



Infant Radiant Warmer & Resuscitation Unit *Hill-Rom Air-Shields* *Resuscitaire RW82VHA-1C*

BRIEF DESCRIPTION

Hill-Rom Air-Shields Resuscitaire RW82 VHA-1C is a micro-processor controlled infant radiant warmer and resuscitator for use in the delivery suite or special care baby units.

MAIN FEATURES

- Maximum heater power output: 750W
- Power settings: 0 to 100% in 10% increments
- Warmer modes: Pre-warm,
Manual
Baby (servo-controlled)
- Temperature display range: 18 - 43°C
- Baby mode temperature range: 34 - 38°C
- Heater head rotation: 90° left or right
- Mattress size: 52cm x 65cm
tilt: variable +10° to -10°
- Apgar Timer: tones at 1, 5 & 10 minutes
- Vertical Height Adjustment (VHA)
- X-ray tray
- Resuscitation module with AutoBreath™
- Air/oxygen blender
- Auxiliary gas supply
- Suction

SUMMARY

Advantages: Easy access bassinet, good temperature stability and uniformity, rapid warming in pre-warm mode. Easy to use heater controls and prominent Apgar timer. AutoBreath™ gas powered resuscitator.

Disadvantages: Awkward storage facilities, small shelving, no labelling of VHA switch, Poor access and labelling of gas supply On/Off switch. Suction bottle compartment awkward to shut. No heater guard (see *manufacturers comments*).

Price (ex VAT)	£ 10,915 (as seen) £ 8,888 (no blender)
Supplier	Hill-Rom Clinitron House, Ashby Park, Ashby de la Zouch, Leicestershire. LE65 1JG
CE Marking	Yes (Annex II, QA route)
Notified Body	KEMA (0344)
Manufactured to Standard	Manufacturer states compliance with IEC 601-1 1998 IEC 601-2-21 1994-02 IEC 601-1-2 1993-04 ISO 10651-1 1993-06-01

Description

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DESCRIPTION

The Hill-Rom Air-Shields Resuscitaire RW82VHA-1C is a combined infant radiant warmer and resuscitator for use in the delivery suite or special care baby unit. The unit evaluated incorporated all optional features.

The radiant heater can be operated in pre-warm, manual and servo controlled temperature modes, and also has an Apgar timer. The resuscitation module incorporates a suction circuit, patient and auxiliary gas supply systems, air/oxygen blender and a gas-powered ventilation system called 'AutoBreath™'. The unit has a large bassinet with an X-ray tray and vertical height adjustment. A storage drawer and instrument tray is provided beneath the bassinet. Additional shelving is also available.

INFANT RADIANT WARMER UNIT

Heating Control Heat is delivered to the mattress area using an overhead, microprocessor controlled, radiant heater, which is started by pressing the rectangular power ON/OFF button. Two control modes, pre-warm and manual, are provided on all Resuscitaire models. Skin temperature servo-control (baby) mode was also installed on the device tested. All controls and the alarm message panel are on the heater control panel at the top of the control column (**Photo 1**). Most control switches are covered with a tactile membrane, and lights indicate which mode is in use. Heater mode controls are selected using the switch on the left of the panel.

Pre-warm mode An automatic cycle initially selects 100% heater power (750 W) for 3 minutes, then 60% power for 12 minutes, and then reduces the heater power to 30%, at which level no alarms will activate.

Manual mode The heater output level can be selected in 10% increments from 0% to 100% of

the 750 W available using the ↑ and ↓ switches under the 'set temperature' display. An alarm warning activates 10 minutes after selecting any power setting above 30%. If the silence/reset button is not reset within 5 minutes the heater will turn off. Connecting the skin probe on the baby's skin only displays the measured skin temperature, it does not control heater output.

Baby mode Heater output is servo-controlled by the micro-processor, using measurements from the skin probe on the baby. The temperature is pre-selected using ↑ and ↓ switches under the 'set temperature' display. The target temperature can be set in the range 34°C to 37°C, in 0.1°C steps, and up to 38°C if the override button is activated.



Photo 1: Heater Control Panel

Skin temperature sensor Disposable or reusable skin temperature sensors are available from the supplier. Both have multi-pin plugs which fit the socket on the heater control panel and a sensor for fixing to the patient's skin using a reflective patch. Skin temperature is displayed on the heater panel to a resolution of 0.1°C.

Heater Alarms An alarm is signalled by an auditory tone, flashing of the 'Silence/Reset' button, and illumination of the appropriate text alarm message. Most alarm conditions have an intermittent tone and can be silenced by pressing the 'Silence/Reset' button. Continuous audible alarms, which cannot be silenced, include warnings of a system or power failure, electrical failure of the skin temperature probe, and alarms relating to the resuscitation module. The most common radiant warmer alarms are:

Check Patient Fifteen minutes of heating in manual mode is permitted before the 'Reset'

Description

button must be pressed. The alarm first sounds after 10 minutes of heating.

Baby Temperature: An alarm sounds if the skin temperature is 1°C above or below the selected Set Temperature. This may indicate the sensor is detached from the skin surface. Pressing the 'Reset' key silences the alarm for 10 minutes. Pressing the key before starting routine medical and nursing procedures will prevent activation of baby temperature alarms for 10 minutes.

High Temperature: The skin probe temperature exceeding 39°C triggers a continuous audible alarm and automatically switches the heater off.

Other Features on the Warmer Control Unit

Apgar Timer: The heater control unit incorporates a timer in the top left corner of the heater panel (see Photo 1). Pressing the ▶ ■ toggle switch will start the timer, which is pre-set to prompt post-delivery assessment of the infant. The Apgar Timer displays elapsed minutes and seconds and an audible alarm will sound 1 minute, 5 minutes and 10 minutes after the timer has been started. Pressing the // button will reset the timer to zero and automatically restarts the Apgar count. Pressing the ▶ ■ switch again will stop the timer.

