Cedar

Healthcare Technology Research Centre

HumiGard: Technical Evaluation, Final Report

Responses to the questions from the MTEP committee

Authors: Megan Dale
James Evans
Kathleen Withers
Helen Morgan
Tony Wilkes
Grace Carolan-Rees

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GIG CYMRU NHS WALES
Bwrdd Iechyd Prifysgol Caerdydd a'r Fro
Cardiff and Vale University Health Board

CARDIFF UNIVERSITY
PRIFYSGOL CAERDYDD

Summary

The MTEP committee presented 4 technical questions on HumiGard, and these have been addressed using literature reviews, company documentation and a user survey.

The information reviewed by Cedar includes a literature search, user questionnaires and company test data. Our review leads to the following conclusions:

- There may be some tissue discolouration visible when using HumiGard in open surgery, but trained users do not find this problematic.
- There is no reason to believe that HumiGard adds undue complexity or restricts the field of vision during open surgery.
- The single use nature of the administration set, and the use of filters makes it unlikely that HumiGard will cause bacterial contamination during surgery. The administration set is not entirely sterile, meaning that there is a possibility of contamination entering the system during setup. The company has submitted a test report to demonstrate that bacteria are not transmitted from the reservoir or sensor to the patient. No evidence has been identified that indicates any increase in infection rates.

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What is HumiGard?

HumiGard is a device for warming and humidifying CO_2 that is being supplied to the surgical site either for insufflations of a laparoscopic procedure, or as part of open surgery. In abdominal open surgery this is for patient warming, in cardiac open surgery it also performs the role of de-airing.

The HumiGard has several components:

- The machine that is reusable and has a "hot-plate" on which the water container is warmed
- Reusable sensor for temperature, flow and ambient conditions
- The single use procedure pack that contains:
    - CO_2 delivery tube, from CO_2 device to HumiGard water container, with filter
    - HumiGard water container, which acts as the humidification chamber
    - Sterile tube for delivery of warm, humidified CO_2 from HumiGard to the patient
- Sterile water is added to the water container at the start of the procedure. The company advised that water temperature is typically 43-54 °C during use.

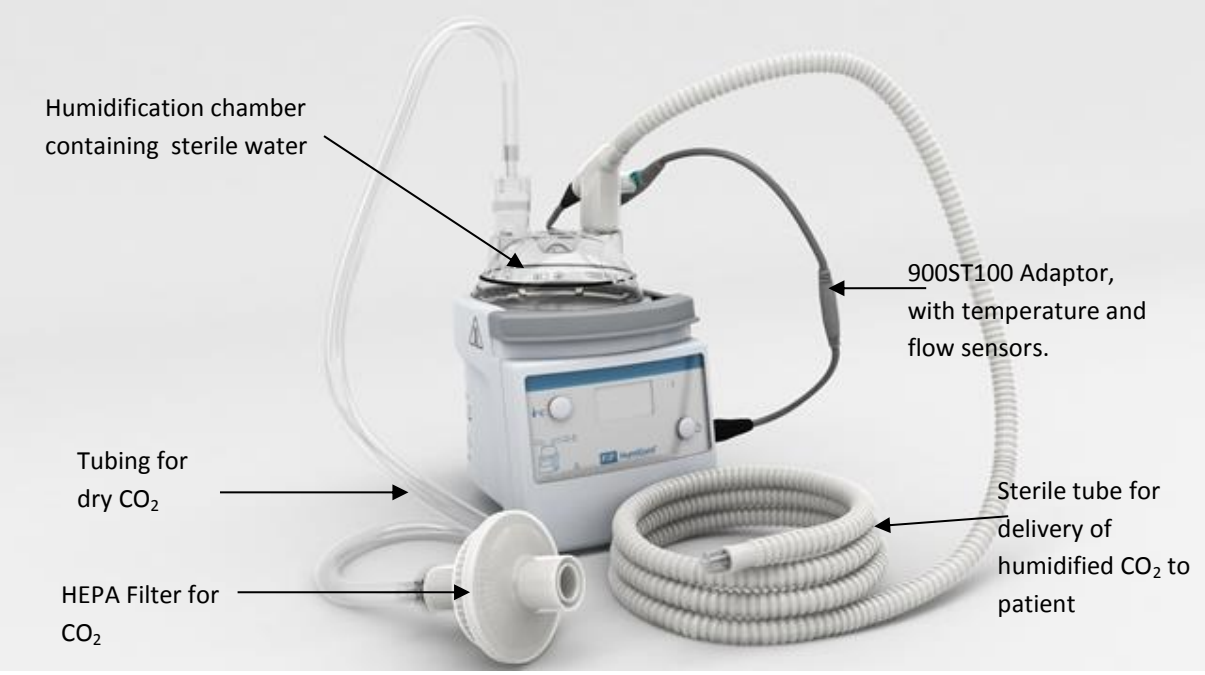

Figure 1 HumiGard system (image courtesy of Fisher and Paykel, labelling by Cedar)

