EAC Assessment
Technical report submission
Inditherm Patient Warming Mattress

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1. Summary

Additional technical information was requested by NICE from Inditherm. Cedar have been asked to comment on the additional submission. The purpose of the request was stated as:

“…to assess if the Inditherm mattress is suitable for use during x-rays and endovascular aortic aneurysm repair (EVAR) surgery. It is also to determine if there is a risk of fluid ingress and if it could affect the performance of the mattress.”

There was some lack of clarity as to why EVAR was of particular interest, and in order to answer the request both the manufacturer and External Assessment Centre (EAC) have made some assumptions. The EAC found that:

- Evidence to show X-ray translucency was inconclusive and results from further testing will be provided in a separate report.
- Specific issues were not identified for EVAR in sufficient detail and therefore could not be addressed.
- Thermal injury from warming poorly perfused areas can be avoided by using appropriately sized mattresses. The manufacturer is in compliance with the relevant standard.
- There is strong evidence that the mattress has adequate protection against fluid ingress.
2. Technical Considerations

The most relevant standard for this product is the international standard *IEC 80601-2-35:2009 Particular requirements for the basic safety and essential performance of heating devices using blankets, pads and mattresses and intended for heating in medical use*. The previous version of the standard, IEC 60601-2-35:1996, which will remains current until the 1st of November 2012 when it will be withdrawn, is also a suitable standard for consideration. Inditherm controllers and mattresses are tested and certified to IEC 60601-2-35:1996.

**2.1 X-ray**

The mattress may be used to warm patients during standard X-ray procedures, or it may be used for patient warming during surgery that requires imaging techniques such as fluoroscopy, a form of X-ray imaging that gives a constantly updated image to the surgical team during the procedure. Any device that is between the patient and the X-ray detector should not cause a deterioration in the image quality, or require the radiation dose to be increased to provide sufficient image quality. There is no standard that prescribes a test for X-ray translucency for similar devices.

**2.2 EVAR**

During endovascular aneurysm repair (EVAR) the aorta is repaired by introducing a stent through the femoral artery, as an alternative to the conventional method of open surgery. It requires a small incision in the groin, and can be performed using general or local anaesthesia. Fluoroscopy is used during the guiding and placement of the stent to provide images of the aorta and instruments. Fluoroscopy uses X-ray technology to provide a constantly updated image to the surgical team.

During open surgery an incision is made in the abdomen and the artery is clamped, interrupting the flow of blood to the lower limbs, before a stent is placed in position. A general anaesthetic is normally required.
EAC Assessment, Technical report, Inditherm mattress

The request was unclear as to what issue was of concern to the MTAC committee, however the manufacturer addressed the issue of thermal injury to areas of poor perfusion, and there is also an issue of image quality during fluoroscopy.

2.2.1 Imaging

EVAR uses fluoroscopy to provide imaging information and this requires that the mattress is X-ray translucent. This is addressed in section 2.1.

2.2.2 Warming of poorly perfused areas

Warming areas of poor perfusion can lead to thermal injury, since the circulatory system is not distributing the heat throughout the body. This is normally addressed by using smaller mattresses to avoid heating the poorly perfused area of the body.

2.3 Fluid Ingress

During the course of a theatre procedure it is possible that fluid may be spilt onto the Inditherm mattress. Post-operatively the Inditherm mattress will be cleaned using a cleaning fluid. If fluid were to leak into the mattress, there are two considerations:

- There is a risk of electrical harm to the patient and to theatre staff.
- There is a risk of damage to the device.

Both IEC 80601-2-35:2009 and 1996 have a requirement that electrically heated applied parts of devices operating at low voltages are tested to IP X2 which is an international standard for protection against fluid ingress.
3. Overview of Safety

The manufacturer stated that there were no safety risks other than those identified in section 2. The EAC searched MHRA and MAUDE (FDA) databases, but did not identify any additional information concerning these issues, or any incidents other than those already reported in the briefing note.

