NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Medical technologies guidance

Assessment report summary

MoorLDI2-BI: a laser Doppler blood flow imager for burn wound assessment

This assessment report summary has been prepared by the NICE Evaluation Pathway team to summarise the evidence evaluated by the External Assessment Centre and highlight key issues and uncertainties. The summary forms part of the information considered by the Medical Technologies Advisory Committee (MTAC) in deciding on its recommendations on the technology.

This report also contains:

Appendix A: Sources of evidence
Appendix B: Comments from professional bodies
Appendix C: Comments from patient organisations
Appendix D: Manufacturer’s comments on the Assessment Report and the External Assessment Centre’s responses

1 The technology

The moorLDI2-BI is a laser doppler blood flow imaging system for the non-invasive mapping of blood flow in an area of skin which has been burned. This can be used to support clinical decisions on burn wound dressings and grafting requirements.

The moorLDI2-BI includes a scan head, scan controller and a touch-screen panel computer, all mounted on a mobile stand that can be used in a ward, operating theatre, consulting room or special laser room. The scan head is mounted on a flexible arm and linked to the computer which has a bespoke software package.

In laser doppler blood flow imaging, a low-power laser beam is directed at the burn wound using a mirror. It is scanned across the burn wound area by rotating the mirror about vertical and horizontal axes. There is no direct contact with the tissue that is being assessed and the laser beam penetrates the full dermis. Laser light scattered from moving blood cells in the tissue undergoes a doppler frequency shift, the average frequency shift is proportional to the average speed of the blood cells. Some of the scattered laser light is collected by the mirror and then focussed by light-collecting lenses on photodiode detectors. The resulting photocurrent is processed to calculate the blood flow in the tissue and this information is displayed as a colour-coded map of the burn wound area. Small (part of a finger) to large (torso) burn wounds can be mapped in this way. Depending on the size of the burn wound and required resolution of the image, the scan takes from 80 seconds to about 5 minutes .Results are displayed as a colour-coded blood flow image and a colour video image of the burn wound. Healing potential results based on the blood flow image are calculated and reported in three categories: < 14 days, 14–21 days and > 21 days.

The moorLDI2-BI is CE marked and registered with the FDA (510K K060976) and with Canada Health (licence number 75477) for use as a burn wound assessment imager.

There have been no published adverse events associated with this device. All operators should be are trained in laser safety.

2 Proposed use of the technology

2.1 Disease or condition

There are four levels of burn wound. Epidermal (level 1) and superficial dermal burn wounds (level 2) tend to heal without scarring or surgical intervention within 21 days. Deep dermal (level 3) and full thickness burn wounds (level 4) heal quicker and with less complications if they are promptly excised and grafted. The moorLDI2-BI is most useful for distinguishing between superficial dermal (level 2) and deep dermal (level 3) burn wounds.

2.2 Patient group

According to a report from the National Burn Care Review Committee (2002) about 175,000 people in the UK attend accident and emergency departments each year with burn wounds from various causes. This represents about 1% of all accident and emergency department admissions. About 16,000 people with burn wounds are admitted to hospital each year and about 1000 of these need active fluid resuscitation. The average yearly number of burns-related deaths is 300.

Children under the age of 5 and adults over the age of 75 are at the highest risk of burn wounds. Young children have a higher risk of scarring. People over the age of 75 often have other medical conditions and higher risks associated with surgery.

2.3 Current management

The assessment of burn wound depth is key in deciding burn care treatment. However, it is difficult to distinguish the more superficial dermal burns which will heal well, from deep dermal burns, where a prolonged healing time will result in hypertrophic scarring, especially at the early stage of treatment. The diagnosis of burn wound depth and its associated healing potential is particularly difficult in children because of the prevalence of mixed depth scald burns, their thin skin and their unpredictable response to injury. Strict categorisation of burn wound depth is complicated by burn wound conversion (where superficial burns progress into deeper wounds because of the death of severely injured cells), oedema and tissue hypoxia.

Clinical evaluation is the most widely used method of assessing burn wound depth and healing potential. This method is based on the subjective, visual and tactile assessment of the external characteristics of a burn wound. The accuracy of this method depends on the experience of the clinician.

