BRIEF DESCRIPTION

The Draeger 5400 transport incubator comprises a single walled baby compartment, which has a transparent hinged acrylic canopy, and heater and oxygen control modules; all mounted on a foldable trolley. The incubator, complete with the trolley, is designed to fit into a UK ambulance, in place of the standard stretcher trolley.

Optional accessories include: a Babylog 2 ventilator; observation lamp; oxygen/air mixer; oxygen analyser; and a 12 V dc, trolley mounted, battery pack and charger. All of these accessories were fitted to the unit evaluated.

A vacuum cushion operated via an aspirator unit were offered as optional accessories but were not evaluated.

MAIN FEATURES

<table>
<thead>
<tr>
<th>Feature</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>power supply</td>
<td>240 V 50 Hz ac or 12 V dc, external supply or optional battery pack</td>
</tr>
<tr>
<td>access</td>
<td></td>
</tr>
<tr>
<td>hand ports</td>
<td>4</td>
</tr>
<tr>
<td>front door</td>
<td>Yes</td>
</tr>
<tr>
<td>tubing ports</td>
<td>6</td>
</tr>
<tr>
<td>tray withdrawal</td>
<td>Yes, front</td>
</tr>
<tr>
<td>controller</td>
<td></td>
</tr>
<tr>
<td>set temperature range</td>
<td>28°C to 39°C (1°C)</td>
</tr>
<tr>
<td>canopy thermometer</td>
<td>15°C to 40°C (1°C)</td>
</tr>
<tr>
<td>alarms</td>
<td></td>
</tr>
<tr>
<td>high air temperature</td>
<td>39°C ± 1°C</td>
</tr>
<tr>
<td>air supply provision</td>
<td>F size cylinder, 1360 litre</td>
</tr>
<tr>
<td>oxygen supply provision</td>
<td>F size cylinder, 1360 litre</td>
</tr>
</tbody>
</table>

SUMMARY

Advantages: stable, good mobility; easy to load, secure, connect to and unload from ambulance; very quiet in use; excellent observation lamp; secure door catches, front tray withdrawal; clear controls easy to use; good user manual; ventilator and mixer easy to use.

Disadvantages: Poor suspension; poor temperature control in the laboratory at low ambient temperatures; alarm provision poor; battery charger poorly constructed; does not fully comply with BS 5724.

Overall: A very good incubator for use in an ambulance. It offers excellent access and is easy to use. Unfortunately its temperature performance in cold air was poor (Draeger claim to have improved this) and it lacked any adequate alarms.

<table>
<thead>
<tr>
<th>Price</th>
<th>£6350</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight</td>
<td>124 kg</td>
</tr>
<tr>
<td>Size H x W x D</td>
<td>1020 x 1630 x 630 mm</td>
</tr>
<tr>
<td>Made In</td>
<td>West Germany</td>
</tr>
</tbody>
</table>

Product certificate? No

DH Registered Manufacturer? Yes, R0221/ME

Note: Manufacturers may be registered, de-registered or re-registered at any time. Consult the latest issue of the DH Register of manufacturers to check current status.

Manufacturer
Draegerwerk AG
D-2400 Lubeck 1
West Germany
DESCRIPTION

The Draeger 5400 is a single-walled transport incubator that is capable of being operated from various power sources and can be mounted on a trolley for ease of movement. A ventilator and oxygen/air mixer are available as accessories. An oxygen analyzer is also available.

The Draeger 5400 comprises a baby compartment, a heater control unit and an optional 12 V dc battery and charger. The baby compartment is enclosed at the top and front by a single-walled, transparent acrylic canopy. An (optional) observation lamp is mounted on the top of the canopy. To the left of the baby compartment an enclosed module houses the heating controls and beneath that an oxygen control module. On the right the Babymix oxygen/air mixer (where fitted) are housed. The 12 V dc battery and charger are mounted in a plastic case which is attached to the trolley. The incubator will operate from an external 240 V ac supply, external 12 V dc supply or from the optional 12 V dc battery pack.

There is a visual alarm for an over-temperature condition.

The incubator is mounted on a trolley which fits into a UK ambulance, in place of the standard stretcher trolley.

User facilities

Access: The whole front panel of the canopy is an access door which is hinged along its top edge and can be opened fully. There are two hand ports in the front access door with spring-loaded doors. The rear panel of the baby compartment (which is not transparent) has two hand ports. There is a tubing port at each end of the access door and ventilator tubing supports at the right hand side.

Baby tray: The mattress rests on a metal tray which can be partially withdrawn straight out of the opened front access door. A vacuum cushion is available which can be shaped to the patient’s body. The evacuation of air from the cushion requires the use of the (optional) aspirator.