Questions from MTEP committee, and general approach

Three general approaches were used to answer questions 1 to 4.

A **literature search** was carried out using Medline, Medline in process and Embase. One literature search was used to address all the questions; with differentiation during the selection process. A total of 390 papers, conference abstracts and posters were identified. From these 32 were selected in the first sift of literature. Further selections were then made for each question, The company also provided relevant references, including 5 that had not been identified in the literature search, either due to being very recent abstracts, or not being well indexed in the databases.

In addition, background information and information on devices that work by a similar mechanism, but for different clinical purposes, was searched for question 3. This search was systematic, using

Medline, but due to the broad nature of the question was not a full systematic review. The company that produces the CO_2 diffuser lists relevant technical papers on their website and these were reviewed for the response to Q4.

Company documentation such as CE marking certification and instructions for use were examined. The company also gave commercial in confidence access to test reports that had been completed by a third party.

An electronic **user questionnaire** was sent to 17 clinicians who use HumiGard during open surgery, as identified by the company. They included 6 users at 4 sites in the UK, 8 users at 4 sites in Australia, 1 user from New Zealand and 1 user from Sweden. The name of one additional clinician in Australia was provided but no e-mail address has been identified for this contact. Seven responses were received, including 3 from the UK. A pdf of the user questionnaire, with the responses, is included at the end of the report in Appendix 1.

All responders indicated that they are happy to be contacted with further questions if they arise, and Cedar contacted them to clarify issues for Q3 regarding bacterial contamination.

1 Does HumiGard cause tissue discolouration in open surgery of a similar appearance to tissue ischaemia?

Cedar identified 3 papers and 1 poster (Frey et al. 2012a, Frey et al. 2012b, Frey et al. 2010, Weinburg et al. 2015) describing the use of HumiGard in open surgery, plus 1 additional paper (Svernarud et al 2004) and 1 poster (El-Gamel et al. 2015a) identified by the company. El-Gamel et al have shared their manuscript as academic in confidence (El-Gamel et al. 2015b). None of these mention tissue discolouration.

From the user questionnaire (responses =7) 1 user had noticed tissue discolouration, and the same user said that colleagues noticed tissue colouration. This user felt that it was a training issue, stating:

Q8. "*Early use with device needed training and understanding of the colour changes when peritoneal cavity was exposed to humidified CO_2. This would not stop me using the device*"

Q13: "This is transient and simply needs training."

Q16: "This discolouration was not indicative of serious harm/ problem but potentially may make differentiating ischaemic non viable tissues from viable tissue difficult. I do not think this is an insuperable problem"

6 users said neither they nor colleagues had noticed tissue discolouration. 1 user said that blood in the abdomen could have a darker colour when using HumiGard.

1 user felt that discolouration could theoretically be mistaken for ischaemia (although they had not noted it), and 2 users felt that it could be mistaken for ischaemia only by new users.

None of the users felt that there was a problem with any discolouration, and stated that there was no concern related to the discolouration.

The full survey responses are included in Appendix 1 at the end of the report.

2 Does the use of HumiGard in open surgery result in added complexity or reduce access or visibility? If so, does this have an impact on its acceptability to surgeons when used during open surgical procedures?

Cedar examined 3 papers , 2 posters and 1 draft manuscript (Frey et al. 2012a, Frey et al. 2012b, Frey et al. 2010 , El-Gamel et al. 2015a, El-Gamel et al.2015b, Weinburg et al. 2015) describing the use of HumiGard in open surgery. Frey et al. (2012a) mention in the discussion that surgeons did not find that the diffuser used with HumiGard got in the way. The remaining literature did not discuss usability.

