

**National Institute for Health and Clinical Excellence
Additional Submission Information**

[NICE331/EP104]

The purpose of this table is to show where the External Assessment Centre relied in their assessment of the topic on information or evidence not included in the original manufacturer submission. This is normally where the External Assessment Centre:

- a) become aware of additional relevant evidence not submitted by the manufacturer
- b) need to check “real world” assumptions with NICE’s Expert Advisers, or
- c) need to ask the manufacturer for additional information or data not included in the original submission

These events are recorded in the table to ensure that all information relevant to the assessment of the topic is made available to MTAC. The table is presented to MTAC in the Assessment Report Summary, and is made available at public consultation.

Submission Document Section/Sub-section number	Question / Request to Manufacturer or Expert Adviser <i>Please indicate whether Manufacturer or Expert Adviser was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.</i>	Response <i>Attach additional documents provided in response as Appendices and reference in relevant cells below.</i>	Action / Impact / Other comments
	Information on search strategy used by manufacturer	Nice submission at 07.09.10 Incl Section 7.2.doc	Further information requested by the manufacturer
	Information on details on the number of hits in the search strategy and request for the in press paper by manufacturer	Email from manufacturer (Alison Willox) with the additional information	Made use of the additional data in the evaluation
	b/ Checked the search terms with the Experts	Search terms are appropriate	No further action required
	b/ check on the affect of dark pigmented skin	In reality it is not as critical as we used to think. All of the colour is in the epidermis, which comes away with a gentle wipe when the blisters are removed. Underneath that layer we are all the same colour! So as long as the skin is prepared properly it isn't an issue. The only bits of skin that don't read properly are the	No further action required

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		unburned areas where the epidermis (and hence the colour) is intact	
	Checked theatre cost with Experts	A list of staff present during a skin graft was supplied.	The EAC worked out the hourly rate for these staff and thus the hour rate for a skin grafting.
	Confirmed the number of LDI units a burns centre would require. Manufacturer	See appendix 1 <i>Manufacture responses in italic</i>	No further action required
	The justification for the 'Nurse operation time' and 'Clinician interpretation time'. Also queried the length of training needed. Manufacturer	See appendix 1 <i>Manufacture responses in italic</i>	No further action required

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	Confirmed the number of LDI units a burns centre would require. Expert	We do around 450 scans	Therefore one unit would be needed, hence 28 for the whole NHS
	Confirmed the training requirements Expert	Seems about right	No further action required

[Insert additional rows if required]

Appendix 1

1. Contents of email from David Boggett, Managing Director, Moor Instruments Ltd.

I work with Maria Kazantzi at KCARE and am looking over your executable spreadsheet. I would like to gain some clarification on a few points within the spreadsheet. Below is an extract from the Excel workbook from the 'Cost to NHS' sheet.

1/ The Excel spreadsheet is based on one Moor LDI unit being used by each of the 28 UK burn centres, is that correct? *The Breakeven points (lease option 21 patients admitted) for each hospital assumes that each of 28 hospitals are using an LDI.*

Breakeven points can also be estimated for the NHS as a whole (lease of 28 LDIs option 576 patients admitted).

Option 1 Leasing: Breakeven point for NHS as a whole (28 burn centres identified) is 576 patients admitted with 70% scanned or 403 patients scanned;

For each burn center identified, the breakeven point is 21 patients admitted or 14 patients scanned.

Option 2 Purchasing: Breakeven point for NHS as a whole (28 burn centres identified) is 485 patients admitted with 70% scanned or 340 patients scanned;

For each burn center identified, the breakeven point is 17 patients admitted or 12 patients scanned.

2/ 'Nurse operation time', I do not see how you get this figure from worksheet 4 Consultation. *The nurse operation of the LDI time has been omitted from the consultation sheet 4. This is an error on our part. Note that the 60 minutes average time takes into consideration that the instrument has to be powered up, a warming up time allowed for the laser, instrument checks, the patient information entered, the scan(s) done, and the instrument returned to store. If the instrument is already warmed and checks done then the LDI scan, data recording etc can be done within 30 minutes. (Am I correct that this 'operation time' is for the use of the LDI? Yes)*

3/ 'Clinician interpretation time', I do not see how you get this figure from worksheet 4 Consultation. *The consultant interpretation time (average 15 minutes) has been omitted in error from consultation sheet 4.*

4/ NHS staff training cost - does this mean a full two days training for six members of staff per unit? Would the staff require two more full days when a later version arrives two years later? *If a later version of the instrument was introduced then staff would need retraining. I estimate this could on average be every 5 years (includes significant user interface software changes). Training of new staff due to staff turnover also needs to be planned for. There is also merit in staff having refresher courses and the hospital allocating staff time for group meetings for staff to learn from the experience of their colleagues. So including the full cost of training 6 staff every 2 years may be an over-estimate of training costs though some of the training funds at the levels suggested can be used to maintain and improve staff performance.*

From 'Cost to NHS' sheet

VARIABLES: (Change variables in Yellow will update all calculations automatically)				
	Parameter	Range	Typical	Reference
	Number of moorLDIs system	25-64	28	UK Burn centres list (see work sheet 5 UK Burn centres)
	Nurse operation time (min)	30-90 min	60	Consultations with users (see work sheet 4 Consultation)
	Clinician interpretation time (min)	5-30 min	15	Consultations with users (see work sheet 4 Consultation)
	NHS staff training cost	-	£3,416	Fixed cost for NHS staff training: 2 days (16 hours) for 1 clinician, 2 registrars and 3 nurses every 2 years