

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance

FINAL SCOPE

HumiGard Surgical Humidification System for the prevention of inadvertent perioperative hypothermia

1 Technology

1.1 *Description of the technology*

The HumiGard system comprises a reusable humidifier and single-use tubing set and is designed to humidify and heat carbon dioxide gas used for insufflation during surgery. The system can be used in any patient undergoing laparoscopic or open surgery with the aim of helping to reduce evaporative cooling, which can also cause tissue desiccation. HumiGard is designed to be used independently of any other intraoperative warming measures, such as forced air warming, which are applied only to the external body surfaces and extremities.

1.2 *Regulatory status*

The HumiGard system received a CE mark in April 2013.

1.3 *Claimed benefits*

The benefits to patients claimed by the company are:

- Decreased incidence of intraoperative and post-operative hypothermia as a result of reduction in evaporative cooling
- Decreased incidence of surgical site infections due to improved intra-operative temperature maintenance
- Improved postoperative recovery (fewer postoperative complications and less pain) and faster discharge.

The benefits to the healthcare system claimed by the sponsor are:

- Reduced overall costs (due to costs no longer incurred), as a result of better patient outcomes including reduced incidence of surgical site infections, reduced length of time spent in hospital for surgery, and reduced length of time in post-operative recovery.

1.4 *Relevant diseases and conditions*

The HumiGard system is intended for use in heating and humidifying insufflant gas for laparoscopy and open surgery, specifically to minimise evaporative cooling and desiccation and prevent intra-operative hypothermia.

NICE guidance on [inadvertent perioperative hypothermia](#) (NICE guideline 65, currently being updated) states that inadvertent perioperative hypothermia is a common but preventable complication of perioperative procedures, which is associated with poor outcomes for patients.

Risk factors for hypothermia include patient characteristics (age, body type, comorbidity); type of anaesthesia (local, regional, general, use of gases); IV fluid administration and environmental factors, such as the extent and duration of surgical exposure, skin preparation and operating room temperature. Perioperative hypothermia can lead to increased postoperative morbidity including platelet dysfunction, bleeding, wound infection, alterations of pharmacotherapeutic effects and shivering.

1.5 *Current management*

NICE guidance on [inadvertent perioperative hypothermia](#) (NICE guideline 65, currently being updated) recommends that all patients should be assessed for their risk of perioperative hypothermia. All patients should receive warmed intravenous fluids and blood products; patients identified as higher risk should be warmed intraoperatively using a forced air warming device, as should any patient receiving anaesthesia for more than 30 minutes. Regular temperature measurement is recommended before, during and after surgery, and forced air warming is recommended for any patient whose core temperature drops below 36°C. NICE medical guidance recommends the [Inditherm patient](#)

[warming mattress](#) as a cost efficient alternative to forced air warming (medical technologies guidance 7).

NICE guideline 65 on [inadvertent perioperative hypothermia](#) relates to the prevention of perioperative hypothermia in the general surgical population and does not make any specific recommendations about the warming of insufflation gas.

2 Reasons for developing guidance on HumiGard for inadvertent perioperative hypothermia

- The Committee considered that the HumiGard Surgical Humidification System may offer benefits to patients and to the healthcare system through its use in patients at higher risk of hypothermia, such as individuals with complex conditions needing prolonged operations. It was concluded that the evaluation should focus on using HumiGard in these high risk patients and that it should be restricted to using HumiGard in abdominal surgery.
- The Committee noted differences in the available evidence and in expert advice about the role of HumiGard in open and laparoscopic surgery: it concluded that both indications should be included in the scope of the evaluation of HumiGard.
- The Committee noted that HumiGard may be used in addition to other technologies aimed at reducing the risk of hypothermia. It considered that the evidence presented to the Committee should address the impact of Humigard used alone and Humigard used as an adjunct to other technologies.

