure 1-1 MR10 old case design (for serial numbers from 30,000 to 80,000)

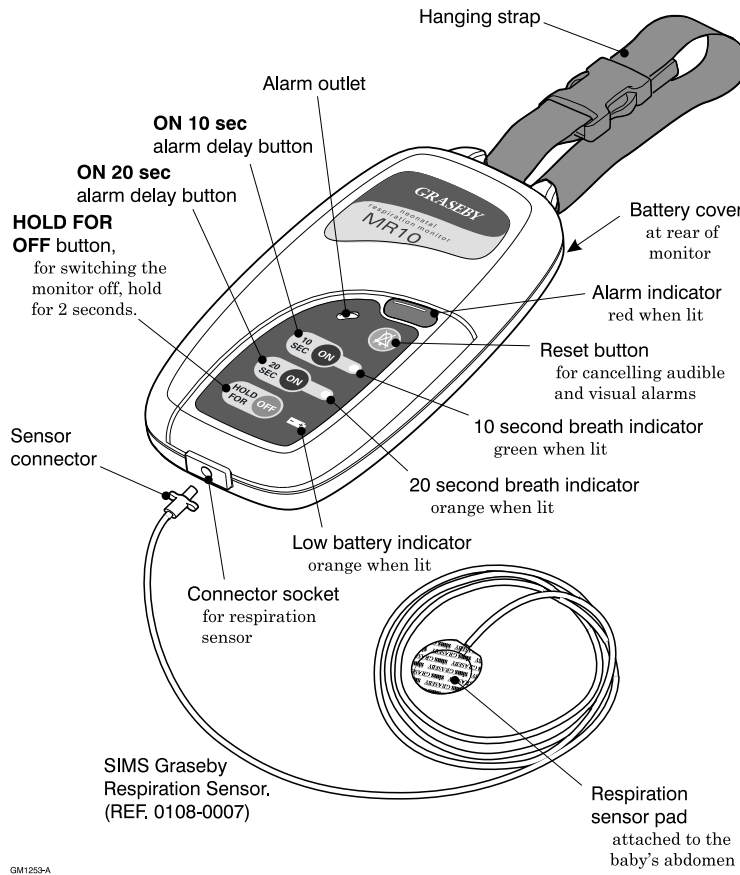


Figure 1-2 MR10 new case design (for serial numbers from 80,000)

Specification

Dimensions:

Old case design 159 x 77 x 24 mm (H x W x D) for serial number *below 80,000*

New case design 170 x 85 x 30 mm (H x W x D) for serial numbers *above 80,000*

Weight:

Old case design 240 grams (with batteries fitted).

New case design 275 grams (with batteries fitted).

Indicators

A green LED is lit when the **10 sec.** Alarm delay button is set

A orange LED is lit when the **20 sec.** Alarm delay button is set

Sensitivity:

When delivered, the monitor will be adjusted to detect breathing within certain limits. These limits are defined in terms of a pneumatic signal connected to the transducer inlet port. This signal is measured in microlitres (μl) of air volume (limits 0.23 μl to 0.37 μl).

Timing accuracy:

+ /- 0.8% or 0.5 second, whichever is the greater.

Signal detection and filtering:

The monitor filters the respiration signal before the breath detection process. This removes features of the signal which could otherwise cause erroneous results. This includes removal of signals caused by movement, the unwanted DC component of the pneumatic signal, electrical interference (e.g. mains hum), and the cardiac pressure pulse (which is reduced in intensity by the low pass filter).

The monitor expects the breathing rate to be between 40 and 140 per minute (this corresponds to a frequency range of 0.67 Hz to 2.3 Hz).

The filter type is bandpass, with a frequency response of 0.5 Hz to 3.0 Hz (-3 dB).

The presence of a breath is detected by a threshold comparator. The threshold is set to detect the inhalation part of the signal; it will be near the beginning of the inhalation for a large signal but a small signal will not be detected until later. The filter also introduces a time lag into the detection process.

Batteries:

4 x 1.5 V (6 V), type IEC, LR6 (AA size), e.g. Duracell MN1500 (alkaline).

The battery life should be approximately 60 days with continuous use (with up to 150 alarms, each of 2 minutes duration).

SIMS Graseby advises users not to use batteries other than the alkaline type. This is because the life of other battery types is much lower, and the low battery indication is less effective with non alkaline cells.

Low battery indicator

The low battery LED lights orange with each breath, when the supply voltage is 3.5 to 4.4V.

The monitor produces a non-resetable alarm if the supply voltage falls $0.5\text{ V} \pm 0.1\text{ V}$ below the voltage at which the primary low battery detector is triggered.

External sensor:

SIMS Graseby disposable item for single use (part No. 0108-0007).

