The Journal of Health Design

RESEARCH

Monitoring and alleviating the effects of pressure-related injuries for spinal surgery—a need for improvement?

Nicolette Dullesco Sizer[1], Francesco Luke Siena[1], Bronek Boszczyk[2], Philip Breedon[3]

1. Product Design Department, Nottingham Trent University, Nottingham, UK.
2. Nottingham University Hospitals NHS Trust, Nottingham, UK
3. Medical Engineering Design Research Group, Nottingham Trent University, Nottingham, UK

To Cite: Sizer, NS, Siena, FL, Boszczyk, B, Breedon, P. Monitoring and alleviating the effects of pressure-related injuries for spinal surgery—a need for improvement? JHD. 2020;5(2):280–292. https://doi.org/10.21853/JHD.2020.105

Corresponding Author:
Professor Philip Breedon
Nottingham Trent University
School Of Science & Technology
Nottingham
philip.breedon@ntu.ac.uk

SUMMARY
The development of pressure injuries (PIs) is a common complication arising during surgery. Monitoring and alleviating PIs is currently not possible during lengthy spinal and orthopaedic surgeries, especially if a patient requires x-rays. We interviewed surgical staff to gain an understanding of attitudes regarding current methods and approaches for the management of PIs to allow the development of new devices based on staff feedback. Interviewees provided insights regarding the possible design of a new device used to monitor and alleviate pressure injuries in a surgical environment. From the interviews we derived key themes, including current devices/systems, current risk assessment/scales, and design considerations. As a result, we identified critical design requirements and an appropriate product design specification.

Key Words
Pressure injuries, pressure sores, patient monitoring, closed-loop system, radiolucency.

ABSTRACT

Background

Complications can arise when perioperative staff are monitoring a patient's health status during surgery, including the development of pressure injuries (PIs). It is important to reduce the incidence rates of developing PIs intraoperatively, and thereby mitigate both increased costs and negative impacts to patients and care providers. Current pressure relief supports offer limited monitoring abilities throughout the perioperative environment.

Aim

The aim of this study is to establish clear design requirements and a product design specification that enables a new closed-loop product solution to be developed with real-time pressure monitoring during surgery.

Method

We conducted semi-structured interviews with nine different clinical staff members involved in the perioperative environment. We conducted the interviews over a two-week period with two major teaching hospitals within the East Midlands, UK. Questions focused on healthcare

professionals' perceptions of current methods and their approaches to managing PIs. We recorded and transcribed participants' data using NVivo software.

Conclusion

The interview data identified a need for an improved method to manage and monitor PIs. We established that the incorporation of live feedback to reduce the prevalence of PIs is a critical design priority. Based on the interviews, we developed design criteria and a product design specification (PDS). Interview transcripts suggest a new device design should focus on a novel radiolucent pressure redistribution solution capable of reducing PIs intraoperatively while incorporating live feedback.

BACKGROUND

Throughout the hospital setting, clinical staff face the ongoing challenge of preventing skin injuries during patients' stay. Pressure injuries (PIs) are one often overlooked area occurring in the perioperative environment. PIs are harmful and preventable; they remain a significant complication;[1] and they can increase the risk of mortality,[2] the length of hospital stay, and healthcare costs.[3,4] Hospital-acquired pressure injuries (HAPIs) are adverse hospital events that cause substantial patient discomfort and impact quality of life.[5]

Clinical staff struggle with positioning and monitoring the development of PIs intraoperatively. Currently, staff assess positioning visually to approximate patient comfort levels intraoperatively; however, the limited preventative methods in place offer static support and do not allow for monitoring of the patient throughout surgery. Some surgeries such as spinal surgery can last more than six hours; this is a significant period during which the patient's skin integrity is not being monitored. A skin inspection conducted preoperatively may not reveal any skin damage, yet skin damage can become visible days later in postoperative check-ups.[6] This lack of monitoring may occur because during high-risk surgeries it is imperative that the patient remains still and positioned to the surgeon's preference to access the surgical site and limit infection spread. This positioning method is beneficial to the surgeon and clinical staff because it limits risk to the patient and increases efficiency in surgical times; however, prolonged pressure will result in an occlusion of blood flow, ischemia, and potentially cell necrosis.[7]

