

## Smiths Medical Publications

This publication has been compiled and approved by Smiths Medical for use with their respective products. It is supplied in this format to permit users to access the text and illustrations for their own use e.g. training and educational purposes.

Users of the equipment must ensure that they have read and understood the contents of the complete manual including the warnings and cautions and have been trained in the correct use of the product.

Smiths Medical cannot be held responsible for the accuracy and any resulting incident arising from information that has been extracted from this publication and compiled into the users documentation.

This publication maybe subject to revision and it is the users responsibility to ensure that the correct version of manual/text/illustration is used in conjunction with the equipment.

ACCEPT

REJECT

# smiths

**Smiths Medical MD, Inc.,**

1265 Grey Fox Road, St. Paul, MN 55112, U.S.A.

European representative:

**Smiths Medical International Limited**

Watford, Herts, UK, WD24 4LG

[www.smiths-medical.com](http://www.smiths-medical.com)

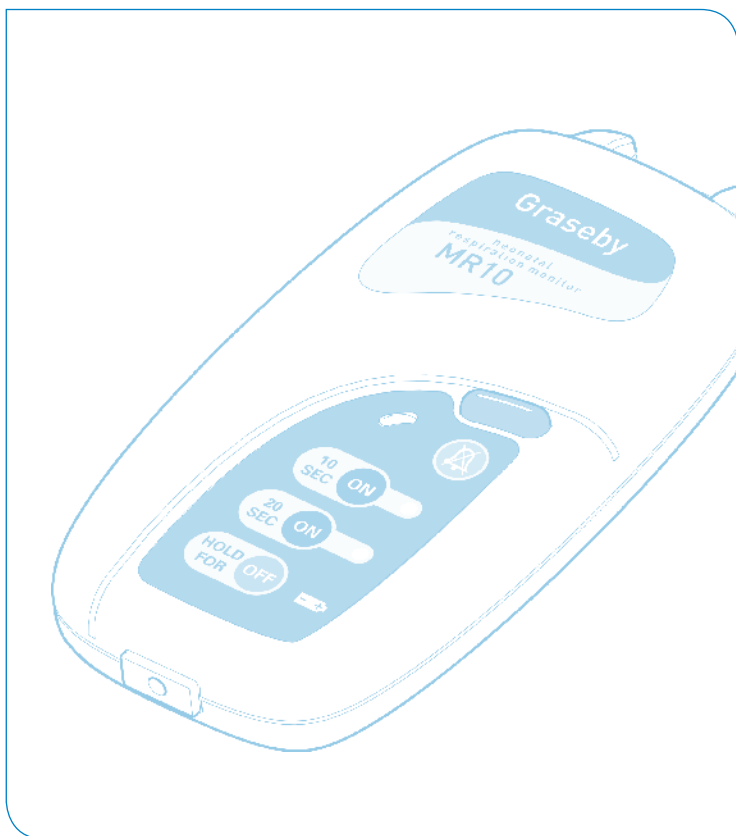
© 2005 Smiths Medical family of compaines. All rights reserved.

**smiths**

Smiths Medical - A part of Smiths Group plc

# Graseby MR10

## Neonatal Respiration Monitor



**Instruction Manual**

smiths medical

Published by Smiths Medical PM, Inc.

All possible care has been taken in the preparation of this publication, but Smiths Medical accepts no liability for any inaccuracies that may be found.

Smiths Medical reserves the right to make changes without notice both to this publication and to the product which it describes.

© 2007 Smiths Medical family of companies. All rights reserved.

No part of this publication may be reproduced, transmitted, transcribed, or stored in a retrieval system or translated into any human or computer language in any form or by any means without the prior permission of Smiths Medical.

**Smiths Medical PM, Inc.**

N7 W22025 Johnson Drive, Waukesha, WI 53185-1856, U.S.A.

European Representative:

**Smiths Medical International Limited**

Colonial Way, Watford, Hertfordshire, UK, WD24 4LG

Australian Representative:

**Smiths Medical Australasia Pty. Ltd.**

61 Brandl Street, Eight Mile Plains, QLD 4113, Australia

[www.smiths-medical.com](http://www.smiths-medical.com)

Registered in England.

Company number 362847

**Trademarks and acknowledgements:**

Graseby and the Smiths design mark are a trademarks of the Smiths Medical family of companies. The symbol ® indicates the trademark is registered in the U.S. Patent and Trademark office and certain other countries.