Environmental control

Temperature control: All controls and indicators are located on the heater control panel. The desired nursing air temperature is set by a rotary control marked from 28°C to 37°C in 1°C control graduations and is continuously variable. In order to prewarm the incubator the air temperature may be set up to 39°C. Heater operation is indicated by an orange lamp. The air temperature is monitored and controlled by the primary sensor located in the top left front corner of the baby compartment. An indication of air temperature is given by a spirit-in-glass thermometer.
mounted horizontally in the top right hand front corner of the baby compartment.

**Humidity and oxygen control:** Supplementary oxygen can be administered directly via an inlet port into the baby compartment and a concentration of oxygen of 30 to 60% in 10% steps can be selected. Alternatively, oxygen can be administered for bag ventilation at a flow rate of 0 to 15 l/min. The oxygen supply is automatically available when either of these two functions is operated.

There is no humidifier.

**Air circulation:** The Draeger 5400 does not have a fan, but relies on natural convection currents to carry warm air around the baby compartment. The electrical heater is located behind the rear wall of the baby compartment.

**Alarms**

A visual alarm is given by a red lamp for an over temperature condition. This alarm is not self-resetting. There are no other visual, and no auditory alarms, and specifically there are no power failure alarms.

**Ventilation**

Ventilation facilities are provided by an optional Babylog 2 time-cycled ventilator which is pneumatically operated. The ventilator has IPPV, PEEP and CPAP capabilities. The required oxygen concentration (21 to 100%) is set by a rotary control on the Babymix gas mixer. The delivered oxygen concentration can be monitored by the (optional) Oxydig oxygen monitor whose sensor can be fitted in the inspiratory line. The Babylog 2 and the Babymix have been fully evaluated in HEI 160, November 1986.

Gas supplies are provided by an F-size oxygen cylinder and an F-size medical air cylinder. These are strapped on to the stretcher trolley below the baby compartment. Space is provided below the baby compartment for "D" size oxygen cylinders, but this cylinder size is non-standard in the UK. Oxygen and air supplies are automatically available for the ventilator when this is operated.

**Power supplies**

The Draeger 5400 can be operated from one of three sources: the 240 V ac mains supply; the ambulance 12 V dc supply using a low voltage power cable; or the optional 12 V dc battery using the same cable. It is not possible to connect both dc power supplies simultaneously. The low voltage cable is fitted with a DIN car connector which will fit the supply of most UK ambulances but an adaptor is also available to enable it to be connected to the ambulance by spade terminals. Both power cables are mounted on spring loaded built-in cable drums which enable them to be retracted when not in use.

A switch on the heater control panel enables the correct power source to be selected and this is indicated by a white lamp. The incubator does not automatically switch between available power supplies as necessary. There is no auditory or visual alarm of a power failure.

The battery supplied is a 12 V dc sealed, maintenance-free lead acid type. This is mounted in a plastic casing which houses a battery charger. The battery charger must be plugged independently into the ac mains supply for the battery to be charged. The state of the battery charge is indicated by a bar display when the charging current is disconnected. Draeger state that the incubator will operate for at least 3.5 hours on a fully charged battery and the battery will be charged to 80% of its full capacity in 12 hours.

**Incubator trolley**

The incubator trolley is of tubular construction and is designed to fit into a UK ambulance in place of a standard stretcher trolley. The trolley has a single shelf. The incubator is located on the trolley by four pins. Disengaging these pins allows the incubator and the ventilator (but not the F-size gas cylinders or the battery supply) to be removed from the trolley. The trolley has four castors and foot actuated brakes on two of the wheels.

**USER EVALUATION**

The Draeger 5400 was used for a period of approximately nine months in each of three special care baby units (SCBUs), now known as Neonatal Units. Both internal and external transfers were undertaken. All our users received the standard Draeger training and demonstration (rated by our evaluators as very good). Following this, all said that the incubator was easy to use and that the controls were well laid out and easily visible in the ambulance.

Internal transfers were between Labour ward and neonatal unit or theatre and each transfer took generally less than 10 minutes. Both ventilation and increased baby compartment oxygen were administered on occasion without problem. In most cases the baby was in good condition and was maintained so during transfer.

On two occasions babies were delivered in theatre by Caesarian section and were immediately placed in the incubator and ventilated. They were then transferred to the neonatal unit. For the next 90-120 minutes while the baby was stabilized the incubator was operated on the internal 12 V dc battery and the gas supply. The babies were catheterized in-situ and there was excellent access and visibility for these
Draeger 5400

procedures. In each case the baby was then immediately transferred in the incubator to another hospital.

External transfers were made to and from outlying hospitals at distances of up to 40 miles within the immediate area, also to London and Southampton. The journey times were up to four hours and the incubator was powered by either the internal 12 V dc battery or that of the ambulance. In each case the temperature and condition of the baby were maintained.

The general mobility and ease of loading and unloading from the ambulance were good, after the crews had been trained to side lift the incubator into and out of the ambulance.