Keypad Lock: The toggle 'keypad lock' switch can be used to deactivate the Up/Down Arrows and Select Mode Keys on the Heater Controls.

Examination Light: The 'Exam Light' switch activates a small halogen lamp in the warmer head to give additional illumination of the bassinet.

Bassinet: A removable, plastic-covered mattress lies in the bassinet. The clear acrylic sides can be folded down for easy access and removed for cleaning. One of the short walls has several cut-outs for tubing. The mattress can be tilted to a maximum of 10° head up or feet up position by rotating the large knob on the front of the bassinet. The X-ray cassette shelf below the mattress can be accessed by lifting a side panel.

Vertical Height Adjustment (VHA): The height of the bassinet and control column may be altered to improve ease of access. The mattress height is continuously adjustable between 89cm and 110cm above floor level using the switch on the side of the control column (see Photo 4 on page 5).

Storage: Under the bassinet the Resuscitaire RW82 has a deep, pass-through drawer, with a removable drawer organiser tray, accessible from

both sides. A pull out shelf on the right side of the bassinet and a compartment on the front of the unit for storing suction tubing and accessories are fitted as standard (see Photo 2). Additional shelves and/or IV poles may be attached to the central column.



Photo 2: Storage facilities

RESUSCITATION UNIT

The model tested included both blender and 'AutoBreath™' optional modules, as well as the basic resuscitation facilities of patient and auxiliary oxygen supply and suction. All controls are on the three resuscitation panels on the control column (Photo 3) below the heater control panel. The gas supply required to activate all of these functions is controlled by the metal ON/OFF switch at the base of the control column. Separate ON/OFF switches for suction and for the blender must also be switched on to use these specific modules.

Blender module: Oxygen enriched air mixtures at pre-set oxygen concentrations can be delivered through the patient supply port when the unit is switched on. Rotating the knob permits oxygen concentrations from 21% to 100% to be selected. Normally the blended gases are delivered to the patient in a continuous flow unless the AutoBreath™ module is installed and activated.

AutoBreath™ module: This is a constant flow generator with pressure limiting. It automatically cycles ventilation pressure of oxygen or blended gas. Inflation pressure is adjustable but an additional pressure relief valve limits the maximum pressure to 59 cmH₂O. The air pressure applied to the lungs during expiration, known as positive end expiratory pressure (PEEP), can be varied between zero and 18 cmH₂O, but the actual PEEP values are not marked. Breathing rate is adjustable from 18 to 60 breaths per minute at a fixed Inspiration:Expiration ratio of 1:2.

Description

Patient Supply: The flow rate of oxygen or blended gases can be adjusted between 0 – 15 litres per minute ($L \cdot \text{min}^{-1}$), using the "Flow Rate" knob, to the left of the patient outlet connector. The patient gas supply also has a negative pressure relief valve so that air can be inspired in the event of gas failure. Inflation pressures between 0 cmH_2O and 49 cmH_2O can be selected but the actual pressure values are not marked. Airway pressure is indicated by a large pressure gauge, pneumatically connected to the machine end of the breathing system. All gas outlets have pressure limiting mechanisms to prevent the development of excessive pressures.

Auxiliary Flow: An additional patient outlet for the supply of pure oxygen can be activated by rotating the Auxiliary Flow knob from zero. Flow rates from 0 to $15 L \cdot \text{min}^{-1}$ can be selected.

Gas Supply: The suction and blender module, can be supplied from either pipelines or cylinders. Where both are connected the Resuscitaire is usually configured for cylinder priority. Pipeline priority is an option, but the adjustment must be made by the supplier or manufacturer. An alarm within the blender module indicates failure of one or other gas supply. **CEDAR note:** Pipeline priority is recommended so that the gas supply is automatically switched to cylinders only in an emergency and the cost and inconvenience of repeated replacement of cylinders can be avoided.

Patient connectors: The single-use breathing system consists of a 90 cm length of 10 mm diameter corrugated tube with a 15 mm male conical connector at one end and a 15 mm female patient connection at the other. A diaphragm exhalation valve is incorporated into the patient connector and is operated by pressure supplied through a narrow bore tube.

The exhaust port of the patient connector is shaped so that it is easy to occlude with a finger to provide a manual inflation. A T-piece is provided so that airway pressure can be monitored by a separate alarm system.

In units without the AutoBreath™ option a tube from the patient's breathing circuit must be connected to a port mounted beneath the airway pressure gauge (not shown in **Photo 3**) for monitoring the supplied gas pressure.

Airway Pressure Indicator: The airway pressure gauge is marked with coloured sectors: yellow (up to 30 cmH_2O), orange (30 to 40 cmH_2O) and red

(above 40 cmH_2O). The airway pressure control has equivalent coloured sectors in addition to 'min' and 'max' markings.

Suction: The suction unit is powered by the compressed gas (oxygen) supply to generate a negative pressure. Suction pressure is adjustable and is displayed on a gauge. A suction receiver bottle is located behind a hinged cover under the front of the bassinet. Suction catheters can be attached to the extension tube emerging from behind the cover.