All other names and marks mentioned are the trade names, trademarks or service marks of their respective owners.

# 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 Graseby MR10 Neonatal Respiration Monitor gives an indication of an apnoea attack; it cannot prevent it. Failure to observe this warning may cause infant injury or death.**
2. **WARNING: When the Monitor is first unpacked, inspect it for physical damage. The Monitor must not be used if damage is evident and must be returned to an authorised technician for repair before being returned to clinical use. Failure to observe this warning could affect the functions of the Monitor and may cause infant injury or death.**
3. **WARNING: The clinician should ensure that the performance offered by the Monitor is fit for the intended purpose. Failure to observe this warning could affect the functions of the Monitor and may cause infant injury or death.**
4. **WARNING: Only use the Graseby Respiration Sensor (part number 0108-0007). The performance of the Monitor can only be guaranteed with this Sensor. Failure to observe this warning may cause infant injury or death.**
5. **WARNING: Before using the Monitor and its accessories, ensure that you have been fully trained in its correct set up and operating procedures. Failure to observe this warning could affect the functions of the Monitor and may cause infant injury or death.**
6. **WARNING: The Monitor is not suitable for use on infants with pacers. Failure to observe this warning may affect the functions of the Monitor and may cause infant injury or death.**
7. **WARNING: The Monitor should only be used in the home environment under the direction of a clinician. Failure to observe this warning may cause infant injury or death.**
8. **WARNING: The Monitor is not suitable for use with adults or children over the age of 18 months. Failure to observe this warning may cause injury or death.**
9. **WARNING: The Monitor must not be covered by bedding or other objects so that audible and visual alarms are impaired. Failure to observe this warning could result in infant injury or death.**
10. **WARNING: If you suspect that the Monitor is not operating correctly, do not use it; return it to Smiths Medical or a suitably qualified technician for testing. Failure to observe this warning could result in infant injury or death.**
11. **WARNING: To prevent the Monitor being accidentally switched off, it must not be placed within reach of the infant. Failure to observe this warning could result in infant injury or death.**
12. **WARNING: The Monitor must not be pushed into confined spaces, possibly resulting in pressure being exerted on the keypad buttons causing it to be switched off or the settings changed. Failure to observe this warning could result in infant injury or death.**

13. **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.
14. **WARNING:** Carefully route cabling to reduce the possibility of infant entanglement or strangulation. Failure to observe this warning could result in infant injury or death.
15. **WARNING:** The Monitor must be operated within the specified parameters, e.g. temperature, see Technical Specification on page 1-14. Failure to observe this warning could affect the functions of the Monitor and may cause infant injury or death.
16. **WARNING:** The performance of the Monitor is dependent on the selection of the correct monitoring rate for the infant and the environment of use. Failure to observe this warning could affect the functions of the Monitor and may cause infant injury or death.
17. **WARNING:** When an infant is being Monitored, it is essential that the clinician or carer remains within both visual and audible range of the Monitor so that the alarms can be seen and heard. Failure to observe this warning may cause infant injury or death.
18. **WARNING:** If the main audible and visual alarms are activated, immediately attend to the infant. This is of prime importance before any other actions are taken. In the event of any alarms, the infant must first be made safe and comfortable. Failure to observe this warning may cause infant injury or death.
19. **WARNING:** Excessive movement may adversely affect the Monitor's performance. Care must be taken when used in an ambulatory situation and the Monitor placed in a secure position free from excessive movement, suspend using the strap supplied. Failure to observe this warning could affect the functions of the Monitor and may cause infant injury or death.
20. **WARNING:** The Graseby Respiration Sensor (*part number 0108-0007*) should only be used on one infant and for a maximum of 7 days. Using the same sensor on more than one infant increases the risk of cross infection. Failure to observe this warning may cause infant injury or death.
21. **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. Failure to observe this warning could affect the functions of the Monitor and may cause infant or user injury.
22. **WARNING:** When the Low Battery orange indicator is lit, it is essential to ensure that new batteries are installed. Failure to observe this warning could affect the functions of the Monitor and may cause infant or user injury.
23. **WARNING:** Remove the Monitor and sensor from the infant before using a defibrillator. Failure to observe this warning could affect the functions of the Monitor.
24. **WARNING:** This equipment is not suitable for use in the presence of flammable anaesthetic, oxygen-enriched or explosive atmospheres. The use of the device in such atmospheres can lead to explosion or fire.
25. **WARNING:** The Monitor must not be used in the presence of, or in combination with Magnetic Resonance Imaging (MRI) machines. Failure to observe this warning can cause incorrect monitoring or loss of monitoring resulting in infant injury or death.