Securing the trolley in the ambulance was easy and effective (it fitted in place of the standard stretcher trolley) and in this position the incubator was normally located on the offside of the ambulance. To give a smoother ride and more comfortable journey, the incubator was normally located on the nearside. This did sometimes worsen the ride. In addition, the lack of any adequate suspension on the trolley meant that the baby was often subjected to a bumpy journey even on a good road surface. There were no straps to restrain the baby (such straps would need to be prohibitively tight to be effective). A vacuum cushion is available which may be evacuated to mould it to the baby's shape, but this requires an aspirator to evacuate it and we did not have this. A temporary solution was to pad the baby with blankets.

It was very easy to connect the incubator to the ambulance power supply. It was an advantage to have the power cables on self-reeling drums as this stored them neatly and prevented them becoming caught up.

Our users felt that the lack of an auditory alarm, if the power supply failed, was a shortcoming, especially since the incubator did not switch automatically to an alternative power supply (see Manufacturer's Comments).

The incubator controls were well laid out, easy to use and were clearly visible in the ambulance. The canopy thermometer was well positioned. It was very easy to place the baby in the incubator and remove him without disturbing tubing or monitor leads and there was adequate space within the canopy for tubing and leads. There was excellent access at all times and observation was simple, aided especially by the bright observation lamp. The canopy doors were secure in transit and the tubing ports held tubes and leads securely. However, care had to be exercised when closing the doors because the tubes sometimes prevented the front access door from closing properly (a red flash on the door catch is visible when the door is insecurely closed).

The Draeger Babylog 2 ventilator (not specifically evaluated here, but familiar to the users), was easy to use and gave a good performance. The F-size air and oxygen cylinders were adequate for most transfers, but their use added greatly to the weight of the incubator. They did, however, have the advantage of having the same bull-nose connectors as the ambulance oxygen supply and therefore a back-up cylinder was always available. We bought and tried a light weight oxygen cylinder sold by Draeger, but we used this only once since it was only fractionally lighter than the F-cylinder and held less gas. Because it was non-standard it would have been necessary to purchase four cylinders and a filling kit to operate the system efficiently.

The controls for supplementing the oxygen concentrations within the baby compartment were satisfactory but the system could be extravagant in its consumption of oxygen. In addition, the incubator suffered greatly from the effects of draughts in the ambulance: in a large draught the maximum baby compartment oxygen concentration achievable dropped from 60% to 30%.

The incubator was very easy for nursing staff to dismantle and clean.

---

**PRODUCT SUPPORT**

| supplier     | Draeger Ltd  
The Willows  
Mark Road  
Hemel Hempstead  
Hertfordshire  
HP2 7BW  
Tel: 0442 3542 |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>guarantee</td>
<td>1 year</td>
</tr>
<tr>
<td>maintenance provisions</td>
<td>Yes &amp; co-operation with hospitals' own maintenance schemes</td>
</tr>
<tr>
<td>service contract</td>
<td>Yes</td>
</tr>
<tr>
<td>will service engineer call?</td>
<td>No, but normally next day</td>
</tr>
<tr>
<td>maximum response time quoted</td>
<td>Yes</td>
</tr>
<tr>
<td>temporary equipment replacement?</td>
<td>Yes</td>
</tr>
<tr>
<td>spare parts</td>
<td>8 years</td>
</tr>
<tr>
<td>spares availability</td>
<td></td>
</tr>
</tbody>
</table>