PIs cause significant pain that impacts the patient's quality of life.[5] PIs can lengthen the patient's hospital stay and increase healthcare provider costs.[2] Since 2004, the cost of treatment of PIs for the UK National Health Service (NHS) is between £1.4Bn to £2.1 billion per annum.[8] Although PIs are persistent, they can be prevented by paying greater attention to care, assessment, prevention equipment use, and by reviewing official guidance documentation. If PIs were documented throughout the intraoperative process, clinicians could potentially prevent the onset of this debilitating complication. There is evidence to suggest that prevention is more effective than treatment[9] in the form of a device and human intervention. Schuurman et al.[10] suggest both strategies are equally effective at preventing PIs. Due to advancements in practice and technology over the last two decades, the efforts of diagnosing, monitoring, and treatment have shifted from the clinician to medical devices; however, potential hazards and adverse events do still occur.[11,12]

Human fallibility directly affects patient outcomes and policies in many countries.[13–15] Tarnow-Mordi et al.[16] conducted a four-year study in the UK and found that when patient volume was high, clinician workload was a contributing factor to the fact that patients were twice as likely to die when compared to patients admitted during relatively quiet periods. Shifting the workload from clinicians to a medical device can offer faster treatment and decrease human fallibility.

In this paper, the authors aimed to ascertain clinicians' attitudes towards the prevention of PIs during surgery. The authors sought insights in relation to whether the monitoring and diagnosis of skin integrity could be improved using a medical device that would be offered as a "closed-loop system". Closed-loop systems are used to automate a process with minimal human interaction from diagnosis to action, in this case repositioning. This closed-loop system could be used to tackle the current staffing crisis the NHS faces by automating monitoring processes and, possibly in the future, data collection and processing. As PIs are the most frequent medical error to occur in health care,[17] it is important to understand where the responsibilities lie for addressing these challenges.

METHOD

This study was approved by Nottingham Trent Universities Joint Inter College Ethics Committee. All interviewees were located at two major teaching hospitals within the East Midlands, UK. We selected interviewees based on proximity to Nottingham Trent University and access to staff with the relevant expertise and facilities. Interviewees gave informed consent verbally and through information sheets and signed consent forms.

Given that patient care is the clinician's responsibility, it was imperative to interview clinicians with different roles to understand their differing responsibilities, as well as to identify clinicians whose responsibility would be best suited to interact with a potential new device. The authors presented participants with semi-structured interview questions (Figure 1) during a two-week period set up for interviews using a thematic framework. The interviews were put in place to gain an understanding of surgical staff attitudes towards current methods and approaches of managing PIs and how to improve current management systems and devices based on staff preferences. The authors formed an inductive approach based on interviewees' responses to the potential implementation of a closed-loop system during surgical procedures.

The authors designed the interviews to gain insight into the types of technological interactions surgeons want during surgery and how visual feedback data could be improved. The interview questions aimed to gain insights into the attitudes of the potential user based on their understanding of PIs. The authors also assessed participants' preferences towards the implementation of a new device within surgery. The collected data allowed the identification of a set of design criteria and generated a product design specification for the design or re-design of a product capable of monitoring PIs that could be situated within the surgical environment and used by medical professionals.

Figure 1: Interview questions

Interview Questions:

1. Could you describe some of your responsibilities?
2. How do you currently prevent pressure injuries during the perioperative environment?
3. Where do you think the prevention is lacking? Is there a specific area that needs to be improved?
4. What methods of pressure injury prevention do you use?
5. Can you tell when pressure is acting on the patient's skin?
6. As a potential user, would you want the ability to monitor the ongoing development of pressure?
7. When a patient is positioned there is a health and safety concern for the positioners, do you believe the patient positioning method can be improved for the patient? How?
8. Do you have any suggestions of how pressure injuries can be prevented?
9. If a device could be used in surgery to limit pressure injuries how would you use it?
10. How would you, as the potential user, want to control it? How can it be used by the overall surgical team?

Before the interviews, all interviewees completed an introductory survey to ascertain basic information on their age range, grade of their profession, and if they had ever received training on PI prevention (PIP) (Table 1). We conducted the interviews in single sessions during which participants answered semi-structured questions asked by the interviewer (Figure 1). The authors used a semi-structured approach to incorporate user reflection on a future product development that could be hypothetically implemented into their current environment. Interviews were recorded and then written transcripts were generated and interpreted. We combined and coded initial comments into different themes that allowed the definition of the critical design considerations (Table 2).