Environmental conditions:

Temperature range: Operating 10 °C to +40 °C
Storage -10 °C to +55 °C

Humidity range: Operating 30 to 75 % RH
Storage 10 to 95 % RH

Pressure range: Operating 700 hPa to 1060 hPa
Storage 500 hPa to 1060 hPa

Alarm:

Alarm limits: Adjustable to 10 or 20 seconds

Alarm output: Visual (red indicator lamp) and audible (3 kHz pulse)

Materials used

Monitor: Case: ABS, Brass inserts, Acrylic

Adhesive: PVC

All metal components are of stainless steel, the printed circuit boards are made of epoxy glass fibre.

Packaging: Expanded polystyrene foam, Corrugated cardboard

Respiration Sensor: PVC, ABS

Operating position:

Any. A loop is provided on top of the monitor to allow it to be attached to a suitable fixing for vertical operation using the hanging strap supplied with the monitor.

Standards

Electrical Safety



An electrical safety classification in the international safety standard for medical electrical equipment, Type BF. If the Monitor is used as intended there will be no risk of a serious electrical shock. The Monitor is not suitable for direct connection to the heart.

EMC

Law relating to electromagnetic compatibility, Group 1, Class B, emitted RF radiation to EN55011:1991, suitable for domestic use.

Design Standards

EN 60601-1, EN 60601-1-2

Fluid Ingress Protection



IPX1 In the normal operating position the Monitor is protected against drops of water falling vertically onto it. It is not safe to use the Monitor in more severe wet conditions.

CE Marking



The CE mark demonstrates that the Monitor conforms to the requirements in the European Council Directive 93/42/EEC concerning medical devices.

The number 0473 identifies the Notified Body under which the Quality Systems operated within SIMS Graseby Ltd are assessed.

Disposal

When the time comes to dispose of the Monitor, its batteries, or any of its accessories, do so in the best way to minimise any negative impact on the environment.

You may be able to use special recycling or disposal schemes. To find out about these contact your local waste disposal service. Separate any other parts of the equipment where arrangements can be made for their recovery, either by recycling or energy recovery.

Important: Existing national or local regulations concerning waste disposal must take precedence over the above advice.

Chapter 2

Introduction

The SIMS Graseby Respiration Sensor is connected to a sensitive capacitive transducer that is mounted inside the monitor. The transducer consists of a fixed plate and a moving plate, both made of metallised film.

As the baby breathes, the sensor detects the abdominal movements caused by the baby's respiration. This in turn causes minute air movements which are detected by the transducer and are passed to the associated circuits.

The monitor incorporates a high integration silicon chip (see Fig. 2.1) that contains a digital signal processor; a signal conditioning circuit; the alarm and timing logic circuits, and a low battery detection circuit.

