CEP buyers’ guides are intended to provide prospective purchasers of healthcare products on the UK market with general guidance on the technical, operational, and economic considerations to be taken into account in selecting the most appropriate product where a range of similar products exists. They do not include product-specific information, which is published separately via market reviews (which contain product specifications and expert commentary) or evaluation reports (which contain additional technical and / or user evaluation data). Readers are encouraged to check CEP’s web site for updates.

Forced air warming devices

A forced air warming device is a medical electrical device used to keep patients warm during anaesthesia and surgery. Forced air warming devices are used mostly in the operating theatre and the recovery room or critical care environment. They are also used in other clinical areas where patients are at risk of hypothermia. The clinical staff that use forced air warming devices are those who care for patients in these settings, including nurses, operating department practitioners, anaesthetic assistants and anaesthetists.

Inadvertent perioperative hypothermia

Inadvertent perioperative hypothermia is a common and preventable complication of surgery. Inadvertent perioperative hypothermia is defined as a drop in core body temperature below 36ºC and is associated with poor outcomes for patients [1].

Inadvertent perioperative hypothermia is distinguished from the deliberate induction of hypothermia for medical reasons eg during cardiac surgery [1]. In this document where the term ‘hypothermia’ is used it refers to inadvertent perioperative hypothermia as defined above.

Causes of inadvertent perioperative hypothermia

During the first 30 to 40 minutes of anaesthesia, a patient’s temperature can fall below 35ºC. The reasons for hypothermia include [1]:

- loss of the body’s normal response to cold due to anaesthetic drugs
- dilation of peripheral blood vessels (also due to anaesthetic drugs) causing heat loss
- patients getting cold while waiting for surgery
- exposure of the body during surgery
- fluid deprivation before anaesthesia
- the use of unwarmed intravenous (IV) or irrigation solutions.
The degree of heat loss is also influenced by operating theatre air temperature, airflow and skin preparation [1].

**Consequences of inadvertent perioperative hypothermia**
The possible consequences of hypothermia are [1]:

- increased blood loss during and after surgery
- longer recovery from anaesthesia
- shivering and feeling cold after surgery
- heart problems during and after surgery
- altered drug action
- increased risk of wound infection
- increased risk of pressure sores
- reduced patient satisfaction
- longer hospital stay.

**Prevention of inadvertent perioperative hypothermia**
Simple measures before and after surgery, such as wearing warm clothing and using a duvet or blankets on the hospital ward can help to prevent hypothermia [1].

There are also several types of active patient warming device that have been designed for use in the operating theatre and critical care environment [1]. These include:

- electric blankets and mattresses, including carbon polymer blankets and mattresses
- heated fluid filled mattresses and garments
- electric radiant heaters
- intravenous fluid warmers (used to warm IV fluids and irrigation fluids before use)
- forced air warming devices.

**How forced air warming devices work**
A forced air warming device comprises a controller plus a compatible disposable blanket. The controller contains the following components:

- electric motor and fan
- electric heating element
Introduction

- thermostat
- air filter
- hose.

To operate a forced air warming device the user connects the hose nozzle to the disposable blanket. In operation, the fan draws in air through the filter and the heating element heats it to a selected temperature, controlled by the thermostat. Heated air travels through the hose to the blanket, which inflates. The patient contact surface is permeable to air and the warm air exits the blanket and moves over the patient’s skin, transferring heat to the patient by convection.

Forced air warming devices may be used for warming adults and children, by simply selecting the appropriate blanket. Manufacturers provide a range of blanket shapes and sizes for different situations.

Scope

This buyers’ guide applies to forced air warming devices that:
- are designed to prevent and treat perioperative hypothermia
- transfer heat by convection as described above
- are suitable for use in the operating theatre.

This buyers’ guide does not cover devices restricted to comfort warming outside of the operating theatre (see Technical considerations). It does not cover other methods of active warming such as electric blankets or mattresses, heated fluid filled mattresses or garments, radiant warmers and IV fluid warmers.

National guidance

The National Institute for Health and Clinical Excellence (NICE) recommends forced air warming as the primary method of active perioperative warming [1]. NICE noted that there is emerging evidence that other active methods of warming (specifically electric heating mattresses, electric heating pads and heated water garments) may be as effective as forced air warming in preventing hypothermia but that this evidence is insufficient to support a NICE recommendation for their use [1].

The NICE recommendation for forced air warming applies to healthcare providers in England, Wales and Northern Ireland, and health professionals (and the organisations who employ them) are expected to take it fully into account when deciding what treatments to provide [2].
NICE recommends forced air warming for all patients undergoing anaesthesia for longer than 30 minutes. Forced air warming should also be used for patients at a higher risk of hypothermia even where they undergo anaesthesia for less than 30 minutes. NICE also recommends that forced air warming be used if the patient core temperature falls below 36°C at any stage during pre- and post-operative monitoring [1].

Maintaining normal body temperature is widely recognised as an important factor in reducing wound infections. Patient warming is included in the World Health Organisation (WHO) surgical safety checklist adapted for England and Wales by the National Patient Safety Agency (NPSA) [3]. The original WHO surgical safety checklist does not refer to patient warming [4]. The reduction of wound infections by maintenance of normal body temperature is promoted as a key factor in the Patient Safety First campaign in England [5] and the 1000 Lives Campaign in Wales [6].

