

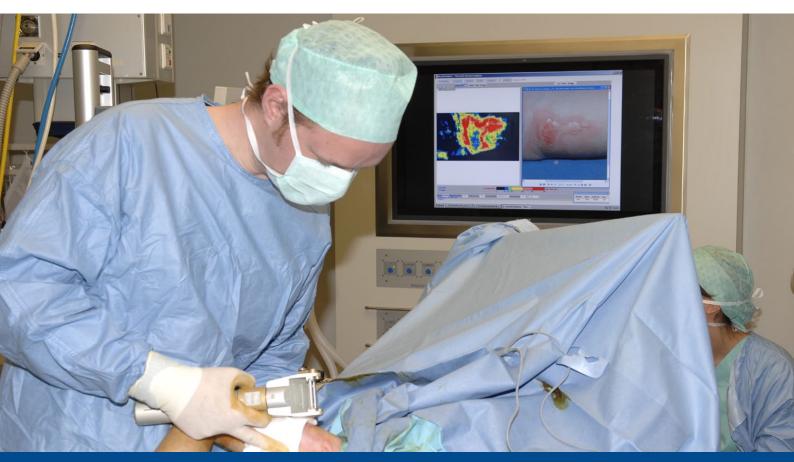


About Us

Moor has consulted with burns surgeons worldwide for over 15 years to develop laser Doppler imaging as a powerful aid to burn wound assessment.

Working with clinicians we have been involved with international, multi-centre clinical trials for the assessment of burns using Moor laser Doppler imagers. If you are using laser Doppler or plan to do so, we can help you with imager selection and provide technical information, competence based training and comprehensive support.

moorLDI2-BI image - In use in theatre (reproduced with kind permission of the Burn Centre, University Hospital Ghent, Belgium).

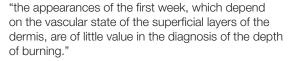


The Challenge of Early Burn Assessment...

Accurately
diagnosing the
severity of burns has
always been difficult,
even for experienced
clinicians.

Moor now offer a solution by providing a choice of laser Doppler imagers to assist with your treatment decisions. Our imagers assess and map skin blood flow - clinically proven to relate closely to the healing potential of burn injuries.

Describing burn injuries, Jackson (1953) stated that:



Jackson DM (1953) The diagnosis of the depth of burning. Br J Surg. 40(164)pp 588-596.

The accuracy of LDI in the assessment of burn depth was 97%, compared with 60–80% for established clinical methods. This audit confirms that LDI is a very accurate measurement tool for the assessment of burn wound depth. We recommend that all burns of intermediate depth should be analysed in this way in order to ensure appropriate management of the burn, to avoid unnecessary surgery and to reduce hospital stay and costs."

Pape et al (2001) An audit of the use of laser Doppler imaging (LDI) in the assessment of burns of intermediate depth. Burns 27 pp 233-239.

Hoeksema et al (2009) recommend that:

"all burns of intermediate depth should be analyzed with a combination of both LDI scanning and clinical evaluation....

Ensuring early appropriate management of the burn wound by avoiding unnecessary surgery and therefore reducing mortality, hospital stay and costs."

Hoeksema, H. Van de Sijpe, K. Tondu, T. Hamdi, M. Van Landuyt, K. Blondeel, P. Monstrey, S (2009) Accuracy of early burn depth assessment by laser Doppler imaging on different days post burn. Burns. 35 (1) p36-45.

Benefits for Patients and Staff using Moor Laser Doppler Imaging for Burn Assessment

Benefits for Burn Care Staff

Earlier and more accurate burn assessments lead to a reduction in work-load. Accurate assessment of clinically indeterminate burns avoids unnecessary surgery and avoids unnecessary delays where surgery is required. Early, appropriate wound management can reduce the incidence of infection and leads to hospital savings. Accurate wound imaging also enables the most appropriate use of advanced skin substitutes, biological and semi-biological dressings and other treatments.



Benefits for Financial Administration

Hospitals, insurances and reimbursements vary widely within each continent and even within each country.

With the NICE review (National Institute for Health and Clinical Excellence), based on UK centres using Moor Laser Doppler, the committee concluded that "the available evidence supported a clinical benefit and 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".

National Institute for Health and Clinical Excellence [on line] (2011) 'MTG2 moorLDI2-BI: a laser doppler blood flow imager for burn wound assessment'. Committee Report. http://publications.nice.org.uk/moorldi2-bi-a-laser-doppler-blood-flow-imager-for-burn-wound-assessment-mtg2/conclusions.