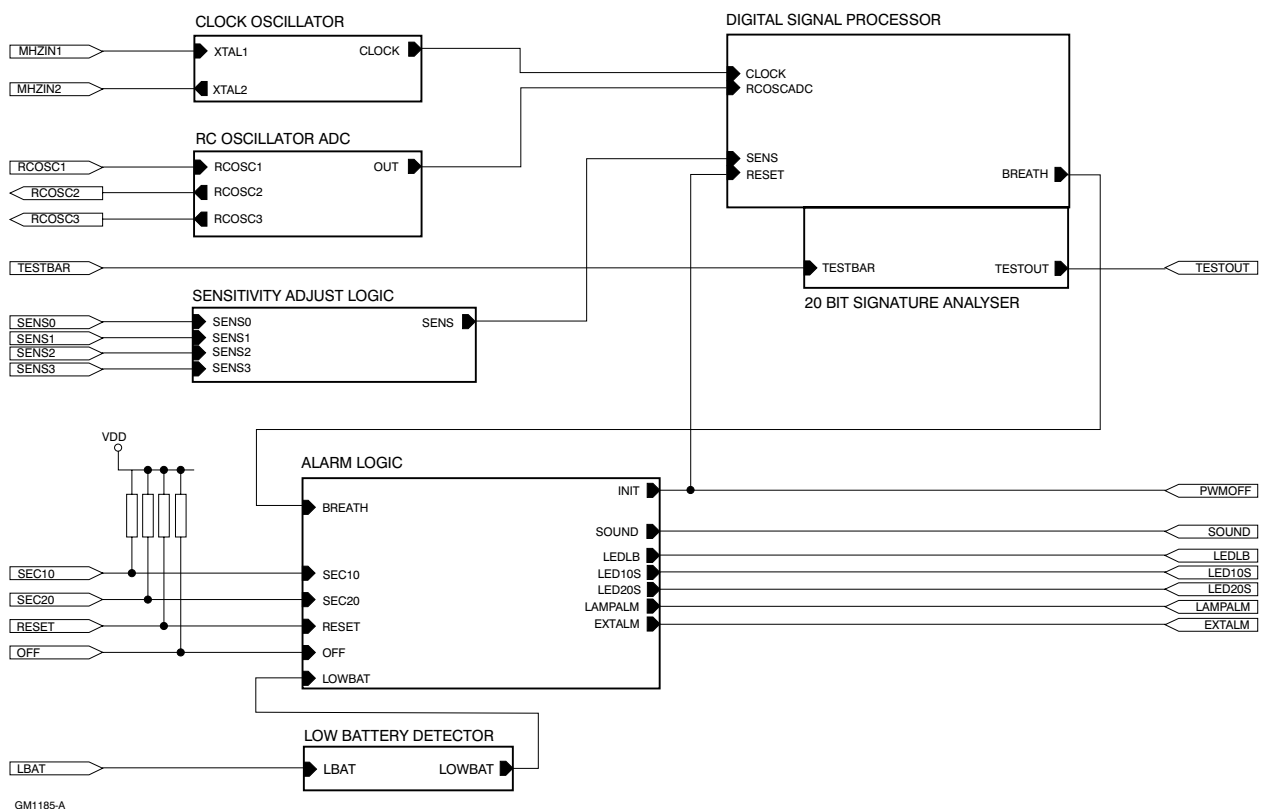


Figure 2.1 Block diagram of silicon chip

Circuit Description

Master Clock

The timing for the system is controlled by a 1M Hz ceramic resonator, X1 (see page 7-5), with associated components C3, C4, R6. Loading this circuit, for example with an oscilloscope probe, may prevent the oscillator from starting. Connect the probe after the monitor is operating.

Transducer oscillator

The transducer is used in an RC oscillator, the frequency of which is measured and compared with the master clock. At ICI, pin 25, a square wave should be present, at a frequency of about 6.5 kHz. This frequency varies if a pneumatic signal is injected into the transducer port.

The transducer oscillator is controlled by the Digital Signal Processor (DSP). The square wave occurs in a burst of 16 cycles. The oscillator is restarted by the system every 7.8 ms.

This circuit has a separate power pin (pin 27) to ensure the stability of the oscillator during supply voltage fluctuations, that may be caused by the alarm. C7, R11 and D1 provide voltage stabilisation.

Alarm circuit

The piezo-electric sounder (X2) is used in a self-oscillating circuit. Q2, R1, R2, R9 and L1 form this circuit. The inductor provides voltage boosting to increase the sound level. D3 protects ICI from voltage transients generated by the alarm oscillator.

Visual indicators

The three rectangular LED's (LED 1, 2 and 3) are driven directly by ICI, with resistors R4 and R5 providing current limiting. The red alarm light (LED 4) is a special high brightness device which is driven through transistor Q1.

Battery protection

D2 prevents ICI from being damaged if the batteries are reversed.

Sensitivity adjustment

The link block LK1 provides 16 sensitivity settings, which allows the monitor to be adjusted to give a sensitivity to the stated specification. The sensitivity adjustment procedures must be carried out using the Graseby Apnoea Sensitivity Test Rig kit (Part No. 0512-0114).

The part number for the Instruction Leaflet for using the Graseby Apnoea Sensitivity Test Rig is 0512-0116.