---

evaluation no 9 April 1990
### RESULTS TABLE

<table>
<thead>
<tr>
<th>Feature</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>electrical safety</td>
<td>PASS</td>
</tr>
<tr>
<td>earth leakage current (PAS ≤1000 µA)</td>
<td>PASS</td>
</tr>
<tr>
<td>patient leakage current (PAS ≤1000 µA)</td>
<td>PASS</td>
</tr>
<tr>
<td>air temperature control</td>
<td></td>
</tr>
<tr>
<td>ac operation</td>
<td></td>
</tr>
<tr>
<td>air temperature stability (PAS ≤0.5°C)</td>
<td>PASS</td>
</tr>
<tr>
<td>air temperature uniformity (PAS ≤1.0°C)</td>
<td>PASS</td>
</tr>
<tr>
<td>difference from set temperature (PAS ≤1.0°C)</td>
<td>FAIL</td>
</tr>
<tr>
<td>dc operation</td>
<td></td>
</tr>
<tr>
<td>air temperature stability (PAS ≤0.5°C)</td>
<td>PASS</td>
</tr>
<tr>
<td>air temperature uniformity (PAS ≤1.0°C)</td>
<td>PASS</td>
</tr>
<tr>
<td>difference from set temperature (PAS ≤1.0°C)</td>
<td>FAIL</td>
</tr>
<tr>
<td>accuracy of temperature displays</td>
<td></td>
</tr>
<tr>
<td>digital display</td>
<td>None</td>
</tr>
<tr>
<td>canopy thermometer</td>
<td>Within 1°C</td>
</tr>
<tr>
<td>safety systems</td>
<td></td>
</tr>
<tr>
<td>max. air temperatures (PAS ≤40.0°C)</td>
<td>PASS</td>
</tr>
<tr>
<td>normal operation</td>
<td>PASS</td>
</tr>
<tr>
<td>with primary sensor failure</td>
<td>FAIL⁴</td>
</tr>
<tr>
<td>fan failure³ (PAS ≤5 min)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>ac mains power failure</td>
<td>FAIL⁴</td>
</tr>
<tr>
<td>dc power failure</td>
<td>FAIL⁴</td>
</tr>
<tr>
<td>audible alarms (PAS &gt;65 dB(A))</td>
<td>FAIL</td>
</tr>
<tr>
<td>operational conditions</td>
<td></td>
</tr>
<tr>
<td>access to infant³</td>
<td>Excellent</td>
</tr>
<tr>
<td>ease of changing from ac to dc operation³</td>
<td>Excellent</td>
</tr>
<tr>
<td>ease of charging the battery³</td>
<td>Good</td>
</tr>
<tr>
<td>battery charge indicator³</td>
<td>Poor</td>
</tr>
<tr>
<td>warning of low battery voltage³</td>
<td>Unacceptable</td>
</tr>
<tr>
<td>ease of loading/unloading from ambulance³</td>
<td>Good</td>
</tr>
<tr>
<td>baby compartment environment</td>
<td></td>
</tr>
<tr>
<td>noise, normal operation (PAS 60 ≤dB(A))</td>
<td>PASS</td>
</tr>
<tr>
<td>noise, alarm conditions (PAS ≤90 dB(A))</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

### TECHNICAL EVALUATION

The results of the technical evaluation of the Draeger 5400 are given below and are summarized in the Results Table. A full list of deviations is given below under ‘Compliance with Standards’.

**Safety and performance:** The Draeger 5400 met most of the safety and performance requirements. There were no major safety shortcomings but the following 12 deviations from the standards deserve the manufacturer’s special attention:

(a) The wheel locks did not hold the incubator on a test slope.
(b) The incubator did not automatically switch to an alternative power supply if the operating supply failed.
(c) There were no auditory alarms.
(d) There were no power fail alarms (see Manufacturer's Comments).
(e) The dc indicator lamps were incorrectly rated: if these fail an erroneous assumption of power failure might be made.
(f) The cross-sectional area of the dc power cord was too small.
(g) The battery charger was not protected against the ingress of fluids (see Manufacturer’s Comments).
(h) The battery charger transformer was unable to meet single fault conditions (see Manufacturer’s Comments).
(i) The ac mains supply cord for the battery charger was too short (see Manufacturer’s Comments).
(j) Performance on internal 12 V dc battery or ac power at low ambient temperatures did not

---

Notes:
1. At maximum control temperature
2. PASS implies that the incubator also turns off the heater
3. Scale used: excellent/good/satisfactory/poor/unacceptable
4. See Manufacturer’s Comments
meet the requirements of the standard (see Manufacturer's Comments).

(k) The response to overheating was inadequate: an incubator air temperature ('incubator air temperature' has a very specific meaning in the standards) of 43°C was reached before the operation of the alarm under test conditions (see Manufacturer's Comments).

(l) The incubator was unable to maintain the incubator air temperature at an ambient temperature of -5°C (see Manufacturer's Comments).

Detailed test findings are as follows:

**Incubator stability and security:** The incubator trolley was stable in normal use. However, the wheel locks were not effective in holding the incubator stationary on the test slope. The catches on the canopy doors were good: there was no possibility that they could be insecurely closed or pushed open from within (however, see user comments). The mattress tray was well supported when withdrawn through the front access door.

**Air temperature indication:** The temperature indicated by the spirit-in-glass thermometer was higher than the incubator air temperature by between 0.5°C and 1°C. The greatest discrepancy occurred at the highest incubator air temperature.

**Air temperature control:** The air temperature control was assessed at different control temperatures under different ambient conditions using ac, external dc and the battery pack to simulate the use of the incubator within the hospital or during transit in an ambulance.

**Mains operation:** When operated on ac, the incubator air temperature was held stable over the whole temperature control range when tested in the ambient temperature range of 10°C to 30°C. The air temperature at points over the mattress differed by no more than 0.6°C from the incubator air temperature. At ambient temperatures above 15°C the incubator temperature was close to the control temperature. However, at ambient temperatures in the range 10°C to 15°C, the incubator air temperature was always below the control temperature, by approximately 2°C.