Introduction of a Moor laser Doppler imager typically results in earlier surgery for burns that require it (with an average of 2 bed days saved) and optimal choice of dressings where conservative management is indicated. Early and accurate diagnosis enables early and accurate treatment planning and best use of valuable resources such as the more expensive dressings and skin substitutes.

Although patient and staff benefits are universal we recognise there are differences in hospital procurement practises so Moor is happy to help with financial justifications on an individual basis.

Benefits for Patients

Early and accurate burn assessment enables prompt and appropriate treatment with a consequent reduction in length of stay and better cosmetic outcomes. For wounds that appear deep by clinical assessment but are shown to be more superficial by Moor laser Doppler, unnecessary surgery, scarring and pain of a donor site can be avoided. This enables an earlier return to family, education or work.

Benefits for Researchers

First-hand experience of laser Doppler at Moor Instruments dates back to 1978 and we have a wealth of experience in many research areas including burns. Many applications can take advantage of the speed, scan size and flexibility of the Moor laser Doppler imagers - ideal for research as well as clinical use.

In burns research most protocols rely on accurate burn assessment prior to subsequent treatment; it is increasingly found that clinical judgement alone is not accurate enough for this, especially for intermediate depth burns. The objective burn assessment offered by moorLDI allows confident grouping of similar burns. This enables meaningful comparisons of different treatments. MoorLDI software eases data collection and analysis, aiding users to make valid conclusions.

Moor Instruments is the world leader in laser Doppler burn assessment systems. Our burn assessment systems are in use in over 50 burn centres worldwide and research installations are found in more than 45 countries. Whatever your research application we are happy to discuss, in confidence, how we can help.

Benefits of using Moor

Moor offers you;

- Early and accurate burn diagnosis from 48 hours post burn – avoid unnecessary delays
- Improve assessment accuracy to more than 96% increase confidence in treatment decisions
- Non contact imaging pain free assessment with improved infection control
- Instant results enables prompt assessment and treatment planning within the burn unit
- Clinically proven software with touch screen interface
 easy to operate by trained burn team staff
- Unique colour coded palette easy to interpret, proven accuracy in numerous published studies and clinical trials
- CE marked, 510k registered specifically for clinical burn diagnosis and recommended by National Institute for Health and Clinical Excellence (NICE) – independent evidence of suitability for purpose
- Comprehensive competency based training courses available – ensuring safe and correct use

..... Clinical evidence has shown that the moorLDI2-BI scans increase the accuracy of predicting burn wound healing and also that this information can be used to facilitate treatment plans.

..... moorLDI2-BI, when used in addition to clinical evaluation, can enable earlier surgical treatment in some patients and avoid the need for surgery in others, or reduce the extent of surgery.

The Packages

Whichever Moor system you choose, we offer the complete package including imager, clinical mobile stand, touch screen panel PC kit with dedicated software and on going support and servicing.

A vital part of the package is the installation and certified competence based training course which has been refined with direct clinical experience. Documentation provided includes an extensive Burn Atlas together with course notes. You will also be invited to join The Moor Burn Forum putting you in direct contact with a rapidly growing user group, who can share practical experience and measurement tips.

Our dedicated software has been developed and refined with our clinical advisors for over 10 years. Designed to be easy to use by non technical staff in a clinical environment. The built-in patient database aids accurate record keeping, which enables easy retrieval of previous patients to re-examine or print reports. A colour photograph is also taken at the time of the scan, which is essential for clinical records and image interpretation.



Large area imaging is a key feature of the moorLDI2-BI.

Areas up to 50cm x 50cm can be mapped in one scan

(rather than a sequence that needs to be "stitched"

together), with scan times ranging from 40 seconds up to 2

minutes.

- Non contact imaging
- Scan times from 40 seconds
- Large assessment area of up to 50cm x 50cm
- Long reach mobile stand
- Results available immediately
- Both large areas (full torso) and small areas (finger) can be scanned



How It Works

Laser light penetrates the skin and is scattered by tissue and by moving blood cells in capillaries, arterioles and venules. The moving blood cells in the tissue cause Doppler frequency shifts, which are processed to produce a colour coded map of flow across the skin.

A digital camera records a colour clinical photograph at the same time, corresponding closely with the blood flow image in size and aspect.