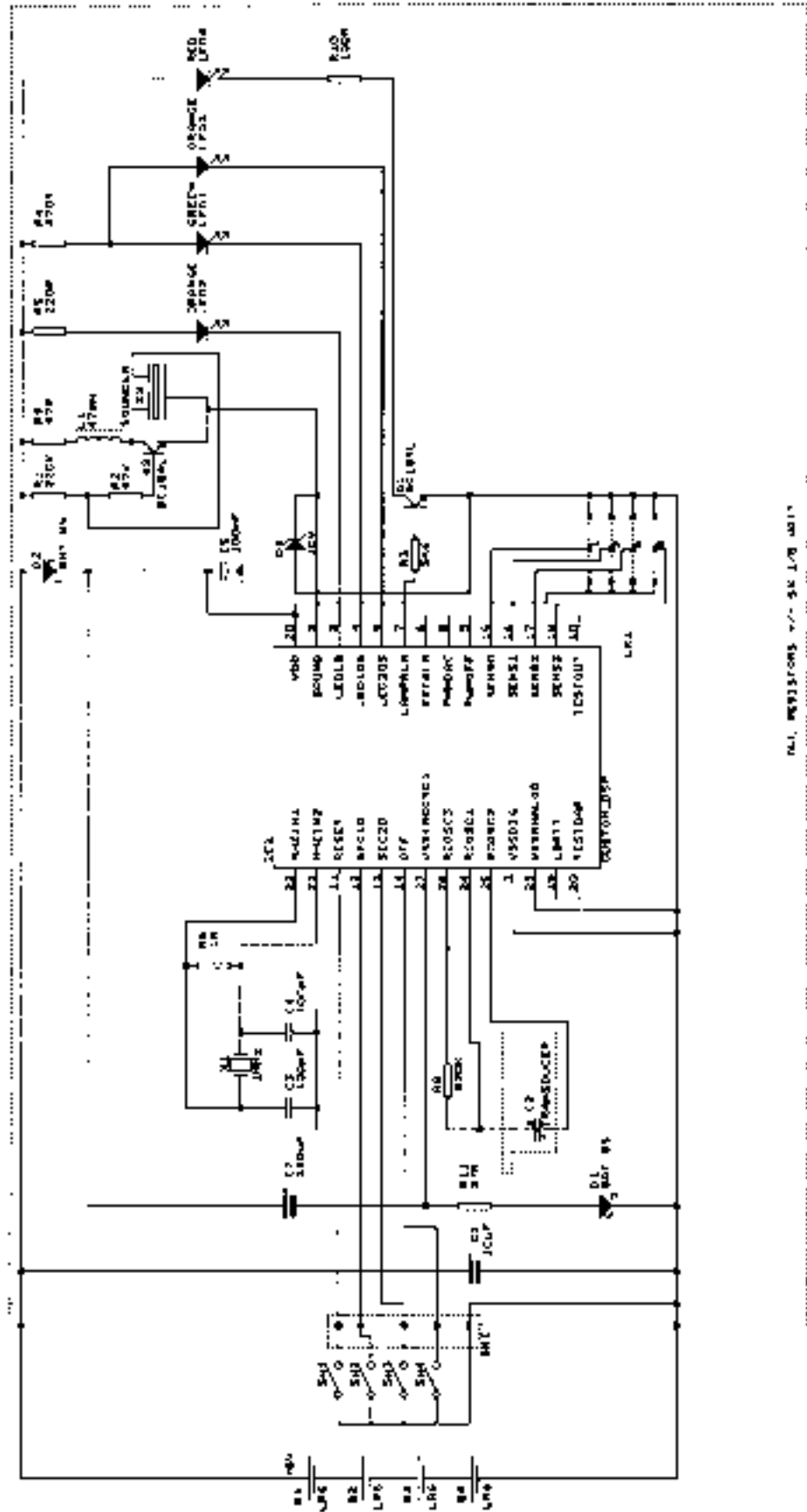




Figure 2.2 Circuit diagram


Chapter 3


Acceptance and Routine Tests

The following test procedures should be carried out to verify that the monitor is working correctly when the monitor is received, and at pre-determined intervals.

1. Press **ON 10 SEC** and check that the green LED lights briefly and a bleep is heard. Wait 10 seconds and check that the alarm sounds and the alarm lamp flashes.
2. Press  / **RESET** and check that the alarm lamp and sound is cancelled.
3. Press **ON 20 SEC** and check that the orange LED lights briefly and a bleep is heard. Wait 20 seconds and check that the alarm sounds and the alarm lamp flashes.
4. Press  / **RESET** to cancel the alarm lamp and sound.
5. Using the Graseby Apnoea Sensitivity Test Rig apply a pneumatic volume change of 0.6 microlitres at 1.0 Hz (approx.) to the sensor inlet socket. Check that the orange LED flashes and an audible click occurs with each detected breath.

If a Graseby Apnoea Sensitivity Test Rig is not available, use your finger tip to apply a light alternating pressure to the sensor inlet socket in order to obtain the above response.

6. Press **ON 20 SEC** and  / **RESET** simultaneously and check that the audible click is inhibited.
7. Remove the monitor input and wait 20 seconds until the red alarm lamp and the sounder become activated, then re-apply the monitor input.
8. Check that the red alarm lamp keeps flashing (temporarily) and the sounder stops.
9. Check that the red alarm lamp stops flashing 60 seconds after the monitor input has been re-applied.
10. Press and keep pressed **HOLD FOR OFF** and check that a short bleep sounds.
11. Release **HOLD FOR OFF** and check that the audible clicks disappear.

Note: The front panel keypad for the new case design, **RESET** has been replaced with the following symbol 

Chapter 4

Cleaning and Maintenance

Cleaning

Routine maintenance is limited to keeping the monitor clean. The Monitor should be wiped clean using only a cloth slightly moistened with a liquid disinfectant. Never use a dripping wet cloth.

Do **not** use harsh solvents.

Do **not** immerse the monitor in water.

Ensure that water does **not** enter the sensor port.

Maintenance

When used as described in the Instruction Manual the Monitor does not require any routine maintenance apart from replacing the batteries and occasional cleaning.

It is recommended that the performance of the Monitor is checked at least annually by a qualified SIMS Graseby engineer. If the Monitor is damaged in any way the performance must always be checked before it is used again.