- 26. WARNING: Mobile communication devices e.g. mobile phones, should not be used at a distance of less than one metre to the Graseby 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. Malfunction of the Monitor can cause incorrect or loss of monitoring resulting in infant injury or death.**
- 27. 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.**
- 28. WARNING: Following a significant liquid spill onto the Monitor, it should be wiped dry and inspected by an authorised technician before being returned to clinical use. Failure to observe this warning could affect the functions of the Monitor and may cause infant or user injury.**

## 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: Do not autoclave, steam sterilise, ETO sterilise or subject the Monitor to temperatures in excess of 45° C (113° F). Excessive temperatures may cause damage to the Monitor.**
3. **CAUTION: Do not use unapproved cleaning agents.**
4. **CAUTION: To prevent serious damage to the Monitor it must *not* be immersed in any liquids or exposed to strong organic solvents. Wipe off spills immediately. Do not allow fluid or residues to remain on the Monitor. Additionally, the Monitor is not designed to allow it to be sterilised. Failure to observe these cautions may cause internal damage to the Monitor.**
5. **CAUTION: Do not lift the Monitor by the sensor tubing. The carry strap may be used.**
6. **CAUTION: Ensure that replacement LR6 alkaline batteries are available at all times.**

# Contents

<b>Introduction</b> .....	<b>1 - 3</b>
<b>Overview of the Monitor</b> .....	<b>1 - 3</b>
<b>Parts of the Monitor</b> .....	<b>1 - 4</b>
<b>Alarm system test</b> .....	<b>1 - 5</b>
<b>Using the Monitor</b> .....	<b>1 - 6</b>
Attaching the Respiration Sensor .....	1 - 6
Monitor set up .....	1 - 7
Switching on the Graseby MR10.....	1 - 7
Silencing the 'clicking sound' .....	1 - 8
Changing the alarm delay .....	1 - 8
Checking alarm output .....	1 - 8
Monitoring the infant .....	1 - 8
Switching off the Graseby MR10.....	1 - 9
<b>If the alarm sounds</b> .....	<b>1 - 9</b>
<b>Batteries</b> .....	<b>1 - 10</b>
Battery alarm.....	1 - 10
Battery replacement.....	1 - 10
<b>Faults, causes and actions</b> .....	<b>1 - 12</b>
<b>Care and maintenance</b> .....	<b>1 - 13</b>
Maintenance .....	1 - 13
Cleaning the Monitor.....	1 - 13
Respiration Sensor .....	1 - 13
<b>Technical specification</b> .....	<b>1 - 14</b>
<b>Standards</b> .....	<b>1 - 15</b>





## Introduction

Thank you for choosing a Graseby MR10 Neonatal Respiration Monitor. This Instruction Manual contains important information on operating and looking after your Monitor. To become completely familiar with all the Monitor's features, please take time in reading this manual before use.

It is not known why some infants stop breathing. The following advice may help to reduce the risk of this happening:

- position the infant as advised by your clinician,
- do not smoke near the infant and avoid smoky atmospheres,
- take steps to prevent the infant becoming too hot,
- contact a doctor immediately if you suspect that the infant is unwell.

The Monitor should only be used under the direction of a clinician who will provide full instruction in the handling of the Monitor where necessary. It is also essential that the parents or carers are able to use the most recent infant resuscitation techniques in emergency (if necessary consult a clinician).

It is important to use the Monitor correctly. Always make sure the alarms are working by testing them every time the Monitor is used. If you are unsure about any aspect of the Monitor's use contact your clinician.

**WARNING: The clinician should ensure that the performance offered by the Monitor is fit for the intended purpose. Failure to observe this warning could affect the functions of the Monitor and may cause infant injury or death.**

## Overview of the Monitor

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

When an infant is being monitored it is essential that the user remains within visual and audible range of the Monitor so that the alarms can be seen and heard.