RESULTS

Based on the results from the conducted interviews where existing solutions and alleviation approaches were identified and discussed, we gained insights on prospective users' perspectives and attitudes regarding PIs during surgery. We present five key themes that emerged through the interview coding:

- Theme 1: Current risk assessments and preventative methods used
- Theme 2: Affected areas of PI occurrence, difficult aspects of surgery, and perceived solutions
- Theme 3: The need for radiolucency
- Theme 4: Potential users and interaction
- Theme 5: Design considerations and attitudes on how the device may be perceived

Based on the interview data collated and formulated into key themes, we generated a range of design requirements (Table 3). Based on these key themes, we summarised a product design specification with key product-defining criteria (Table 4). The interviews conducted provided insights into how the implementation of new pressure alleviation devices and systems could be used effectively in surgery. We established a range of clear design requirements and defined

potential product features that facilitated the formulation of a PDS and initial concepts and resulted in the manufacture of initial test models and systems.

Theme 1: Current risk assessments and preventative methods used

The interviewees suggested that patient positioning, the type of operating table, and the attachments used often significantly affect patient PIs. One interviewee noted that possible PIs were also assessed postoperatively, categorised based on patient positioning, and visualised on a chart for monitoring. The interviewee comments included the following:

"You must take it to it into factor the different table design people use. There is a huge variation they have like five or six different table here." (P2)

"That happens regularly and, unfortunately, there's not very much else we can use we have got different props and we have got the Allen table, even still they still create pressure." (P4)

"So, there is a chart where we have to look at when the patient comes out of the table from the operation, from the operating table on to the bed (recovery phase–postoperativity), so we always check for pressure areas." (P6)

Theme 2: Affected areas of PI occurrence, difficult aspects of surgery, and perceived solutions

Clinicians perceive PI occurrence to be related to poor patient positioning both in surgery and postoperatively. Healthcare professionals have identified several problematic areas of the body, including the face, chest, and breasts, but note that PIs can occur anywhere on the body. PI management techniques do not appear to be standardised and patients are often positioned visually in positions healthcare practitioners think are comfortable for them. Positioning based on objective data could reduce the likelihood of PI development. Our interviewees noted the following:

". . .chest area, this is always a problem for women, chest and breasts." (P2)

". . .prone position we have to concentrate on the face and knees, feet, hands, shoulders, breasts." (P4)

"The difficulty we have it's not every patient is the same shape so trying to find a particular setup that works for a variety of shapes and sizes is the real challenge." (P7)

". . .anything that's going to be in direct contact with the surgical beds are relatively hard and they need to be to maintain the patients still. So, something that would keep them still, yet also be soft enough in the right places would certainly being useful thing." (P8)

"We position them in what we feel looks comfortable, what we would think would be comfortable." (P9)

Theme 3: The need for radiolucency

The need to complete x-rays is a common task during surgery, especially during lengthy spinal

and orthopedic surgeries. As such, a key design requirement established from the interviews was the need for any new PI alleviation device to be radiolucent to ensure that clear, unobstructed x-ray or CT images can be obtained. Our interviewees expressed the following:

". . .ideally radiolucent, that's a massive thing in getting the surgeons on board to use it. If it's in the way of the x-ray it's not coming in, so that's big thing." (P1)

". . .for the spinal point of view we are operating on the back of the body and then front is the pressure areas, how to do that you need radiolucent, you need everything radiolucent, the table, everything, when we x ray all these points everything should be radiolucent." (P3)

"Yes, yeah definitely for orthopedics yeah." (P5)

Theme 4: Potential users and interaction

A key theme that emerged from the interviews concerned which member of staff would use a PI monitoring device. There was no consistent answer to this question, and it became apparent that this type of device should be simple and easy to operate by any member of the surgical team, be it the anesthetists, surgeons, nurses, etc. Our interviewees made several remarks:

". . .when I'm working with the doctors and anesthetists we have to make sure that the patient is very safe because the surgeon will be concentrating on the actual surgery, they'll be focused on the procedure, at that time they will not be seeing what's going on underneath the drape." (P6)

"I think we should create device maybe to understand that pressure is building up, skin is getting damaged." (P6)

"It should be simple to use so that it can be applied for a range of nursing staff, help care assistance and ODPs." (P7)

"So, I would like it to be nice and simple, it would need to not interfere with x-ray imaging, CT imaging" (P7)

"It would probably be us [anesthetists] to interact with it, most of the patient relation things that we interact with during the case are our responsibilities." (P8)

Theme 5: Design considerations and attitudes on how the device may be perceived

Based on our interviews, we established key design considerations and requirements and defined common features and functions. Given that operating theatres are busy environments, the systems shouldn't add further distractions or affect the safety of the patient being treated. Determining ongoing pressure visually with minimum interaction and an alert system are necessities. From the patient perspective, the device must be capable of providing relief from the moment the patient is placed intraoperatively until they are moved to the recovery room.

