

# moorLDI2-BI: a laser doppler blood flow imager for burn wound assessment

Medical technologies guidance

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[www.nice.org.uk/guidance/mtg2](https://www.nice.org.uk/guidance/mtg2)

## Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should [assess and reduce the environmental impact of implementing NICE recommendations](#) wherever possible.

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This guidance should be read in conjunction with MIB251.

# 1 Recommendations

NICE medical technology guidance addresses specific technologies notified to NICE by manufacturers. The 'case for adoption' is based on the claimed advantages of introducing the specific technology compared with current management of the condition. This 'case' is reviewed against the evidence submitted and expert advice. If the case for adopting the technology is supported, then the technology has been found to offer advantages to patients and the NHS. The specific recommendations on individual technologies are not intended to limit use of other relevant technologies which may offer similar advantages.

- 1.1 The case for adopting the moorLDI2-BI in the NHS is supported when it is used to guide treatment decisions for patients in whom there is uncertainty about the depth and healing potential of burn wounds that have been assessed by experienced clinicians.
- 1.2 There is evidence of benefit for patients and for the NHS when the moorLDI2-BI is used in addition to clinical evaluation compared with clinical evaluation alone, in burn wounds of intermediate (also known as indeterminate) depth. By demonstrating which areas of any burn wound require surgical treatment and which do not, the moorLDI2-BI enables decisions about surgery to be made earlier and for surgery to be avoided in some patients.
- 1.3 The estimated average cost saving when the moorLDI2-BI is used in addition to clinical evaluation is £1,281 per patient scanned (if the equipment is purchased) or £1,274 per patient scanned (if the equipment is leased). This is based on an assumption of a 17% reduction in the number of skin graft operations at a cost of £2,319 each. [2017]

## 2 The technology

### Description of the technology

- 2.1 The moorLDI2-BI (Moor Instruments Ltd) is a laser doppler blood flow imaging system for the non-invasive mapping of blood flow in an area of skin that has been burned. This can be used in addition to clinical evaluation to guide decisions about the need for surgical treatment of burn wounds.
- 2.2 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 or consulting room as well as in rooms designed specifically for laser equipment.
- 2.3 The moorLDI2-BI uses a low-power laser beam, directed at the burn wound using a mirror. The laser beam scans across the burn wound by rotating the mirror and there is no direct contact with the burned skin. Laser light scattered from moving blood cells in the tissue undergoes a doppler frequency shift, proportional to the average speed of the blood cells. Some of the scattered laser light is focused onto photodiode detectors and the resulting photocurrent is processed to calculate the blood flow in the tissue. Results are displayed as a colour-coded blood flow image and a colour video image of the burn wound. Depending on the size of the burn wound and required resolution of the image, the scan takes from 80 seconds to about 5 minutes. Healing potential results based on the blood-flow image are calculated and reported in three categories: less than 14 days, 14 to 21 days and more than 21 days.
- 2.4 The moorLDI2-BI can be purchased at a cost of approximately £53,942 with an annual servicing cost of approximately £8,301, or it can be leased at an inclusive cost of approximately £22,000 per year. **[2017]**

## Current management

- 2.5 Current provision for inpatient treatment of burn injuries within England and Wales, based on the recommendation of the National Burn Care Review, is by specialised burn care services which consist of burn centres, burn units and burn facilities.
- 2.6 The assessment of burn wound depth and healing potential is fundamental in planning burn wound management. An experienced clinician can easily identify a burn that is epidermal and will heal without surgery, or a full thickness burn that requires surgical excision and grafting. However, it is often difficult to distinguish the superficial dermal burns that will heal well, from deep dermal burns, when a prolonged healing time will result in hypertrophic scarring (when the scar is swollen and red). It is difficult to assess burn wound depth and healing time in children because of the prevalence of mixed-depth scald burns and their thin skin.
- 2.7 Diagnosis of burn wound depth and healing potential is also difficult in patients with dark skin (including those with suntan, birthmarks or tattoos). Identifying the level of burn injury can be complicated by other factors such as oedema, tissue hypoxia and burn wound conversion, when superficial burns progress into deeper wounds because of the death of severely injured cells.
- 2.8 Clinical evaluation is the most widely used method of assessing burn wound depth and healing potential. This method is based on visual and tactile assessment of the external characteristics of the burn. The accuracy of clinical examination depends on the experience of the clinician. Other less widely used methods such as thermography and fluorescein injections are also available for burn wound assessment.
- 2.9 The surgical procedure for treatment of burn wounds usually involves removing the damaged skin (using excision or debridement) followed by skin grafting. Skin grafting is the transplantation of skin from a healthy part of the body. This procedure is used for deep dermal wounds because it reduces the wound healing time and wound complications. Even after excision and skin grafting there will be scarring, and hypertrophic scarring may occur.