The Association for Perioperative Practice (AfPP) also recommends that there be a system in place for managing the risk of perioperative hypothermia for patients undergoing a clinical intervention [7].

The Medicines and Healthcare products Regulatory Agency (MHRA) provides general guidance on the purchasing, deployment, maintenance, repair and disposal of medical devices [8]. MHRA report that forced air warming devices are safe when used correctly according to the manufacturers’ instructions [9].

The design safety of forced air warming devices is covered currently by the international standard IEC 60601-2-35 Ed 1 (1996) [10]. However, this will soon be replaced by a revised standard IEC 80601-2-35 Ed 2, which is at an advanced stage of development [11]. The revised standard provides more content than its predecessors on the design of forced air warming devices, including new safety tests and requirements for safety labelling and user safety instructions. Tests include hose disengagement and maximum permissible contact surface temperatures [11,12].

Scale of use

Forced air warming devices are widely used, with a good safety record. It is estimated that forced air warming devices are used at least seven million times a year in the USA [11]. In the UK, forced air warming devices are not a new technology and there are currently six suppliers to the UK market.

The clinical criteria specified in the NICE guideline for starting forced air warming capture the majority of patients who undergo surgery [1]. For this reason the NICE recommendation is likely to increase significantly the use of forced air warming in the UK. In 2008 NICE estimated the total number of forced air warming blankets
Introduction

purchased in England per year at 913,000 blankets and estimated this to rise to 2.3 million blankets per year, based on full implementation of the guideline [13]. NICE also estimated the total expenditure on blankets in England to be £14.3 million in 2008 rising by £21.6 million to £35.9 million after full implementation of the guideline [13].

Published evidence

The recent NICE guideline *Management of perioperative hypothermia in adults* included a comprehensive, systematic literature review of perioperative warming, to inform its recommendations [1]. NICE made the following conclusions based on the clinical and economic evidence:

- active patient warming results in better outcomes for surgical patients than no active warming
- there is stronger evidence to support forced air warming than the other types of active warming device, so NICE recommends forced air warming as the principal method of preventing and treating hypothermia
- forced air warming is a cost effective method of preventing the adverse effects of hypothermia, ie using forced air warming devices results in an economic saving to healthcare providers by avoiding the cost of treating preventable complications of hypothermia
- there are documented cases of harm arising from forced air warming eg burns, but if users follow the manufacturers’ instructions for use and maintenance, then the risk to patients is small and is outweighed by the benefits.

Efficacy of different forced air warming devices

Production of this buyers’ guide included a review of published studies that compare two or more forced air warming devices. The methods are described in *Appendix 2: Literature review methods*. There is an inadequate volume of high quality evidence comparing the efficacy of two or more forced air warming devices [14-20]. No study compares all devices that are currently marketed in the UK.

Three randomised trials [16,19,20] found no difference in the efficacy of different forced air warming devices. One non-randomised volunteer study [18] suggests that there are differences in efficacy between devices. Randomised studies provide more reliable evidence than non-randomised studies.

The findings of three simulation studies using mannequins [14,15,17] cannot be applied directly to the clinical situation [21] but the studies suggest that there is variation in the performance of different forced air warming devices.
Technical considerations

Design and intended use

There are two types of forced air warming device. This buyers’ guide applies only to forced air warming devices that are designed to both prevent and treat hypothermia and that are designed for use in the operating theatre. This arises from two design elements:

- capability to deliver warm air at a temperature and rate sufficient to rapidly warm a cold patient
- presence of an air filter capable of removing very small (0.2-0.3 µm) airborne particles from the air drawn into the device, as an infection control measure.

A second type of forced air warming device is a smaller, patient controlled device, designed for keeping patients comfortably warm in the hospital ward. This type of device typically does not have the same thermal output and level of air filtration as the larger devices and is not designed for use in the operating theatre.

Compatibility

The operator manual for each controller states which blankets are compatible. In general, manufacturers instruct the operator to use only the manufacturer’s controller with the manufacturer’s blankets, as a matter of patient safety. However, some manufacturers may specify that their blankets are compatible with the controllers of some other manufacturers.

Reusable and disposable parts

The controller unit of a forced air warming device, including the hose, is reusable with a life expectancy of typically at least seven years. Some parts, eg hose, may be periodically replaced by qualified staff as wear and tear occurs.

All blankets are intended for single patient use and are disposable.

Controller technical features

Controller units do not vary significantly in size or appearance. All controllers have very simple controls and indicators, including between three and five temperature settings. Some controllers have ambient (room) air temperature as a setting, which can be used to cool patients. Typical temperature settings are 32°C, 38°C and 43°C and some devices have a boost setting which may be as high as 46°C. Indicator light emitting diodes (LEDs) show which setting is selected.
Safety features
All controllers have a thermostat to control the temperature of the heated air and a thermal cut out and audible alarm, which activate if an excessively high temperature arises following thermostat failure. Some devices may have additional thermostats and secondary alarms eg for under temperature conditions. The IEC draft standard states that the hose should be marked within 15 cm of the nozzle with a “No free hosing” safety warning [11]. Free hosing is device misuse by directing the hose under a standard hospital blanket or drape without using the compatible forced air warming blanket and can lead to patient burns [11].