**Battery operation:** When operated on a fully charged battery (see below), the incubator air temperature was held stable and close to that set by the user over the whole temperature control range for periods of up to one hour when operated in the ambient temperature range of 20°C to 30°C. However, at ambient temperatures in the range 10°C to 20°C, the incubator air temperature was always below the control temperature by at least 2°C. In addition, the stability of the incubator air temperature

---

**MANUFACTURER'S INFORMATION**

<table>
<thead>
<tr>
<th>manufacturer</th>
<th>Draegerwerk</th>
</tr>
</thead>
<tbody>
<tr>
<td>DH manufacturer registration?</td>
<td>Yes, R0221/ME</td>
</tr>
<tr>
<td>Certificated product?</td>
<td>No</td>
</tr>
<tr>
<td>country of origin</td>
<td>West Germany</td>
</tr>
<tr>
<td>cost</td>
<td>£6350</td>
</tr>
<tr>
<td>dimensions</td>
<td>overall (HxWxD) mm: 1020 x 1630 x 630, baby tray (WxD) mm: 590 x 290, weight with trolley and cylinders: 124 kg</td>
</tr>
<tr>
<td>battery type</td>
<td>12 V dc lead acid, sealed</td>
</tr>
<tr>
<td>access and handling</td>
<td>hand ports: 4, access doors: 1 front, tubing ports: 6</td>
</tr>
<tr>
<td>tray withdrawal</td>
<td>Yes, front</td>
</tr>
<tr>
<td>means of securing infant</td>
<td>Optional vacuum mattress</td>
</tr>
<tr>
<td>air temperature</td>
<td>air temperature control: 28°C to 39°C (1°C)</td>
</tr>
<tr>
<td>temperature displays</td>
<td>air: None, canopy thermometer: Yes, 15°C to 40°C (1°C)</td>
</tr>
<tr>
<td>heater power indication</td>
<td>On/off lamp</td>
</tr>
<tr>
<td>alarms</td>
<td>ac mains power failure: No, dc mains power failure: No, low dc: No, fan failure: Not applicable, sensor failure: No, high air temperature electrical fault: Yes, 39°C ± 1°C</td>
</tr>
<tr>
<td>air</td>
<td>humidification: No, filter: Disposable, supply for ventilator: F size cylinder, 1360 litres</td>
</tr>
<tr>
<td>oxygen provision</td>
<td>inlet port: Yes, flow meter: Optional, ventilator: Yes, Bablog 2, oxygen cylinder size: F size, 1360 litres</td>
</tr>
</tbody>
</table>

**NOTES:**

1 - Manufacturers may be registered, de-registered or re-registered at any time. Consult the latest issue of the DH Register to check current status.

2 - Values in table are range and (resolution).
Draeger 5400

was degraded and steady temperature condition began at 2°C below the control temperature and fell by a further 1°C after a period of two hours operation. The standard requires that the incubator air temperature does not differ from the control temperature by more than 1°C during this test.

The poor performance of the Draeger 5400 at low ambient temperatures on ac and dc power, in the laboratory, was thought to result from there being no fan in the incubator and reliance placed on natural convection to give the required temperature distribution. The results of measurements in Cardiff indicated that in the absence of a patient in the baby compartment there was a large temperature gradient between the mattress and the top of the canopy. The primary air temperature sensor was located at the warmest point and therefore all other points within the baby compartment were maintained at a lower temperature. The temperature gradient suggested that there was little natural convection. This was probably not the case when the incubator was occupied because the baby, through breathing and heat losses, might be expected to set up convection currents. Indeed, clinical use indicated no problems in maintaining the temperature of patients.

Operation at an ambient temperature of -5°C at a control temperature of 36°C was unsatisfactory (see Manufacturer's Comments). After 15 minutes at minus 5°C, the incubator air temperature had fallen to 33.1°C and when the ambient temperature was increased to room temperature (20°C), the incubator air temperature overshot the control temperature by 0.8°C. The standard allows only a +2°C deviation about the control temperature during this test.

**External DC supply**: Operation on an external dc supply simulates the performance of the incubator when operated from the ambulance, dc supply. The performance on this supply was similar to that on battery operation.

**Battery Charging**: The battery was continuously charged when connected to the mains supply and it was not possible to overcharge it. The state of charge of the battery was indicated by a bar display. The meaning of the display was not satisfactorily explained in the operators' manual and the display itself was ambiguous. When the battery was fully charged (indicated by a bar display) there was sufficient capacity to operate the incubator for a period of two hours with only a 1°C fall in incubator air temperature (but see battery operation above).

The battery charger was not intended primarily for medical use. It was incorrectly rated for use at UK mains voltage and was not adequately protected against spillage. The charger transformer did not meet the requirements of the standard for operation under single fault conditions. A different battery and charger unit are now used - (see Manufacturer's Comments).

**Overheat Alarms**: The overheat alarm was unsatisfactory. When tested with a simulated fault of the primary air sensor, the secondary air sensor did not deactivate the heater until an incubator air temperature of 43.3°C had been reached within the baby compartment. The standard permits a maximum air temperature of 40.0°C. In addition, only a visual alarm was activated: there was no auditory alarm provided. This is a very poor response to overheating (see Manufacturer's Comments).