## 3 Clinical evidence

### Summary of clinical evidence

- 3.1 The key outcome for moorLDI2-BI laser doppler blood flow imaging is the development of an appropriate treatment plan based on an accurate assessment of burn wound depth and healing potential. Other performance measures are the sensitivity, specificity, negative predictive value and positive predictive value of the wound healing potential before 14 or 21 days. Clinical utility outcomes associated with the technology are avoiding unnecessary operations, extent of surgery, number of dressing changes, complications and length of stay in hospital. Longer-term outcomes are extent and type of scarring and the recovery of pre-injury function.

### Accuracy of the moorLDI2-BI

- 3.2 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. Comparisons were made with clinical and histological evaluation of burn wound depth.
- 3.3 Pape et al. (2001) reported an audit of wound healing at 21 days for 76 intermediate depth wounds in 48 patients. Results showed the moorLDI2-BI to be 97% accurate (74/76) in predicting wound healing at 21 days compared with 70% (53/76) for clinical evaluation (no statistical comparison reported).
- 3.4 Hoeksema et al. (2009) investigated the changing accuracies of laser doppler imaging and clinical evaluation over days 0, 1, 3, 5 and 8 after injury. 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% respectively by clinical evaluation, and 55%, 80%, 95%, 97% and 100% respectively by laser doppler imaging. The burn wound depth accuracy

using the moorLDI2-BI was significantly higher than clinical evaluation on day 3 ( $p < 0.001$ ) and day 5 ( $p = 0.005$ ) but not on days 0, 1 or 8.

- 3.5 Jeng et al. (2003) described a prospective blinded trial comparing laser doppler imaging using the moorLDI2-BI versus clinical evaluation by an experienced burn wound surgeon to decide whether or not to operate. Forty-one wounds of intermediate depth were analysed. Biopsy confirmation was obtained for 21 wounds. 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 wounds biopsied. The moorLDI2-BI was 100% (7/7) accurate in wounds for which it indicated a need for excision.
- 3.6 Monstrey et al. (2011) 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 94.5%, specificity 97.2%, positive predictive value 94.5% and negative predictive value 97.2%.
- 3.7 La Hei et al. (2006) scanned 50 burns in 31 paediatric patients. Two experienced burn wound surgeons independently reviewed the scans, photographs and a basic patient history, without meeting the patient. One surgeon identified 82 areas of differing depth, the other identified 76 areas, and both surgeons predicted healing times (superficial heal: less than 14 days or deep heal: more than 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.
- 3.8 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. Scans using moorLDI2-BI were also more specific, correctly diagnosing 96% (27/28) of superficial partial thickness burns compared with 71% (20/28)



from clinical evaluation alone (no statistical comparison reported).

- 3.9 Niazi et al. (1993) reported results from a pilot study that analysed 17 burn wounds on 13 patients. Punch biopsies were used to confirm burn wound depth at 72 hours after injury. Clinical evaluation was correct for 41% (7/17) of the 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 burn wounds (no statistical comparison reported).
- 3.10 Mill et al. (2009) compared moorLDI2-BI image colours with wound outcomes in 85 burns on 48 children. Analysis of the image colour regions was found to be significantly related to re-epithelialisation ( $p < 0.003$ ), grafting ( $p < 0.001$ ) and active scar management ( $p = 0.003$ ).