Delivery of heat to the blanket
In all devices, the heating element is located inside the controller. In operation, heated air will begin to cool as it travels along the hose. The manufacturers’ operator manuals specify the temperature of the heated air as a range, referenced usually at the nozzle. For example, at a user-selected setting of 43°C, the air temperature at the nozzle may be 43°C ± 2°C. Buyers should refer to this detail for each device. Some devices have a thermostat located in the nozzle to regulate the temperature, and in these cases, the manufacturers tend to specify a narrower air temperature range at the nozzle.

Some controllers have different hose lengths available. Using a longer hose enables the controller to be placed further away from the operating table. In order to deliver air at the correct temperature with a longer or shorter hose, the controller may require adjustment by a qualified person according to the manufacturer’s instructions.

Service indicator
Some, but not all, controllers have an hour meter or an indicator to alert the user when routine servicing is due, eg air filter change.

Motor speed
All controllers marketed in the UK have one motor speed and therefore the rate of airflow is not selectable by the user. Future devices may have multiple selectable motor speeds and hence multiple rates of airflow.

Use with other equipment
Forced air warming devices are not suitable for use with MRI imaging.

The controller is an electrical device and may therefore cause electromagnetic interference with other equipment used in the operating theatre. Most devices meet standards for electromagnetic interference, eg IEC 60601-1-2. If interference occurs, users may need to turn equipment on and off to identify the source device and increase the separation distance between devices.
Blanket technical features

Generally, all blankets are:

- made of plastic or non-woven polypropylene or polyethylene
- latex free
- designed to meet flammability standards
- transparent to X-ray and other imaging systems.

Forced air warming devices are designed to warm dry patient skin. If the skin is wet, evaporative cooling may result. The blanket material typically has a degree of water repellence.

All blankets are permeable to air on the patient contact side. This is achieved either through puncture holes that are typically one or two millimetres in diameter, or by permeable blanket fabric. The puncture holes tend to produce jets of air under the blanket and the permeable fabric produces a more general movement of air. There is no evidence that either type of design is superior.

Manufacturers do not specify the air temperature inside or under the blanket in their operator manuals.

Infection control

NICE and MHRA concluded that forced air warming devices do not present a risk of infection when used correctly and that the devices reduce the risk of infection by keeping patients warm [1,9]. The ease with which the hose nozzle can be stored on the controller when the device is not in use, by use of a hook or similar, is a useful technical consideration because it may enable users to keep the open nozzle away from potential sources of contamination such as the hospital floor.

A minority of blanket models from some suppliers are available as sterile products for specific situations, eg marketed as ‘cardiac blankets’. A sterile blanket may be positioned in the sterile field and may complement draping and skin preparation. Sterile blankets may come with a sterile hose or a sterile sheath to place over the existing hose, to extend the sterile field around the patient. Sterile blankets generally cost more than non-sterile blankets. The majority of blankets are not sterile but are supplied in individual protective packaging and are suitable for use in operating theatres outside of the sterile field.
Universal contraindications

Forced air warming devices have general contraindications for their use. These exist for patient safety and are the same for all devices:

- do not ‘free-hose’, which is a misuse of the device by which heat is applied from the hose nozzle, which is placed under theatre drapes or hospital blankets, and without the compatible forced air warming blanket
- do not use on limbs where arteries have been surgically cross-clamped
- do not use on ischaemic or poorly perfused limbs
- do not apply the flow of warm air to open wounds
- do not use in the presence of flammable anaesthetic gases, nitrous oxide or oxygen.

All forced air warming blankets are intended for single patient use only.

Management of the patient

The device manufacturers also provide guidance for patient management when using the devices:

- anaesthetic staff should check the patient’s temperature frequently; manufacturers typically state at 15-20 minute intervals, ie more frequently than the 30 minute interval specified in the NICE guideline on perioperative hypothermia [1]
- the selected temperature should be reduced, or warming therapy discontinued when the desired patient core temperature is reached.

Availability and choice of blankets

All controllers are designed for both adult and paediatric use and manufacturers supply compatible blankets for adults, children, neonates and specific surgical situations, eg lithotomy, cardiac catheterisation. Blankets are available in different shapes and sizes to cover as much surface area of the patient as possible while permitting surgical access and protecting the sterile field. The precise range of available blankets varies between manufacturers and buyers should carefully consider which blanket types to stock according to the types of surgery performed. Some blankets may be best suited to relatively few procedures whereas others may be used widely across a range of procedures.
Blankets of the same basic design (e.g., upper body) but from different manufacturers vary somewhat in terms of:

- size (active heating area and total area)
- the degree to which they drape around the patient
- the presence of ties to secure the blanket during use.

**Disposal of blankets**

Forced air warming generates a large volume of waste. In general, blankets require disposal in hospital as clinical waste, which receives further treatment before final disposal. It is possible that in some non-theatre settings, used but unsoiled blankets may be disposed of as hospital domestic waste according to local hospital waste policies.

**Infection control**

Forced air warming blankets are for single patient use. Forced air warming blankets are generally not sterile unless specified, therefore the theatre team are required to place the blanket carefully to provide optimal patient skin coverage while protecting the sterile field around the operation site. It is standard practice during surgery to cover the patient in sterile drapes and all manufacturers’ blankets are designed to function when covered in sterile drapes. Some blanket designs have adhesive tape to stick to the patient’s skin close to the site of surgery. This is an infection control measure, intended to avoid blowing air directly into the patient’s wound or sterile field.