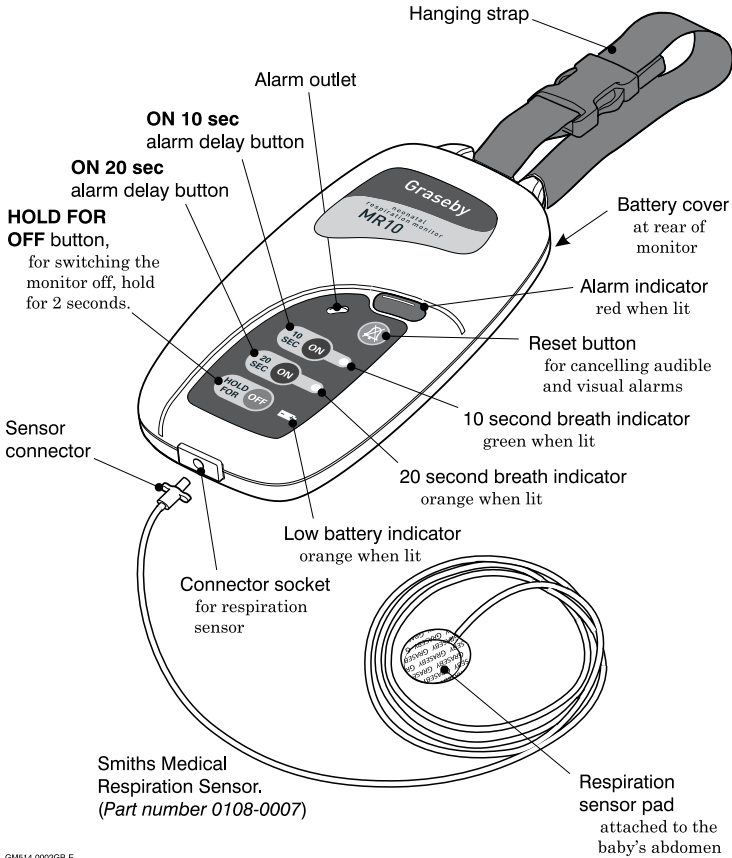
The breathing signal is picked up by a soft, foam-filled Sensor (Respiration Sensor) that is attached to the infant's abdomen.

During breathing, expansion of the abdominal wall causes a small amount of air to pass through the Sensor and tube to the Monitor. This triggers an audible click and simultaneous visual indication.

The Monitor is powered by 4 LR6 (AA) alkaline batteries, for further information see page 1-10, *Batteries*.

**WARNING: The Graseby MR10 Neonatal Respiration Monitor gives an indication of an apnoea attack; it cannot prevent it. Failure to observe this warning may cause infant injury or death.**

# Parts of the Monitor



GM514-0002GB-E

**WARNING: When the Monitor is first unpacked, inspect it for physical damage. The Monitor must not be used if damage is evident and must be returned to an authorised technician for repair before being returned to clinical use. Failure to observe this warning could affect the functions of the Monitor and may cause infant injury or death.**

**WARNING: Before using the Monitor and its accessories, ensure that you have been fully trained in its correct set up and operating procedures. Failure to observe this warning could affect the functions of the Monitor and may cause infant injury or death.**

## Alarm system test

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

- Prior to connecting a Respiration Sensor, press the **ON 10 sec** alarm delay button. The Graseby MR10 confirms the button selection by a short beep and the **ON 10 sec** light briefly illuminates.
- The audio visual alarm (flashing red alarm indicator) should trigger after 10 seconds.
- The Graseby MR10 is turned off by pressing the **HOLD FOR OFF** button. (Keep the button pressed until you hear a short beep).
- If the Alarm system test is unsuccessful, see page 1-12, *Faults causes and actions* for further information .

**WARNING: If the main audible and visual alarms are activated, immediately attend to the infant. This is of prime importance before any other actions are taken. In the event of any alarms, the infant must first be made safe and comfortable. Failure to observe this warning may cause infant injury or death.**

**WARNING: If you suspect that the Monitor is not operating correctly, do not use it; return it to Smiths Medical or a suitably qualified technician for testing. Failure to observe this warning could result in infant injury or death.**

## Using the Monitor

**IMPORTANT:** Carry out the Alarm system test each time the Graseby MR10 is used, see page 1-5, *Alarm system test*.

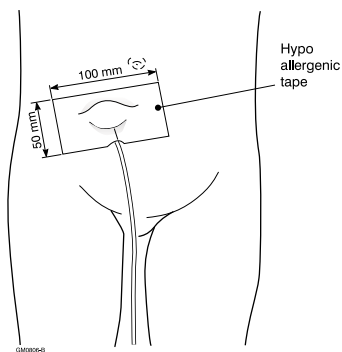
**CAUTION:** Do not lift the Monitor by the sensor tubing. The carry strap may be used.