Fundamentally, any new system or device should be as simple, reusable, and intuitive as possible, therefore, a plug-and-play system with little training or technical assistance is a must. New device adoption is more likely if the device simply tells the user what to do and when there are issues. Our interviewees shared the following:

"Now if you're going to use something which is going to be reusable for a time that would be beneficial." (P6)

"so, it shouldn't interfere with any of the current technology in theatres. It should be simple to use so that it can be applied for a range of nursing staff, help care assistance and ODPs. . . ideally it should be affordable, so we can use it within the NHS and it should work with current tables and systems where possible. . ." (P7)

"It needs to be reliable because one thing that particularly as a surgeon we do use stuff we trust, once that trust is broken is very difficult to build that up again, so with any new technology the moment something goes wrong it creates a doubt in your mind and your very unhappy because at the end of the day you're responsible for everything. . ." (P7)

"So, a lot of our beds have got a CPR mode on them, do we need a CPR mode on this thing? Because if it is soft, we can't do chest compressions. What is the weight limit going to be?" (P9)

DISCUSSION

A key product requirement was the need for the device to be retrofitted onto different operating tables and surfaces. This is due to NHS Trusts systematically updating damaged and outdated operating tables and equipment. Our initial research and investigation into the realised themes revealed that identifying areas of the body most prone to PI development was a key consideration. Previous research conducted by Sizer[18] demonstrated that the forehead and chin are key areas of the body to focus upon; several leading spinal surgeons and consultants we interviewed validated this finding. Further research revealed that the chest is another area of focus, especially in longer surgeries. Women with larger breasts and men with larger chests are more vulnerable; in worst-case scenarios, deaths can occur due to unrelieved pressure in these areas. A key design consideration when focusing on the chest area is the need for any developed product to be radiolucent due to the need for regular and repetitive x-rays taken during spinal surgery.

When positioning patients in PI-prone positions, most clinicians visually gauge how comfortable a patient is. The patient's comfort level may be difficult to establish, thus affecting the patient's safety. All interviewees said patients with large breasts or chests that sit uncomfortably on the surfaces below present difficult scenarios during surgery. Overall, the interviewees provided a range of insights and preferences, which directed the key design considerations presented in Table 3.

Design teams must consider that a wide range of clinical healthcare professionals work within the intraoperative environment. Clinicians must work together to maintain different aspects of the patient's wellbeing, and they use different assessments and scales to evaluate the patient's wellbeing throughout surgery. Due to prone positioning being high risk, we sought to understand

the measures clinical staff use. We discovered that surgeons and operating department practitioners (ODPs) will generally position the patient in a way that they gauge as visually comfortable. This is precisely where the implementation of a device with a closed-loop system could help to limit the underlying pressure that occurs during positioning. Similarly, patient positioning varies according to the type of surgery, the surgeon, and depends on access to the surgical site rather than patient comfort. Other positions such as supine and lateral still have potential for PIs to develop, but these PIs will occur in bony prominences of the body, which necessitates the need for specific pads designed for each surgical position. One of the most interesting design considerations identified was the possible need for a CPR mode in emergency scenarios. A simplistic user interface design was another area of focus with a need to have a self-explanatory solution (Table 4).

Although this research predominantly focuses on developing a closed-loop system for spinal surgery, after successful testing, the product can be adapted for other surgeries with patients in different positions. However, different design considerations and alterations would be necessary to ensure that accurate monitoring can achieved based on monitoring different areas of the body. In addition, possible limitations to the use of the device include setup time and operator training. However, the reduction of incidence of postoperative pressure sores and subsequent care required could be mitigated easily by a slight increase in pre-operation setup.