## Clinical utility outcomes

- 3.11 Two studies evaluated whether or not using the moorLDI2-BI enabled appropriate skin grafting decisions to be made earlier than using clinical evaluation alone. Jeng et al. (2003) described a prospective blinded trial that compared laser doppler imaging versus clinical evaluation by an experienced burn wound surgeon, in deciding whether to operate or not on 41 burn wounds of intermediate depth. There was agreement on wound depth between the imaging and clinical evaluation in 56% (23/41) of cases. In these cases the moorLDI2-BI determined wound depth a median of 2 days (minimum 0, maximum 4) earlier than clinical evaluation alone (no statistical comparison reported). Kim et al. (2010) described a non-randomised cohort study of 196 children with an acute burn injury who 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 the decision to graft was 8.9 days in the moorLDI2-BI group compared with 11.6 days in the group assessed by clinical evaluation alone ( $p = 0.01$ ).

## Committee considerations

- 3.12 The committee considered that there was good clinical evidence that information

from moorLDI2-BI scans increases the accuracy of predicting burn wound healing and also that this information can be used to facilitate treatment plans. Using the moorLDI2-BI in addition to clinical evaluation can enable earlier surgical treatment in some patients and avoid the need for surgery in others. It may also reduce the extent of surgery.

- 3.13 Burn wounds on dark skin can be difficult to assess clinically. The committee considered that the moorLDI2-BI offers particular advantages for assessing burn wounds on dark skin.
- 3.14 The committee was advised that additional patient and system benefit could be obtained by using the moorLDI2-BI to define accurately the margins of surgical areas for the skin graft operations, so helping to limit the extent of excision and grafting in some patients.
- 3.15 There are many factors that are known to have a detrimental effect on moorLDI2-BI images or their interpretation, including infected wounds, patient movement, old scars and tattoos. These are acknowledged in the published studies and also recognised by the manufacturer in its user guide. It was therefore considered important that moorLDI2-BI images should only be taken and interpreted by a clinician trained in use of the technique.
- 3.16 The committee was advised that the moorLDI2-BI can be used to assess burns treated by biological and semi-biological dressings.
- 3.17 The committee considered that there was no evidence to suggest patients were likely to be harmed by the moorLDI2-BI used by trained clinicians.

## 4 NHS considerations

### System impact

- 4.1 System benefits associated with the moorLDI2-BI for burn wound assessment are based on reducing the length of hospital stay and avoiding unnecessary skin grafting operations.
- 4.2 Timing of moorLDI2-BI imaging is important because burn wounds change rapidly in the first 48 hours after injury. The evidence suggested that the best time for imaging is 48 to 72 hours after the injury, but the device can be used up to 5 days after injury.
- 4.3 Wound assessment using the moorLDI2-BI needs a trained clinician to operate the device and to interpret the results. In a study to assess clinical benefit, La Hei et al. (2006) reported an increase in accuracy of interpretation of the laser doppler images by a new assessor from 83% (15/18) to 96% (73/76) over a 6-month period.

### Committee considerations

- 4.4 The committee considered that earlier and more accurate prediction of the need (or lack of need) for surgery using the moorLDI2-BI would benefit the system by reducing unnecessary operations and by saving on inpatient care. These are considered further in the cost modelling (see [section 5.2](#)).
- 4.5 The committee was advised that training is important for all staff to operate this device and interpret the images. The cost model includes costs for 2 days' training for one consultant, two registrars and three nurses every 2 years for each device.

