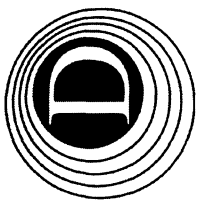


DALE40

Phototherapy Radiometer



DALE TECHNOLOGY

Operating Manual

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Revision History		
Revision	Description	Date
A	Initial Release	7/03

Copyright

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Unpacking and Inspection

Follow standard receiving practices upon receipt of the instrument. Check the shipping carton for damage. If damage is found, stop unpacking the instrument. Notify the carrier and ask for an agent to be present while the instrument is unpacked. There are no special unpacking instructions, but be careful not to damage the instrument when unpacking it. Inspect the instrument for physical damage such as bent or broken parts, dents, or scratches.

Claims

Our routine method of shipment is via common carrier, FOB origin. Upon delivery, if physical damage is found, retain all packing materials in their original condition and contact the carrier immediately to file a claim.

If the instrument is delivered in good physical condition but does not operate within specifications, or if there are any other problems not caused by shipping damage, please contact Dale Technology or your local distributor.

Standard Terms and Conditions

Refunds & Credits

Please note that only serialized products (products labeled with a distinct serial number) and accessories are eligible for partial refund and/or credit. Nonserialized parts and accessory items (cables, carrying cases, auxiliary modules, etc.) are not eligible for return or refund. In order to receive a partial refund/credit of a product purchase price on a serialized product, the product must not have been damaged by the customer or by the common carrier chosen by the customer to return the goods, and the product must be returned complete (meaning all manuals, cables, accessories, etc.) within 90 days of original purchase and in "as new" and resellable condition. The Return Procedure must be followed to assure prompt refund/credit.

Restocking Charges

Only products returned within 90 days from the date of original purchase are eligible for refund/credit. Products returned within 30 days of original purchase are subject to a minimum restocking fee of 15%. Products returned in excess of 30 days after purchase, but prior to 90 days, are subject to a minimum restocking fee of 20%. Additional charges for damage and/or missing parts and accessories will be applied to all returns. Products not returned within 90 days of purchase, or products which are not in "as new" and resellable condition, are not eligible for credit return and will be returned to the customer.

Return Procedure

Products sent to Dale Technology for repair must be sent via UPS or FedEx® fully insured to:

Dale Technology
 Service Department
 5200 Convair Drive
 Carson City, NV 89706

The unit should be wrapped in at least 2 inches of Styrofoam filler or similar packing material. Unit should be accompanied by a written explanation detailing problem with the unit. For assistance please contact the Service Department at 1-800-265-7586.

Certification

This instrument was thoroughly tested and inspected and found to meet Dale Technology's manufacturing specifications when it was shipped from the factory. Calibration measurements are traceable to the National Institute of Standards and Technology (NIST). Devices for which there are no NIST calibration standards are measured against in-house performance standards using accepted test procedures.

Warranty

Warranty and Product Support

This instrument is warranted by Dale Technology against defects in materials and workmanship for one full year from the date of original purchase. During the warranty period, we will repair or, at our option, replace at no charge a product that proves to be defective, provided you return the product, shipping prepaid, to Dale Technology. This warranty does not apply if the product has been damaged by accident or misuse or as the result of service or modification by other than Dale Technology. IN NO EVENT SHALL DALE TECHNOLOGY BE LIABLE FOR CONSEQUENTIAL DAMAGES.

Only serialized products and their accessory items (those items bearing a distinct serial number tag) are covered under this one-year warranty. PHYSICAL DAMAGE CAUSED BY MISUSE OR PHYSICAL ABUSE IS NOT COVERED UNDER THE WARRANTY. Items such as cables and nonserialized modules are not covered under this warranty.

This warranty gives you specific legal rights, and you may also have other rights which vary from state to state, province to province, or country to country. This warranty is limited to repairing the instrument to Dale Technology's specifications.

When you return an instrument to Dale Technology, for service, repair, or calibration, we recommend using United Parcel Service, Federal Express, or Air Parcel Post. We also recommend that you insure your shipment for its actual replacement cost. Dale Technology will not be responsible for lost shipments or instruments that are received in damaged condition due to improper packaging or handling. All warranty claim shipments must be made on a freight prepaid basis. Also, in order to expedite your claim, please include a properly completed copy of the Service Return Form. Recalibration of instruments, which have a recommended semiannual calibration frequency, is not covered under the warranty.

Use the original carton and packaging material for shipment. If they are not available, we recommend the following guide for repackaging:

- Use a double-walled carton of sufficient strength for the weight being shipped.
- Use heavy paper or cardboard to protect all instrument surfaces. Use nonabrasive material around all projecting parts.
- Use at least four inches of tightly packed, industrial-approved shock-absorbent material around the instrument.

Warranty Disclaimer

Should you elect to have your instrument serviced and/or calibrated by someone other than Dale Technology, please be advised that the original warranty covering your product becomes void when the tamper-resistant Quality Seal is removed or broken without proper factory authorization. We strongly recommend, therefore, that you send your instrument to Dale Technology for factory service and calibration, especially during the original warranty period.

In all cases, breaking the tamper-resistant Quality Seal should be avoided at all cost, as this seal is the key to your original instrument warranty. In the event that the seal must be broken to gain internal access to the instrument (e.g., in the case of a customer-installed firmware upgrade), you must first contact Dale Technology's technical support department at 800-265-7586. You will be required to provide us with the serial number for your instrument as well as a valid reason for breaking the Quality Seal. You should break this seal only after you have received factory authorization. Do not break the Quality Seal before you have contacted us! Following these steps will help ensure that you will retain the original warranty on your instrument without interruption.