2.4 Proposed management with new technology

The technology is most relevant to treatment decisions for patients with intermediate level burns. The moorLDI2-BI can be used 48–72 hours postburn to assess the burn wound depth and healing potential. This information can be used to develop a burn wound treatment plan.

2.5 Equality and diversity issues

No equality and diversity issues have been identified.

3 Issues for consideration by the Committee

In summary, the clinical evidence demonstrated that use of the moorLDI2-BI in addition to clinical evaluation can improve the accuracy of burn wound assessment compared with clinical evaluation alone. This means that burn wound management decisions can be made sooner. The cost model reported a saving of £1248 per patient scanned based on an operation cost of £2043 and the purchase option (£1232 per patient scanned for the lease option). It was assumed that use of the moorLDI2-BI would reduce the number of operations needed by 17% and save an average of 2 days hospital stay per patient scanned.

3.1 Main issues

- It was considered that there is good clinical evidence, primarily from observational studies and audits, that information from moorLDI2-BI scans increases the accuracy of predicting wound healing and also that this information can be used to facilitate an earlier decision to operate.
- Timing of moorLDI2-BI scans is important because burn wounds change rapidly in the first 48 hours after injury. The evidence suggests that the best time for scanning is 48–72 hours after the burn injury but the device can be used up to 5 days after injury.
- There are many factors that are known to have a detrimental effect on the moorLDI2-BI images or their interpretation, including infected wounds, patient movement, old scars and tattoos. These are discussed in the literature, (for example La Hei et al. [2006] and Montrey et al. [in press])

and also recognised by the manufacturer in their user guide. Therefore, moorLDI2-BI images should only be taken and interpreted by a trained clinician. La Hei et al. (2006) refer to a short learning curve for an assessor of the laser doppler images whose accuracy increased from 83% (15/18) to 96% (73/76) accuracy by the end of the study.

- No evidence was found on the other outcomes specified in the scope, that is reduction in wound dressings or wound complications.
- All analyses showed moorLDI2-BI to be cost saving when used as an aid to clinical evaluation for diagnosing burn wound depth and healing potential for intermediate burns and making treatment decisions.
- The estimated hourly operating cost for burn wounds in the manufacturer’s base case (£4593) was considered too high. A lower hourly cost of £2043 was considered more accurate by the External Assessment Centre. However, using moorLDI2-BI remained cost saving at £1248 per patient scanned (for the purchase option).
- The cost analysis only included the additional costs and savings associated with the use of moorLDI2-BI alongside clinical evaluation of intermediate burn wounds at initial admittance and did not include longer-term cost consequences such as follow-up appointments for active scar management or pressure garments costs.
- It was assumed in the manufacturer’s cost analysis that each patient scanned would benefit from a 2-day reduction in length of hospital stay. An additional analysis showed that even when there was no reduction in length of hospital stay, if a 17% reduction in operations was achieved (at a cost of £2043 per hour), using moorLDI2-BI was still cost saving.

4 The evidence

4.1 Identification of evidence

The manufacturer’s submission identified 21 studies. Ten of these were excluded by the manufacturer because they had not been peer reviewed or published.

Searches by the External Assessment Centre identified an additional seven studies (see appendix 1 of the Assessment Report): three reviews, one economic study and three observational studies. The External Assessment Centre reviewed these studies and found that none of the additional studies contradicted the outcomes of the studies included in the manufacturer's submission and, in general, supported the use of laser doppler imaging for the assessment of burn wounds.

4.2 Summary of evidence of clinical benefit

The most relevant evidence for moorLDI2-BI came from 10 published studies and one study submitted for publication (two non-randomised studies, five observational studies, one blinded trial and two audits). Baker et al. (2009) was an in-depth statistical analysis of data from the Monstrey et al. (in press) study. Brown et al. (1998) was a pilot animal study and was not considered because of the more relevant clinical evidence available.

The clinical effectiveness of the device is described by the accuracy of of the clinician in predicting healing time and in facilitating earlier surgical decisions using the information from the scans.

.

Accuracy of the moorLDI2-BI in predicting healing time

The accuracy of the moorLDI2-BI in the assessment of burn wounds was examined in eight studies with a variety of criteria including ability to predict healing within 14 or 21 days and by comparison with clinical and histological assessment of burn depth.