The user questionnaire results, for open surgery, were:

Question 20: Please answer the following questions for open surgery (n=7)	Agree	Mildly agree	Mildly disagree	Disagree
Using HumiGard adds complexity to the surgical procedure	0	0	1	6
HumiGard does not reduce visibility	7	0	0	0
I find HumiGard easy to use	6	1	0	0

When asked what drawbacks there might be to using HumiGard during open surgery, 3 respondents said there were none, the other four responses were:

"Theatre teams need to be trained to use this equipment. This is part of a bundle of team training and human factors"

"$ETCO_2$ may be slightly elevated. This is mild and can be easily managed by adjusting minute ventilation."

"Positioning in the abdomen can be difficult and sometimes difficult to cover the whole open abdomen but very good in the chest as it sits nicely away from where you are working and works on while thoracic cavity [SIC]"

"Catheter can get displaced"

The full survey responses are included in Appendix 1 at the end of the report.

3 Bacterial infection and associated biofilms

3.1 Does the use of HumiGard result in increased risk of bacterial infection and associated biofilms forming in the areas of the device exposed to water?

3.1.1 What is a biofilm and how might bacteria be transmitted?

Biofilms occur when microorganisms attach to surfaces and are made up of microbial cells and an extracellular polymeric substance (EPS) matrix. In this environment genetic transfer between cells occurs readily; where resistance to antibiotics may be transferred to other cells through conjugation or DNA uptake. The EPS is thought to be a major component of the resistance of biofilms to a range of antimicrobial compounds and is thought to impede the mass transport of antibiotics through the biofilm. From a public health perspective biofilms are a problem. Detachments of viable cells or aggregates can result in infections; while their architecture gives rise to a markedly reduced susceptibility to antimicrobial agents and antibiotic resistance genes may be exchanged between microbes (Donlan 2002). If a medical device is contaminated with microorganisms there are several variables that will determine whether a biofilm develops or not. Donlan (2001) states that “first microorganisms must adhere to the exposed surfaces of the device long enough to become irreversibly attached”. These variables according to Donlan include the number of cells in the liquid to which the device is exposed, the flow rate of the liquid through the device and the physiochemical properties of the device surface. Mulla and Revdiwala (2011) state that once these cells have become irreversibly attached and produce EPS to develop a biofilm the rate of growth is “influenced by flow rate, nutrient composition of the medium, antimicrobial drug concentration, and ambient temperature”. In their work Feldman et al. (1999) have shown that endotracheal tube colonisation (biofilm formation) begins after 12 hours and is most abundant after 96 hours and this colonisation commonly gives rise to nosocomial pneumonia.

The HumiGard is a humidifying device and while the temperature could potentially provide suitable conditions for microbial growth; the procedure times are unlikely to reach 12 hours. In addition, endotracheal tubes are subjected to microbial contamination from the patient. For HumiGard equipment during open surgery there is unlikely to be any risk of contamination into the device from the patient. For laparoscopic surgery it may be possible to have flow back into the device from the patient if there is any external pressure on the abdomen, but this will be much less probable than in endotracheal tubes.

3.1.2 Water vapour, droplet nuclei and aerosol

HumiGard generates humidity and heat for use with a CO_2 insufflator. When water is heated in the HumiGard reservoir, it starts to evaporate, releasing water molecules as vapour. Any particles such as bacteria, that are in the liquid, remain in the liquid water. However if water droplets are formed as an aerosol, bacteria may be carried by these. When aerosols are formed, some remain as droplets and travel relatively short distances, others evaporate and form droplet nuclei where bacteria can remain airborne for several hours. Tang et al. (2006) state that aerosols are “a suspension of solid or liquid particles in a gas” and that “infectious aerosols contain pathogens”. In addition they describe a droplet nucleus as “the airborne residue of a potentially infectious (micro-organism-bearing) aerosol

from which most of the liquid has evaporated". If the water in the reservoir is undisturbed and the only mechanism for water entering the CO_2 stream is by evaporation, then bacteria cannot move from the water to the patient. If water droplets can be formed, (ie due to the surface being disturbed by a high gas flow) then bacteria may be transmitted, if they are present.

3.1.3 Evidence relating to similar devices

A similar design of humidifier has been used for many years for warming and humidifying gas delivered from mechanical ventilators. There are numerous studies investigating possible associations between ventilation, contamination and pneumonia. There are many factors in the ventilation circuit clinical set up that makes these inapplicable for HumiGard. These include the length of time that ventilation circuits are left in situ, the use of endotracheal tubes and the likelihood of contaminants travelling from the patient back to the device.