4. The Evidence

4.1 Search Methodology

The manufacturer did not complete any literature search. The EAC did a short literature search, limited by time constraints. The EAC ran the following search strategy in the Medline database (1996 – present) on 9th November 2010:

1. exp hypothermia/ (3207)
2. exp body temperature regulation/ (8850)
3. (hypo?therm$ or normo?therm$ or thermo?regulat$).tw. (17333)
4. exp heat/ (33228)
5. exp rewarming/ (737)
6. exp hypothermia, induced/ (5020)
7. 1 or 2 or 3 or 4 or 5 or 6 (57026)
8. exp "Equipment and Supplies"/ (470770)
9. (warm$ adj3 (device$ or system$)).tw. (336)
10. (mattress$ or pad$).tw. (17889)
11. 8 or 9 or 10 (485896)
12. exp perioperative care/ (29859)
13. exp intraoperative complications/ (19990)
14. ((intra$ or peri$) adj operative$).tw. (6781)
15. 12 or 13 or 14 (53770)
The literature search identified 180 papers. After searching titles and abstracts, 11 were selected and 10 read in full\(^{(3-12)}\). The EAC was unable to obtain one full paper\(^{(13)}\) in the time available, however it is described in the briefing note and no adverse events were mentioned.

The search was limited by time, and only one database (Medline) was searched, and with no grey literature searching. It was noted that the briefing note contained some abstracts and unpublished papers that were not identified by the search. Where the EAC was able to obtain these, they were also read for mention of adverse effects\(^{(14-16)}\).

Given the relatively small amount of literature identified, there was no systematic search specifically for adverse events or X-ray, EVAR or fluid ingress, since this would further narrow the papers available. A more thorough literature search was carried out as part of the original assessment report, which commented on adverse events.

### 4.2 Assessment of evidence

The papers identified were read by the EAC, but no adverse events concerning Inditherm were noted.

#### 4.2.1 X-ray

The manufacturer provided expert statements from two clinical users of Inditherm regarding X-ray translucency. The statements do not provide sufficient information to be sure that there is no change in image quality or patient radiation dose when using
Inditherm. They do however provide anecdotal evidence of the use of Inditherm during X-ray procedures.

The procedures and imaging equipment used by the experts are not specified. It is not clear if the imaging equipment used has a manual or automatic exposure control. Where exposure is adjusted automatically, the dose may be increased without operator intervention. If fixed exposure factors are used the radiation dose to the patient would not be affected by the attenuating effects of the mattress, but image quality could be degraded.

Attenuation of X-rays by the mattress could cause a change in image quality that was not grossly identifiable but could be significant in procedures requiring a high degree of anatomical detail.

Both of these issues can be addressed by testing the mattress. Testing has been commissioned by NICE and is discussed in an accompanying report.

4.2.2 EVAR

The manufacturer also provided a statement from a clinician who has used Inditherm during EVAR cases. Given that no specific concerns with EVAR were identified in the request, and no incidents have been identified by the EAC literature and database search, then there is no additional information that could be submitted.

4.2.3 Warming poorly perfused areas

Inditherm supply mattresses of different sizes that can be used to warm the patient whilst avoiding the area that is poorly perfused. The instructions for use state that:

“It is the responsibility of the user to determine whether warming is appropriate for each individual patient. The patient warming system should not be used on patients where clinical considerations indicate that warming of the patient is not advisable.”
There is no requirement for any further warning in IEC 60601-2-35:1997, however it may be worth noting that IEC 60601-2-35:2009 requires that controllers for forced air devices (alternative warming devices using a blanket and warm air) are marked with a warning against using the device distal to arterial cross clamping.

4.2.4 Fluid Ingress

The manufacturer has had no feedback or complaint of fluid ingress to the mattress, additionally none was identified from the adverse event databases and literature searched. The EAC established that the mattresses and controllers have been tested and certified as compliant with IEC 60601-2-35:1996. This requires that the mattress is tested to IPX2. The lack of adverse events and compliance with the relevant international standards is strong evidence that the mattress has adequate protection against fluid ingress.

4.3 Summary of evidence

- X-ray translucency evidence was inconclusive and results from further testing will be provided in a separate report.
- Specific issues were not identified for EVAR and therefore could not be addressed.
- Thermal injury from warming poorly perfused areas can be addressed by using appropriately sized mattresses. The manufacturer is in compliance with the recommendations of the relevant standard.
- There is strong evidence that the mattress has adequate protection against fluid ingress.
5. Equality Issues
No equality issues were identified.

6. References


(6) Wong PF, Kumar S et al. Randomized clinical trial of perioperative systemic warming in major elective abdominal surgery.


(13) Wong PF, Kumar S et al. Systemic warming as an adjunct to resuscitation in peritonitis: a pilot, randomized controlled trial.