### Attaching the Respiration Sensor

1. Clean and dry the infant's abdomen.
2. The most suitable position for attaching the Respiration Sensor is just below the navel, slightly to the left or right.

Fix the Respiration Sensor pad and tube using hypo allergenic tape 50 mm wide and 100 mm long. Position the Sensor tube down between the infant's legs to the Monitor, so that it is away from the neck, or so that the infant cannot play with it (see illustration). The Respiration Sensor can be worn under clothing (even nappies). In this case, however, ensure that the Sensor tube is passed through the clothing.

3. It is important to ensure that the Respiration Sensor connector is pushed firmly into the Monitor's connector socket using a slight twisting action. Do not apply excessive pressure.



**NOTE:** When attaching the Respiration Sensor pad ensure that the tape is long enough and does not interfere with the Respiration Sensor.

The tape should not be stretched too tightly over the Sensor pad. Only the Smiths Medical Respiration Sensor should be used, *part number 0108-0007*.

**WARNING:** The Graseby Respiration Sensor (*part number 0108-0007*) should only be used on one infant and for a maximum of 7 days. Using the same sensor on more than one infant increases the risk of cross infection. Failure to observe this warning may cause infant injury or death.

**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.

**WARNING:** Carefully route cabling to reduce the possibility of infant entanglement or strangulation. Failure to observe this warning could result in infant injury or death.

## Monitor set up

### Switching on the Graseby MR10


Always check that the Monitor has been fitted with batteries, see page 1-10, *Batteries*.


With the Respiration Sensor attached to the Monitor, switch the Monitor on by pressing either the **ON 10 sec** or **ON 20 sec** alarm delay button. The choice of which alarm delay button to use should always be determined by a clinician.

- The **ON 10 sec** alarm delay button, will alarm if no breath is detected after 10 seconds.
- The **ON 20 sec** delay button, will alarm if no breath is detected after 20 seconds.

For every breath detected, the Monitor will make a clicking sound accompanied by a green **ON 10 sec** or, an orange **ON 20 sec** flashing light.

When the Monitor is first switched on there may be a small delay before it starts to detect the infant's breaths.

If the selected alarm time is breached an audiovisual alarm is triggered, this can be silenced by pressing , see page 1-9, *If the alarm sounds*.

Should the infant start to breath again before  is pressed then the audible alarm will stop, but the red alarm light will continue to flash for another 60 seconds.


**WARNING: The Monitor should only be used in the home environment under the direction of a clinician. Failure to observe this warning may cause infant injury or death.**

**WARNING: The Monitor must be operated within the specified parameters, e.g. temperature, see Technical Specification on page 1-14. Failure to observe this warning could affect the functions of the Monitor and may cause infant injury or death.**

**WARNING: The performance of the Monitor is dependent on the selection of the correct Monitoring rate for the infant and the environment of use. Failure to observe this warning could affect the functions of the Monitor and may cause infant injury or death.**

**WARNING: Excessive movement may adversely affect the Monitor's performance. Care must be taken when used in an ambulatory situation and the Monitor placed in a secure position free from excessive movement, suspend using the strap supplied. Failure to observe this warning could affect the functions of the Monitor and may cause infant injury or death.**

## Silencing the 'clicking sound'

The clicking which sounds each time a breath is detected, can be silenced by simultaneously pressing the  button and the selected alarm delay button.


To restore the click repeat the above procedure. However, breathing continues to be indicated by the flashing indicator lamp.

## Changing the alarm delay

If the Monitor is set to an alarm delay interval of 10 seconds and a 20 second alarm interval is required. This can be selected by pressing the **ON 20 sec** button without switching the Monitor off. You can also change from a 20 second alarm delay to a 10 second by pressing the **ON 10 sec** button.