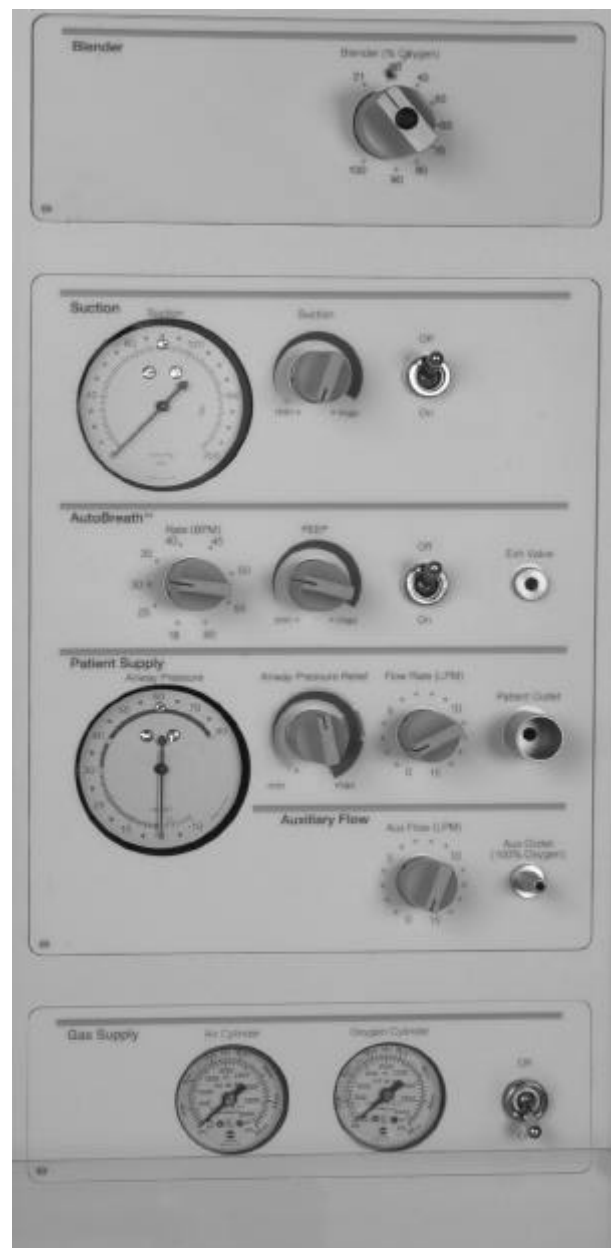


Photo 3: Controls for Resuscitation

User assessment

USER ASSESSMENT

Eighty staff in seven hospitals participated in the user assessment of the Hill-Rom Air-Shields Resuscitaire. The distribution of users is shown in **Table 1**; more midwives completed questionnaires than neonatal care staff.

Table 1. Participants in User Assessment

Hospital	Neonatal staff	Midwives
A	9	15
B	5	11
C		8
D	4	6
E	5	3
F		5
G	9	
Total	32	48

Hospital A used the Resuscitaire RW82VHA-1C for a one-month trial in the Neonatal Unit. Two owned units were already in clinical use in the Delivery Suite.

Six hospitals (B-G) had purchased Resuscitaires and their clinical staff also participated in the user assessment. However, not all Resuscitaires on every unit were the same age nor had the specification of the Resuscitaire evaluated in the technical assessment. In hospitals A to G one or more Resuscitaire was located in the delivery suite; in hospitals E and G Resuscitaires were also located in the special care baby unit (SCBU).

In the UK most Resuscitaires are located in delivery units. Primary users are midwives who require a warm, safe environment for aspirating, resuscitating and assessing the newborn infant after delivery. Neonatal care staff may also use the unit in the delivery suite when they are called to assist in resuscitation of a baby presenting with respiratory or neonatal problems.

In SCBU Resuscitaires are used for stabilising and assessing new admissions, providing ventilation and suction en route to theatre or from the delivery suite, and for performing intensive medical interventions.

Midwives and neonatal care specialists (both neonatal nurses and medical staff) completed identical questionnaires, rating their opinion about specific features as *unacceptable*, *poor*, *satisfactory*, *good* or *excellent*. Midwives and neonatal care staff need to use different features on the Resuscitaire, and we observed that the distribution of their responses differed.

Consequently the responses of the two groups have been summarised separately in both **Table 2** and **Appendix 1**

The most common response for each Resuscitaire feature was either *satisfactory* or *good* (see **Table 2** on page 6). Neonatal nurses tended to have a higher opinion of most features than midwives. Some users found specific Resuscitaire features to be *excellent* and others were rated *poor* or *unacceptable*. As these issues may be important for clinical practice in some units readers are encouraged to study the complete questionnaire and user opinion data provided in **Appendix 1**.

Features most or least liked by users are discussed below.

GENERAL FEATURES

Mobility: The newer Resuscitaire model is larger than earlier versions because of increased mattress size. Most users welcomed the larger mattress. However, those working in wards with narrow doors found manoeuvring the Resuscitaire between rooms awkward. Some users also considered the unit "cumbersome" and "heavy". More neonatal staff were pleased with the mobility but commented that the suction compartment cover dropped open and the drawer tended to slide out when in transit.

Vertical Height Adjustment: VHA is a useful feature, smoothly adjusting the height of the mattress and control column. But, where VHA was installed few staff used it as the switch is poorly visible, being located on the side of the column behind the bassinet, and not labelled. (**Photo 4**)



Photo 4: VHA switch is behind the bassinet

User assessment

Table 2: Summary of the user assessment questionnaire responses. User scores for each group of features have been summed and are expressed as a percentage. The most frequent response is marked in **BOLD**. User responses to each individual question can be found in Appendix 1.

Opinions of Neonatal Staff					Hill-Rom Air-Shields Resuscitaire features listed in the same order as on the questionnaire and in Appendix 1	Opinions of Midwives				
Unacceptable	Poor	Satisfactory	Good	Excellent		Unacceptable	Poor	Satisfactory	Good	Excellent
2%	9%	34%	50%	5%	General Features	1%	7%	48%	36%	8%
	1%	30%	57%	11%	Warmer Controls		7%	45%	40%	8%
	1%	40%	57%	1%	Skin Temperature		8%	67%	25%	
	6%	39%	51%	4%	Warmer Alarm	1%	8%	55%	33%	4%
2%	11%	29%	49%	9%	Patient Area		5%	37%	46%	12%
	1%	39%	50%	11%	Nursing Procedures		3%	41%	44%	12%
		20%	64%	15%	Medical Procedures			36%	48%	16%
	2%	27%	60%	11%	Auxiliary Oxygen		2%	46%	45%	7%
		20%	61%	19%	Blender	<i>No users responded</i>				
	1%	24%	65%	10%	Pressure Control		4%	62%	18%	16%
	3%	30%	51%	16%	Auto-breath				80%	20%
	2%	28%	67%	3%	Suction		4%	46%	42%	8%

Cupboard/drawer space: The deep drawer is accessible from both sides and contains an upper removable tray. Overall, users found this arrangement satisfactory but a significant number of staff (>20%) rated this feature as *poor* or *unacceptable*. They reported that it was “difficult to access disposables and equipment with one hand alone” and “poorly designed to organise equipment”. To resolve this issue some ward protocols limited storage to items required for standard resuscitation procedures only.