Pape et al. (2001) reported an audit of wound healing at 21 days for 76 intermediate depth wounds in 48 patients. Results showed moorLDI2-BI to be 97% accurate (74/76) in predicting wound healing at 21 days compared with 70% (53/76) for clinical evaluation.

Hoeksema et al. (2009) investigated the changing accuracies of laser doppler imaging and clinical evaluation over days 0, 1, 3, 5 and 8 postinjury. Forty patients with intermediate depth burn wounds were scanned using the moorLDI2-BI. The final assessment of wound depth showed a deep partial or full thickness burn in 14 patients, 12 of whom had a skin graft, and a superficial dermal burn in 26 patients. Accuracies on days 0, 1, 3, 5 and 8 were 41%, 62%, 53%, 71% and 100% by clinical evaluation; and 55%, 80%, 95%, 97% and 100% by laser doppler imaging. The burn wound depth accuracy using moorLDI2-BI was significantly higher than clinical evaluation on day 3 ($p < 0.001$) and day 5 ($p = 0.005$).

Jeng et al. (2003) described a prospective blinded trial comparing the use of laser doppler imaging versus clinical evaluation by an experienced burn wound surgeon in deciding whether or not to operate. Forty-one wounds of indeterminate depth were analysed. There was agreement on wound depth between laser doppler imaging and clinical evaluation in 56% (23/41) of cases. The surgeon’s determination of burn wound depth was accurate in 71% (15/21) of the 21 biopsied wounds. The moorLDI2-BI was 100% (7/7) accurate in wounds where the laser doppler scan determined a need for excision.

Monstrey et al. (in press) compared healing prediction based on interpretation of a moorLDI2-BI scan with actual wound healing as recorded photographically for 433 burn wounds in 139 patients. This assessment found an overall accuracy for the moorLDI2-BI of 96.3% with sensitivity of 94.5%, specificity 97.2%, positive predicitve value of 94.5% and negative predictive value of 97.2%.

La Hei et al. (2006) scanned 50 burns in 31 paediatric patients. Two experienced burn wound surgeons independently reviewed burn scans and photos plus a basic history without meeting the patient. One surgeon identified 82 areas of differing depth and the other identified 76 areas and both surgeons predicted healing times (‘superficial heal: < 14 days’ or ‘deep heal: > 14 days or graft ‘). Overall, 97% (154/158) of predicted healing times were correct with four deep burn areas incorrectly predicted to heal within 14 days. No superficial wounds were reported as deep.

Holland et al. (2002) investigated the ability of laser doppler imaging to evaluate burn wound depth in children by scanning 58 patients and comparing the predicted outcome (from either the scan or from clinical evaluation) with the subsequent wound outcome at 12 days. One patient was excluded because there was too much movement for the scan to be interpreted. Clinical evaluation correctly identified 66% (19/29) of deep partial or full thickness burns between 36 and 72 hours after injury compared with 90% (26/29) using moorLDI2-BI scans. MoorLDI2-BI scans were also more specific, correctly diagnosing 96% (27/28) of superficial partial thickness burns compared with 71% (20/28) from clinical evaluation alone.

Niazi et al. (1993) reported results from a pilot study that analysed 17 burn wounds in 13 patients. Punch biopsies were used to confirm burn wound depth at 72 hours postburn. Clinical evaluation was correct for 41% (7/17) burns, overestimated depth in 41% (7/17) and underestimated depth in 18% (3/17). Burn wound depth assessed from moorLDI2-BI scans was correct for 100% (17/17) of wounds.

Mill et al. (2009) compared moorLDI2-BI image colours with wound outcomes in 85 burns on 48 children. The predominant colour of the scan was found to be significantly related to re-epithelialisation ($p < 0.003$), grafting ($p < 0.001$) and active scar management ($p = 0.003$).

Time to surgical decisions

Two studies provide evidence that using the moorLDI2-BI is associated with making appropriate skin grafting decisions sooner.