CAUTION: Refer all service, repair and calibrations only to qualified technical personnel. Unauthorised modifications to the Monitor must not be carried out.

CAUTION: Failure to observe the following cautions may cause internal damage to the monitor.

- Do not autoclave, steam sterilise, pressure sterilise or gas sterilise this monitor.
- Do not expose this monitor to temperatures in excess of 40°C (104° F).
- Cleaning Do not immerse the monitor in any liquid
- Wipe off any liquid spills immediately, do not allow any fluid or residues to remain on the monitor.
- Do not use abrasive agents or strong organic solvents.

Battery replacement

1. To replace the batteries open the battery compartment cover located on the rear of the Monitor.

Old case design (models with serial number below 80,000)

To remove the battery cover push down and slide the away from the Monitor.

New case design (models with serial number above 80,000)

The battery cover can be opened by inserting a small coin or other suitable tool into the locating screw on the cover. Turn the screw anti-clockwise and remove the cover.

2. Remove the 4 old batteries
3. Insert 4 new batteries type LR6 alkaline into the battery compartment. Observe correct polarity as shown inside battery compartment
4. Close the battery compartment cover.
5. Carry out the Alarm system test before use, see page 1-4 *Alarm system test*.

Alarm system test

The operation of the alarm system must always be checked as follows before the Monitor is used:

1. Before connecting a Respiration Sensor, press the **ON 10 sec** alarm delay button. The MR10 confirms the button selection by a short beep and the **ON 10 sec** light briefly illuminates.
2. The audio visual alarm (flashing red alarm indicator) should trigger after 10 seconds.
3. The MR10 is turned off by pressing the **HOLD FOR OFF** button. (Keep the button pressed until you hear a short beep)
4. If Alarm system test was unsuccessful, check that the batteries are fitted correctly and that they are not discharged.

WARNING: Use only type LR6 alkaline batteries. Rechargeable batteries are unsuitable and must not be used as they could affect safe operation of the Monitor.

Disassembly of the monitor

1. Remove the batteries, see *Replacing the batteries* page 4-1.

Old case design (models with serial number below 80,000)

2. Remove the two screws located just above the battery compartment and separate the two case halves, taking care not to damage the interlocking fingers at the other end of the case.

The PCB is located in the front case by five support pillars, and secured by a fixing screw. To remove the PCB undo the fixing screw and release the flexible connector from socket SK1 on the PCB, care should be taken not to damage the tail of the connector, as it is easily damaged.

New case design (models with serial number below 80,000)

2. Using a T10 TX tamperproof torque tool, undo the four screws on the rear of the Monitor and remove the rear case assembly.

Remove and retain the strap handle located at the top of the front case sub assembly.

The PCB is located in the front case by five support pillars, and secured by a fixing screw. To remove the PCB undo the fixing screw and release the flexible connector from white socket SK1 on the PCB by lifting the socket with a small screw driver, care should be taken not to damage the tail of the connector, as it is easily damaged.

Handling precautions

CAUTION: The Printed Circuit Board (PCB) contained in the monitor is electrostatically sensitive. Always use an earthing strap when handling the PCB to avoid electrostatic damage to the components. Ensure that replacement PCB are stored in anti-static containers.

Replacing the transducer

The transducer has a nominal standing capacitance of 70 pF with a range of 55 to 90 pF. A faulty transducer is normally identified by being outside this range.

Do not attempt to replace the transducer unless a Graseby Apnoea Sensitivity Test Rig is available. Replacing the transducer is simple. Make sure that the adapter is pushed on firmly to prevent the possibility of an air leak.

If the transducer is replaced, a sensitivity test of the monitor must be carried out to ensure that it is operating correctly. The sensitivity is set by using a Graseby Apnoea Sensitivity Test Rig (see page 4-4).

Sensitivity setting

The Graseby Apnoea Sensitivity Test Rig (Part No. 0512-0114) enables the sensitivity of the Monitor to be correctly set. The instructions and procedures for setting the Monitor's sensitivity and for operating the Sensitivity Test Rig are supplied with the Graseby Apnoea Sensitivity Test Rig.