Fixing ancillary equipment: Additional shelving is available for the RW82. The users thought that the shelving supplied was too small and they would have liked a larger lip to prevent equipment slipping off.

Mattress tilt: Nurses reporting poor performance used an earlier model with a different tilt mechanism. Users rated the new design more favourably, but some staff reported that the side covers concealing the tilt mechanism “easily fall off, startling baby and staff”. (See the long curved cover above the storage drawer in **Photo 2.**)

Security of the side panels: Front and side clear plastic panels enable the new born baby to be left in a safe environment while midwives attend to the mother after delivery. Staff reporting this feature as *poor* were referring to the side covers concealing the tilt mechanism (see above).

X-ray Facility: The X-ray tray is valuable when using the RW82 for prolonged periods on SCBU. Some users found positioning of the plate within

User assessment

the tray was awkward, especially when the mattress was tilted.

Aesthetic Appeal: Most of midwives and neonatal staff rated this as *satisfactory* or *good*. However, some midwives rated it as *poor* and commented that it appeared “very technical”.

Radiant Heater and Temperature Control: Most SCBU staff were pleased with the warmer system on the Resuscitaire. In general midwives were less enthusiastic, as explained below.

Heater controls: These are located at the top of the control column. Shorter staff reported that they were difficult to reach when standing in front of the bassinet. Most users found the controls clear, and easy to use, and thought the labelling was clear. However, some commented that the lettering was too small to read at a distance. **CEDAR note:** The lettering is in Arial 11 point but the mid tone grey may make visibility difficult due to poor contrast.

Some midwives considered the pre-warm did not heat the towels sufficiently and turned the heater to maximum heat in manual mode towards the end of delivery. The resulting 10 minute ‘Check patient’ alarm was then found to be a nuisance, disturbing the expectant mother and distracting midwives attending the final stages of the birth.

Skin Temperature Sensor: Midwives considered this facility unnecessary. Most did not use the skin probe, preferring other thermometry systems for temperature measurements of new born infants. More neonatal staff used the probe, both for monitoring skin temperature in manual mode and occasionally for servo-control of the heater in baby mode. The baby mode may only be fully used if an infant is nursed on the Resuscitaire for a prolonged period in SCBU.

Warmer alarm systems: Some nurses commented that the labelling of the alarm captions was very small and difficult to read especially when they were positioned in front of the bassinet resuscitating a baby. **CEDAR note:** The lettering is in Arial 8 point.

General Nursing and Medical Procedures

Most respondents found the Resuscitaire bassinet provided easy access for performing a range of medical and nursing procedures whilst the heater effectively maintained the baby’s temperature.

Suction: The suction facility was used by most respondents and was generally well liked.

However, several users reported that the suction storage compartment was difficult to shut and they found it difficult to store the pipeline back in its compartment; they also found the compartment spontaneously opened during transportation (see **Photo 2**). **CEDAR note:** The jar and pipe will only store away safely if they are in exactly the right position. Training is necessary for this but an easier arrangement for storage would be helpful for the users.

Ventilation and Oxygen Supply: The blender, pressure control system and Autobreath™ facilities were nearly all rated as *good* by neonatal staff. Only a few midwives used these features.

Neonatal staff found it very useful to use AutoBreath™ to continue ventilating a baby on the Resuscitaire whilst in transit from the neonatal unit to theatre or X-ray. One respondent commented that it was “extremely useful - frees up a pair of useful hands”. However, another found that it was being switched on when not needed and suggested “a cover on the AutoBreath™ switch or a clear label” to state that this should only be switched when required. When AutoBreath™ was switched on at the same time as manual resuscitation was in progress, the two processes competed and severely reduced the effectiveness of the resuscitation.

The main “gas” switch, simply labelled ON/OFF, was often mistaken for an electrical switch. Medical and nursing staff confused the switches for the various ventilation and gas modules, which could be dangerous especially in an emergency. Use of the controls was not considered intuitive. These problems have been resolved by training. Trust staff in some units have added extra labels. **Photo 3** shows the panels built into the control column of the high specification model. Not all modules are necessary for the delivery suite.

Some users complained that the gas cylinders leaked and needed to be replaced too often. This problem was traced to the Resuscitaire taking gas from the cylinder in preference to the pipeline supply. If a pipeline supply is available the Resuscitaire should be “pipeline priority” in order to conserve the gas in the cylinders. The gas supply and the blenders should also be switched off when not in use, otherwise gas will slowly leak out through the blender.

Technical evaluation

TECHNICAL EVALUATION

Radiant Warmer

The radiant warmer was operated in different modes to simulate its use in the delivery suite and neonatal care settings. Heating of the bassinet area of the Resuscitaire RW82 has been assessed by measuring the temperature change within five matt black aluminium discs positioned on the mattress, in accordance with the test conditions outlined in the British Standard Specification for infant radiant warmers (BS EN 60601-2-21:1997).

Changes in the core temperature of the central test disc in situations simulating clinical use of the Resuscitaire are summarised in **Table 3**.

Table 3 Summary Data for Radiant Warmer

(a) Temperature rise using	
Manufacturer's Pre-warm mode	
- after 30 minutes	6°C
Maximum heat (manual mode)	
- after 15 minutes	8°C
(b) Time to warm disc to 36.5°C	
Maximum heat – from 23°C	27.5 minutes
Maximum heat – from 32.5°C	9.5 minutes
(c) Tilt – temperature difference	1.9°C
(d) Heater swung away from bassinet for 10 minutes	
Temperature drop	1.6°C
Time to regain temperature	10.5 minutes

Pre-heating the mattress using the Resuscitaire's own **pre-heat mode** for 30 minutes raised the core temperature of the central disc to 29°C, 6°C above the room temperature of 23°C.