The measurement is non contact and can quantify differences in flow over an area of tissue.

Rapid Imaging with moorLDLS-BI

Rapid imaging is an essential feature of moorLDLS which is most useful when scanning patients who are unable to keep still for long. With scan times of around 4 seconds for areas up to 15cm x 20cm the system is ideal for paediatric cases and can also be used for adults with easy to use repeat imaging to cover separate wounds or adjacent areas of large burns.

- Non contact imaging
- Scan times from 4 seconds
- Areas up to 15cm x 20cm
- Compact, battery backed mobile stand
- Repeat image mode for multiple scans
- Results available immediately

There are two main modalities with unique advantages for adult and paediatric burns;

moorLDI2-BI



Single point imaging scans a laser beam back and forth across the tissue, building a blood flow map. This enables a single scan of an adult torso.

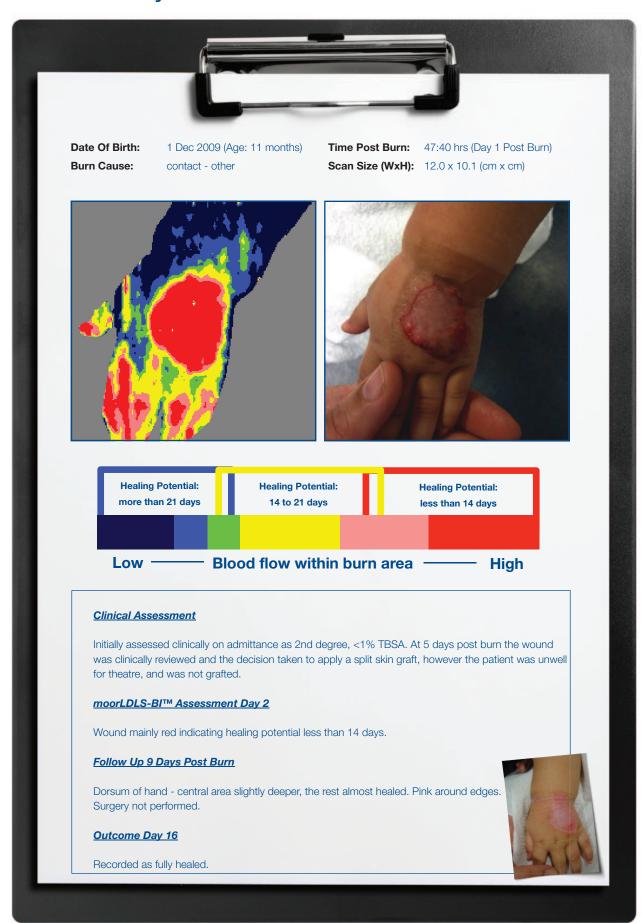
moorLDLS-BI



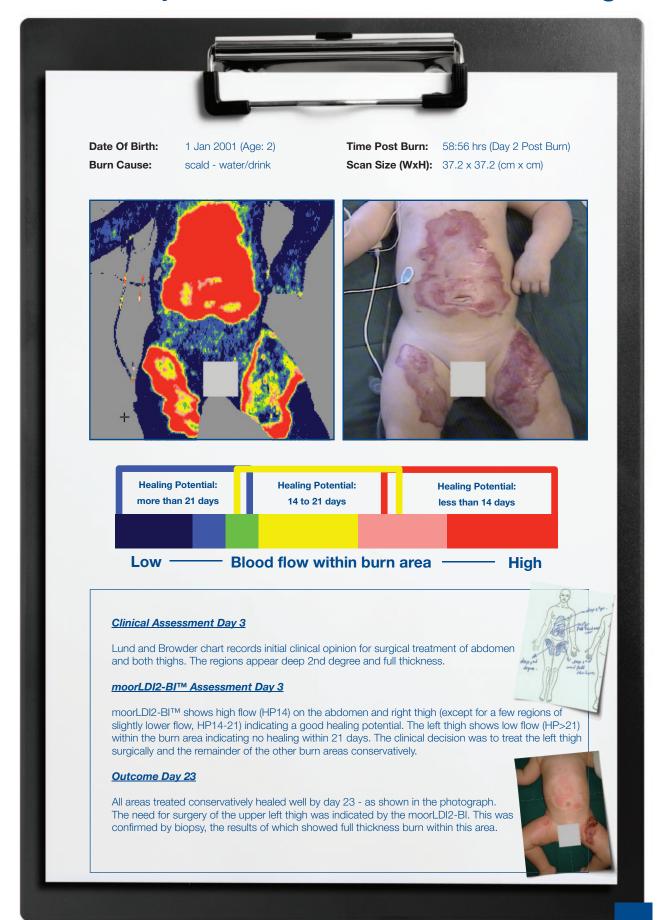
Line scanning uses a line of laser light to sweep quickly across the tissue, building the map more quickly. The scan size produced is smaller than single point imaging – around the size of an adult hand or the whole chest of an infant.