## 5 Cost considerations

### Cost evidence

- 5.1 The evidence comprised a cost analysis to assess the costs and savings to the NHS from use of the moorLDI2-BI for the assessment of burn wounds of intermediate depth, as described in the manufacturer's submission. The costs and savings from using the moorLDI2-BI in addition to clinical evaluation were compared with those from using clinical evaluation alone. The cost analysis balanced the additional equipment and staff costs of burn wound assessment with the moorLDI2-BI against the cost benefits from earlier more appropriate treatment decisions based on information from moorLDI2-BI images.
- 5.2 The cost model assumed 10,000 patients, based on Enoch et al. (2009), admitted each year to 28 'burns centres' in England and Wales. For the purposes of the cost model the term 'burns centre' encompasses burns centres, units and facilities (as defined in the National Burn Care review).
- 5.3 The cost model assumed that 70% of the admitted patients were likely to have intermediate burn wounds and be scanned. To calculate a per patient cost in the base case, each burns centre was assumed to have one imager with annual staff training costs of £5,160. Nurse scanning time per patient was 1 hour and clinician time per patient for interpreting results was 15 minutes. The cost savings included were based on a reduction of 17% in the number of skin graft operations and a 2-day reduction in the length of hospital stay. These parameter values were based on evidence from clinical studies. In the model the cost per hour for an operation to treat burn wounds was £4,593, based on the figures presented in Hemington-Gorse et al. (2009). Expert advice to the external assessment centre was that this hourly cost was high, so it derived a lower figure of £2,043, this has been adjusted for inflation to £2,319 per hour. **[2017]**
- 5.4 A range of scenario analyses were done, including best- and worst-case scenarios using the ranges for the proportion of patients scanned, number of bed days saved and operating time. Additional analyses were done by the external assessment centre to assess the impact of changing the hourly cost for an

operation to £2,043, this has been adjusted for inflation to £2,319. [2017]

- 5.5 The cost saving per patient scanned from using the moorLDI2-BI in addition to clinical evaluation compared with clinical evaluation alone for the base case was £1,281 for the purchase option and £1,274 for the lease option (both based on an hourly cost of £2,043 per operation). The worst-case scenario for the purchase option, based on 2011 prices resulted in a cost saving of £734 per patient and the best-case scenario resulted in a saving of £2,860 per patient scanned. All analyses presented in the assessment report showed that the total cost saving from reducing length of hospital stay and number of operations was greater than the costs associated with the purchase and operation of the moorLDI2-BI. [2017]
- 5.6 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 the moorLDI2-BI. This demonstrated that the moorLDI2-BI would still achieve a cost saving of £159 per patient scanned when a 17% reduction in operations was assumed (based on the purchase option and an hourly cost of £2,043 per operation).

## Committee considerations

- 5.7 The committee considered the implications of purchasing the moorLD12 BI for use in units or facilities, which may deal with smaller numbers of burns patients and with less specialised resources. All units and facilities should have access to a trained specialist to interpret the scan, and to break even, the cost model for the base case showed a minimum of 21 burns patients a year needed to be admitted to a burns centre, of which 70% would be scanned.
- 5.8 The committee was informed that the device had been available to the NHS for a number of years and was already used routinely in some burn care services.
- 5.9 The base case in the manufacturer's submission included costs of 1 hour scanning time and 1 hour skin graft procedure associated with an average intermediate burn. The committee was advised that 30 minutes scanning time is

more appropriate for burn wounds requiring a 1-hour skin grafting procedure. Using this time for a scan, the cost saving per patient scanned in the base case was recalculated as £1,254 for the purchase option and £1,270 for the lease option.

- 5.10 The cost analysis focused on cost savings associated with inpatient care. The committee was advised that additional savings, including avoidance of hospital admission, might be obtained by using the device as an aid to clinical decision-making for outpatients with small burns of uncertain depth.
- 5.11 The time horizon for the cost analysis was the initial period of hospitalisation, and no longer-term cost consequences were included. 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 anti-scar therapy or any therapy. Anti-scar therapy includes fitting pressure garments and follow-up hospital appointments.

## 6 Conclusions

- 6.1 The committee concluded that the available evidence supported a clinical benefit and a cost saving when the moorLDI2-BI is used to guide treatment decisions for patients in whom there is uncertainty about the depth and healing potential of burn wounds that have been assessed by experienced clinicians.

## 7 Implementation

NICE has developed [tools and resources](#), in association with relevant stakeholders, to help organisations put this guidance into practice:

- [Slide set](#) highlighting key messages for local discussion.



# Appendix A: Committee members and NICE lead team

## Medical technologies advisory committee members

The medical technologies advisory committee is a standing advisory committee of NICE. A list of the committee members who took part in the discussions for this guidance appears below.