3 Statement of the decision problem

	Draft scope issued by NICE	
Population	People undergoing abdominal surgery, as an open or laparoscopic procedure	
Intervention	HumiGard surgical humidification system for: <ul style="list-style-type: none"> • Open abdominal surgery • Laparoscopic abdominal surgery 	
Comparator(s)	Open abdominal surgery: <ul style="list-style-type: none"> • No insufflant Laparoscopic abdominal surgery: <ul style="list-style-type: none"> • Unheated, unhumidified insufflant gas 	
Outcomes	The outcome measures to consider include: <ul style="list-style-type: none"> • Incidence of hypothermia in the intra- and post-operative period (defined as a core body temperature <36°C) • Incidence of surgical site infections • Length of stay in post-operative recovery • Total length of hospital stay • Device-related adverse events • Patient-reported pain 	
Cost analysis	Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared. Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed.	
Subgroups to be considered	<ul style="list-style-type: none"> • People receiving adjunctive warming, such as from forced air warming devices or warming mattresses • High-risk groups as described in NICE guideline 65 (any 2 of: ASA grades II-V, preoperative temperature below 36°C, combined general and regional anaesthesia, major or intermediate surgery or at risk of cardiovascular complications) 	
Special considerations, including equality issues	None	
Special considerations, specifically related to equality issues	Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristics?	No
	Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?	No
	Is there anything specific that needs to be done now to ensure MTAC will have relevant information to consider equality issues when developing guidance?	No

4 Related NICE guidance

Published

- Inadvertent perioperative hypothermia: The management of inadvertent perioperative hypothermia in adults. NICE clinical guideline CG65 (2008). Available from: <http://www.nice.org.uk/guidance/CG65>
- Surgical site infection: Prevention and treatment of surgical site infection. NICE clinical guideline CG74 (2008). Available from: <http://www.nice.org.uk/guidance/CG74>
- Surgical site infection. NICE quality standards QS49 (2013). Available from: <http://www.nice.org.uk/guidance/QS49>
- Inditherm patient warming mattress for the prevention of inadvertent hypothermia. NICE medical technologies guidance MTG7 (2011). Available from: <http://www.nice.org.uk/guidance/MTG7>
- Endovascular stent–grafts for the treatment of abdominal aortic aneurysms. NICE technology appraisal guidance TA176 (2009). Available from: <http://www.nice.org.uk/guidance/TA167>
- Laparoscopic repair of abdominal aortic aneurysm. NICE interventional procedure guidance IPG229 (2007). Available from: <http://www.nice.org.uk/guidance/IPG229>
- Laparo-endogastric surgery. NICE interventional procedure guidance IPG25 (2003). Available from: <http://www.nice.org.uk/guidance/IPG25>
- Laparoscopic surgery for colorectal cancer. NICE technology appraisal guidance TA105 (2006). Available from: <http://www.nice.org.uk/guidance/TA105>
- Ultra-radical (extensive) surgery for advanced ovarian cancer. NICE interventional procedure guidance IPG470 (2013). Available from: <http://www.nice.org.uk/guidance/IPG470>
- Laparoscopic mobilisation of the greater omentum for breast reconstruction. NICE interventional procedure guidance IPG253 (2008). Available from: <http://www.nice.org.uk/guidance/IPG253>