Jeng et al. (2003) described a prospective blinded trial that compared the use of laser doppler imaging with clinical evaluation of an experienced burn wound surgeon in determining the decision to operate or not on 41 burn wounds of indeterminate depth. There was agreement between the imaging and clinical evaluation on wound depth in 56% (23/41) of cases. In these cases the use of moorLDI2-BI saved a median of 2 days (minimum = 0, maximum = 4) compared with the time the surgeon took to determine wound depth.

Kim et al. (2010) describe a non-randomised cohort study of 196 children with an acute burn injury that required surgical treatment. Laser doppler imaging was used in addition to clinical evaluation on 49% (96/196) and 51% (100/196) were assessed by clinical evaluation alone. The mean time from date of injury to decision making for grafting procedure was 8.9 days in the moorLDI2-BI group compared with 11.6 days in the group assessed by clinical evaluation alone (p = 0.01).

4.3 Summary of economic evidence

No relevant economic studies of moorLDI2-BI were identified. The economic evidence comprises a new cost analysis to assess the costs and savings to the NHS from the use of moorLDI2-BI for the assessment of burn wounds of indeterminate depth.

4.3.1 Model Structure

Clinical evaluation alone was considered to be the most relevant NHS comparator for the cost analysis.

The manufacturer did not submit a comparative cost analysis for burn wound assessment (moorLDI2-BI and clinical evaluation compared with clinical evaluation alone) that included all the healthcare costs in the care pathway associated with the diagnosis and treatment of burn wounds. It assumed that use of moorLDI2-BI did not affect how clinical evaluation was done (because it is an aid rather than a replacement) and so costs included in the analysis should only be those in addition to clinical evaluation.

The cost analysis balanced the additional equipment and staff costs of burn wound assessment with moorLDI2-BI against the cost benefits from earlier more appropriate treatment decisions based on information from the moorLDI2-BI scans. The annual number of patients who are admitted to the 28 specialist burns centres was estimated at 10,000 based on Enoch et al. (2009). It was assumed that 70% of these patients would have intermediate burn wounds and be scanned, based on the evidence (Enoch et al. 2009). To calculate a per patient cost for purchasing or leasing, and maintaining the moorLDI2-BI, it was assumed that each centre would have one imager so the annual device costs were multiplied by the number of burns centres and then divided by the 7000 patients to be scanned. The additional nurse time for operating moorLDI2-BI and the clinician time for interpreting results was included for each patient.

4.3.2 Costs

The moorLDI2-BI can be purchased at a cost of approximately £50,000 plus a servicing cost of approximately £8,000 per year or it can be leased at a cost of approximately £22,000 per year.

The cost savings included in the manufacturer's cost analysis were for reducing the number of skin graft operations and length of hospital stay from earlier and more accurate diagnosis of burn wound depth and healing potential.

The value included in the base case analysis for reduced length of hospital stay was 2 bed days and the percentage of operations saved was 17%. These parameter values were based on clinical trials that evaluated the time to diagnose and accuracy of burn depth using laser doppler imaging and clinical assessment, compared with clinical assessment (Pape et al. [2001], Jeng et al. [2003]). In the model the cost per hour for an operation to treat burn wounds was £4593, based on the figures presented in Hemington-Gorse et al. (2009). The External Assessment Centre considered this to be too high and a lower figure of £2043 per hour was derived, in consultation with an expert adviser. The breakdown of the hourly cost for an operation to treat a burn wound is presented in table 1.

The additional healthcare costs associated with the use of moorLDI2-BI were nurse time taken to operate the imager and clinician time beyond clinical evaluation to interpret the results from the imager. In the base case, nurse operating time was 60 minutes and interpretation of results took 15 minutes.

Table 1. Hourly cost for an operation to treat a burn wound

Resource	Cost per hour	Total cost
2 consultants 1 anaesthetic, 1 surgical	£170*	£340
2 registrars 1 anaesthetic, 1 surgical	£61*	£122
3 nurses 1 anaesthetic, 2 surgical	£45*	£135
1 healthcare assistant	£16*	£16
Theatre running costs	£993***	£1430
Hourly cost of theatre with staff		**£2043**

*Unit cost of Health and Social Care 2009
** Griffiths *et al*. 2006 (plus 20% + 20%)

It was assumed that each of the 28 centres would incur a training cost of £3416 every 2 years. This would train one clinician, two registrars and three nurses over 2 days.