Another consideration is the ease with which the controller may be cleaned between surgical cases. All controllers should be cleaned with a clean, damp cloth and a mild detergent or hospital disinfectant. The hose exterior surface is generally corrugated to provide flexibility and strength and clinical users report difficulty in cleaning contaminants from the corrugations [22]. A flexible, plastic outer hose covering or sheath, where present, may be easier to clean than the underlying corrugations.

**Risk of thermal injury**

NICE, IEC and MHRA state that forced air warming devices are very safe when used as indicated [1,9,11]. Noting the particular contraindication of free hosing, it is also good practice to keep the hose clear of the patient’s skin.

**Mounting the controller**

All controllers have instructions for the mounting options that are available for each controller. These typically include IV pole, bedrail, hard surface or purpose built cart.
Operational considerations

Users should observe the manufacturer's instructions that apply, eg maximum mounting height and minimum wheelbase for IV stand mounting. Controller units should not be placed in hospital beds with the patient and users should avoid blocking the controller air inlet.
Cost effectiveness of forced air warming

NICE reviewed the clinical and economic evidence for active warming methods, including forced air warming [1]. The clinical evidence showed that forced air warming is effective in preventing hypothermia. There was inadequate economic evidence to determine whether forced air warming is cost effective, so NICE constructed an economic model to compare the cost effectiveness of forced air warming compared to ‘usual care’ ie no forced air warming [1]. The economic model included:

- the cost of providing forced air warming
- the saving achieved by preventing, through use of forced air warming, the cost of treating the consequences of hypothermia: wound infections, blood transfusions, morbid cardiac events, need for intensive care, pressure ulcers and longer hospital stay.

The economic model measured the benefits of preventing hypothermia in quality-adjusted life years (QALY). The QALY measures not only life years gained or lost, but also quality of life. NICE used the value of £20,000 per QALY gained as the threshold for cost effectiveness. The economic model considered different groups of patients at different risk of hypothermia.

The economic model showed that forced air warming is cost effective in preventing hypothermia, including for patients who are at low risk of hypothermia [1]. This means that it is cheaper for an NHS organisation to use forced air warming than it is to omit forced air warming and bear the cost of treating the consequences of hypothermia.

Estimation of cost of forced air warming – worked example

NICE produced a population-based costing template to enable an NHS organisation to estimate its cost of implementing the NICE recommendations [23]. The NICE costing template covers forced air warming and other measures and is published with a costing report [13].

The following worked example is a second method of estimating the total annual cost to an NHS organisation of using forced air warming devices. The worked example uses information from the NICE costing template [23] but instead starts with the number of blankets purchased per year and includes the costs of energy consumption and disposal of clinical waste.

The worked example is generic, however the scale of use is based upon Cardiff and Vale University Health Board (UHB), a large, tertiary care and teaching centre with two surgical hospitals, twenty five operating theatres and a critical care department.
The estimated cost of forced air warming on this scale is summarised in table 1 and figures 1-2 and is explained in more detail in the following text. The text contains calculations and boxes which purchasers may use to input their local information, because there is variation in utility costs [24,25] and the price paid for disposable forced air warming blankets.

Purchase of disposable forced air warming blankets is by far the largest component of the cost of using forced air warming devices [13]. Therefore, the price paid for blankets has a large influence on forced air warming expenditure. Manufacturers provide "list" prices for forced air warming blankets but report that a high degree of negotiation takes place when arranging blanket contracts [22]. Blankets are usually purchased in bulk and may be considerably cheaper than the list price [13,22]. NICE estimated the mean blanket price to be £15 [1,13,23], whereas analysis of procurement figures for the year 2008/9 from Cardiff and Vale UHB provides a mean blanket price of £6 [26]. Table 1 and figures 1-2 show cost summaries based on a cost per blanket of £15 and a cost per blanket of £6.

Table 1. Estimated expenditure on 32,000 episodes of forced air warming for a large NHS organisation over one year

<table>
<thead>
<tr>
<th>Item</th>
<th>Estimated cost at £15 per blanket</th>
<th>Estimated cost at £6 per blanket</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purchase of 32,000 forced air warming blankets</td>
<td>£480,000</td>
<td>£192,000</td>
</tr>
<tr>
<td>Controller servicing</td>
<td>£10,200</td>
<td>£10,200</td>
</tr>
<tr>
<td>Disposal of 32,000 used blankets as clinical waste</td>
<td>£1,523</td>
<td>£1,523</td>
</tr>
<tr>
<td>Energy cost</td>
<td>£2,232</td>
<td>£2,232</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>£493,955</strong></td>
<td><strong>£205,955</strong></td>
</tr>
<tr>
<td><strong>Usage cost per blanket</strong></td>
<td><strong>£15.44</strong></td>
<td><strong>£6.44</strong></td>
</tr>
</tbody>
</table>

The ‘usage cost per blanket’ row estimates the whole cost of using forced air warming, per blanket. In this example the non-blanket costs are constant at £0.44 per blanket.
Economic considerations

Figure 1. Estimated expenditure on 32,000 episodes of forced air warming for a large NHS organisation over one year: blanket purchase price of £15 per blanket, total expenditure £480,000

Cost breakdown structure: blanket price £15

Figure 2. Estimated expenditure on 32,000 episodes of forced air warming for a large NHS organisation over one year: blanket purchase price of £6 per blanket, total expenditure £192,000

Cost breakdown structure: blanket price £6

In figure 1 and figure 2 the non-blanket costs are equal at £0.44 per blanket but represent a larger proportion of the total cost at the lower blanket price of £6.
**Economic considerations**

**Cost estimation for purchase of forced air warming blankets**
Cardiff and Vale UHB performs an estimated 32,000 surgical procedures each year under general or spinal anaesthesia [27]. This example assumes that all these patients receive forced air warming. In reality, some patients may not require warming or may be warmed by other means than forced air warming. From April 2008 to March 2009 however, Cardiff and Vale UHB purchased 26,000 forced air warming blankets and it is reasonable to assume that this figure will increase in response to the NICE guideline [1]. Applying a price of £15 per forced air warming blanket [13] to 32,000 blankets creates an annual blanket purchase cost of £480,000.