Cedar identified three non-clinical studies that looked particularly at the transmission of particles found in humidifier reservoirs to the patient connected part of the circuit. None of these use the HumiGard device, and may not be directly applicable.

Wenzel et al. (2005) investigated the need for sterile water in humidifiers, in order to avoid respiratory tract infections during nasal continuous positive airway pressure (nCPAP) therapy. A Sirius convection heated humidifier was used where the gas passes over the surface of the heated water, in a similar method to HumiGard. 400ml of water in the reservoir was radioactively labelled with 400 MBq 99mTc- diethylentriamine penta-acetic acid (DTPA), as a surrogate for bacterial contamination. Testing was carried out first with oxygen at flow rates of 2 l/min, 4 l/min, and 6 l/min). Testing was then continued with air at flow rates of 31 l/min and 46 l/min. Tests were run for 10 minutes, and 7 humidifiers were tested.

A positive control was used where aerosols were generated and the filter was seen to collect and detect all of the radioactivity. However, no radioactivity was detected during testing of oxygen flow rates of 2 l/min, 4 l/min, and 6 l/min and no radioactivity was detected during nCAP at rates of 31 l/min and 46 l/min. The authors surmise that water in the humidifier is not aerosolised and only produces water vapour, with solutes remaining in the liquid. Furthermore, due to the much smaller size of molecules of 99mTc-DTPA compared to bacteria they conclude that it's highly unlikely bacteria would be aerosolised and carried in this manner.

Ortolano et al. (2007) noted that the use of heated humidifiers during nCPAP, particularly if not cleaned, increases the risk of respiratory infections. Therefore, they conducted experiments in order to determine whether the water in a heated humidifier can be aerosolised and therefore pose an infection risk. 11 trials of heated humidifiers for nCPAP were conducted in total. Humidifier water was contaminated with 350 ml of *Brevundimonas diminuta* and *Serratia marscens* at an anticipated concentration of 5 to 10 x 10^7 CFU/ml. Humidifiers were set at 37°C and were monitored over a week. Bacteria were recovered from the breathing tubes of 9 humidifiers at around 10^3 CFU/ml at a flow rate of 60 l/min. The authors concluded that the humidifiers in the study aerosolised bacteria allowing them to be recovered from the breathing tubes. This study is in contradiction to the conclusions of Wenzel et al (2005). The flow rate in this study is higher than used by Wenzel, and both studies use considerably higher flow rates than typically used for HumiGard. The maximum output flow stated in HumiGard instructions for use is 15 l/min, and 10 l/min is quoted in some

studies (Frey et al 2012a, Svenarud et al 2004), or lower at 6.5l/min in others (Herrmann and de Wilde 2014). It is plausible that high flow rates may disturb the liquid surface in the reservoir and cause aerosols to form. The duration of the study is one week, which is a clinically valid time length for studying ventilation, however the HumiGard delivery circuit is single use and is only used for the duration of a single operation in theatre.

Greib et al. (2008) studied the use of humidifiers to carry the anaesthetic Ropivacine at 0.75% and 0.2%. Different humidifiers were tested in this experiment including a cold evaporating device, a nebulizer and 2 hot (50°C) evaporating devices each at a flow rate of 3 l/min. The results showed that neither of the hot evaporating devices carried the anaesthetic, and the cold evaporating device carried an extremely small amount (<0.0001%), while the nebulizer delivered 89.1% of 0.2% Ropivacaine, and 93.7% of 0.75% Ropivacaine. While this study did not measure bacterial contamination it adds further evidence that water vapour is unable to carry solutes while aerosolised water can.

3.1.4 HumiGard components, sterility and cleaning

HumiGard is made up of a reusable surgical humidifier (MR860), an adapter for temperature, flow and ambient sensing (900ST100) and a single-use laparoscopic humidification kit (ST310).