## Checking alarm output

To check the alarm output, remove the Respiration Sensor connector from the Monitor; the audible alarm should sound after 10 seconds (or 20 seconds), and the alarm indicator flashes. Replace the Respiration Sensor connector, the audible alarm stops and the visual alarm continues to flash for about 60 seconds. The Graseby MR10 immediately reverts to the monitoring function.

However, in order to save battery power it is recommended that the visual alarm be cancelled as soon as possible by pressing the  button.

**WARNING: Mobile communication devices e.g. mobile phones, should not be used at a distance of less than one metre to the Graseby 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. Malfunction of the Monitor can cause incorrect or loss of monitoring resulting in infant injury or death.**

## Monitoring the infant

While the infant is being monitored by the Graseby MR10 it is essential that the user remains within audible and visual range of the Monitor. If using the Monitor in an infant's cot position it away from the infant i.e. at the bottom of the cot or use the hanging strap (supplied with the Monitor) and hang the Monitor from the cot bars. The infant can also be monitored at any other time, for example: in a buggy, car seat etc.

**WARNING: Excessive movement may adversely affect the Monitor's performance. Care must be taken when used in an ambulatory situation and the Monitor placed in a secure position free from excessive movement, suspend using the strap supplied. Failure to observe this warning could affect the functions of the Monitor and may cause infant injury or death.**

To maintain the Monitor's effectiveness, the Respiration Sensor should be replaced after a maximum of 7 days to minimise false alarms.

## Switching off the Graseby MR10

To switch the Monitor off press the **HOLD FOR OFF** button (for about 2 seconds) until a short beep is heard.

**WARNING: The Monitor is not suitable for use on infants with pacers. Failure to observe this warning may affect the functions of the Monitor and may cause infant injury or death.**

**WARNING: The Monitor is not suitable for use with adults or children over the age of 18 months. Failure to observe this warning may cause injury or death.**



**WARNING: The Monitor must not be covered by bedding or other objects so that audible and visual alarms are impaired. Failure to observe this warning could result in infant injury or death.**

**WARNING: To prevent the Monitor being accidentally switched off, it must not be placed within reach of the infant. Failure to observe this warning could result in infant injury or death.**

**WARNING: The Monitor must not be pushed into confined spaces, possibly resulting in pressure being exerted on the keypad buttons causing it to be switched off or the settings changed. Failure to observe this warning could result in infant injury or death.**

## If the alarm sounds

**WARNING: If the main audible and visual alarms are activated, immediately attend to the infant. This is of prime importance before any other actions are taken. In the event of any alarms, the infant must first be made safe and comfortable. Failure to observe this warning may cause infant injury or death.**


1. Go to the infant but do not panic.
2. If the infant has stopped breathing carry out the resuscitation techniques that you have learned and immediately seek medical assistance.
3. If the red alarm indicator is flashing but the audible alarm is silent, this shows that a previous alarm condition was present. Press the  button to cancel the visual alarm indication and observe the infant for a while. If an audible alarm sounds again, carry out the Alarm system test see page 1-5, *Alarm system test*.
4. If the audible alarm is repeated, press the  button again and observe the infant.
5. If the infant is safe and breathing normally but the Monitor is not indicating the infant's breath, there is possibly a technical fault, see page 1-12, *Faults, causes and actions*.



## Batteries

**CAUTION:** Ensure that replacement LR6 alkaline batteries are available at all times.

### Battery alarm

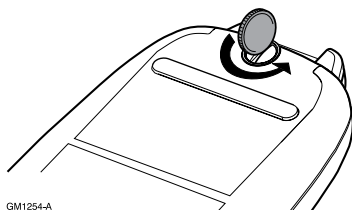
If the battery power is reduced, the low battery symbol  will flash. Although the Graseby MR10 will continue to operate for a time, for safety the batteries should be replaced immediately.

**NOTE:** If an audible alarm sounds in addition to the low battery symbol, and cannot be cancelled by pressing the reset alarm button, the batteries must be replaced immediately, otherwise safe respiration monitoring can no longer be guaranteed.

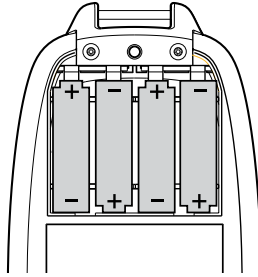
The operational life of the batteries depends on the frequency of the alarms. However, a service life of approximately 60 days can generally be assumed. The batteries should be removed if the Graseby MR10 is not to be used for a prolonged period. It is recommended that at least one full set of spare batteries is always available.