<table>
<thead>
<tr>
<th>No. of blankets used per year</th>
<th>Cost per blanket (£)</th>
<th>Total cost of blankets per year (£)</th>
</tr>
</thead>
<tbody>
<tr>
<td>32,000</td>
<td>15</td>
<td>480,000</td>
</tr>
</tbody>
</table>

**Cost estimation for controller servicing**
Each controller requires a small amount of routine servicing. The supplier may charge for controller servicing as a separate item, or the NHS organisation may opt to service controllers using qualified NHS staff. The annual cost to Cardiff and Vale UHB for servicing medical equipment using internal clinical engineering staff is 7.5% of the device’s capital value [28]. The capital value of forced air warming controllers ranges from £100 to £2625 [29]. Cardiff and Vale UHB has 68 forced air warming controllers [30]. Using a nominal controller capital value of £2000 the annual cost of servicing the controllers is £10,200.

<table>
<thead>
<tr>
<th>No. of forced air warming controllers</th>
<th>Capital value of each controller (£)</th>
<th>Annual service cost of 7.5%</th>
<th>Total servicing cost per year (£)</th>
</tr>
</thead>
<tbody>
<tr>
<td>68</td>
<td>2000</td>
<td>0.075</td>
<td>10,200</td>
</tr>
</tbody>
</table>
Cost estimation for disposal of blankets

NHS organisations pay for waste disposal at a rate per tonne specific to the category of waste. Forced air warming blankets used in operating theatres are disposed of as clinical waste, which incurs a higher charge per tonne than non clinical waste due to the waste processing requirements. Assuming that a disposable forced air warming blanket weighs 170g [29], then 32,000 blankets create 5.44 tonnes of clinical waste. Assuming a clinical waste haulage, processing and disposal fee of £280 per tonne [24], disposal of 32,000 blankets per year costs £1,523 each year.

<table>
<thead>
<tr>
<th>No. of blankets used per year</th>
<th>Weight of each blanket (g)</th>
<th>Total weight of blankets (g)</th>
<th>Conversion factor, grams to tonnes</th>
<th>Total weight of blankets (t)</th>
</tr>
</thead>
<tbody>
<tr>
<td>32,000</td>
<td>170</td>
<td>5,440,000</td>
<td>1,000,000</td>
<td>5.44</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Total weight of blankets (t)</th>
<th>Waste disposal charge per tonne (£)</th>
<th>Cost of blanket disposal per year (£)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.44</td>
<td>280</td>
<td>1,523</td>
</tr>
</tbody>
</table>
Cost estimation for energy use
Forced air warming devices consume energy as electricity. The energy cost of using 32,000 blankets per year may be estimated on the following assumptions:

- 32,000 blankets represent surgical patients each receiving forced air warming for one hour
- devices operate at 800 W during operation [29]
- an electricity charge of £0.0872 per kWh [25].

The forced air warming electricity charge to the NHS organisation for one year is estimated as £2,232.

### Table

<table>
<thead>
<tr>
<th>No. of blankets used per year</th>
<th>Device operating time per use (h)</th>
<th>Total device operation time per year (h)</th>
</tr>
</thead>
<tbody>
<tr>
<td>32,000</td>
<td>1</td>
<td>32,000</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Total device operation time per year (h)</th>
<th>Device power (W)</th>
<th>Conversion factor, Watts to Kilowatts</th>
<th>Electricity used per year (kWh)</th>
</tr>
</thead>
<tbody>
<tr>
<td>32,000</td>
<td>800</td>
<td>1000</td>
<td>25,600</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Electricity used per year (kWh)</th>
<th>Electricity charge per kWh (£)</th>
<th>Electricity cost per year (£)</th>
</tr>
</thead>
<tbody>
<tr>
<td>25,600</td>
<td>0.0872</td>
<td>2,232</td>
</tr>
</tbody>
</table>
Economic considerations

Capital cost
In rare circumstances, an NHS organisation or a smaller department may opt to buy a small number of controllers, for example, for infrequent use, where no large volume contract exists. This will incur the controller capital cost. The broad range in controller capital cost of £100 to £2,625 [29] may arise because it is blanket sales that generate the majority of income for the device suppliers, rather than controller sales. Controller purchase cost rarely applies to NHS organisations using forced air warming and is therefore excluded in table 1 and figures 1-2.
Purchasing procedures

The Trust Operational Purchasing Procedures Manual provides details of the procurement process [31].

European Union procurement rules apply to public bodies, including the NHS, for all contracts worth more than £90,319 (from 1 January 2008) [32], Appendix 1. The purpose of these rules is to open up the public procurement market and ensure the free movement of goods and services within the EU. In the majority of cases, a competition is required and decisions should be based on best value.