- Laparoscopic surgery for inguinal hernia repair. NICE technology appraisal guidance TA83 (2004). Available from: <http://www.nice.org.uk/guidance/TA83>
- Laparoscopic hysterectomy (including laparoscopic total hysterectomy and laparoscopically assisted vaginal hysterectomy) for endometrial cancer. NICE interventional procedure guidance IPG356 (2010). Available from: <http://www.nice.org.uk/guidance/IPG356>
- Combined endoscopic and laparoscopic removal of colonic polyps. NICE interventional procedure guidance IPG503 (2014). Available from: <http://www.nice.org.uk/guidance/IPG503>
- Laparoscopic cystectomy. NICE interventional procedure guidance IPG287 (2009). Available from: <http://www.nice.org.uk/guidance/IPG287>
- Laparoscopic gastrectomy for cancer. NICE interventional procedure guidance IPG269 (2008). Available from: <http://www.nice.org.uk/guidance/IPG269>
- Laparoscopic live donor simple nephrectomy. NICE interventional procedure guidance IPG57 (2004). Available from: <http://www.nice.org.uk/guidance/IPG57>
- Single-incision laparoscopic cholecystectomy. NICE interventional procedure guidance IPG508 (2014). Available from: <http://www.nice.org.uk/guidance/IPG508>
- Laparoscopic techniques for hysterectomy. NICE interventional procedure guidance IPG239 (2007). Available from: <http://www.nice.org.uk/guidance/IPG239>
- Laparoscopic radical prostatectomy. NICE interventional procedure guidance IPG193 (2006). Available from: <http://www.nice.org.uk/guidance/IPG193>
- Laparoscopic partial nephrectomy. NICE interventional procedure guidance IPG151 (2006). Available from: <http://www.nice.org.uk/guidance/IPG151>
- Ex-vivo hepatic resection and reimplantation for liver cancer. NICE interventional procedure guidance IPG298 (2009). Available from: <http://www.nice.org.uk/guidance/IPG298>

- Laparoscopic radical hysterectomy for early stage cervical cancer. NICE interventional procedure guidance IPG338 (2010). Available from: <http://www.nice.org.uk/guidance/IPG338>
- Laparoscopic nephrectomy (including nephroureterectomy). NICE interventional procedure guidance IPG136 (2010). Available from: <http://www.nice.org.uk/guidance/IPG136>
- Single-port laparoscopic nephrectomy. NICE interventional procedure guidance IPG414 (2011). Available from: <http://www.nice.org.uk/guidance/IPG414>
- Laparoscopic cryotherapy for renal cancer. NICE interventional procedure guidance IPG405 (2011). Available from: <http://www.nice.org.uk/guidance/IPG405>
- Laparoscopic gastric plication for the treatment of severe obesity. NICE interventional procedure guidance IPG432 (2012). Available from: <http://www.nice.org.uk/guidance/IPG432>

5 External organisations

5.1 Professional organisations

5.1.1 Professional organisations contacted for expert advice

At the selection stage, the following societies were contacted for expert clinical and technical advice:

- Association for Perioperative Practice
- British Anaesthetic & Recovery Nurses Association
- British Cardiovascular Intervention Society
- Royal College of Anaesthetists
- Royal College of Nursing
- Royal College of Physicians
- Royal College of Surgeons
- The Society for Cardiothoracic Surgery in Great Britain and Ireland

5.1.2 Professional organisations invited to comment on the draft scope

The following societies have been alerted to the availability of the draft scope for comment:

- Association for Perioperative Practice
- British Anaesthetic & Recovery Nurses Association
- British Cardiovascular Intervention Society
- Royal College of Anaesthetists
- Royal College of Nursing
- Royal College of Physicians
- Royal College of Surgeons
- The Society for Cardiothoracic Surgery in Great Britain and Ireland

5.2 Patient organisations

At the selection stage, NICE's Public Involvement Programme contacted the following organisations for patient commentary and alerted them to the availability of the draft scope for comment:

- Beating Bowel Cancer
- Bowel Cancer UK
- British Cardiac Patients Association (BCPA)
- British Heart Foundation
- British Obesity Surgery Patients Association (BOSPA)
- Cardiac Risk in the Young (CRY)
- Cardiovascular Care Partnership (UK)
- Colostomy Association
- Crohn's and Colitis UK (NACC)
- IA (Ileostomy and Internal Pouch Support Group)
- Pumping Marvellous
- Royal College of Surgeons of England
- The Somerville Foundation (Previously Grown Up Congenital Heart Patients Association)