Case Study 1 - Paediatric Hand



Case Study 2 - Paediatric Abdomen / Thigh



Case Study 3 - Paediatric Chest



Frequently Asked Questions

Q. When should scanning be performed?

A. Evidence from our clinical trial suggests that the earliest reliable time for imaging is at least 48 hours after the injury, as burn wounds can change rapidly in the first 48 hours (the device can be used up to 5 days after injury). A study by Hoeksema et al (2009) showed accuracies on days 0, 1, 3, 5 and 8 to be 55%, 80%, 95%, 97% and 100% respectively, when aided by laser Doppler imaging.

Q. How long does a scan take?

A. It depends upon the scan size and resolution, but typically the scan time is $1\frac{1}{2}$ minutes with the moorLDI2-BITM and 4 seconds with the moorLDLS-BITM.

Q. How deep does the laser penetrate?

A. As the skin and microvasculature are not homogenous this is a difficult question to answer. Approximately 2 mm is a good estimation. However, this has not been found to limit burn assessment accuracy in areas where skin is thicker (e.g. the back).

Q. How accurate is the moorLDI2-BI?

A. Studies have shown the accuracy of the moorLDI2-BI™ in conjunction with clinical evaluation to be consistently better than 95% compared to approximately 65-75% for clinical evaluation alone. Our dedicated colour palette has been derived and validated through a rigorous, multicentre, worldwide clinical trial. On-going studies continue to support and corroborate these findings.

Q. Is the imager software difficult to use?

A. No, we have been consulting with Clinicians for over 15 years and have designed and developed the software to be very user friendly. Full training and support is provided for all users.

Q. What is the largest area you can image with moor laser Doppler imagers?

A. The image area is dependent on the scan area selected as well as the distance from the scan head to the patient. This allows the study of areas up to 20cm x 15cm (a large adult hand) with the moorLDLS-BI™ and 50cm x 50cm (an adult torso) with the moorLDI2-BI™.

Q. How often should the burn imagers be calibrated?

A. We recommend that the calibration should be checked every month; re-calibration is only required when indicated during a calibration check.

Q. Where can the scanners be used?

A. Both the moorLDI2-BI™ and moorLDLS-BI™ are fully mobile so can be used in the operating room, out-patient's department, treatment/dressing rooms or at the patient's bedside. Low powered lasers are used but local guidelines and policies should be followed regarding designated laser areas, so please consult your laser safety officer.

Q. Why does the blood flow image of normal, unburned skin look the same as for deeper wounds?

A. Skin blood flow at most unburned sites is usually fairly low when there has not been any insult or injury to the area. With clinical observation, these areas are unlikely to be confused with burn wounds as it is very easy to distinguish the difference visually. This is why visual and clinical assessment of the wound area is essential for accurate interpretation of a moorLDI image.

References and Testimonials

"We have devised a new colour palette for LDI burn imaging based on healing times of a series of burns."

Pape, S.A. Baker, R. D. Wilson, D. Hoeksema, H. Jeng, J.C. Spence, R.J. Monstrey, S (2011) Burn wound healing time assessed by laser Doppler imaging (LDI). Part 1: Derivation of a dedicated colour code for image interpretation **Burns.** 38 (2) p187-194.

"LDI can be used in a standardised way as a valid tool for improving on clinical assessment of burn wounds. This can enable earlier appropriate management."

Monstrey, S.M. Hoeksema, H. Baker, R.D. Jeng, J. Spence, R.J. Wilson, D. Pape, S.A. (2011) Burn wound healing time assessed by laser Doppler imaging. Part 2: Validation of a dedicated colour code for image interpretation. **Burns.** 37 (2) p249-256.