In an emergency rapid warming of the mattress can be achieved in manual mode, using 100% heater power. After 15 minutes in this mode, the core temperature of the central disc was raised to 31°C, 8°C above the room temperature. Repeated silencing of the alarm permitted the central disc to reach 36.5°C after 28.5 minutes, from the starting temperature of 23°C.

We tested the ability of the radiant heater to maintain the selected temperature in baby mode.

The skin temperature sensor was attached to the top surface of the central disc using a disposable reflective patch. The core temperature of the five discs, one positioned centrally and four placed midway between the centre and corners of the bassinet were continuously monitored while typical nursing procedures were simulated.

Temperature stability over time was assessed by monitoring the central disc core temperature. Over an hour the maximum change was less than 0.3°C. During the same period room temperature fluctuated by 0.3°C, between 24.6°C and 24.9°C. Temperature stability is therefore considered to be very good, as illustrated by the final ten minute trace (30-40 minutes) in **Figure 1** when the temperature varied by less than 0.1°C.

Uniformity of heating across the mattress was assessed by monitoring the four corner aluminium test discs whilst maintaining the central disc at 36.5°C using baby servo-control. The maximum difference between the average temperature of any corner disc and the average temperature of the central disc was 1.2°C when the mattress was level. This result is well within the specifications of BS EN 60601-2-21. At the maximum tilt, 10°, the greatest difference between any discs was 1.9°C. The uniformity of heating across the mattress is judged to be very good.

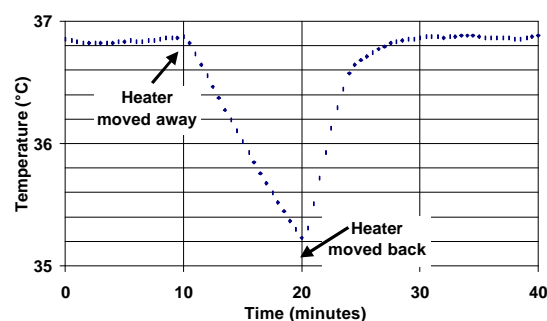


Figure 1 Heater moved away from bassinet

To simulate staff performing a mobile X-ray the overhead heater was turned 90° to the side for ten minutes; heater output continues when the head is rotated. This caused a temperature drop of 1.6°C in the central test disc (see **Figure 1**). When the heater was replaced the previous temperature of 36.8°C was regained in 10.5 minutes.

Uniformity of heating across the mattress was also assessed by measuring the surface temperature. A

Technical evaluation

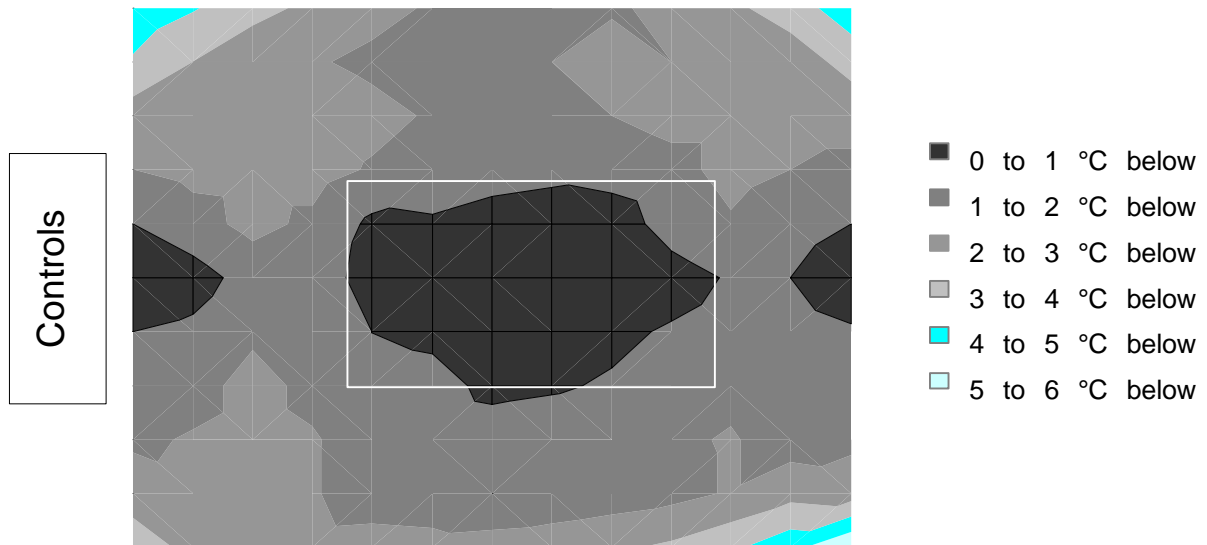


Figure 2: Surface temperature of mattress at 50% power in manual mode. The maximum temperature of 37.6°C was measured in the centre of the mattress. White box 20cm x 30cm

black cotton polyester felt sheet marked with grid lines at 5cm intervals was used to cover the mattress. The surface temperature was measured at the marked intervals after the radiant warmer heater had been in manual mode at 50% power output for one hour. The temperatures ranged from 37.6°C to 31°C across the mattress as seen in the contour plot (**Figure 2**).

The darkest region shows where the mattress surface temperature is within 1°C of the maximum. This central area, 30cm long and 20cm wide, shown by the white box, is approximately the size of an underweight newborn infant.

The radiant warmer consists of a quartz tube, with a metal bar underneath and a large curved metal reflector above to distribute the heat across the mattress (see **Photo 5**). The two "guard" rods beneath the heater element do not prevent access or finger contact with metal reflector. After the warmer had been at 50% power for an hour some accessible regions of the reflector had surface temperatures in excess of 85°C, and close to the heater element measurements exceeded 100°C.