**Fan fail alarm**: This incubator did not have a fan.

**Sensor fail alarm**: There was no sensor fail alarm. Although this is not required by the standard, the poor response to overheating caused by sensor failure (see above) makes the provision of such a feature desirable.

**Power fail alarm**: There was no power fail alarm for the failure of any source, nor did the incubator switch automatically to an alternative power source if the operating source failed. Furthermore, the indication of state of charge of the battery was very poor and made any assessment of remaining operating time very difficult (see Manufacturer's Comments).

**Incubator noise and alarm sound level**: The air circulation in the Draeger 5400 was by natural convection and therefore the incubator did not have a fan. The absence of a fan and a fan motor meant that the Draeger 5400 was very quiet in use.

There was no auditory alarm for any alarm state. An auditory alarm is required by the standard.

**Reliability**: There were no equipment failures during hospital trials. The incubator and trolley were robust and well constructed and we found reliability to be good. However, the 12 V dc battery and charger first tested at BSI were faulty.

**Serviceability and manuals**: The user manual, overall, was good. It had many illustrative photographs and a description of accessories that were available. Good cleaning and fault-finding information was given. Unfortunately, the trolley described in the manual was not the one available in the UK. In addition, the description of the gas supply requirements related to German gas cylinders.

The servicing manual was not supplied routinely, was poorly photocopied and contained no circuit descriptions. There was no information on access for servicing. Because of Draeger's insistence that service technicians attend their training course, in-house servicing was not assessed. Draeger offer service contracts and will undertake to train hospital staff.

The documentation supplied with the battery and charger was very poor. Operating and technical in-
formation was brief, and there was no servicing information. The instructions for fitting the charger to the incubator were in German.

It was not easy to connect the gas supplies within the ventilator because of a lack of space.

**COMPLIANCE WITH STANDARDS**

BS 5724 is the current British Standard for the safety of medical electrical equipment. Part 1 applies to all types while Section 2.21 adapts it specifically for nursing incubators (see appendix 2). The UK Health Departments recommend that purchasers specify compliance with both Part 1 and Section 2.21.

The manufacturer claimed on the EMQ1 form submitted with this equipment that the Draeger 5400 complied with IEC 601-1. However, the sample tested at BSI was found to have the following points of non-compliance with BS 5724: Part 1:

1. External markings missing from battery charger
2. External markings missing from incubator body
3. Internal markings missing from incubator and battery charger
4. Indicators incorrectly marked red
5. Power consumption on battery exceeded rated value by more than 10%
6. Battery compartment inadequately protected against ingress of fluids
7. No documentary evidence of compliance of mains parts
8. Components wrongly rated
9. Resistors unsupported
10. Battery wiring not marked with polarity
11. Battery operation indicator lamps incorrectly rated
12. Mains and battery supplies not provided with isolating switch (in this instance DH do not require compliance with this clause)
13. Supply cables too short
14. Cross-sectional area of 12 V supply cable below maximum required
15. Special tool required to replace mains lead for battery charger
16. The 12 V dc supply cable terminals were not readily accessible
17. The mains supply cable was not wired to terminals
18. The charger transformer failed to meet the requirements of Appendix J under single fault conditions
19. Inadequate creepage and clearance distances on some printed circuit boards
20. Fuses in battery charger not protected against ingress of fluids

In addition, the following points of non-compliance with BS 5724 Section 2.21 were found:

1. Resolution of air temperature control inadequate
2. Statements missing from operator manual
3. Trolley wheel locks inadequate
4. Under single fault conditions, temperatures of the inner surfaces of the baby compartment considerably exceeded permissible values
5. Inadequate response to power failure
6. Inadequate performance at -5°C
7. Response to overheating inadequate. No auditory warning of overheating
8. Maximum set temperature too great
9. No warning of failure of power supplies
10. No operator test facility for overtemperature indicator

63.1 Incubator unable to maintain adequate temperature control when operated on 12 V dc battery and external 12 V dc power at low ambient temperatures

63.1 Capacity of battery inadequate to maintain temperature performance for at least two hours

We suggest that before possible purchase of this equipment, the claims of the supplier are checked against our findings above.

**MANUFACTURER’S COMMENTS**

The report was sent to the manufacturer Draegerwerk AG, who has responded as follows:

1. The auxiliary battery and charger unit has been replaced by a unit designed by Draegerwerk AG to fulfill the requirements of BS 5724. The battery is a Dryfit sealed lead acid type of 36 Ah capacity.
2. The incubator has been modified to reduce heat loss, and the requirements of low ambient temperatures (-5°C) are now met.
3. We do not have a power failure alarm to BS, only visually as required by DIN. With the transport incubator, it is assumed there will always be people in attendance. If the IEC makes this alarm into a requirement, we will provide it.
4. Overheat alarm. The same remarks as 3 above. The heater switches out at 40°C, and an optical alarm operates. Each unit is checked for this during the production process and again later during service. This fulfills the requirements of 56.6."
ACKNOWLEDGEMENTS