NHS Supply Chain (www.supplychain.nhs.uk), a ten year contract operated by DHL on behalf of the NHS Business Services Authority, offers OJEU compliant national contracts or framework agreements for a range of products, goods and services. Use of these agreements is not compulsory and NHS organisations may opt to follow local procedures.

The most common purchasing arrangement in the NHS is that the NHS organisation enters into a contract with a supplier to purchase a large volume of disposable blankets. In return for the volume commitment, the controllers are often provided free of charge.

Blankets may also be available from other sources including regional procurement hubs or NHS Supply Chain, which aim to create an economy of scale by buying and supplying healthcare products in large volume.

In 2008 NICE estimated that 80% of the forced air warming market in England was held by NHS Supply Chain with the remaining 20% being purchased from other sources [13]. NHS Supply Chain currently supply disposable blankets from three of the six suppliers in the UK market [33].

Sustainable procurement

The UK Government launched its current strategy for sustainable development, Securing the Future [34] in March 2005. The strategy describes four priorities in progressing sustainable development:

- sustainable production and consumption – working towards achieving more with less
- natural resource protection and environmental enhancement – protecting the natural resources and habitats upon which we depend
- sustainable communities – creating places where people want to live and work, now and in the future
climate change and energy – confronting a significant global threat.

The strategy highlights the key role of public procurement in delivering sustainability.

Energy consumption

Energy use may be quantified in terms of the amount of carbon dioxide (CO₂) produced through the process of releasing energy from its original resource, eg coal, and storing the energy in the desired form, eg electricity.

The section Economic considerations includes a generic example of a large NHS organisation performing 32,000 episodes of forced air warming for an hour long period each, with the devices consuming power at 800 W. This consumes 25,600 kWh of electricity per year and by multiplying by a factor of 0.4, the volume of CO₂ released to the atmosphere per year is estimated in kg [25]. This is shown in table 2 below, along with a different example where a single controller operates for seven hours per day at 800 W for 365 days of the year:

Table 2. Estimated annual energy consumption and CO₂ released due to use of forced air warming devices use based on worked examples

<table>
<thead>
<tr>
<th>Worked example 1</th>
<th>Energy consumed per year (kWh)</th>
<th>CO₂ produced per year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Large NHS organisation: 32,000 cases in a year, each 1 hr long at 800 W</td>
<td>25,600 kWh</td>
<td>10,240 kg</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Worked example 2</th>
<th>Energy consumed per year (kWh)</th>
<th>CO₂ produced per year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single device operating 7 hours per day at 800 W for 1 year</td>
<td>2044 kWh</td>
<td>818 kg</td>
</tr>
</tbody>
</table>

The energy consumption when the devices are placed on standby is likely to be negligible; in practice, operators are likely to switch off the main power switch in between patients.

Noise

Forced air warming devices emit noise at a level of 52-58 dB(A) in normal use [12]. These values are well under the limits specified in The Control of Noise at Work Regulations 2005 [35].
End of life disposal

Consideration should be given to the likely financial and environmental costs of disposal at the end of the product’s life. Where appropriate, suppliers of equipment placed on the market after the 13 August 2005 should be able to demonstrate compliance with the UK Waste Electrical and Electronic Equipment (WEEE) regulations (2006) [36]. The WEEE regulations place responsibility for financing the cost of collection and disposal on the producer. Electrical and electronic equipment is exempt from the WEEE regulations where it is deemed to be contaminated at the point at which the equipment is scheduled for disposal by the final user. However, if it is subsequently decontaminated such that it no longer poses an infection risk, it is again covered by the WEEE regulations, and there may be potential to dispose of the unit through the normal WEEE recovery channels.

Forced air warming generates a large volume of disposable blanket waste, treated usually as clinical waste.

The controller units are likely to be straightforward to decommission at the end of their life (approximately seven years) and are made of metal, plastic and composite parts, some of which may be recycled.

Controller units on loan from manufacturers as part of high volume blanket purchase contracts may be returned to the manufacturers at the end of their useful lives.
We should like to thank the following for their contribution to this buyers’ guide.

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George Meakin, Senior Lecturer in Paediatric Anaesthesia, Association of Paediatric Anaesthetists of Great Britain and Ireland
Sherran Milton, Education Officer, Association for Perioperative Practice
Peter Robinson, Buyer, NHS Supply Chain
Ian Patterson-Waterston, Senior Medical Device Specialist, Medicines and Healthcare products Regulatory Agency
Jennie Wilson, Senior Nurse/Programme Leader - SSI surveillance, Health Protection Agency
Arizant UK Limited
Cardiac Services
Central Medical Supplies Limited
Cincinnati Sub-Zero Medical
Covidien
Gaymar
Pajunk UK Medical Products Limited
Smiths Medical
The Surgical Company International BV
Vital Signs Limited
   Last accessed: 22/09/2009

   Last accessed: 22/09/2009

   Last accessed: 22/09/2009

   Last accessed: 22/09/2009

   Last accessed: 22/09/2009

   Last accessed: 22/09/2009


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Last accessed: 22/09/2009

Last accessed: 22/09/2009

Last accessed: 22/09/2009
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Lease options

National frameworks are in place for operating leases to help the NHS procure leases more cost efficiently and effectively. Further details are available from the PASA website [37].