### Battery replacement

1. To replace the batteries open the battery compartment cover located on the rear of the Monitor. Insert 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 old batteries
3. Insert 4 new batteries into the battery compartment. Observe correct polarity (see illustration below).
4. Close the battery compartment cover.
5. Carry out the Alarm system test before use, see page 1-5 *Alarm system test*.



GM1255-A

**NOTES:**

- Old batteries should not be disposed of in household waste.
- If after inserting new batteries no clicking signal is produced when the Sensor pad is pressed, use another set of new batteries.
- It is important to bear in mind that even new batteries can be discharged after being stored for a long time.

**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. Failure to observe this warning could affect the functions of the Monitor and may cause infant or user injury.**

**WARNING: When the Low Battery orange indicator is lit, it is essential to ensure that new batteries are installed. Failure to observe this warning could affect the functions of the Monitor and may cause infant or user injury.**

## Faults, causes and actions

**WARNING: If the main audible and visual alarms are activated, immediately attend to the infant. This is of prime importance before any other actions are taken. In the event of any alarms, the infant must first be made safe and comfortable. Failure to observe this warning may cause infant injury or death.**

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

Fault:	Cause:	Action:
Monitor does not work.	No batteries fitted. Batteries fitted incorrectly. Batteries discharged.	Fit new batteries. Check that the batteries have been fitted as indicated in the battery compartment. Fit new batteries.
No respiration signals.	Respiration Sensor not connected to the Monitor. Sensor pad has become loose on the skin.	Make sure that the Sensor connector is inserted in the Monitor's connector socket, using a twisting motion. Remove the Sensor; clean and dry the infant's skin. Attach the Sensor pad with new hypo allergenic tape. See page 1-6, <i>Attaching the Respiration Sensor</i> .
Monitor has become defective.	Internal fault. Respiration Sensor is defective.	Test by removing the Sensor tube from the Monitor (with a slight turning movement) and by pressing gently with a finger over the inlet socket. This should produce signals on the Monitor. If it does not, the Monitor is faulty and must not be used. Contact Smiths Medical or a suitably qualified Technician Attach a new Respiration Sensor to the Monitor, see page 1-5, <i>Attaching the Respiration Sensor</i> . If the Respiration Sensor still does not work, the Sensor may be faulty. Contact Smiths Medical.

# Care and maintenance

## Maintenance

When used as described in these instructions 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 Smiths Medical engineer. If the Monitor is damaged in any way the performance must always be checked before it is used again.

For details of technical and maintenance information, including annual checks, refer to the Graseby MR10 Technical Service Manual, *part number 0514-0045*. For further information, contact Smiths Medical, Customer Care, an authorised technician or your local distributor.

## Cleaning the Monitor

**CAUTION: Do not autoclave, steam sterilize, ETO sterilise or subject the Monitor to temperatures in excess of 45°C (113°F). Excessive temperatures may cause damage to the Monitor.**

**CAUTION: Do not use unapproved cleaning agents.**

**CAUTION: To prevent serious damage to the Monitor it must *not* be immersed in any liquids or exposed to strong organic solvents. Wipe off spills immediately. Do not allow fluid or residues to remain on the Monitor. Additionally, the Monitor is not designed to allow it to be sterilised. Failure to observe these cautions may cause internal damage to the Monitor.**

The Monitor should be wiped clean using only a cloth slightly moistened with a liquid disinfectant. Never use a dripping wet cloth.

Refer to the Graseby MR10 Technical Service Manual, *part number 0514-0045* for details of cleaning agents.

**WARNING: Following a significant liquid spill onto the Monitor, it should be wiped dry and inspected by an authorised technician before being returned to clinical use. Failure to observe this warning could affect the functions of the Monitor and may cause infant or user injury.**

## Respiration Sensor

Sensors are single use items, they must not be cleaned or sterilized and with regular use should be replaced after a maximum of 7 days. Never use the same Sensor with more than one infant.