Replacing the front panel keypad membrane

1. Disassemble the two case halves and remove the flexible tail from the PCB, see *Disassembly of the monitor*.
2. Remove the old front panel keypad membrane by lifting an edge of the label and pulling it away from the case.
3. Remove all traces of adhesive from the front panel recess and clean the recess with a suitable degreasing agent (e.g. Arklone or white spirit).
4. Partly peel back the backing paper from the top of the new label.
5. Push the flexible lead through the slot in the case, taking care not to damage the delicate exposed conductors at the end of the lead.
6. Feed the end of the flexible tail into the entry port of the keyboard connector, with the conductive side down (i.e. towards the PCB). Push the tail in until it hits the end stop and lock it in position:

into the black connector for *Old case design models with serial numbers below 80,000* .

or

by pushing the white socket SK1 with a small screw driver for *New case design models with serial numbers above 80,000* .,
7. Align the top edge of the label with the top of the recess, and align the right hand side of the label with the right hand edge of the recess. Carefully rub down the top edge of the label to give light adhesion, then lift the bottom end of the label, ensuring that the top is not displaced.
8. Remove the remainder of the backing paper, and ensure that the inlay section next to the readout also has its backing paper removed.
9. Lay the label back into the recess, and working from the top downwards (with light pressure) push out any air bubbles.
10. When the label is positioned correctly in the recess (i.e. no overhanging edges) rub it down firmly with a soft cloth.

Chapter 5

Illustrated Parts List

When ordering spare parts for the MR10 please check that the parts you ordering are for the correct MR10 design assembly list.

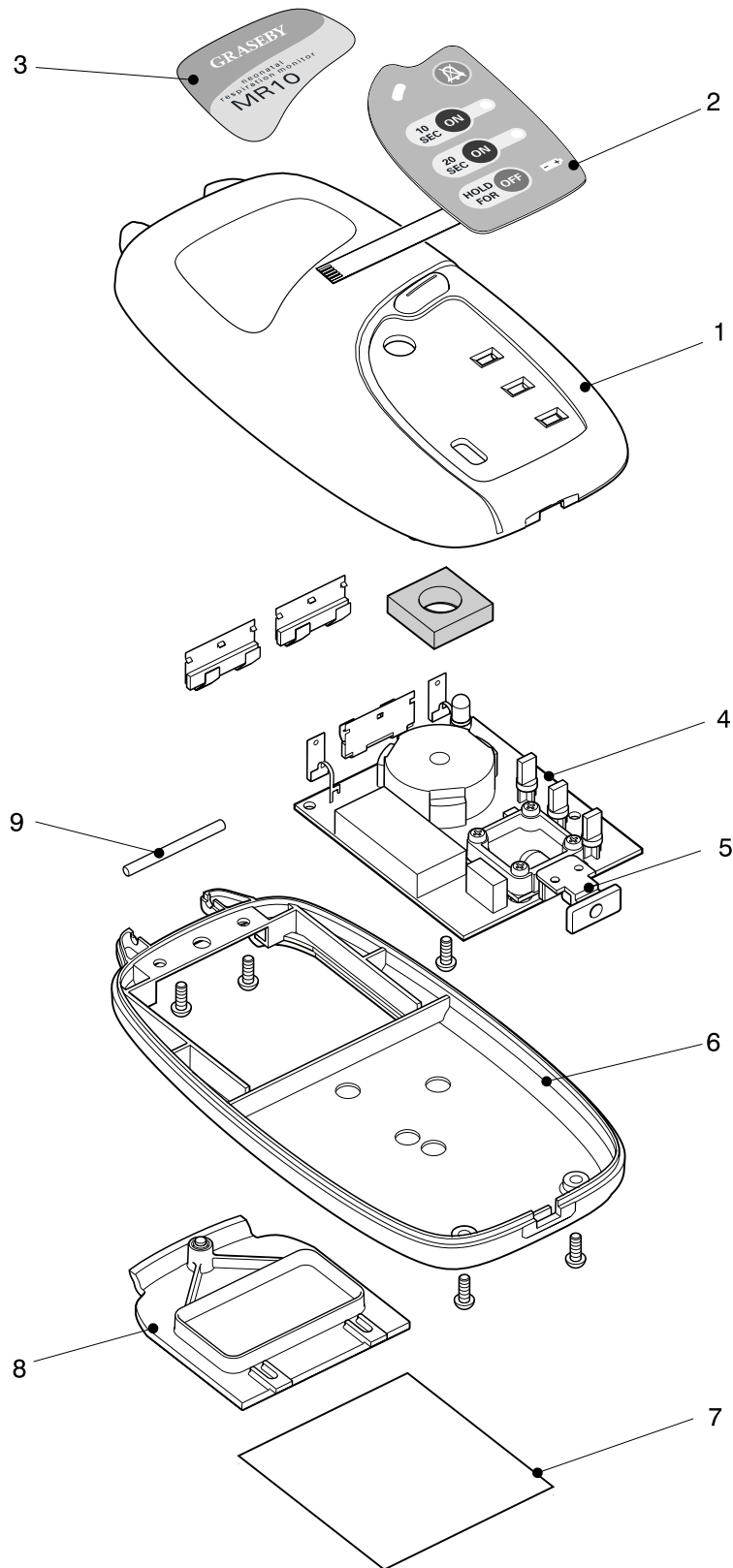
for *Old case design* serial numbers below 80,000 see page 5-4

for *New case design* serial numbers from 80,000 see page 5-2

For prices and the availability of other parts not included in the above list, please contact SIMS Graseby.