CEDAR Note Hot surfaces present a hazard to the touch, and to any flammable material which may inadvertently touch them. The "guard" does not comply with section 42.5 of the safety standard BS EN 60601-1 1990 in that it fails to protect users from the hot surfaces.

In manual mode the Resuscitaire uses cyclical switching of the heater element to maintain power

output at the pre-selected level. This prevented direct mapping of the uniformity of radiant heat output. However, maximum irradiance measured in the 780nm to 1400nm waveband (IR(A)) was 13.2mW.cm⁻²; this is greater than the 10mW.cm⁻² stated in the standard but higher levels are permissible for a few minutes. No harmful incidents had been reported at the time of the standard's publication.



Photo 5: Radiant quartz tube and reflector

Technical evaluation

Gas Supply System

Gas is supplied by an integrated system housed within the control column. The ON/OFF switch at the base of the column **must be activated** in addition to specific gas supply and suction controls (see **Photo 4**). The bassinet panel impairs access to the main gas ON/OFF switch and reduces visibility of switch position and supply gauges, especially when the bassinet is tilted (as in **Photo 6**) or covered with bedding.



Photo 6: Access to Main gas ON/OFF switch can be impaired by the rear bassinet panel

Oxygen-air blender: Oxygen concentrations were within 4% of the pre-selected setting. The largest errors occurred in the middle of the range and were influenced by the flow through the blender. At low flow rates the oxygen concentration slightly exceeded the set value while at flows above 5 L.min⁻¹ the concentrations fell below the set value. These errors are within the precision to which users can pre-set oxygen concentration, as markings are broad and selector scale is short. In normal use the errors should be insignificant.

Varying the oxygen or air pressures had negligible effect on concentration, within the range of pressure declared by the manufacturer. An audible reed alarm operated when the oxygen or air pressure fell below the minimum level. This alarm is made of metal and produced a varying tone during technical testing indicating that it was faulty when the unit was delivered. It failed during the reconfiguration to "pipeline priority" (see **Gas supply** on page 4) and was replaced by a Hill-Rom engineer. In one hospital sampled a technician noted that reed alarms on several units delivered to his Trust had also failed.

Gas flow rate: The delivered gas flow rate from the patient outlet and oxygen auxiliary outlet was within 5% of the setting. The airway pressure gauge slightly under read the actual pressure, but was always within 0.3 cmH₂O. The maximum pressure attainable was 53 cmH₂O. The pressure limiting mechanism was only slightly affected by the flow setting.

Breathing system connections: These were correctly dimensioned except for the patient gas supply outlet. The taper on this connector was incorrect and in normal use allowed the plug gauge to rock. A secure connection was only made when using the breathing system supplied by the manufacturer, as it had a deformable plastic connector. Alternative breathing systems from other manufacturers may not fit securely.

Gas supply: The cylinder pressure gauges were marked in both imperial and metric scales but there are no pressure range markings to indicate when the cylinder is full or empty. On delivery, the Resuscitaire was configured to cylinder priority. CEDAR asked the manufacturer's service engineer to change the gas supply to pipeline priority, so that cylinder gas would only be used if the pipeline supply failed. (see page 4).

Suction System

The suction system was capable of generating a sub-atmospheric pressure of 146 mmHg and a maximum flow of 13.9 L.min⁻¹. The suction gauge was within 10% of the displayed reading.

User Manual: This generally makes good use of photographs, diagrams and tables to explain the functions of the Resuscitaire. However, it did not make it sufficiently clear that the Gas "ON/OFF" switch (see **Photo 6**) must be "ON" before the resuscitation and suction modules can be used.

CERTIFICATION AND STANDARDS

The RW82-1C carries CE marking in respect of the Medical Devices Directive(MDD). By affixing CE marking the company has declared compliance with UK regulations implementing the MDD. Hill-Rom Air-Shields submitted a copy of a certificate confirming compliance with 93/42/EEC. The assessment route was a quality audit certified to ISO 9001 & EN 46001. The notified body was KEMA, Arnhem, The Netherlands, (0344). The certificate states compliance with 93/42/EEC; IEC 601-1,1998; IEC 601-2-21,1994-02; IEC 601-1-2 1993-04; ISO 10651-1 1993-06-01.

Manufacturer's data

MANUFACTURER'S COMMENTS

Manufacturers comments:

Reflector The product successfully passed the relevant tests based on the interpretation of the standards by the CITECH Medical Device Testing in 1993 and Underwriter Laboratories in 1994. Hill-Rom Air-Shields has addressed this report's concern regarding the heater guard and a design change has been initiated and is undergoing testing and validation. The new guard will easily mount on current systems and will be made readily available by early September 2001.

Pipeline priority This issue was resolved by the company fitting a new regulator on all units with NIST fittings in 21/1/01. The unit tested was issued prior to the release of the new regulator.

Sidecovers of tilt mechanism The mattress tilt mechanism is covered by a shroud. To maintain the shroud a new rivet mechanism has been designed and will replace the existing rivet.

Suction bottle By inserting the suction bottle with suction tubing on the right side it prevents obstruction of the closure catch

ON/OFF switch on the Gas Supply. No formal complaints have been received but based on the observation in this evaluation report Hill-Rom Air-Shields will accentuate the switch labelling.