**WARNING: The Graseby Respiration Sensor (*part number 0108-0007*) should only be used on one infant and for a maximum of 7 days. Using the same sensor on more than one infant increases the risk of cross infection. Failure to observe this warning may cause infant injury or death.**

## Technical specification

<b>Description</b>	Neonatal respiration Monitor with passive pneumatic Sensor system. Battery-operated, visual and audible alarm output, digital electronic filtering and timing
<b>Power supply</b>	4 IEC type 6V LR6 (AA) alkaline batteries
<b>Battery life</b>	Approx. 60 days, depending on usage and number of alarms
<b>Dimensions</b>	170 x 85 x 30 mm (H x W x D)
<b>Weight</b>	275 g (including batteries)
<b>Alarm limits</b>	Adjustable to 10 or 20 seconds
<b>Alarm output</b>	Visual (red indicator lamp) and audible (3 kHz pulse)
<b>Indicators</b>	Green (10 sec.), orange (20 sec.)
<b>Battery indicator</b>	Orange (battery nearly discharged)

### 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

<b>EMC</b>	Law relating to electromagnetic compatibility, Group 1, Class B, emitted RF radiation to EN55011:1991, suitable for domestic use.
------------	---

### 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:	Polyetheleyne foam, Corrugated cardboard
Respiration Sensor:	PVC, ABS

**Note:** all materials used in this product are latex free

### Accessories

Respiration Sensor, *part number 0108-0007*  
Instruction Manual , *part number 0514-0182*

## 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.

---

### 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 Smiths Medical are assessed.



### Disposal (EU Countries)

Under the Waste Electrical and Electronic Equipment (WEEE) Directive 2006/96/EC and implementing regulations, all devices and service items within the scope of the Directive purchased new after August 13, 2005 must be sent for recycling when ultimately becoming waste. Devices and items must not be disposed of with general waste.

If purchased before that date, they may also be sent for recycling if being replaced on a one-for-one, like-for-like basis (this varies depending on the country).

Recycling instructions to customers using Smiths Medical products are published on the internet at:

<http://www.smiths-medical.com/recycle>



### Disposal (other countries)

When disposing of the pump, its batteries or any of its accessories, ensure that any negative impact on the environment is minimised. Contact your local waste disposal service and use local recycling or disposal schemes. Separate any other parts of the equipment where arrangements can be made for their recovery; either by recycling or energy recovery.

The main batteries are potentially harmful and will require separate disposal according to manufacturer's instructions or local regulations.

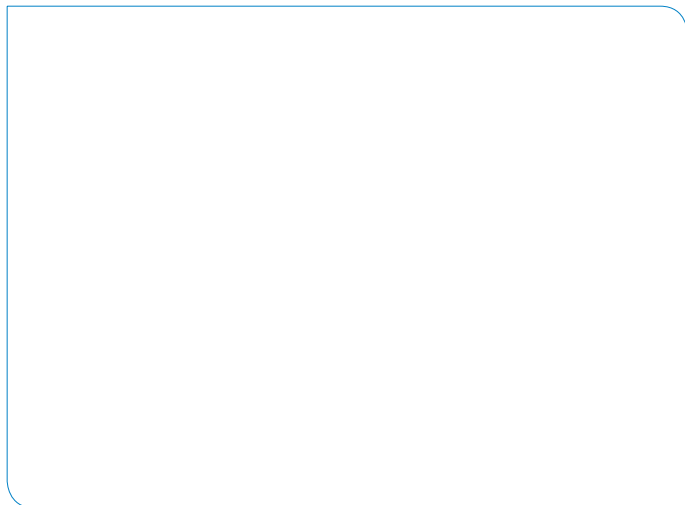
Note: If applicable, EU, national or local regulations concerning waste disposal must take precedence over the above advice.







For further information, please contact your local distributor or  
Smiths Medical direct on +44 (0)1923 246434



**Smiths Medical PM, Inc.**

N7 W22025 Johnson Drive, Waukesha, WI 53185-1856, U.S.A

European Representative:

**Smiths Medical International Limited**

Watford, Hertfordshire, UK, WD24 4LG

Australian Representative:

**Smiths Medical Australasia Pty. Ltd.**

Brisbane, QLD 4113, Australia

[www.smiths-medical.com](http://www.smiths-medical.com)

**Smiths Medical - part of the global technology business Smiths Group**

© 2007 Smiths Medical family of companies.  
All rights reserved.

Revision issue date: September 2007

Part No. 0514-0182-102



**smiths medical**