CONCLUSION

We conducted semi-structured interviews to gather interviewees' opinions about managing, monitoring, and alleviating the effects of PIs. Accurate monitoring of PIs is a common issue for the entire perioperative and surgical team. For spinal surgery, the lead consultant/clinician within the surgical environment oversees patient care, although the management of PIs should be a shared task between the entire team, and most interviewees shared this viewpoint. We discovered multiple themes, but fundamentally device simplicity, radiolucency, and an intuitive graphical data visualisation interface were priorities for any new device or system. Although improved products are beneficial, accurate patient positioning is essential and all interviewees wanted a product that could help this process. Correct positioning before surgery will reduce the likelihood of pressure-related injuries. The defined design requirements derived from the interviews helped to generate a product design specification so a product could to be designed and developed into a functional advanced prototype for initial testing and bench studies. Next steps include sharing the outcomes of the critical design elements with the study participants and further validating the PDS. External review with a medical device company is ongoing to develop the proposed product and test it within the clinical setting.

REFERENCES

1. Agrawal K, Chauhan N. Pressure ulcers: Back to the basics. Indian journal of plastic surgery: official publication of the Association of Plastic Surgeons of India. 2012 May;45(2):244.
2. Padula WV, Pronovost PJ, Makic MB, et al. Value of hospital resources for effective pressure injury prevention: a cost-effectiveness analysis. BMJ Qual Saf. 2019 Feb 1;28(2):132–41.
3. Lim ML, Ang SY. Impact of hospital-acquired pressure injuries on hospital costs-experience

of a tertiary hospital in Singapore. Wound Practice & Research: Journal of the Australian Wound Management Association. 2017 Mar;25(1):42.
4. Nguyen KH, Chaboyer W, Whitty JA. Pressure injury in Australian public hospitals: a cost-of-illness study. Australian Health Review. 2015 Jul 6;39(3):329–36.
5. Jackson D, Durrant L, Bishop E, et al. Pain associated with pressure injury: A qualitative study of community-based, home-dwelling individuals. Journal of advanced nursing. 2017 Dec;73(12):3061–9.
6. Farid KJ. Applying observations from forensic science to understanding the development of pressure ulcers. Ostomy/wound management. 2007 Apr;53(4):26–8.
7. Salcido R, Popescu A, Ahn C. Animal models in pressure ulcer research. J Spinal Cord Med. 2007;30(2):107-16. doi: 10.1080/10790268.2007.11753921
8. Bennett G, Dealey C, Posnett J. The cost of pressure ulcers in the UK. Age and Ageing. 2004 May 1;33(3):230–5.
9. Fulbrook P, Miles S, Coyer F. Prevalence of pressure injury in adults presenting to the emergency department by ambulance. Australian Critical Care. 2019 Nov 1;32(6):509–14.
10. Schuurman JP, Schoonhoven L, Defloor T. Economic Evaluation of Pressure Ulcer Care: A Cost Minimization Analysis of Preventive Strategies. Nursing Economics. 2009 Nov;27(6):390–415.
11. Amoore J, Ingram P. Learning from adverse incidents involving medical devices. BMJ. 2002 Aug 3;325(7358):272–5.
12. Jacobson B, Murray A. Medical devices: Use and Safety. New York: Elsevier, Limited. 2007.
13. Aiken LH, Clarke SP, Sloane DM, et al. Hospital nurse staffing and patient mortality, nurse burnout, and job dissatisfaction. Jama. 2002 Oct 23;288(16):1987–93.
14. Mark BA, Harless DW, McCue M, et al. A longitudinal examination of hospital registered nurse staffing and quality of care. Health services research. 2004 Apr;39(2):279–300.
15. Tourangeau AE, Doran DM, Hall LM, et al. Impact of hospital nursing care on 30-day mortality for acute medical patients. Journal of advanced nursing. 2007 Jan;57(1):32–44.
16. Tarnow-Mordi WO, Hau C, Warden A, et al. Hospital mortality in relation to staff workload: a 4-year study in an adult intensive-care unit. The Lancet. 2000 Jul 15;356(9225):185–9.
17. Van Den Bos J, Rustagi K, Gray T, et al. The $17.1 billion problem: the annual cost of measurable medical errors. Health Affairs. 2011 Apr 1;30(4):596–603.
18. Sizer N. Design of Pressure Monitoring and Alleviating Device Used in Surgery and Intense Care Unit [Undergraduate Thesis]. Nottingham: Nottingham Trent University; 2018.

ACKNOWLEDGEMENTS

The authors would like to acknowledge the support provided by the Product Design Department and the Medical Engineering Design Research Group at Nottingham Trent University.

PEER REVIEW

Not commissioned. Externally peer reviewed.

CONFLICTS OF INTEREST

The authors declare that they have no competing interests.