The additional resource use and costs associated with the introduction of moorLDI2-BI used in the cost model are presented in table 2. This includes the value used in the base-case analysis for each parameter and the range of values that could be analysed in the sensitivity analysis.

Table 2: Cost and resource use implications to the NHS

Parameter	Range	Base case
Number of moorLDI2 systems	25 to 64	28
Leasing cost	-	£22,000
Purchasing cost	-	£50,000
Servicing cost	-	£8000
Nurse operation time (min)	30 to 90	60
Nurse hourly rate	-	£45
Clinician interpretation time (min)	5 to 30	15
Clinician hourly rate	-	£170
Registrar hourly rate	-	£61
Administration cost	-	£15
NHS staff training cost	-	£3416

Table 3 represents the base-case value and range for the parameters that were used to calculate the potential cost savings from improved treatment decisions associated with the use of moorLDI2-BI.

Table 3: Parameters for calculating the cost benefits to the NHS

Parameter	Range	Base case
Number of patients admitted	8000–16,000	10,000
Percentage of patients scanned	10–100%	70%
Percentage of adults scanned	60–90%	60%
Percentage of children scanned	10–40%	40%
Number of bed days saved	2–3 days	2
Percentage of operations saved	10–30%	17%
Average time of operation	1–4 hours	1
Cost of day bed adult	£320–772	£378
Cost of day bed child	£320–794	£794
Cost of operation per hour	£3000–5000	£4593

The time horizon for the analysis was the initial period of hospitalisation, which was considered to be 7–8 days. No longer-term cost consequences were included in the analysis. The manufacturer described but did not quantify the longer-term cost benefits from improved treatment decisions. Avoiding unnecessary grafting or making earlier decisions to graft could avoid the need for long durations of prophylactic antiscar therapy or any therapy. Antiscar therapy includes fitting pressure garments and follow-up hospital appointments.

No adverse events have been reported from the use of moorLDI2-BI so no adverse event costs were included in the analysis.

4.3.3 Sensitivity analyses

The assumptions in the cost model addressed by the manufacturer in the sensitivity analyses were: the percentage of admitted patients that would have intermediate burns, the number of bed days saved and the average operation time saved.

A set of six scenario analyses including the base case were also carried out. These included a best- and worst-case scenario using the ranges for the proportion of patients scanned, number of bed days saved and operating time.

An analysis of the number of patients that need to be scanned to break even for the lease and purchase options was also undertaken.

Additional analyses were undertaken by the External Assessment Centre to assess the impact of changing the hourly cost for an operation to £2043, changing the proportion of patients scanned to 30%, modelling use of moorLDI2-BI in five adult burns centres instead of 28 burns centres and modelling use in five paediatric burns centres instead of 28 centres.

4.3.4 Results

The cost saving per patient scanned from the use of moorLDI2-BI alongside clinical evaluation compared with clinical evaluation alone was £1681. This is based on the purchase option for moorLDI2-BI at a cost of £50,000, using an hourly cost of £4593 per operation. The lease option reduces cost savings to £1665 per patient scanned.

When a more conservative hourly cost of £2043 per operation is used, the cost saving per patient scanned is £1248 for the purchase option and £1232 for the lease option.

The worst-case scenario for the purchase option resulted in a cost saving of £1167 per patient and the best-case scenario resulted in a saving of £4594 per patient scanned. All analyses presented in the Assessment Report showed that the total cost savings from reducing hospital length of stay and number of operations were greater than the costs associated with the purchase and operation of moorLDI2-BI.

An area of uncertainty in the cost analyses was the impact on the cost per patient scanned of the assumption that all patients scanned would achieve on average a 2-day reduction in length of hospital stay. An additional analysis was undertaken that modelled the assumption that there was no length of stay reduction from using moorLDI2-BI. This demonstrated that moorLDI2-BI would still achieve a cost saving of £159 per patient scanned when a 17% reduction in operations is assumed (based on the purchase option and an hourly cost of £2043 per operation).

5 Ongoing research

No details of any ongoing studies were submitted by the manufacturer. There were five presentations at the ANZBA meeting (Darwin, Australia 5–8 Oct, 2010) on studies involving moorLDI2-BI. It is likely these will be published within the next 12 months.