General assembly of the MR10 new case design (serial numbers from 80,000)

Item No.	Description	Part Number	Remarks
1	Front case sub assembly contains the following items: Front case, Alarm light lens	0514-0003	
2	Keypad membrane - English	0514-0020	
	Vitalaire - German	0514-0021	
3	Front label - top English	0514-0022	
	Vitalaire - German	0514-0023	
4	PCB assembly	0514-0010	See Fig 2 A
5	Pneumatic Transducer kit	0108-0122	
6	Rear case sub assembly contains the following items: Rear case, Rubber foot	0514-0005	
7	Rear label - CE marked English	0514-0024	
	CE marked Vitalaire	0514-0025	
8	Battery cover	0514-0006	
9	Strap handle	0514-0019	
10	Strap and buckle assembly	0514-0004	Not illustrated
11	Instruction manual - English	0514-0035	Not illustrated
	Vitalaire - German	0514-0036	
12	Service manual English	0514-0045	Not illustrated
	Vitalaire - German	0514-0046	
13	Respiration Sensor	0108-0007	Not illustrated
14	Graseby apnoea sensitivity test rig	0512-0114	Not illustrated

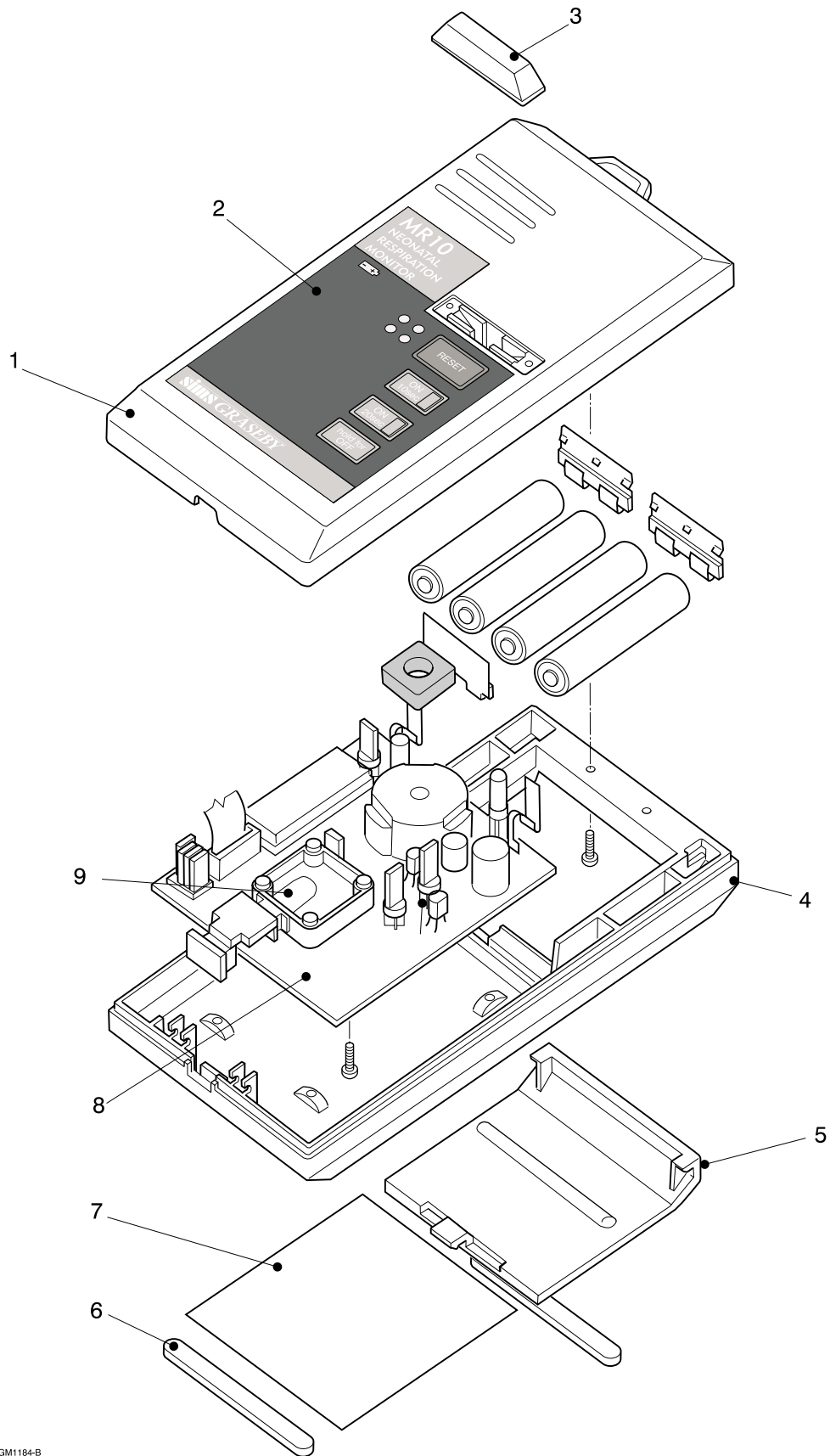


GM514_0006GB-A

Figure 5-1A General assembly of the MR10 new case design
(for serial numbers from 80,000)