The single-use laparoscopic humidification kit contains:

a. Sterile components - gamma irradiated, in accordance with ISO11137 (sterilisation of health care products – radiation), supplied in sterile packaging

- the tube that connects the humidifier to the patient

b. Non-sterile components

- HEPA filter (independently tested for bacterial and viral filtration efficiency)
- Tubing between filter and reservoir
- Reservoir
- Funnel and adaptors

Figure 2 Sterile component (image courtesy of Fisher and Paykel)

Figure 3 Non-sterile components (image courtesy of Fisher and Paykel)

Components (from CO_2 supply towards patient)	Single Use	Sterile	Additional information (from instructions for use and communication with company)
Filter	✓		0.3 µm HEPA filter
Tubing	✓		Bioburden tested (ISO 11737-1:2006)
Reservoir	✓		
Water (not included in kit)	✓	✓	
HumiGard device			This is not in contact with CO_2 or water. **Cleaning:** with either Isopropyl alcohol or dishwashing detergent.
900ST100 Adaptor:			The main body of the adaptor is not in contact with CO_2 or water, however the temperature probe is inserted into the elbow of the sterile tubing. **Cleaning:** If visible matter is seen on the 900ST100 Adaptor, wipe clean with an alcohol swab
Tubing	✓	✓	Sterilised using gamma radiation in accordance to ISO11137 Sterilisation of Healthcare products – radiation.
CarbonVITA diffuser (for open surgery, not included in kit)	✓	✓	Supplied sterile separately

The CO_2 passes through the HEPA filter (specified as a bacterial and viral filtration efficiency of 99.9999%). It then passes along tubing and into the top of the water reservoir. The water is warmed by the MR860 humidifier, causing evaporation of water molecules which humidifies the CO_2. The humidified CO_2 passes over the temperature sensor and along the sterile tubing to the patient. The temperature of the delivered CO_2 is controlled by the temperature sensor by feedback to the humidification chamber. The humidified CO_2 may be delivered via an insufflation port for laparoscopic surgery, or a CarbonVITA diffuser for open surgery

There is very little potential for the build-up of biofilm within the HumiGard system, as the humid gas is only in contact with single use components, with the exception of the temperature probe. During open surgery there is unlikely to be flow back into the device from the patient. During laparoscopic surgery it may be possible to have flow back from the patient to the device if there is any external pressure on the abdomen.

There is potential for bacteria or other contaminants to be introduced into the HumiGard system, as several components are not sterile, and also set up and filling the reservoir may allow the introduction of contaminants. For this to reach the patient, the bacteria would have to be transmitted via the humidified CO_2.

3.1.5 Device testing commissioned by Fisher and Paykel

The company provided a signed statement that the HumiGard sterile components are compliant with ISO 11137-1:2006 and ISO 11137-1:2013 Sterlization of health care products – Radiation, parts 1 & 2. The company stated “process monitoring and bioburden testing on this product is performed on a regular basis. The testing is conducted in accordance with ISO11737 [*ISO 11737-1:2006 Sterilization of medical devices. Microbiological methods. Determination of a population of microorganisms on products*]. Results are reviewed and trended against defined action limits. If the action limits were to be breached an investigation would commence as per the documented reaction plan. The quality management system and manufacturing processes are audited annually by TUV SUD”. Cedar have seen certification for the full quality assurance system audit in accordance with Medical Device Directive (MDD) Annex II, required for CE marking, by TUV-SUD (notified body number: 0123). The audit was carried out in March 2015, and is valid until March 2020.

The air filter in the laparoscopic humidification kit is supplied by Air Safety Limited. This filter is a pleated mechanical 0.3 µm high-efficiency particulate arrestance (HEPA) filter, with 99.9999% bacterial filtration efficiency (BFE) and viral filtration efficiency (VFE). Testing of this filter is carried out independently. The humidified insufflator tube is also sterile so must be handled with correct aseptic technique.

Fisher and Paykel provided a test report by the Centre for Pharmaceutical Research, University of South Australia investigating the risk of bacteria reaching the patient from either contamination of the probe or the water.

[redacted]

[redacted]

3.1.6 User opinions

Additional questions were sent to the 7 users who had replied to the questionnaire, 5 responses were received. They were asked if they were aware of any issues caused in practice by the use of non-sterile components, and if they thought it was possible for bacteria to be transmitted via the CO_2 flow. The respondents generally agreed that they were not aware of any issues with this in practice, but that it may be possible for contamination to occur in this way. One replied that in a small study of 22 patients undergoing liver transplants, no infections had occurred in either the intervention or control group.

3.1.7 Literature

Cedar examined 4 papers, 2 posters and 1 draft manuscript (Frey etal. 2012a, Frey et al.2012b, Frey et al. 2010 , El-Gamel et al. 2015a, El-Gamel et al.2015b, Weinburg et al. 2015) that compared the use of HumiGard with no insufflation for open surgery in clinical trials. None reported infections rates in their outcomes.

