



Customer Complaint Report		CCR	98
		Date	17/12/01
Customer	WARWICK HOSPITAL	P.O	
File Number		Invoice	
Address			
Product	COT LIDS		
Serial Number/s	N/A	Dispatched	
Manufacturer/Supplier	VIA MARI		
Nature of Complaint	Not an official complaint more "query" Baby kicked cot lid off and it fell into cot.		
Result of Investigation	Cot lid modified		
Signed		Date	
Corrective Action	Will ensure to be asked if they want approval		
External	Approved (T.M.W.) informed of modification. Will note back to be of standard new design		
Internal			
Signed		Date	
MDA Informed	NO YES		QC12

Cot Lids Some Basic Information

Cot Lids have been in use in neonatal units for over 30 years in one form or another. Usually they were home-made devices consisting of a flat hinged transparent plastic. Viamed has taken the basic original ideas and translated them into a product which can be manufactured to current standards.

A normal Full term baby loses approximately 40 ml/Kg/day through the skin from insensible water loss. The more premature the baby the higher the skin loss, as the skin becomes thinner and the relative surface area to body volume becomes greater.

In addition the evaporation of the fluid from the skin removes energy as heat and some babies, when nursed in open cots, often cannot maintain a normal body temperature.

Compensating for this massive fluid loss, by replacing it intravenously, brings with it considerable difficulties. Intravenous fluids have to be isotonic, that is, at the same dilution as blood, otherwise it will cause disruption and breakage of blood cells as it enters the body. Consequently the fluid has to be administered either as saline or dextrose solution. At volumes adequate to replace these torrential fluid losses the baby may get too much salt (hypernatraemia) or sugar (hyperglycaemia)

A alternative and better way would be to control the losses from the skin. This has been described in the United States as “swamping” that is putting the baby into a near 100% humidified micro-environment (like in a swamp). When enclosed in this atmosphere fluid loss from the skin can drop to close to zero and daily fluid replacement can be at a much more reasonable levels of 60-80 ml/Kg/day, mostly to replace urinary, stool and respiratory losses.

For borderline babies requiring some assistance to achieve this environment the baby can be placed in a normal bassinet with a cot lid into which 100% warmed and humidified air is introduced from a humidifier. Cot lids can be supplied with louvres to assist in the flow through of humidified gases.

More common is to use the cot lid without humidity and using the babies own warmth in a closed environment.

Babies have been nursed under cot lids for many years with complete safety and success at controlling not only fluid loss but convective heat loss as well.

The cot lid is not a substitute for treating babies but method of helping borderline babies without using Hi-tech equipment.

It can be used safely even in cases where it is not totally justified . e.g. It makes the nursing environment easier.

Cot Lids

Background

The cot lid is used in conjunction with a basinet to reduce heat loss in an infant.

It is used in non-critical situations when an incubator would be inappropriate

They have been in use many years and classed as Class I have not required a user /instruction sheet.

Classification is being examined but as the device is only a sheet of Perspex and is used only to prevent heat loss and possibly insensible water loss from the infant in the basinet it is believed that it will remain Class I.

It is not used to deliver energy, gases, or drugs and is used in conjunction with a Class I device (the basinet)

In July 1995 an incident was reported that infants were kicking the cot lids off the basinet and they were falling into the basinet.

This incident was investigated and first thoughts were.

The cot lid is too heavy to be kicked off by neonates and must have been applied incorrectly or have been moved by the mothers.

In conjunction with the MDA at that time the cot lid design was modified so that it had to be raised higher for the lid to be lifted over the edges of the basinet. This was achieved by:

1. Extending the lid and bending the last inch on both sides so that it overlapped the basinet
2. As a new basinet appeared two versions were made available.
3. All existing cot lid users were contacted and the cot lids exchanged.

For 17 years there have been no reported cases of the cot lid being kicked off and no reported cases of any incident involving patient harm.

In December 2001 a complaint was received that babies were kicking off the cot lids.

Investigation revealed:

1. This has been a regular occurrence, perhaps twice per year;
 - a. Babies are getting bigger
 - b. Some are very robust and active
 - c. No reports of injuries
 - d. The lids are kicked clear and land on the floor breaking
 - e. It was suggested that this might mean there could be a limit on the size of infant that can be treated with cot lids.
2. Solutions are available:
 - a. The flap extending over the cot lid can further extended and bent back under the cot lid edge
 - b. Existing cot lids can have an extra piece added to form a fold over
 - c. A prototype has been manufactured and is acceptable to the Hospital.
 - d. It works.
3. Next Steps
 - a. Need to enquire whether or not any infant's feet (toes) have been or can be damaged if they kick too hard against the fixed cot lid. Enquiry in progress.
 - b. Our current belief: based on informal discussions with hospital staff is:
 - i. The infant will not self inflict damage
 - ii. They do not actually kick the lid off but use the soles of their feet to push it off
 - iii. The cot lids are not falling into the cot

South Warwickshire Hospital Visit (19.12.01)

Those present at meeting.

