

HI-Light

Vitiligo Trial



The University of
Nottingham

UNITED KINGDOM • CHINA • MALAYSIA

MED TESTING

Training Resource

By Dr Jonathan Batchelor

*With thanks to Melody MacGregor, Sally-Ann Bell,
Vanessa Unsworth and Natasha Rogers*

Introduction

- **Prior to commencing treatment** with narrowband UVB, a **Minimal Erythema Dose test**, also known as an **MED test**, is performed to identify a patient's individual sensitivity to narrowband UVB.
- This purpose of this training resource is to demonstrate **how to perform an MED test**. The MED test ensures that the patient receives a **starting dose of narrowband UVB suitable for their individual skin**.
- In the HI-Light trial all participants will start at the same starting dose, and the MED test is **mainly performed to rule out photosensitivity**, but we will also be recording the MED test result in the medical notes.

The MED test involves a small hand held machine, which exposes the skin to **ten fixed incremental doses** of narrowband UVB.

Readings are taken 24 hours later when the effect of the narrowband UVB has reached its peak. The **MED** is the **lowest dose needed to produce a clearly demarcated area of redness**, or erythema, on the skin.

The instructions in this training resource relate to use of the **Dermalight 80 MED tester**, which is being issued to sites for use in the HI-Light trial. **Please refer to the 'Dermalight® 80 MED-Tester operating instruction manual' for more information.**

Some sites may choose to carry out MED testing using their own equipment, so some steps of the procedure will be slightly different.



If this is the case, please take advice from the local phototherapy nurses and medical physics department.

These instructions assume that the MED tester has been calibrated prior to use. This should be done by your local medical physics department.

Med Testing

• Determine the **skin type of the patient** - ask the patient about how their skin responds to sun exposure and refer to the table in the Dermalight 80 MED tester manual (summarised below).

Step 1

• Having determined the skin type of the patient, use the other tables at the back of the manual to **determine the exposure time to be used for the MED test**. If the patient is skin type 4, 5 or 6, please use the exposure time given for type 4 skin.

• In the manual there are three tables, based on the MED tester having three slightly different outputs. Having calibrated the MED tester, **the medical physics department will be able to tell you to which of these tables to use**.

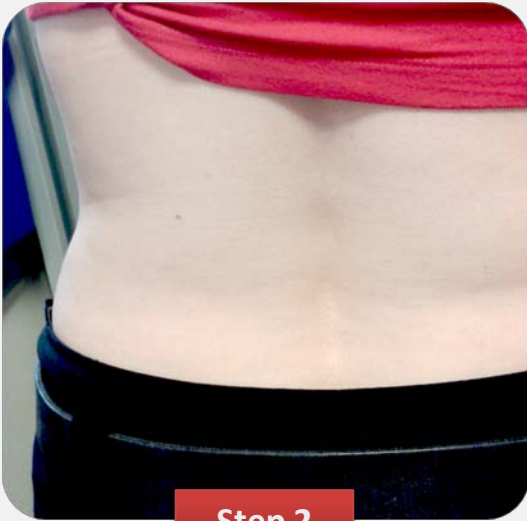
- **Skin type 1** Always burns, does not tan (Celtic type)
- **Skin type 2** Burns easily, tans poorly (fair European type)
- **Skin type 3** Sometimes burns; tans gradually after repeated sun exposure (dark-skinned European type)
- **Skin type 4** Rarely burns; tans easily (Mediterranean type)
- **Skin type 5** Very Rarely burns, tans darkly easily
- **Skin type 6** Never burns, always tans darkly

Dr. Hönle Medizintechnik GmbH **dermalight® 80 MED tester**
OPERATION INSTRUCTIONS

Attachment 1: Dosage tables
MED determination
Testing dosage UVB 311 nm narrowband
max. irradiation intensity: 8,0 mW/cm² with UV-meter (Fa. Waldmann)
The testing may be carried out only after the lamps have been switched on for approx. 4 minutes!