Two papers have been submitted for publication in Burns Journal:

Pape SA, Baker RD, Wilson D et al. (pre-publication). Burn wound healing time assessed by laser Doppler imaging (LDI) Part1: derivation of a dedicated colour code for image interpretation

Monstrey S.M, Hoeksema H, Baker R.D. et al. (pre-publication). Burn wound healing time assessed by laser Doppler imaging (LDI) Part2: validation of a dedicated colour code for image interpretation

6 Authors

This section will be removed before the assessment report summary is placed on the website.

Bernice Dillon, Lizzy Latimer, NICE Evaluation Pathway Programme for Medical Technologies

November 2010

Appendix A: Sources of evidence considered in the preparation of the assessment report summary

A Kazantzi M, Emerton D., Lawinski C, KCARE, moorLDI2-BI a laser Doppler blood flow imager for burn wound assessment. October 2010

B Submissions from the following manufacturer/sponsors: Moor Instruments Ltd.

C References

1. Baker RD, Weinand C, Jeng JC, et al. (2009) Using ordinal logistic regression to evaluate the performance of laser-Doppler predictions of burn-healing time. BMC Medical Research Methodology 9:11, ISSN 1471–2288
2. Brown RF, Rice P, Bennett NJ (1998) The use of laser Doppler imaging as an aid in clinical management decision making in the treatment of vesicant burns. Burns 24: 692–8.
3. Enoch S, Roshan A, Shah M (2009) Emergency and early management of burns and scalds. BMJ 338: b1037.
4. Hemington-Gorse SJ, Potokar TS, Drew PJ et al. (2009) Burn care costing: The Welsh experience. Burns 35: 378–82.
5. Hoeksema H, Van de Sijpe K, Tondu T et al. (2009) Accuracy of early burn depth assessment by laser Doppler imaging on different days post burn. Burns 35(1): 36–45.
6. Holland AJ, Martin HC, Cass DT (2002) Laser Doppler imaging prediction of burn wound outcome in children. Burns 28(1): 11–7.
7. Jeng JC, Clarke TJ, Bridgeman A et al. (2003) Laser Doppler Imaging Determines Need for Excision and Grafting in Advance of Clinical Judgement: A Prospective Blinded Trial. Burns 29: 665–70.
8. Kim LH, Ward D, Lam L et al. (2010) The Impact of Laser Doppler Imaging on Time to Grafting Decisions in Pediatric Burns. Journal of Burn Care Research 31: 328–32.
9. La Hei ER, Holland AJ, Martin HC (2006) Laser Doppler Imaging of Paediatric Burns: Burn wound outcome can be predicted independent of clinical examination. Burns 32(5) 550–3.
10. Mill J, Cuttle L, Harkin DG et al. (2009) Laser Doppler imaging in a paediatric burns population. Burns 35(6), 824–31.
11. Monstrey SM, Hoeksema H, Baker RD et al. (2010) Burn wound healing time assessed by laser Doppler imaging. Part 2: Validation of a dedicated colour code for image. Interpretation Burns (In Press).

National Burn Care Review Committee [on line] (2002) ‘Standards and Strategy for burn Care: A review of burn care in the British Isles’. Committee Report. Available from http://www.nbcg.nhs.uk/national-burn-care-review/

12. Niazi ZBM, Essex TJH, Papini R et al. (1993) New laser Doppler scanner, a valuable adjunct in burn depth assessment. Burns 19(6): 485–9.
13. Pape SA, Skouras CA, Byrne PO (2001) An audit of the use of laser Doppler imaging (LDI) in the assessment of burns of intermediate depth. Burns 27: 233–9.