"Overall performance is that diagnoses are over 90% correct. Related questions addressed were what was the best blood flow summary statistic and whether, given the blood flow measurements, demographic and observational variables had any additional predictive power (age, sex, race, % total body surface area burned (%TBSA), site and cause of burn, day of LDI scan, burn center). It was found that mean laser-Doppler flux over a wound area was the best statistic. New medical findings are that age and %TBSA are not important predictors of healing time when the LDI results are known."

Baker, R.D. Weinand, C. Jeng, J.C. Hoeksema, H. Monstrey, S. Pape, S. A. Spence, R. Wilson, D (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.

"The accuracies of burn depth assessments with LDI at days 0, 1, 3, 5 and 8 were 54.8%, 79.5%, 95%, 97% and 100% compared with the accuracies of clinical assessment alone of 40.6%, 61.5%, 52.5%, 71.4% and 100%." "... all burns of intermediate depth should be analyzed with a combination of both LDI scanning and clinical evaluation... ensuring early appropriate management of the burn wound by avoiding unnecessary surgery and therefore reducing mortality, hospital stay and costs."

Hoeksema, H. Van de Sijpe, K. Tondu, T. Hamdi, M. Van Landuyt, K. Blondeel, P. Monstrey, S (2009) Accuracy of early burn depth assessment by laser Doppler imaging on different days post burn. **Burns.** 35 (1) p36-45.

"The predominant colour of the scan was found to be significantly related to the re-epithelialisation, grafting and scar management outcomes and could be used to predict those outcomes.......Laser Doppler imaging is accurate and effective in a paediatric population with a low-resolution fast-scan."

Mill, J. Cuttle, L. Harkin, D G. Kravchuk, O. Kimble, R. M (2009) Laser Doppler imaging in a paediatric burns population. **Burns.** 34 p824-831.

"We believe that use of the moorLDI will allow burn clinicians to distinguish between burns with a healing potential of less than 21 days (low risk of HTS) and those with a healing potential of more than 21 days (high risk of HTS)"

Cubison, T.C.S. Pape, S.A. Parkhouse, N. (2006) Evidence for the link between healing time and the development of hypertrophic scars (HTS) in paediatric burns due to scald. **Burns.** 32 p992-999.

"LDI in children appears to be extremely accurate in predicting burn wound outcome in children.....burns surgeons should be guided by LDI data."

La Hei, E.R. Holland, A.J.A. Martin, H.C.O (2006) Laser Doppler Imaging of Paediatric Burns: Burn wound outcome can be predicted independent of clinical examination. **Burns.** 32 (5) p550-553.

"LDI allowed for earlier, objective determination of need to operate." "LDI should be seen as an effective aid to clinical judgment when contemplating excision of burns with indeterminate depth."

Jeng, J C. Clarke, T J. Bridgeman, A. Shivnan, L. Thornton, PM. Alam, H. Clarke, TJ. Jablonski, KA. Jordan, M H (2003) Laser Doppler Imaging Determines Need for Excision and Grafting in Advance of Clinical Judgement: A Prospective Blinded Trial. **Burns.** 29 p665–670.

"The LDI was also more specific; correctly diagnosing 96% of superficial partial thickness burns as opposed to 71% on clinical examination."

Holland, AJ. Martin, HC. Cass, DT (2002) Laser Doppler imaging prediction of burn wound outcome in children. **Burns.** 28(1) p11–17.

"The accuracy of LDI in the assessment of burn depth was 97%, compared with 60–80% for established clinical methods." "We recommend that all burns should be scanned by the LDI system."

Pape, S A. Skoura,s C A. Byrne, P O (2001) An audit of the use of laser Doppler imaging (LDI) in the assessment of burns of intermediate depth. **Burns.** 27 p233-239.

"The LDLS was found to be as accurate as the LDI in predicting burn wound HP in children. Whilst the LDLS scan resolution was lower, with more scans of larger burns required, its smaller size and greater scan speed proved valuable in children."

Holland, AJ. Ward, D. La Hei, ER. Harvey, JG (2013). Laser Doppler Line Scan Burn Imager (LDLS-BI): Sideways move or a step ahead? (Article in Press) **Burns.**

"This study indicates that LDI can be used for predicting the risk of hypertrophic scarring and for guiding burn care"

Wang, X Q. Mill, J. Kravchuk, O. Kimble, R M (2010) Ultrasound assessed thickness of burn scars in association with laser Doppler imaging determined depth of burns in paediatric patients. **Burns.** 36 (8) p1254-62.