FUNDING

None

ETHICS COMMITTEE APPROVAL

Ethics approval for this project was received from Nottingham Trent University Joint Inter College Ethics Committee (JICEC) granted on 29/03/2019.

Table 1: Interviewee survey data

Participant ID	Profession	Grade	Years in Profession	Age Category	Training For PIP Management
P1	Clinical Nurse	6	6–10	40–55	Yes
P2	Surgeon	ST6	10–15	35–40	Yes
P3	Surgeon	Consultant	10–15	55+	No
P4	Other: ODP (Theatre Practitioner)	5	3–6	30–35	No
P5	Clinical Nurse	Unknown	15+	40–45	Yes
P6	Clinical Nurse	5	3–6	25–30	Yes
P7	Surgeon	Consultant	10–15	35–40	Yes
P8	Anesthetist	Consultant	10–15	40–45	Yes
P9	Anesthetist	Consultant	15+	40–45	Yes

Table 2: Coding themes to develop critical design considerations

Themes/Codes	Theme Words	Number of Times Referenced Throughout All Interviews
Current Devices/Systems	Pads; Tables; Support; Surfaces	7
Current Risk Assessment/Scale	Risk; Scale; Monitoring; Assessment; Method	3
Design Consideration	Design; Features, Elements; Areas of incidence/PIs; Regulations; Rules; Safety; Interface	14
Difficult Aspects of Surgery	Time; Length; Type; Positioning; Placement; Monitoring; Surgery	13
Potential Users	Preferences; Attitudes, Interactions; User;	3
Radiolucency	X-ray, Radiolucent, Radiopaque	7

Table 3: Design requirements derived from interviews

Design Requirement ID	Design Requirement Description
DR1	The device must not distract the user when in operation.
DR2	The device must allow the surgical and anesthetic team to determine the ongoing pressure visually with minimum interaction.
DR3	The device must provide relief from the moment the patient is placed intraoperatively until they are moved to the recovery room.
DR4	The device must be a "plug and play" device that offers minimum training and technical assistance.
DR5	The device must contain a "CPR" mode that deflates the pads allowing for easy compressions in case of an emergency.
DR6	The product must actuate at least every 15 minutes as pressure build up can occur in 30 minutes.
DR7	The materials used must be compliant with medical standards and regulations.
DR8	The materials used for actuation method must be radiolucent.
DR9	The device must undergo clinical tests and trials prior to commercialisation.
DR10	The device must be able to withstand multiple uses and be used as an intermittent device.
DR11	The device must provide a straight forward user interface that is easy for any user to use.
DR12	The device must be used to assist the user with monitoring and alleviating of PIs intraoperatively.

Table 4: Summarised product design specification (PDS)

Specification Category	Critical Specification Points
Performance	1. The product must actively reduce pressure in real time when pressure pads are positioned on the forehead, chin, and chest. 2. The device must provide relief from the moment the patient is placed on the device intraoperatively until they are moved to the recovery room, postoperatively. 3. The product must be self-explanatory and not distract the user when in operation. 4. The product must actuate at least every 15 minutes to reduce developing pressure. 5. The product must allow the surgical team to view the ongoing pressure on a simplistic graphical user interface with minimum interaction.
Material	1. Materials must be compliant with regulatory medical standards, including BS EN 60601:2010 and ISO 13485:2016. 2. Materials used must be radiolucent to x-rays. 3. Actuation material must be medical and food grade safe. 4. Materials specified must be easily sterilisable or autoclavable.
Safety	1. The product must be flame retardant and comply with fire safety requirements in the operating room. 2. The product must use non-toxic materials. 3. The device must contain a failsafe to completely shut off in the event of an emergency. 4. The device to contain a "CPR" mode that deflates pressure relieving pads and create a surface that allows easy compressions. 5. The user must follow the instructions displayed on a simplistic graphical user interface and operation instructions supplied with the device when purchased. 6. The product must comply with BS EN 60601-1-11:2010 for medical electrical systems.
Maintenance	1. The pressure-relieving pads must require no servicing and once used within their lifecycle can be disposed of and replaced. 2. The monitoring system requires maintenance every 6 months with recalibration and updates needed for hardware and software.
Environment	1. The product is to be used only within the intraoperative environment. 2. The product is to be used within direct contact of the patient's skin. 3. The product is to be retrofitted onto existing devices. 4. The pressure relieving pads must be stored in a vacuum sealed bag and only unsealed when required or to replace an old pressure relieving pads. 5. The pressure relieving pads need to be sterilised after each use.