19 papers, abstracts or posters were identified that reported the use of warm, humidified insufflation gas in laparoscopic procedures. One additional paper was identified from the company submission (Herrmann and de Wilde 2015). Alternative devices were not searched for, however some were identified during the search. From the 19 papers or abstracts, 10 used HumiGard as the

intervention, but these only related to 5 separate studies (Yu et al. 2013, Herrmann and de Wilde 2015, Noor et al. 2015, Sammour et al. 2010, Manwarring et al. 2008). Of the remaining papers, 6 were concerning an alternative device (Insuflow), including 1 letter, and 3 were reviews or meta-analysis.

Two abstracts specifically address infection rates (Noor et al. 2015, Mason et al. 2015) during laparoscopic surgery. Both authors are based at Colchester Hospital, and appear to report on the same patient group. Noor et al. found that in a retrospective cohort study of 252 patients, the incidence of secondary site infection was significantly reduced from 12% to 4.7% following introduction of HumiGard ($p = 0.047$). Mason considered the cost effectiveness of the intervention.

One paper (Farley et al. 2004) used an alternative device for humidification (RCT, n=101) and reported one case of infection in each group during a question and answer section at the end of the paper.

The remainder of the papers and abstracts do not report infection rates.

3.2 Is there any evidence that HumiGard can promote the spread of bacteria during a surgical procedure?

Cedar examined 4 papers , 2 posters and 1 draft manuscript (Frey et al. 2012a, Frey et al. 2012b, Frey et al. 2010 , El-Gamel et al. 2015a, El-Gamel et al. 2015b, Weinburg et al. 2015) describing the use of HumiGard in open surgery. None of these reported infection rates.

During open-surgery, a diffuser is used as an alternative to an open-ended tube that has been commonly used. The VITA-diffuser by Cardia Innovation AB has been specifically designed to be used in conjunction with the single-use laparoscopic humidification kit produced by Fisher & Paykel. Persson and Van der Linden (2004) have evaluated whether the diffuser influences the rate of airborne contamination of the cardiothoracic wound through the use of agar plates and a cardiothoracic wound cavity model. In total 3 experiments were designed in order to compare the rate of airborne contamination in an open-ended tube versus the diffuser, air versus carbon dioxide and carbon dioxide flow through the diffuser at 5 l/min versus 10 l/min. Briefly, the diffuser showed a decrease in airborne contamination with both air and carbon dioxide compared with the open-ended tube. However, airborne contamination was lower when using the diffuser with carbon dioxide than when used with air. Finally, a carbon dioxide flow rate of 10 l/min through the diffuser showed a decreased contamination rate.

Microbiological analysis of the effect of carbon dioxide on the growth of *Staphylococcus aureus*, a Gram positive organism that is frequently found as part of the normal human skin flora, has been previously carried out (Persson et al. 2005). *S. aureus* can cause skin infections, abscesses and endocarditis in addition to a whole range of other infections. In addition, methicillin resistant *S. aureus* (MRSA) can cause severe nosocomial infections due to its difficulty to treat. Persson et al. (2005) have examined the effect of incubating cultures of *S. aureus* on blood agar plates for 24 hours in the presence of air, anaerobic gas and carbon dioxide. *S. aureus* incubated in the presence of carbon dioxide showed a ~2-$\log_{10}$ reduction than in anaerobic gas ($p=0.001$) and a ~3-log reduction than in air ($p=0.001$). Furthermore, broth cultures of *S. aureus* insufflated separately with carbon dioxide and air were compared. Following 8 hours of insufflation, cultures insufflated with carbon

dioxide showed viable counts (CFU/ml) which were ~3-$\log_{10}$ lower than air (p=0.003). The results from these experiments suggest that the use of carbon dioxide as an insufflation gas could lower the numbers of *S. aureus*, a potentially pathogenic commensal skin organism. It must be noted that the results of this experiment show the effect of CO_2 on *S. aureus* alone. These results therefore, may not be directly applicable to other potentially pathogenic bacteria of the human skin microbiome in addition to contamination from other sources. However, the results do show the inhibition of growth of a common commensal of the human skin microbiome which has the potential to be pathogenic.

4 Is the mechanism of action of heated, humidified carbon dioxide different for open surgery compared to laparoscopic surgery?