VHA switch. An international adjustment symbol will be placed around this switch to improve identification

PRODUCT DATA

Size (W x D)	72cm x 112cm	
Height	171cm	198cm with VHA
Mattress Height	100cm	89cm – 110 cm with VHA
Weight	91kg	127kg with VHA
Power requirement	220-240V, 50/60Hz, 750W	220-240V, 50/60Hz, 1300W with VHA
Heater Output (max.)	750W	
Manual Heat Control	Adjustable in 10% increments from zero to full power (100%)	
Examination Light	50W Quartz halogen lamp, light output > 0.18 lumens/cm ²	
Apgar timer	0-59 minutes / 0-59 seconds (accuracy ± 0.5sec, resolution 1sec)	
Operating temperature range	18°C to 30°C	
Relative humidity operating range	5% RH to 95% RH, non-condensing	
Wall supply pressure	2.8 to 5.2 bar	
Cylinder pressure	199.8 bar maximum	
Cylinder diameter	10 – 12 cm (maximum)	
Oxygen consumption	50 litres per minute (maximum)	
Suction circuit	Adjustable suction intensity 0 to 150 mmHg	
<u>Patient gas supply</u>		
Airway pressure limit	0 – 4.9 kPa [0 – 49 cmH ₂ O] operator adjustable (accuracy ± 10%)	
Fixed pressure relief	5.9 kPa ± 20% factory set	
<u>Autobreath™ Circuit (optional)</u>		
I:E Ratio	Fixed at 1:2 ± 20%	
PEEP	1.8 kPa ± 0.4 kPa [18 cmH ₂ O ± 4 cmH ₂ O]	
Breath Rate	18 to 60 BPM (accuracy ±10% of setting)	
<u>Auxiliary Gas Supply</u>		
Flow range	0 to 15 litres per minute	
Supply pressure limit	16 kPa [160 cmH ₂ O] ± 10%	
Data Port	2400 bits/second fixed Baud rate, RS232C Compatible	

Manufacturer's data

PROCUREMENT DATA

Manufacturer	Hill-Rom Air-Shields, 330 Jacksonville Road, Hatboro, PA, 19040. USA.	
Country of Origin	USA	
Supplier	Hill-Rom Clintron House, Ashby Park, Ashby de la Zouch, Leicestershire, LE65 1JG	Tel : 01530 411000 Fax: 01530 411555 Website : www.hill-rom.com

Prices (ex VAT)	Resuscitaire with warming system# and integrated resuscitation module *, blender and autobreath ventilator (variable height stand)	£ 10,915
	Resuscitaire with warming system# and integrated resuscitation module *and blender (variable height stand)	£ 9,875
	Resuscitaire with warming system# and integrated resuscitation module * (variable height stand)	£ 8,888
	Mobile warming system# incorporating a tilting bassinets, organiser front and rear panels (no resuscitation module)	£ 6,235
	Wall mounted warming system # (no resuscitation module)	£ 2,860
	# warming system incorporates built-in digital Apgar timer, prewarm manual and patient servo (baby) control modes, pivoting warmer head and examination light	
	* integrated resuscitation module incorporates suction, patient gas supply, adjustable airway pressure relief, manometer and two reserve cylinder fittings.	

Accessories & Disposables

X-ray cassette tray	£ 106
Monitor shelf	£ 250
IV mounting pole	£ 192
Resuscitaire Service Manual	£ 37
Re-usable skin temperature probe	£ 108
Reflective patches to affix reusable skin probe (box of 100)	£ 133
Disposable skin temperature probe (box of 10)	£ 146
Re-usable 750ml glass suction bottle	£ 52
Disposable bacterial filters for reusable suction bottle (box of 25)	£ 78
Disposable 800ml suction bottle and tubing (box of 100)	£ 551
Reusable breathing circuit – autobreath version	£ 86
Disposable diaphragms for re-usable breathing circuit (box of 25)	£ 146
Disposable breathing circuit - autobreath version (box of 25)	£ 291
Disposable breathing circuit for basic or blender use (box of 10)	£ 60

PRODUCT SUPPORT

Guarantee	1 year guarantee	
Servicing Prices (ex VAT)	First line/in house maintenance	£ Price on Application
	Planned Preventive Maintenance (PPM)* Two visits per annum.	£ 546
	Comprehensive (Annual Premier)* Two visits per annum and breakdowns.	£1,077
	Minimum on site call out charge during normal working hours (additional labour at £75 per hr)	£ 225
	Minimum on site call out charge for customers with PPM contract (additional labour at £57.50 per hr)	£ 201

**Charges are reduced for lower specification Resuscitaire Radiant Warmers*

Appendix 1

User assessment data from questionnaire. The number of users sharing the same opinion about a feature is recorded, eg 13 neonatal staff thought general mobility was good. The most common response is marked in **BOLD**.

Number	Question	Neonatal Staff					Midwives				
		Unacceptable	Poor	Satisfactory	Good	Excellent	Unacceptable	Poor	Satisfactory	Good	Excellent
Part 1 General											
1	What is your opinion of the general mobility of this device?		3	10	13	2		7	21	16	1
2	What is your opinion of wheel locks ?			5	18	2			24	14	6
3	What is your opinion of the stability of this device?		1	8	15	3			16	22	7
4	What is your opinion of the vertical height adjustment of the device?	1	2	7	9				8	10	4
5	What is your opinion of the VHA mechanism of the device?	2	1	5	8				9	11	3
6	What is your opinion of the cupboard/drawer space on the unit?	1	5	11	9	2		2	7	21	13
7	What is your opinion of the fixing of ancillary equipment to this device?		5	11	6	1			4	26	10
8	What do you think about the aesthetic appeal of the unit?			10	19				4	21	14
Part 2 Controls For The Warmer Unit											
9	Please indicate your opinion of the accessibility of controls			7	18	2			3	18	18
10	What is your opinion of the general ease of use of all the warmer controls ?			8	18	3			3	20	18
11	How clear do you find the controls?		2	7	17	3			5	22	15
12	How visible are the controls?		1	8	17	3			6	17	19
13	How easy do you find it to change the warmer mode between 'pre-warm', 'manual' and 'baby'?			6	12	9			3	21	14
14	How easy do you find it to use the warmer controls in ' pre-warm ' mode?			10	15	3			4	19	15
15	How easy do you find it to use the warmer controls in ' manual ' mode?			10	14	4			3	24	13
16	How easy do you find it to use the warmer controls in ' baby ' mode	1	1	7	11	3			4	20	9
17	What is your opinion of the range of heater control in manual mode?			12	16				2	24	14
18	What is your opinion of the examination light control ?		1	7	17	3				11	26
19	What is your opinion of the keypad lock control ?			8	15	1				14	16
20	Consider the Apgar timer - what is your opinion of its controls?			8	16	2			3	13	14
21	What is your opinion of the ease of use of the Apgar timer ?			6	15	3			2	12	16
PART 3 Skin Temperature Control and Sensor											
22	What is your opinion of the skin temperature control range ?		1	5	12				1	7	2
23	What is your opinion of the display of skin temperature ?			4	13				2	4	5
24	What type of skin sensor do you use - disposable or reusable?	Reusable for 70% of users									
25	What is your opinion of skin sensor's size & shape ?			11	6					5	
26	What do you think of the length of the lead ?			7	7	1				4	1
27	How easy do you find it to fix the sensor to patient?			6	9					4	1