Emission rate	Test field 1	Test field 2	Test field 3	Test field 4	Test field 5	Test field 6	Test field 7	Test field 8	Test field 9	Test field 10	
											100 %
1	0 : 50	0,400	0,360	0,320	0,280	0,240	0,200	0,160	0,120	0,080	0,040
	0 : 56	0,450	0,405	0,360	0,315	0,270	0,225	0,180	0,135	0,090	0,045
2	1 : 03	0,500	0,450	0,400	0,350	0,300	0,250	0,200	0,150	0,100	0,050
	1 : 15	0,600	0,540	0,480	0,420	0,360	0,300	0,240	0,180	0,120	0,060
3	1 : 28	0,700	0,630	0,560	0,490	0,420	0,350	0,280	0,210	0,140	0,070
	1 : 40	0,800	0,720	0,640	0,560	0,480	0,400	0,320	0,240	0,160	0,080
4	1 : 53	0,900	0,810	0,720	0,630	0,540	0,450	0,360	0,270	0,180	0,090

For each skin type, two exposure times (in seconds) are given please use the **shorter** of these two times.



Step 2

- Examine the patient's skin and **select a suitable site** on which to perform the MED test.
- The best site is the **lower back or buttocks**, as these are not commonly exposed to the sun.
- The test area should be **normal skin, not affected by vitiligo** or any other skin rash.
- If necessary, the inner upper arm can be used but this is not recommended.



Step 3

- The patient must **wear protective goggles or glasses**, as should the person performing the test.
- Anyone else in the room during the MED test must also wear protective goggles or glasses.
- The person performing the test should also **wear protective cotton gloves**.



Step 4

- Switch on the MED machine and allow it to **warm up** for at least 4 minutes prior to MED testing.



- Once switched on, it should be laid face down on a table and covered with the **device's case** or with a **fabric cover** such as a pillowcase.



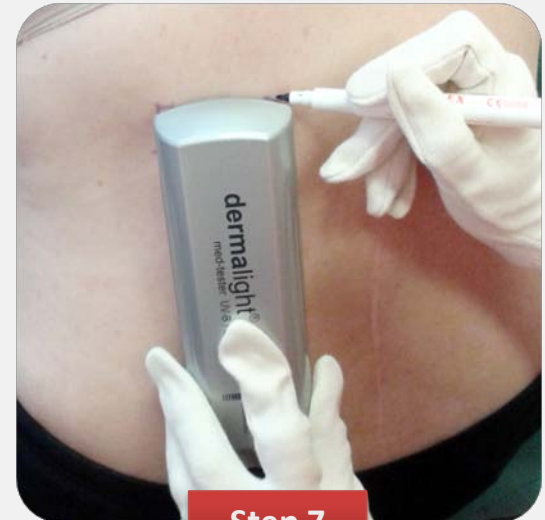
Step 5

Adjust the exposure time, as determined in step 1, using the (-) or (+) buttons.



Step 6

- Once the MED tester has warmed up, hold it lightly but firmly on the selected area of skin and press the MODE (or START/STOP) button to start the timer.
- The end of the exposure time is indicated by a beep and the MED tester is switched off automatically.



Step 7

- Before removing the MED tester from the skin, mark the skin with a skin marker at both ends of the tester. This will enable the person reading the test result on the following day to know which area of skin was exposed to the UVB.
- Ask the patient to keep the area as dry as possible for 24 hours so that the markings are kept as clear as possible.

NAME		REG NO.	DERBY HOSPITALS	
Joe Bloggs		21.04.1968	Consultant	
DATE & TIME		CONFIRMATION NOTES		PRINT NAME, DESIGNATION & BLEEP NO. ALONGSIDE SIGNATURE
08/10/2015		DHRD/2015/037 HI-Light Study PI Dr J. Batchelor		
Visit 1				
Hospital				
In-Patient				
Out-Patient				
Patient has attended Dermatology clinic today for assessment of Vitiligo patches and possible entry into the above study. Patient has previously received Patient information sheet (V 1.1-3 March 2015) Study information fully discussed, and inclusion/exclusion criteria reviewed. Informed consent given by PI Dr. Batchelor and consent form signed (V 1.0 1 August 2014)				
Full skin assessment performed and Vitiligo patches identified for treatment by Dr. Batchelor:				
1) Right cheek				
2) Left lower arm Please see pictorial diagram				
3) Right foot				
MED performed today for skin type 3. Light applied to lower back for 1.05 seconds as per protocol. All safety procedures followed.				
RESEARCH NURSE: [Signature]				

Step 8

Complete the medical notes with date and time the procedure was performed and sign the entry.