The DH thanks the following staff from the Bioengineering Unit at Cardiff Royal Infirmary, South Glamorgan and Ogwr Health Authority, who were responsible for the evaluation and preparation of the text:

Dr D Spendley; Mr Russell Vine, and Mr Justin McCarthy

We also thank the following consultants for their cooperation in the hospital trials:

Professor Peter Gray, Department of Child Health, University Hospital of Wales;
Dr Mark Drayton, Consultant Neonatologist, Special Care Baby Unit, University Hospital of Wales;
Dr John Morgan, Consultant Neonatologist, Special Care Baby Unit, East Glamorgan Hospital;
Dr R Verrier-Jones, Consultant Neonatologist, St David's Hospital, Cardiff
and all the nursing and medical staff of the special care baby and neonatal units who helped in the evaluation.

APPENDIX 1: HOW TO BUY WITH CONFIDENCE

Compliance with standards
BS 5724: Part 1 is officially recognised by the Department of Health\(^1\) (DH): when purchasing equipment preference should be given to products which comply with this standard. (For this product, see the Technical Evaluation and Manufacturer's Comments on pages 5 & 8.)

Manufacturer's Quality Control
The summary on page 1 shows whether the manufacturer has registered, or applied for registration, under the DH Registration Scheme for Manufacturers of this category of medical electrical equipment. The Scheme has been in operation since April 1985. A manufacturer seeking registration for a specific category of medical equipment is required to declare that the quality system used to control the manufacture of that category is in compliance with the requirements of the DH Guide to Good Manufacturing Practice for Medical Equipment (the "Green Guide").

The quality system subsequently becomes subject to inspection by the Supplies Technology Division of the Department's, NHS Procurement Directorate, in order to assess its compliance. (In general, Registration does not imply that all products offered by the manufacturer are from registered manufacturing sources: you should ask the supplier whether the particular product you want is manufactured under the DH Registration Scheme.)

NOTE
1. See HEI 145 Item 18/85.

APPENDIX 2: STANDARDS USED FOR TESTING

TECHNICAL STANDARDS
The technical performance and safety assessments in this issue were carried out by BSI Testing Services at Hemel Hempstead. Supplementary testing was done at the evaluation centre in Cardiff.

For this evaluation, two samples were assessed: one at BSI, the other at Cardiff. The conclusions are therefore based on the assumption that the samples tested were typical of normal production.

SAFETY
The Electromedical Laboratory of BSI Testing Services tested a unit for compliance with the following British Standards to assess the technical safety aspects of the equipment:

BS 5724: Part 1:1979 Medical electrical equipment: specification for general safety requirements.
BS 5724: Section 2.21:1983 Medical electrical equipment: specification for transport incubators.
BS 5724 Part 1 is the UK equivalent of the international standard IEC 601-1. Revised versions of both standards have been published.

USER EVALUATIONS
The protocol used for the user evaluations was devised in co-operation between DH, clinicians and nursing staff involved in the trials and the medical physicists of the evaluation centre.
3. Control over test voltages used
Testing to BS 5724 by BSI or under a Joint Agreement also ensures that the tests on the mains section are carried out at the UK's nominal mains supply voltage of 240 volts. Certificates of compliance obtained under other circumstances may 'conceal' the fact that tests were done at 220 or 115 volts: components suitable for these lower voltages may not be adequate for UK applications.

4. Control over content of testing
GS (Geprüfte Sicherheit) certificates issued by test houses in the Federal Republic of Germany may not cover all the requirements of IEC 601, but may include additional tests. This is because the German Ministry of Labour requires the country’s test houses to ensure the safety of medical electrical equipment, and leaves the test house to apply what tests it thinks necessary.

TUV (Bayern) = Technischer Überwachungsverein, Bayern e.V., Munich
IMQ = Istituto Italiano del Marchio di Qualità, Milan
SEMKO = Swedish national certification body

2. Control over interpretation of standards
Testing by BSI or under a Joint Agreement also means that agreed interpretations of certain clauses of BS 5724 are applied. These are established by the BSI Committee which represents all UK interests and which acts as the UK input to the ongoing process of revising the international standard IEC 601-1, and are published to UK manufacturers associations as BS 5724 Advisory Notices.
ABOUT 'EVALUATION'

'EVALUATION' REPORTS
Evolving from the evaluation issues of 'Health Equipment Information' (HEI), 'Evaluation' is a publication dedicated to evaluation reports on medical equipment available to the NHS. Each issue will normally report on a single product, so minimising publication delays. We shall maintain the same high standard of reporting that was established in HEI.

For most product categories, there will be a short changeover period, during which some evaluation reports now in the pipeline may appear in HEI. This will continue as a separate publication, carrying items of general interest to the NHS, and certain other evaluation reports.