EU procedures

The Public Sector Directive (2004/18/EC) has been transposed into UK law via the following statutory instruments:

- the Public Contracts Regulations SI 2006 No.5 (the regulations)
- the Utilities Contracts Regulations SI 2006 No. 6 (not relevant to this guide).

The regulations apply to contracts worth more than £90,319 (from January 1\textsuperscript{st} 2008) [32] over their whole life, and specify the procedures to be followed for public sector contracting, including adherence to strict timetables, requirements for advertising, invitation to tender and the award of contract. Organisations undertaking a procurement exercise covered by the regulations must give all suppliers an equal opportunity to express an interest in tendering for the contract by placing a contract notice in the Official Journal of the European Union (OJEU).

At all stages of the procurement process, the purchaser must be demonstrably fair, as any decision made can be challenged by the unsuccessful suppliers.

Establishing a procurement strategy

To achieve a successful outcome, decisions need to be made on:

- whether an existing contract/agreement can be used
- the need to consider sustainable development issues
- whether EU directives apply
- the type and form of contract
- sourcing potential suppliers
- duration of contract and opportunity to review/extend
- payment schedules
- how to minimise any risks with the chosen strategy, including supplier appraisal and evaluation/clarification of suppliers’ bids.
Preparation of a business case

A business case should be drafted and approved before conducting any procurement exercise. Further guidance on preparing business cases is available from the Office of Government Commerce [38] and an illustrative example is provided in the *NHS PASA Operational Purchasing Procedures Manual, Procedure 1-01* [39].

The EU tendering exercise

EU procurements usually take between 4 and 6 months to complete. This needs to be taken into account in the planning stages. The length of the exercise depends on the chosen procedure (open or restricted). Further information is available from the Department of Health [40].

The procurement panel

A multidisciplinary team should be selected to guide the purchase. Representatives from clinical, user, technical, estates and financial areas should be considered.

Identifying potential suppliers

Criteria for supplier selection must be established. A pre-qualification questionnaire, seeking background information (e.g., on the skills and experience of the service engineers) may be employed as an initial screen to exclude unsuitable suppliers.

Evaluation criteria

Performance specifications should be derived from local operational requirements, and agreed by the procurement panel. They will form the basis for assessing the adequacy of suppliers’ technical specifications, provided in response to the technical specification questionnaire.

It is important to have agreed on the performance specifications of the product, as they will be used in the adjudication against company specifications.

Requests for features that are supplier-specific are not permitted under the regulations. Very specific features which are not supported by operational requirements are also not allowed.

Award of contract

Following award of the contract to the successful supplier, unsuccessful suppliers may need to be debriefed. This is at the supplier’s request.
Buyers must be aware of the ‘Alcatel’ procedure (see the Trust Operational Purchasing Procedures Manual [31], Procedure No.T-08, section 6 - Mandatory Standstill Period).

For more information on procurement, please refer to the Department of Health Website [41].
Introduction

As an early step in producing this buyers’ guide, two existing literature reviews were examined, to determine how they may provide information for NHS purchasers. The recent NICE guideline “Management of perioperative hypothermia in adults” undertook a comprehensive systematic literature review of perioperative warming, to inform its recommendations [1]. The Surgical Materials Testing Laboratory (SMTL) has produced an unpublished literature review of patient warming devices [21]. Both pieces of work examine forced air warming as an intervention but tend not to focus on the efficacy of different forced air warming devices when compared with each other. For this reason, production of this buyers’ guide included a review of published studies that compare two or more forced air warming devices, as follows.

Research question

A research question was defined according to the “population, intervention, comparison, outcome” (PICO) structure, described by the University of Oxford’s Centre for Evidence-based Medicine [42] as shown in the table 3 below.

Table 3. Research question

<table>
<thead>
<tr>
<th>Population</th>
<th>Intervention</th>
<th>Comparison</th>
<th>Outcomes</th>
</tr>
</thead>
</table>
| Patients who undergo surgery under anaesthesia (general or regional) | Intra-operative forced air warming using any device marketed in the UK | Device A versus: Device B versus: Device C, etc | Clinical studies:  
  • prevention of hypothermia  
  • rate of restoration of normothermia  
  • adverse incidents, eg hyperthermia, burns  
  • any user-focused outcome, eg ease of use, capacity for misuse  
  • cost-effectiveness  
Simulation studies:  
  • distribution of heat under blanket (or other variable which may be extrapolated to clinical practice)  
  • cost-effectiveness |
Literature search strategy

Table 4 shows the search strategies that were run on the MEDLINE database (1950-present)