Mr D Jones-Chief Technician-Medical Electronics
Mr Abdul-Senior Technician-Medical Electronics
Mrs J Merriman-Staff Nurse-SCBU
Mr S Hudson-Area Manager-Viamed

- *Pine Haydock*

The purpose of the visit was to find out first hand, details of an incident that was reported to Viamed on the 18.12.01. by Mr Jones the Chief Technician in Medical Electronics. A cot lid (Supplied by Viamed) was reported to have been knocked into a crib containing a small baby on the SCBU.

On arrival onto the SCBU, I was shown into a storage room where equipment that was not being used was kept, several cribs were in the room with the cot lid put to one side. We were unable to attain which crib was being used at the time of the incident but all of the cribs were of the same type (Hoskins), with Karomed, 2 inch blue mattresses fitted.

Mrs J Merriman (Staff Nurse) gave me a run down of the reported incident, as the incident report generated by the department could not be found.

The Cot lid was being used on a standard crib for a baby weighing 2.8Kgs who was receiving Photo Therapy. The babies mother noticed that the cot lid had fallen into the crib and was resting against her sons head, she reported this to the senior member of staff on duty at the time, Sister B Twyman, who raised an incident report and forwarded it to the Ward Manager Sister Boyle who in turn notified both Mr K Reynolds (Risk Manager) and Mr D Jones, it was then reported to the Company.

There was no injury to the baby and the mother gave the impression to the staff that so long as they stopped it happening again she would be happy, the baby has now been moved to another ward as treatment had been completed.

The cot lid in question was inspected by both Mr D Jones and myself, no visible signs of either wear or damage could be found, the cribs were also inspected with no edges showing signs of damage or wear.

One point did come out of our discussions and that was the cot lids are often knocked into the cribs, when I asked how often? The answer was just 'often, it happens'? Mr D Jones was unaware of this and suggested that maybe this could be a problem in other units and that a clip of some sort was required to stop this happening again. He suggested spring loaded pins mounted on both vertical sides of the cot lid so that it locked into place under the rim of the crib, this was rejected by Mrs J Merriman as being too difficult and easily broken, second suggestion was a clip similar to a dog clip that could be clipped across the sides of one end, just to one side of the hinge holding one half firm to the crib and allowing access via the other.

I have agreed to verbally ask other users of cot lids if they have experienced similar problems to the one reported and to keep the Hospital informed as to any further recommendations or changes we introduce.

S.Hudson

*In the past made by AB&B, common for babies to
kick them off:
Babies cannot break ties?*

Pharmacy.
Estates Dept

Jennifer Reed mit wife

FBAR.

2.0 p.m.

Ester Ward Morgan

Othmanpachin →

Mr CLEG Coventry. Walsingham

PHIL HAYCOCK ~~16/05~~ Techn

South Warwickshire General Hospitals **NHS**
NHS Trust

18th October 2002
Our Ref: 520808

FAO Mr. John Lamb
Viamed Ltd
15 Station Road
Cross Hills
Keighley
YORKSHIRE
BD20 7DT

Electro Medical Department
Warwick Hospital
Lakin Road
Warwick
CV34 5BW

Tel: 01926 495321 Ext 4186
Fax: 01926 482011

Dear Mr. Lamb

Some time ago we reported to you that a cot lid supplied by your company had been kicked off by a baby and smashed on the floor. Viamed then produced a prototype modified version and sent it to us for a trial. This has been a great success and we feel should be the design of all lids in the future.

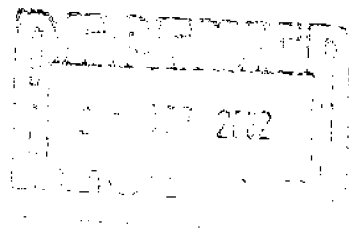
We are currently faced with yet another lid of the conventional design that has been kicked off and smashed and will need to be replaced. We see little point in ordering the old design as it will only be kicked off again so can you supply another modified version to us or does the new design need the CE process?

I shall look forward to your reply

Many sincerely



D.A. Jones
Department Manager



John Lamb

From: "John Lamb" <john@viamed.co.uk>
To: <SHudson553@aol.com>
Sent: Wednesday, February 20, 2002 2:08 PM
Subject: Re: South Warwickshire Headbox Incident
 Steve,

I have not had anymore feedback on the Cot Lids.

Is it a real problem.

I thought we had sorted this out 15 years ago when Stepping Hill had the original problem.

Can you let me know what the current position is before we start to modify the Cot lid.