The device works in the same way for each type of surgery. The differences are the delivery method to the operative site. For open surgery the heated, humidified CO_2 is delivered by a diffuser device that is placed at the edge of the wound area. This device was developed and is manufactured by Cardia, a group based at an academic institution in Sweden. This group have published multiple papers including bench testing, computer simulations and a randomised controlled trial (Frey et al. 2012).

4.1.1 Distribution and flow of CO_2 in the open wound

Cater and van de Linden, 2015: A finite element computer simulation is used to model the flow of CO_2 from a diffuser placed in an oval shape representing an open surgical wound. The wound model is initially placed flat, and then placed at different angles from 0 to 22.5°. Cater and van de Linden found that the denser CO_2 filled the entire wound model, and once this was full to the surface, the CO_2 overflowed from the lowest point. At 10l/min the wound was full after approximately 6 seconds. The authors concluded that "a flow rate of 10l/min was sufficient to maintain a warm carbon dioxide barrier for a moderately sized surgical incision for all likely angles of inclination".

Persson and van de Linden, 2004: This experiment took place in an operating theatre, with a clean air ventilation system running. Particle contamination (5µm and larger) was measured on the operating table, and within a wound model on the table, when two surgeons (dressed as if working in theatre) stood by the operating table. No particles were detected at all. The surgeons then moved around the operating theatre, and pretended to carry out surgical tasks. When there was no CO_2, a median of 18 particles per 0.1 cu ft, were detected (25th and 75th percentiles, 12 and 22.25). When using humidified CO_2, a median of only 1 particle per 0.1 cu ft, was detected (25^{th} and 75^{th} percentiles, 0 to 1.25; $P < 0.001$). No significant difference was found without the cavity.

The rate of CO_2 supplied was 10 l/min, there were 20 tests for each scenario. Charnley–Howorth ventilation system (Exflow Clean Zone 25S) was used in the operating theatre. Particles were detected using a particle counter (Met One 237A, Pacific Scientific Instruments, Grants Pass, OR).

4.1.2 Carbon Dioxide to keep the open surgical wound warm

Topical Humidified Carbon Dioxide to Keep the Open Surgical Wound Warm; Persson, Elmqvist et al 2004.

This reports a laboratory test where the surface temperature and evaporation rate from a wound model was measured during 5 tests, both with theatre lights on and off:

- No insufflations (control)
- Air at 5 l/min dry and humidified
- CO_2 at 5 l/min dry and humidified

Humidification was from a bubble type humidifier (Aquapak 340 ml; HudsonRespiratory Care) heated to room temperature only. HumiGard was not used, the company has informed Cedar that the reservoir water temperature would normally be between 43 to 54 °C . When the theatre lights were on, the control surface temperature was 33.3 C, the surface temperature using air insufflation was slightly higher for both dry (p=0.03) and humidified (p=0.05) air. The actual temperatures measured were approximately 33.5°C (shown only as a graph). The surface temperature using dry CO_2 insufflation was higher (35.2 °C) than the control and dry air (p>0.001). Humidified CO_2 resulted in a surface temperature significantly higher than dry CO_2 (35.6°C, p=0.002)
The authors suggest that there are two mechanisms for the higher surface temperature and lower evaporation rate seen when using CO_2. One is that CO_2 and water vapour are both greenhouse gases, and they suggest that radiant heat from the body is absorbed by the gases to maintain a warmer layer over the wound. This will depend on the infrared wavelength radiating from the wound model being a wavelength that is absorbed by CO_2. The relevance to a clinical effect will also depend if the wavelength of infrared emitted by a human body is absorbed by CO_2. The second mechanism suggested is that because CO_2 is denser than air, it may fill the wound cavity and reduce convection at the wound site (Cater and van der Linden 2015, Persson and van der Linden 2004).

The experimental set up used the humidifier at room temperature to avoid any condensation. This is probably not reflective of normal practice and will have reduced the humidity of the gases delivered to the wound site. This may explain the relatively small effect on temperature and evaporation seen when increasing humidity.

Papers discussing the use of HumiGard during cardiac surgery to reduce the risk of air microemboli were not included since cardiac surgery is outside the MTEP scope.

Papers discussing the use of CO_2 to deliver gaseous antiseptic or other gaseous substances during open surgery were not included since this is not part of normal practice at the current time.

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Appendix 1

Double click the icon to view the survey results. The user survey results are also provided as a separate document.

Appendix 1 User Survey Results