Committee members are asked to declare any interests in the technology to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of each medical technologies advisory committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

### **Professor Bruce Campbell (Chair)**

Consultant Vascular Surgeon, Exeter

### **Dr Dilly Anumba**

Senior Clinical Lecturer/Honorary Consultant Obstetrician and Gynaecologist, University of Sheffield

### **Susan Bennett**

Lay member

### **Professor Bipin Bhakta**

Charterhouse Professor in rehabilitation Medicine and NHS Consultant Physician, University of Leeds

### **Dr Keith Blanshard**

Consultant Radiologist, Leicester Royal Infirmary

### **Dr (Robert) Martyn Bracewell**

Senior Lecturer in Neurology and Neuroscience, Bangor University

**Dr Daniel Clark**

Head of Clinical Engineering, Nottingham University Hospitals NHS Trust

**Professor Karl Claxton**

Professor of Economics, University of York

**Mrs Gail Coster**

Radiography Manager, Strategy, Planning and Governance, Yorkshire NHS Trust

**Dr Craig Dobson**

General Practitioner and Senior Lecturer in Medical Education and General Practice, Hull York Medical School

**Dr Alex Faulkner**

Senior Research Fellow, Centre for Biomedicine & Society, King's College London

**Professor Tony Freemont**

Professor of Osteoarticular Pathology, University of Manchester

**Professor Peter Gaines**

Consultant Interventional Radiologist, Sheffield, Vascular Institute and Sheffield Hallam University

**Mr Harry Golby**

Head of Commissioning, Acute, Access and Diagnostics, Salford NHS

**Dr Peter Groves**

Consultant Cardiologist, Cardiff and Vale NHS Trust

**Matthew Hill**

Lay member

**Dr Paul Knox**

Reader in Vision Science, University of Liverpool.

**Mrs Catherine Leonard**

Reimbursement Manager, Medtronic UK

**Dr Susanne Ludgate**

Clinical Director, Devices Medicines & Healthcare Products Regulatory Agency

**Professor Christopher McCabe**

Professor of Health Economics, Institute of Health Sciences, University of Leeds

**Mrs Jacqui Nettleton**

Programme Director, Long Term Conditions, West Sussex PCT

**Professor Sharon Peacock**

Professor of Clinical Microbiology, University of Cambridge

**Dr Allan Swift**

Director of Quality and Regulatory Affairs, Gen-Probe Life Sciences

**Professor Stephen Westaby**

Consultant Cardiac Surgeon, John Radcliffe Hospital, Oxford

**Dr Janelle York**

Lecturer & Researcher in Nursing, University of Salford

## **NICE lead team**

Each medical technology assessment is assigned a lead team of a NICE technical analyst and technical adviser, a clinical expert, a representative of the external assessment centre, and a non-expert member of the medical technologies advisory committee.

**Bernice Dillon**

Technical analyst

**Mr Donald Emerton**

External Assessment Centre representative

**Lizzy Latimer**

Technical adviser

**Dr Sarah Pape**

Clinical expert

**Dr Allan Swift**

Medical Technologies Advisory Committee (non-expert member)

## Appendix B. Sources of evidence considered by the medical technologies advisory committee

The external assessment centre report for this assessment was prepared by King's Centre for the Assessment of Radiological Equipment (KCARE):

- Kazantzi M, Emerton D and Lawinski C (2010). moorLDI2-BI a laser doppler blood flow imager for burn wound assessment.

Submissions from the following manufacturer/sponsors:

- Moor Instruments Ltd.

The following people gave their expert personal view on moorLDI2-BI by providing their expert comments on the draft scope, assessment report and medical technologies consultation document:

- Dr Steven Jeffery, nominated by the British Burns Association
- Dr Sarah Pape, nominated by the British Association of Plastic Reconstructive and Aesthetic Surgeons (BAPRAS)
- Mr David Wilson, nominated by BAPRAS.

The following individuals gave their expert personal view on moorLDI2-BI in writing by completing a patient questionnaire or expert adviser questionnaire provided to the committee:

- Dr Steven Jeffery, nominated by the British Burns Association
- Dr Sarah Pape, nominated by BAPRAS
- Mr Greg Williams, nominated by Dan's Fund for Burns
- Mr David Wilson, nominated by BAPRAS.

## Update information

**August 2017:** We updated this guidance with changes to costs and savings figures. Go to the [review decision](#) for further details.

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