Appendix B: Comments from professional bodies

British Burns Association
Dr. Steven Jeffery (Consultant Plastic Surgeon)

British Association of Plastic Reconstructive and Aesthetic Surgeons (BAPRAS)
Mrs Sarah Pape (Consultant Plastic Surgeon) has published research using this technology.
Mr. David Wilson (Consultant Burns Surgeon)

- All three advisers have used the technology.
- Two advisers consider it is a significant modification of an existing technology and one adviser considers it thoroughly novel.
- The three advisers agree that it is primarily used for the accurate assessment of burn wounds thereby allowing decisions regarding surgery to be made more easily.
- Dr Pape refers to the 97–9% accuracy of laser doppler imaging for intermediate depth burns and of a variety of comparators including clinical evaluation (50%-73% accurate). Her personal research has shown a 33% decrease in unnecessary surgery with moorLDI2-BI.
- Mr Wilson commented that the laser doppler imaging scan gives a ‘visible product to show parents’ (of the patient) when explaining the burns treatment plan. It is a small, portable device which is less daunting for patients.
- The three advisers agree that the patient benefits will be realised in practice. There will also be improved outcomes for patients in terms of scarring from unnecessary surgery. Likely obstacles include the cost and reluctance of staff to use new equipment.
- The three advisers agree that the additional healthcare system benefits of using the technology include reduced costs associated with, for example, fewer operations, reduced dressing budgets and reduced hospital stays.
- Two of the three advisers consider the cost of the machine to be the main obstacle to the realisation of the healthcare system benefits. Dr. Pape also refers to the recent improvement in the software so that the scans are

simpler to interpret and relate directly to healing time (and hence the need for surgery).

- All advisers agree that some initial staff training is required.
- All three advisers agree that the equipment needs a maintenance contract to ensure regular servicing and software updates and also that there is no controversy about any aspect of this technology.

The Association of Burns and Reconstructive Anaesthetists (ABRA) were contacted and did not respond.

Appendix C: Comments from patient organisations

NICE's Patient and Public Involvement Programme received a response from Dan's Fund for Burns to the patient commentary questions used in the moorlDI2-BI evaluation.

Patient Commentary from Dan's Fund for Burns

Greg Williams FRCS FRCS(Plast) submitted a statement on behalf of three organisations:

- as the Burns Service Lead, Chelsea and Westminster Hospital NHS Foundation Trust
- as the Clinical Director of London and South East of England Burns Network
- as Medical Adviser to Dan's Fund For Burns

The main points of his statement are:

- He uses MoorLDI2-BI as part of his current practice on all patients in whom at 48 hours to 5 days (the current accepted valid period for its use) he is uncertain of the burn depth. The published data suggests that burn depth assessment accuracy is increased from the region of 65–70% with clinical assessment only, to over 95% with clinical and laser doppler assessment. He has found this to be true in his clinical practice over the last 4 years of using it.

- He is unaware of any disadvantages of using it for patients other than the published situations when the assessment may be incorrect for example, moving patient, light glare, undebrided wound etc.

- Mr Williams commented that use of moorLDI2-BI is not appropriate when the depth of burn is obvious to an experienced burns clinician, that is, superficial partial thickness burns or deep dermal/full thickness burns. In addition mooLDI2-BI images should not be interpreted by clinicians unfamiliar with the clinical assessment of burn depth as this should be done at the same time as the scan and should not rely on the evaluation of the accompanying photograph.

- In his opinion there is a risk to patients, in burns services where clinicians wish to have access to a laser doppler imager but do not, that the burn wound assessment may not be as accurate as it could be if the doppler were available.Also the use of moorLDI2-BI is not appropriate outside of the recognised burns centres, units and facilities of which there are a very limited number in the UK and most of the burns centres who wish to already have access to moorLDI2-BI.

- He noted that there is not universal agreement locally, regionally, nationally or internationally amongst burns experts regarding the benefit of using the MoorLDI2-BI.

The following organisations were contacted for patient commentary and did not respond:

- British Skin Foundation
- Changing Faces
- Children's Burn Trust (CBT)
- Counsel and Care
- CritPaL - Patient Liaison Committee of the Intensive Care Society
- ICU Steps
- Let's Face It
- Royal College of Surgeons Patient Liaison Group
- Skin Care Campaign
- The Patients Association.

Appendix D: Manufacturers’ comments and External Assessment Centre responses

The table below summarises factual inaccuracies identified by the manufacturer in the assessment report and their proposed amendments. The final column contains a response from the External Assessment Centre.