Table 4. Literature search strategies

<table>
<thead>
<tr>
<th>Strategy</th>
<th>Date run</th>
</tr>
</thead>
<tbody>
<tr>
<td>General forced air warming search strategy:</td>
<td>20/8/08</td>
</tr>
<tr>
<td>1. exp hypothermia/</td>
<td></td>
</tr>
<tr>
<td>2. exp body Temperature regulation/</td>
<td></td>
</tr>
<tr>
<td>4. exp heat/</td>
<td></td>
</tr>
<tr>
<td>5. exp rewarming/</td>
<td></td>
</tr>
<tr>
<td>6. exp hypothermia,induced/</td>
<td></td>
</tr>
<tr>
<td>7. or/1-6</td>
<td></td>
</tr>
<tr>
<td>8. exp Perioperative Care/</td>
<td></td>
</tr>
<tr>
<td>9. exp Intraoperative Complications/</td>
<td></td>
</tr>
<tr>
<td>10. ((intra$ or peri$) adj operativ$).tw.</td>
<td></td>
</tr>
<tr>
<td>11. or/8-10</td>
<td></td>
</tr>
<tr>
<td>12. exp &quot;equipment and supplies&quot;/</td>
<td></td>
</tr>
<tr>
<td>13. (warm$ adj3 (device$ or system$)).tw.</td>
<td></td>
</tr>
<tr>
<td>14. (force$ adj3 (air or warm$)).tw.</td>
<td></td>
</tr>
<tr>
<td>15. or/12-14</td>
<td></td>
</tr>
<tr>
<td>16. 7 and 11 and 15</td>
<td></td>
</tr>
<tr>
<td>17. forced air warming.tw.</td>
<td></td>
</tr>
<tr>
<td>18. 17 not 16</td>
<td></td>
</tr>
<tr>
<td>Physical testing search strategy:</td>
<td>26/8/08</td>
</tr>
<tr>
<td>1. exp Heat/</td>
<td></td>
</tr>
<tr>
<td>2. exp &quot;Equipment and Supplies&quot;/</td>
<td></td>
</tr>
<tr>
<td>3. exp Models, Biological/</td>
<td></td>
</tr>
<tr>
<td>4. exp Hypothermia/</td>
<td></td>
</tr>
<tr>
<td>5. exp Perioperative Care/</td>
<td></td>
</tr>
<tr>
<td>6. exp Mannikins/</td>
<td></td>
</tr>
<tr>
<td>7. exp Body Temperature/ or exp Rewarming/ or exp Body Temperature Regulation/</td>
<td></td>
</tr>
<tr>
<td>8. exp Materials Testing/</td>
<td></td>
</tr>
<tr>
<td>9. exp Monitoring, Intraoperative/</td>
<td></td>
</tr>
<tr>
<td>10. 1 or 4 or 7</td>
<td></td>
</tr>
<tr>
<td>11. 2 or 3 or 6 or 8</td>
<td></td>
</tr>
<tr>
<td>12. 5 or 9</td>
<td></td>
</tr>
<tr>
<td>13. 10 and 11 and 12</td>
<td></td>
</tr>
</tbody>
</table>
In addition, the citations for all studies included in the NICE guideline were provided by the National Collaborating Centre for Nursing and Supportive Care, and studies relevant to the buyers’ guide were identified from the full guideline. Finally, a request was made for stakeholder organisations to identify unpublished studies. These methods identified 913 studies.

Study eligibility criteria

Any study that assessed the efficacy of two or more forced air warming devices relative to each other was eligible for inclusion. Randomised controlled trials with surgical patients are the most reliable source of evidence and were preferentially included. Healthy volunteer studies were included but are less applicable to the real clinical situation. Simulation studies using mannequins were also included. These provide further physical information about the devices but are less reliable as evidence since their results cannot be applied directly to the real clinical situation [21].

The studies were summarised in a standard format and assessed for quality using the NICE methodology checklists described in the NICE Guidelines Manual [43].

Results

Seven studies were included [14-20]. No study compares all devices that are currently marketed in the UK.

Two randomised, controlled clinical trials have been published, each comparing two different forced air warming devices [16,20]. Despite differences in heating characteristics, both devices were effective in maintaining normothermia in patients undergoing major abdominal and orthopaedic surgery, using upper body blankets [20]. Two different forced air warming devices with different flow rates, air temperature, length of tube and full body blanket design gave rise to similar increases in oesophageal temperature and mean skin temperature during post-operative re-warming after cardiac surgery [16].

These results are consistent with a randomised volunteer study comparing four forced air warming devices using upper body blankets [19]. Differences in measured heat transfer between the systems were significant, but in the clinical situation the most important effect of forced air warming is that the skin under the blanket becomes a source of heat gain rather than heat loss. Taking into account this change in the heat balance, the differences between the forced air warming devices becomes small. An earlier volunteer study using full body blankets found significant differences for heat transfer between the four systems tested [18]. Discrepancies between the studies may arise due to differences in methodology or developments in device technology that occurred between studies.
A series of studies using a validated copper mannequin, report the heat transfer capability of a number of forced air warming devices with upper body [14], lower body [15] and full body [17] blankets. Differences in the change of heat balance between the systems resulted from differences in air flow and air temperature from the blowers, and from differences in blanket design. For lower body blankets no differences were found between the systems tested [15], and relatively small differences were found for upper body blankets [14] but for full body blankets the differences were thought to be clinically relevant [17]. Some full body systems failed to maintain a positive temperature gradient between the blanket and the mannequin surface at a surface temperature of 38 °C and as a result, cooled the mannequin.

Conclusions drawn from the evidence

There is an inadequate volume of high quality evidence comparing the efficacy of two or more forced air warming devices. No study compares all devices that are currently marketed in the UK.

Evidence from a small number of clinical trials suggests that there are no significant differences in the efficacy of the forced air warming devices [16,18-20]. The findings of mannequin or volunteer studies [14,15,17] cannot be extrapolated easily to the clinical situation [21], but suggest that there is variation in the performance of different forced air warming devices.
Buyers’ guide: Forced air warming devices

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