Step 9

- The patient returns 24 hours later for the result to be read.
- The MED is identified using the table in the manual.
- It is the dose given to the area showing a square of erythema that is just visible.

Out-Patient							
Patient has attended Dermatology clinic today for assessment of Vitiligo patches and possible entry into the above study. Patient has previously received Patient information sheet (V 1.1-3 March 2015) Study information fully discussed, and inclusion/exclusion criteria reviewed. Informed consent given by PI Dr. Batchelor and consent form signed (V 1.0 1 August 2014)							
Full skin assessment performed and Vitiligo patches identified for treatment by Dr. Batchelor:							
1) Right cheek							
2) Left lower arm Please see pictorial diagram							
3) Right foot							
MED performed today for skin type 3. Light applied to lower back for 1.05 seconds as per protocol. All safety procedures followed.							
RESEARCH NURSE: [Signature]							
09/10/2015							
Visit 2							
DHRD/2015/037 HI-Light Study PI Dr J. Batchelor							
Patient returned today for results of MED test. Patient is eligible and happy to participate in the study. Randomisation and patient education completed as per protocol. Medical photography pictures of selected areas of vitiligo have been taken.							
MED RESULTS BELOW:							
<table border="0"> <tr> <td> HI-Light Participant ID number: CEN_001 Medical investigator at site: This patient is participating in a 3 arm, placebo controlled, double blind, randomised trial, and receives one of the following treatment combinations: A) Monotherapy (vitiligo 0.1% cream) and dummy NB UVB light B) Vitiligo cream and active NB UVB light C) Monotherapy (vitiligo 0.1% cream) and active NB UVB light </td> <td> Minimal Erythema Dose test (MED) Date MED test performed: 08/10/2015 MED test performed by: [Signature] Incubation period for MED test: 0.5 hours Date MED test read: 09/10/2015 MED test results reading: [Signature] MED Result: 0.45 Joules <input type="checkbox"/> Not readable <input type="checkbox"/> patient didn't return for reading </td> <td> HI-Light </td> </tr> </table>					HI-Light Participant ID number: CEN_001 Medical investigator at site: This patient is participating in a 3 arm, placebo controlled, double blind, randomised trial, and receives one of the following treatment combinations: A) Monotherapy (vitiligo 0.1% cream) and dummy NB UVB light B) Vitiligo cream and active NB UVB light C) Monotherapy (vitiligo 0.1% cream) and active NB UVB light	Minimal Erythema Dose test (MED) Date MED test performed: 08/10/2015 MED test performed by: [Signature] Incubation period for MED test: 0.5 hours Date MED test read: 09/10/2015 MED test results reading: [Signature] MED Result: 0.45 Joules <input type="checkbox"/> Not readable <input type="checkbox"/> patient didn't return for reading	HI-Light
HI-Light Participant ID number: CEN_001 Medical investigator at site: This patient is participating in a 3 arm, placebo controlled, double blind, randomised trial, and receives one of the following treatment combinations: A) Monotherapy (vitiligo 0.1% cream) and dummy NB UVB light B) Vitiligo cream and active NB UVB light C) Monotherapy (vitiligo 0.1% cream) and active NB UVB light	Minimal Erythema Dose test (MED) Date MED test performed: 08/10/2015 MED test performed by: [Signature] Incubation period for MED test: 0.5 hours Date MED test read: 09/10/2015 MED test results reading: [Signature] MED Result: 0.45 Joules <input type="checkbox"/> Not readable <input type="checkbox"/> patient didn't return for reading	HI-Light					
RESEARCH NURSE: [Signature]							

Step 10

Complete the medical notes with date, time of reading, the MED result and signature.

Step 11

When the test is completed the MED tester should not be re-used for 3 to 5 minutes.