Issue 1

Description of factual inaccuracy	**Description of proposed amendment**	**Justification for amendment**	**External Assessment Centre Response**
Section 1.2 ‘none of the studies funded by the manufacturer’ And Pg 15 ‘None of the studies were funded by Moor Instruments Ltd or any other manufacturer.’	None of the studies was funded by Moor Instruments Ltd or by any other manufacturer except for the MHRA approved study. This study was supported by the manufacturer who was in turn supported by a SMART DTI grant. A statement regarding conflict of interest published by the clinical project partners is as follows: The LDI equipment used during this investigation was loaned by Moor Instruments Ltd. to four of the burn centres and subsequently gifted to these institutions. At the fifth burn centre the equipment was purchased already and Moor Instruments Ltd. subsequently made an equivalent donation for unrestricted research. Moor Instruments Ltd. funded travel and accommodation for meetings during the design of the investigation and provided technical support at all stages of the investigation.	The funding of the HMRA approved study was not reported to EAC in the submission.	Added

Issue 2

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	External Assessment Centre Response
Pg 5 section 1.3 The manufacturer reports that for a range of patients with intermediate burns scanned from 10% to 100%,	The manufacture reports that for a range from 10% to 100% of patients admitted to hospital with intermediate burns	EAC wording could confuse the reader into thinking the 10% to 100% refers to the total burn surface area	Re worded for clarification: For patients with intermediate burns, the manufacturer reports that, if a range of 10% to 100% of those admitted are scanned the NHS will save from £1055 to £4594 per patient scanned.

Issue 3

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	External Assessment Centre Response
Section 2.2 'However the time required to train the staff is not considered. '	Delete this sentence	Time to train and costs are considered. See table B10 and spreadsheet sheet 2 'Cost to NHS'.	Deleted, but: This was a quote from the submission page 13, however, the economic model did include the cost of the time for training.

Issue 4

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	External Assessment Centre Response
Section 4.1.2 'Two studies include only adult patients (7, 9),'	One study includes adults patients only (7), one adults and paediatrics (9),	It is important to record that study (9) which was a validation of the colour palette used to indicate healing potential included adult and paediatric patients.	Reworded to say: One study includes only adult patients (7), four studies include only paediatric patients (2, 4, 6, 8), and four include both adult and paediatric patients.

Issue 5

Description of	Description of	Justification for	External Assessment

factual inaccuracy	proposed amendment	amendment	Centre Response
Pg 15 Barques et al. 1998	Barques et al. 1997	reported year of publication incorrect	Changed to 2007 as per submission page 23.

Issue 6

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	External Assessment Centre Response
Pg 16 Pape *et al.* 2004	Pape et al. 1998	reported year of publication incorrect	Changed

Issue 7

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	External Assessment Centre Response
Pg 29 Jerg et al.; Holand et al. (Jerg twice)	Jeng et al; Holland et al.	Name spelt incorrectly	Changed

Issue 8

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	External Assessment Centre Response
Tables 5 and 15 £,869,610	Replace with £1,869,610	Error in entering cost data	Changed

Issue 9

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	External Assessment Centre Response
Pg 40 'The heavy reliance on data from Hemington-Gorse *et al* may be considered a weakness, but given the lack of economic studies identified in the	The reliance on data for the hourly cost of an operation and the daily cost of a standard child's bed may be considered a weakness, but given the lack of economic studies identified in the literature search this is acceptable.	The calculation of cost savings does not have a heavy reliance on data from Hemington-Gorse. See Cost saving spreadsheet sheet 1 Cost Saving. The spreadsheet allows for alternative data values to be used in the estimates of	Reworded to say: The reliance on data from Hemington-Gorse *et al* for hourly cost of an operation may be considered a weakness, but given the lack of economic studies identified in the literature search this is acceptable.

literature search this is acceptable.'		cost savings.	

Issue 10

Description of factual inaccuracy	**Description of proposed amendment**	**Justification for amendment**	**External Assessment Centre Response**
Pg 45 Appendix 1 Hemington-Gorse *et al* (2009). Burn care costing: The Welsh experience. Burns 35: 378-382	Hemington-Gorse SJ.(2005) A comparison of laser Doppler imaging with other measurement techniques to assess burn depth. J Wound Care. Apr;14(4):151-3.	Incorrect publication cited in Appendix 1.	Changed.