General assembly of the MR10 old case design (for serial numbers below 80,000)

Item No.	Description	Part Number	Remarks
1	Front case assembly contains the following items: Front case, Alarm light dome	0126-0062	
2	Front label - English	0126-0025	
	German	0126-0046	
	French	0126-0071	
3	Alarm light dome	0126-0023	
4	Rear case assembly contains the following items: Rear case, Battery lid, Rubber foot	0126-0061	
5	Battery lid	0126-0022	
6	Rubber foot - 2 off	0126-0028	
7	Rear label -		
	IMPORTANT: When ordering a CE marked Rear Label, please supply the serial number details of the Monitor, if this information is not supplied then a Non CE marked label will be issued.		
	It is the responsibility of the owner to ensure that the correct labels are replaced on the Monitor.		
	Non CE marked English	0126 0030	
	Non CE marked Hoyer	0126 0045	
	Non CE marked French	0126-0049	
	CE Marked German	0126-0060	
	CE Marked English	0126 0063	
	CE Marked Dutch	0126-0068	
	CE Marked Hoyer	0126-0069	
	CE Marked French	0126-0070	
	CE Marked Italian	0126-0074	
8	PCB assembly	0126-0004	See Figure 2B
9	Pneumatic Transducer kit	0108-0122	
10	Instruction manual -		Not illustrated
		English	0126-0031
		German	0126-0057
		French	0126-0058
		Dutch	0126-0059
		Italian	0126-0073



GM1184-B

*Figure 5-1B General assembly of the MR10 old case design
(for serial below 80,000)*

Item No.	Description	Part Number	Remarks
11	Service manual	00SM-0514	Not illustrated
12	Respiration Sensor	0108-0007	Not illustrated
13	Graseby apnoea sensitivity test rig	0512-0114	Not illustrated

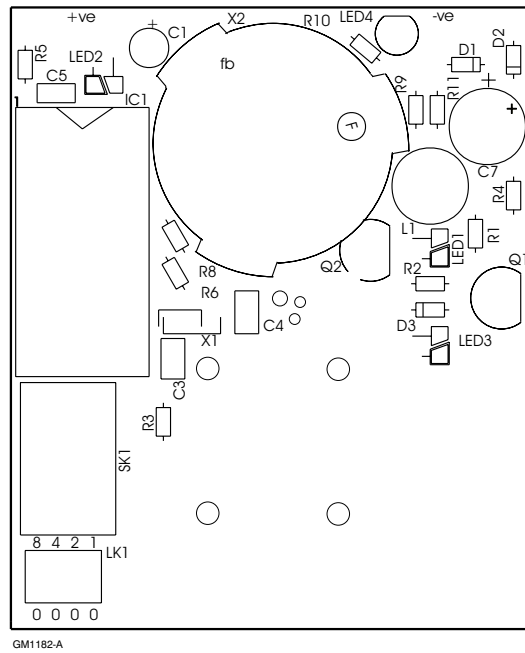


Figure 2 A MR10 PCB layout
Old case design serial numbers below 80,000

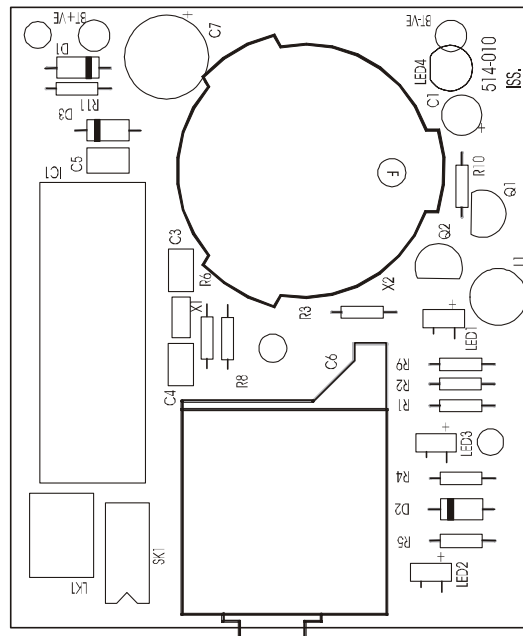


Figure 2 B MR10 PCB layout
New case design serial numbers from 80,000

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