We have several ideas and will be making a prototype soon but I would like confirmation that it is nesecary.

John

-----Original Message -----

From: <SHudson553@aol.com>

To: <john@viamed.co.uk>

Cc: <Steve@viamed.co.uk>; <SHard@viamed.co.uk>

Sent: Monday, December 24, 2001 9:49 AM

Subject: South Warwickshire Headbox Incident

> John,
 > The attachment is a report on my visit to the South Warwickshire
 > Hospital.
 >
 > Steve H
 >

John Lamb

From: <SHudson553@aol.com>
To: <john@viamed.co.uk>
Sent: Saturday, February 23, 2002 11:49 AM
Subject: Re: South Warwickshire Headbox
 John,

Called into Warwick last week, the same thing that was reported before happened again, this time the baby was a very active 6lb. The Cotlid was kicked onto the floor breaking one half nearly in two, no form of retaining clip was being used by the staff.

The medical and nursing staff seem all right, Medical Electronics are causing any problems as the believe we are in the process of modifying or finding a clip that will stop this happening again.

I have been talking to both Steve's about new designs and received an E-Mail from Steve Nixon saying the drawings for a new design are now complete and did I want to see them before Mick Appleyard makes one. I have asked if I can have a copy of the new design to show the Technicians in Warwick as this will confirm that we are taking problem seriously and will have a solution shortly. Nothing has been said about taking the problem any further than it has gone, which at the moment is just internal, I Believe this is because we have taken it as a problem and have already told them we will look into a way of solving it.

Regards
 Steve H

John Lamb

From: <SHudson553@aol.com>
To: <Steve@viamed.co.uk>
Cc: <SHard@viamed.co.uk>;
Sent: Monday, March 04, 2002 9:58 PM
Subject: Warwick Cotlids

Steve,
 Have sent you a fax with Teech's idea from Warwick on how to secure cotlid.

Hospitals suggestion is to use the new design of our cotlid and to add another 'U' at the feet end of the lid and place a small ledge on it so as it clips under the side of the crib. The lid will slide so as the ledge goes under the side of the crib, but still allows easy removal if needed, they pointed out that its the child's legs that kick the cotlid off, so if you clip that end down the cotlid can't be knocked off.

Incident is still in house and staff are very pleased that we are looking into the problem and involving them in sorting it out.

Hope this of help and interest
 Steve H

John Lamb

From: <SHudson553@aol.com>
To: <steve@viamed.co.uk>
Sent: Saturday, February 23, 2002 11:35
Subject: Re: Cot lids

Steve,
 Are we going along the same lines as the cotlid we had made by Rosendale Plastics, if so yes it would be nice to see the drawings so as I can show them to Warwick, which will show that we are very serious regarding the problem they have had.

Thanks
 Steve H

John Lamb

From: <SHudson553@aol.com>
To: <sl@viamed.co.uk>
Sent: Monday, February 25, 2002 10:22
Subject: Re: Cotlids

John,

I'm in Stepping Hill tomorrow afternoon chasing up some disposable orders will call in on post natal while on site to push cabinets.

Steve H

Dear Mr Lamb

Thank you for your letter of 18 July 2002 to Geoff Ali. Geoff has asked me to reply on his behalf.

We have checked our Adverse Incident database and have found no reported incidents of the type you describe, leading us to agree with you that this is not a commonplace scenario.

I have noted the information regarding modifying the cot lid but our remit precludes us from offering any design advice to manufacturers. I would, however, advise that a Risk Assessment covering these aspects would be well worth documenting.

Regarding your device's classification and the requirement for user instructions, I have copied your letter to Mr Tore Johansen of our European Regulatory Affairs section and have asked him to advise you by email. I hope this is useful. Please contact me again if you have any further queries.

Regards,
 Andy Marsden
 Senior Medical Device Specialist

Notes made in warwick by JSL

Babies are getting bigger particularly full term and can occasionally kick off the cot lid particularly if they are very active. We believe the cot beds are pushed off rather than kicked by the babies. There have been no reported cases of the lid falling into the cot.

The proposal to return the lid with a fold over will prevent the lid being kicked off. There is however a real possible risk to the infant feet if large babies using excessive force meet a fixed plastic sheet.

Not a complaint but a question.

Baby kicked into cot lid off? it fell into the basket

Telephoned Dave Jones

Is the correct cot lid being used. (two types)

Is it a good fit.

How big is the baby

Department are using stretch tape

Went to check on sleeping Matt

Dave Jones

Warwick Hosp

Tel. 01926 495321

Ext 4480.

16/12/01

Feb.

length & width
360 mm let hole

4 long steps
20mm deep

180 mm

Bonded with cement & if room drilled
H

End in

90 mm long

20mm deep

Bonded in by handles

28 paces
↓

center