REVIEW ISSUES
Each 'Evaluation' report will be published as soon as it is ready. We shall also publish periodic 'Review' issues on each product category - once a year for the main categories. These will carry evaluation summaries of all products evaluated that are still available, together with an Overall Comparison and general information.

DISTRIBUTION
We send 'Evaluation' to all health authorities, who are asked to arrange its local distribution and availability. We hope that all hospital and health authority libraries will hold at least one copy for reference. See back cover for more details.

WHAT DO YOU THINK?
We hope you like 'Evaluation' and will find it useful. If you do, please write and tell us. If you have any suggestions for improvement, we would also like to hear from you. The address is:

The Editor ('Evaluation')
Room 419
Department of Health
NHS Procurement Directorate
14 Russell Square
London WC1B 5EP

OTHER REPORTS ON TRANSPORT INCUBATORS
This is one of three issues of 'Evaluation' dealing with transport incubators. We have not reported on this category before, but may do so again in the future if more models come onto the UK market. Reports on nursing incubators will also appear in 'Evaluation': we last reported on these in HEI 168 (May 1987).

ENQUIRIES
For information on the evaluation of transport incubators, please contact Peter Oddy, Department of Health, NHS Procurement Directorate, 14 Russell Square, London WC1B 5EP (Tel: 01 636 6811 ext 3023).

'Evaluation' series editor is Charles Herrington, Department of Health, NHS Procurement Directorate, 14 Russell Square, London WC1B 5EP (Tel: 01 636 6811 ext 3053).
**Draeger 5400**

### DISTRIBUTION

This report could improve safety and reduce costs

A copy should be placed in all hospital and health authority libraries. In addition, all staff involved in the use, maintenance and purchase of this type of equipment, including the departments and professions marked below, should be made aware of this issue.

<table>
<thead>
<tr>
<th>Accident &amp; Emergency</th>
<th>Medical Physics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ambulance Officers</td>
<td>Neonatal Units</td>
</tr>
<tr>
<td>Anaesthetics</td>
<td>Nursing</td>
</tr>
<tr>
<td>Cardiac and Coronary Care</td>
<td>Obstetrics &amp; Gynaecology</td>
</tr>
<tr>
<td>Cardiology</td>
<td>Paediatrics</td>
</tr>
<tr>
<td>Dental</td>
<td>Pharmacy</td>
</tr>
<tr>
<td>Dialysis Units</td>
<td>Physiotherapy</td>
</tr>
<tr>
<td>ECG Departments</td>
<td>Radiology</td>
</tr>
<tr>
<td>Electronic Engineering</td>
<td>Renal Services Managers</td>
</tr>
<tr>
<td>Engineering</td>
<td>Renal Units</td>
</tr>
<tr>
<td>Family Practitioner Committees</td>
<td>Rheumatology</td>
</tr>
<tr>
<td>Home Dialysis Adminstrators</td>
<td>Scientific Officers</td>
</tr>
<tr>
<td>HOSPITAL LIBRARIES</td>
<td>Supplies Officers</td>
</tr>
<tr>
<td>HEALTH AUTHORITY LIBRARIES</td>
<td>Surgical</td>
</tr>
<tr>
<td>Intensive Care/Therapy</td>
<td>Theatre Staff</td>
</tr>
<tr>
<td>Maternity/Midwifery</td>
<td>Transplant Units</td>
</tr>
<tr>
<td>Medical</td>
<td>Works officers</td>
</tr>
</tbody>
</table>

### HOW TO OBTAIN COPIES

*Evaluation* is issued by the Department of Health, Scottish Home and Health Department, Welsh Office and Department of Health and Social Services (Northern Ireland).

If you wish to see *Evaluation* regularly, you should talk to your General Manager's office about the possibility of being included on their local distribution list. Copies should be available in your hospital or health authority library. If your library does not receive copies, please first check that it is on the local distribution list. If there is still a problem, please ask your library to contact the Procurement Directorate (Tel: 071 636 6811 ext 3141).

**England:**
- NHS Procurement Directorate
- Room 423
- 14 Russell Square
- London WC1B 5EP
- Tel: 01 636 6811 ext 3179

**Northern Ireland:**
- Department of Health and Social Services
- Estate Services Directorate
- Dfocct Centre
- Stoney Road
- Dundonald
- Belfast BT16 0US
- Tel: 0223 4535 ext 2041

**Scotland:**
- Miss K Glancy
- SHHD
- Room 54H
- St Andrews House
- Edinburgh EH1 3DE
- Tel: 031 556 8400

**Wales:**
- Welsh Office
- Health Management Systems
- Personnel Division
- Cathays Park
- Cardiff CF1 3NO
- Tel: 0222 823641

If you are not an NHS employee, you can subscribe to *Evaluation* details are available from:

- DH (Leaflets)
- PO Box 21
- Stanmore
- Middlesex HA7 1AY
- United Kingdom

evaluation no 9 April 1990

---

Printed in the United Kingdom for HMSO

D/92/64035 5/90 C63 G3390 10170