Appendix 1

Number	Question	Neonatal Staff					Midwives				
		Unacceptable	Poor	Satisfactory	Good	Excellent	Unacceptable	Poor	Satisfactory	Good	Excellent
Part 4 Warmer Alarm System											
28	How do you find the auditory warnings?		1	7	15	1		2	23	16	2
29	How do you find the visual warnings?		1	10	15	1		2	22	16	2
30	How clearly do you understand the alarm caption ?		2	11	10	1	1	7	21	12	1
31	How visible is the alarm caption ?		2	10	10	1		2	26	12	1
Part 5 Patient Area											
32	How easy do you find it to access the patient ?		1	3	17	5		2	13	19	4
33	What is your opinion of the mattress size ?		2	7	16	4		2	14	19	7
34	What is your opinion of the mattress tilt ?	2	3	8	10	1		3	11	16	5
35	What is your opinion of the range of tilt of the mattress ?	1	3	11	9	1		3	12	14	4
36	What is your opinion of the security of side panels ?	1	5	5	15	2		1	15	23	5
37	What is your opinion of suitability of tubing ports ?		2	11	10	2		1	19	20	2
38	What is your opinion of the ease of performing X-rays ?		3	6	8			7	1	1	
Part 6 Nursing Procedures											
39	How easy do you find it to handle the infant and provide general patient care ?			7	14	3		2	10	21	7
40	How easy do you find it to feed the baby ?			5	7	1		1	3	2	1
41	What is your opinion of the ease of access to the infant for nursing procedures ?			7	10	5			10	15	6
42	How easy do you find it to use the suction facility on the device?			8	12	2		1	13	16	5
43	What is your opinion of the operator comfort when you are providing nursing and general care using this device?	1		10	12	1			20	11	3
44	Please indicate your experience of cleaning & disinfection of the unit			11	6	1		1	21	17	1
Part 7 Medical Procedures											
45	How easy is it to perform a medical examination while the infant is in this unit?			8	18	3			13	18	4
46	How easy is it to resuscitate an infant?			5	18	5			15	18	6
47	How easy is it to intubate an infant whilst using this unit?			4	18	5			6	9	5
Part 9 Ventilation and Oxygen Supply											
48	How do you rate the control of flow of auxiliary oxygen?			7	18	3		1	16	15	2
49	How do you rate the range of flow of auxiliary oxygen?	1		6	16	3		1	16	16	2
50	How do you rate the tubing connection from the auxiliary oxygen supply?			7	18	3		1	15	17	2
51	How do you rate the labelling of the auxiliary oxygen supply?	1		9	13	3			16	13	3

Appendix 1

Number	Question	Neonatal Staff					Midwives				
		Unacceptable	Poor	Satisfactory	Good	Excellent	Unacceptable	Poor	Satisfactory	Good	Excellent
Part 9 Ventilation and Oxygen Supply (continued)											
52	Did you use the blender control system?	Yes = 16					Yes = 0				
53	How do you rate the ease of use of blender control?		4	7	3						
54	How do you rate the range of operation of the blender?		1	8	3						
55	How do you rate the range of flow of blended gas?		2	9	2						
56	How do you rate the labelling on the blender ?		4	9	2						
57	Did you use pressure control system?	Yes = 21					Yes = 8				
58	How do you rate the range of operation of pressure control?		5	13	2		1	4	2	1	
59	How do you rate the display of pressure generated?		6	13	2			4	2	2	
60	How do you rate the ease of use of the control?	1	4	13	2		1	4	1	1	
61	How do you rate the ease of connection to the breathing system?		5	13	2			5	1	1	
62	How do you rate the breathing system supplied?		4	14	2			5	1	1	
63	How do you rate the labelling of pressure control system?		4	11	2			6	1	1	
64	Did you use the autobreath facility?	Yes = 18					Yes = 1				
65	How do you rate the ease of use of the auto-breath system?	1	3	10	4			1			
66	How do you rate the range of operation of the auto-breath system?		7	8	3			1			
67	How do you rate the PEEP control of the auto-breath system?		7	8	3			1			
68	How do you rate the effectiveness of the auto-breath system?		7	8	3			1			
69	How do you rate the labelling of the controls of the auto-breath system?	2	3	11	1					1	
70	Did you use the suction facility?	Yes = 22					Yes = 29				
71	How do you rate the range of vacuum of the suction system?		5	17			2	13	12	2	
72	How do you rate the flow capability of the suction system?		6	15			2	13	11	2	
73	How do you rate the size of the reservoir of the suction system?		7	12	1		0	14	11	3	
74	How do you rate the ease of setting up the suction system?	2	3	13	1		1	12	14	2	
75	How do you rate the ease of emptying the suction system?		7	11	1		1	14	12	2	
Part 10 Training and Use of the Device											
76	Did you receive training from the company ?	Yes = 12					Yes = 16				
77	What was your opinion of that training ?		3	3	1		1	5	2	1	
78	Have you read the user manual ?	Yes = 8					Yes = 17				
79	What is your opinion of the user manual ?		1	2				8	4		
80	Did you receive training from colleagues ?	Yes = 13					Yes = 34				

Appendix 2

ACKNOWLEDGEMENTS

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