"...for the actual treatment decisions, laser Doppler imaging is the only technique that has been shown to accurately predict wound outcome with a large weight of evidence. Moreover this technique has been approved for burn depth assessment by regulatory bodies including the FDA."

Monstrey, S. Hoeksema, H. Verbelen, J. Pirayesh, A. Blondeel, P (2008) Assessment of Burn Depth and Burn Wound healing Potential. **Burns.** 34 (6) p761-769.

"These papers and many others through the literature document the usefulness of laser Doppler imaging in burn care. Based on these and other findings, we question how this technique cannot be considered the standard of care for burns of indeterminate depth on physical exam?"

Wolf, S, E. Sterling, J,P. Hunt, J, L. Arnoldo, B,D. (2011) The year in burns 2010. **Burns.** 37 (8) p1275-1287.

In a study by Kim et al (2010) it was shown that;

"in pediatric burn patients, there was a significant reduction in the time to decision making for operative intervention in the LDI group compared with the non-LDI group. The decision of the need for operative intervention made earlier, an average of 3 days, but this also equated to earlier surgery and definitive care. This would translate to potential financial savings, with a reduction in the costs associated with additional dressings and other medical interventions."

Kim, LH. Ward, D. Lam, L. Holland, AJ (2010) The Impact of Laser Doppler Imaging on Time to Grafting Decisions in Pediatric Burns. **Journal of Burn Care and Research.** 31 p328-332.



Specifications

Quality Control

Moor Instruments is certified to ISO 13485:2003.

Moor Instruments laser Doppler imagers are CE marked specifically for clinical burn diagnosis.

The moorLDI2-BI™ is FDA 510k registered for Burns Assessment (application in progress for moorLDLS-BI™).

Use of laser Doppler imaging for Burn Assessment is recommended by the National Institute for Health and Clinical Excellence (NICE) based on evidence from moorLDI2-BI™ trials and publications.

Measurement Technique

Laser Doppler Imaging.

Laser Source moorLDI2-BI™

Visible Red 633nm.

Maximum output power 2.5mW. Class 3R per IEC 60825-1: 2007.



Laser Source moorLDLS-BI™

Near Infra-red 785nm.

Maximum output power 30mW. Class 3R per IEC 60825-1: 2007.



Reliability

Assured by our two year warranty with extended service contract packages available.

Storage Temperature: 0-45°C.

Operating Temperature: 15-30°C.

Power Supply

Universal voltage switch mode power supply.

Electrical Safety Standards

Patient isolation to IEC 60601-1 Class 1.

Patents moorLDI2-BI™

moorLDI2[™] uses a unique continuously moving scanning beam technique, protected by patent.

UK patent Nos. GB2231742 and GB0465524,

European patent No. EP0465524, USA patent No. US5588437, Japan patent No. JP3239952,

Israel patent No. IL93909.

Patents moorLDLS-BI™

moorLDLS™ uses a unique line scanning technique,

protected by patent.

UK Patent No: GB2330719, Europe Patent No: EP0904011, USA Patent No: US6263227, Germany Patent No: DE69727220T.

Lighting Conditions

Normal, ambient lighting.

Computer

Latest specification touchscreen medical grade panel PC with medical grade keyboard.

Software

Windows $\ensuremath{^{\text{TM}}}$ based control, processing and analysis software.

Stand

MS2 "long reach" design used with moorLDI2-BI™.

Compact battery backed MS3b used with moorLDLS-BI™.

Colour Palette

Clinically validated 6 colour palette related to the healing potential of the burn injury.

Full Technical Specification is available at www.moorclinical.com

Moor Instruments reserve the right to change specifications without notice. Latest product will always be supplied at the time of order, unless otherwise agreed.

Scan Speed moorLDI2-BI™

Area and Image Resolution at 100cm (default settings)

Area	Time	Image Resolution (pixels)
25cm x 12.5cm	40 Seconds	256 x 32
25cm x 25cm	1 Minute 20 Seconds	256 x 64
50cm x 25cm	1 Minute	256 x 32
50cm x 50cm	2 Minutes	256 x 64

Higher resolutions can also be used.

Scan Speed moorLDLS-BI™

Area and Image Resolution at 20cm (default settings)

Area	Time	Image Resolution (pixels)
20cm x 15cm	4 Seconds	64 x 64
20cm x 15cm	8 Seconds	128 x 64
20cm x 15cm	15 Seconds	256 x 64

Notes

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