WARNING

Unauthorized user modifications or application beyond the published specifications may result in electrical shock hazards or improper operation. Dale Technology will not be responsible for any injuries sustained due to unauthorized equipment modifications.

Warnings and Precautions

Do not operate the Radiometer when the temperature exceeds 0 - 50°C (32 - 122°F).

Do not subject the Radiometer to excessive shock or vibration.

If the Radiometer is stored for more than two weeks, remove the battery.

The DALE40 Phototherapy Radiometer is a fixed-bandwidth radiometer. It can measure energy only within its specified spectral range and accuracy. It should not be used to measure energy outside the specified effective spectral range.

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General Information

Chapter

1

Inside This Section

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- Standards and Recommendations
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- Radiometer Description
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- Operating Procedures
- Specifications
- Service

DALE40 Phototherapy Radiometer

General Background

Investigators and clinicians have demonstrated the therapeutic effect of blue light irradiance on the bilirubin count of newborns. Dale Technology's Phototherapy Radiometer determines the irradiance (flux density across the spectral bandwidth) of phototherapy lamps used for the treatment of hyperbilirubinemia.

Standards and Recommendations

There are no recognized national or international phototherapy standards. Clinicians either follow the recommendations of national organizations (e.g., Committee on Phototherapy of the National Research Council), or proven techniques developed by other investigators and clinicians. However, *studies have shown that an irradiance below 2- 4 $\mu\text{W}/\text{cm}^2/\text{nm}$ (micro-watts per square centimeter per nanometer) may not be effective* regardless of the clinical technique followed. It is important to measure the blue spectral power emitted by the phototherapy light bulbs to:

1. Optimize treatment of hyperbilirubinemia (jaundice).
2. Measure and/or monitor the output power of the lamps.
3. Determine and/or monitor the irradiance and dosage delivered to a newborn.
4. Establish an effective dose-to-therapeutic response.
5. Determine the deterioration of the lamp's effectiveness. The DALE40 can determine the effectiveness of phototherapy treatment by displaying the irradiance of bilirubin lights.
6. Devise a more meaningful and economical bulb replacement schedule. A hospital may realize real cost savings by implementing a lamp discard plan. Instead of replacing lamps at an arbitrary time, degradation criteria can be used such as 80% of original lamp output. Trending of the lamp may be accomplished and the performance verified with the DALE40.

Effective Phototherapy

The following factors determine whether phototherapy lamps deliver an effective dosage of irradiance.

- Variations in line voltage.
- Irregularities in ballast operation.
- Effects of an incubator.
- Dust on bulbs.
- Operating temperature of bulbs.
- Position and movement of the baby.
- Surface area of baby actually being irradiated.
- Baby to light distance.
- Angle of light incident on the baby.
- Extraneous lighting.
- Type and age of bulbs.
- Output power decay characteristic of bulbs.
- Irradiance of phototherapy lamps
- Wavelength output characteristic of source bulbs.
- Uniform radiation across the treatment field.
- Energy reflected by the patient's body surface.
- Clinical environment, type of therapy, and infant's condition.

Radiometer Description

The DALE40 Phototherapy Radiometer is a portable, fixed- bandwidth, solid-state, battery-operated instrument used to measure irradiance from phototherapy lamps.

The detector assembly consists of a sensitive photodetector probe, which responds to light in the blue region of the visible spectrum (between 420 and 495 nanometers).

The probe is also provided with a special wide-angle lens to match the cosine receiving function of human skin. The readout is calibrated directly in $\mu\text{W}/\text{cm}^2$, which is displayed by a 13 mm high LCD. The radiometer is calibrated at Dale Technology against a standard traceable to the National Institute of Standards (NIST). A Calibration Certificate is furnished with the meter. The radiometer should be calibrated at least once a year.

Testing Phototherapy Light Sources

The DALE40 Phototherapy Radiometer has a peak response at 453 nanometers (nm). Its effective spectral range is 44 nm (429 to 473 nm), based on the 50% response cutoff points on the transmittance vs. wavelength curve.

Applications

Although the in-vivo response of bilirubin to light is still undefined, the phototherapy radiometer does have definite applications.

1. All radiometer readings should be taken with the detector at the level of the infant's chest. If this is not possible, readings may be taken at the level of the incubator with the detector placed in the path of the incident light. This alternate method, however, should be used to take relative instead of absolute readings. A good starting point is 18" from the light source.
2. All measurements should be taken under the same test conditions, to maintain consistency.

3. More important than an "optimum irradiance," the radiometer should provide consistent readings (standard error). Thus if the power density of energy in the blue region is increased (or decreased) at the level of the infant, the magnitude of this increase (or decrease) would be reflected in the measurement.
4. Radiometers from different manufacturers may display different readings under the same test conditions:
 - A. Irradiance may be represented in either of two units of measurement ($\mu\text{W}/\text{cm}^2$ or $\mu\text{W}/\text{cm}^2/\text{nm}$).
 - B. The range and spectral power response characteristics may be different for different photodetectors. Interpretation of irradiance with respect to units, and the rationale for effective spectral range may differ among manufacturers.

NOTE: The DALE40 Phototherapy Radiometer has an effective bandwidth of 44 nm. Bandwidth is determined using the points corresponding to 50% of peak transmission. For comparison of radiometers that measure in the units of $\mu\text{W}/\text{cm}^2/\text{nm}$, bandwidth must be determined the same way. i.e. some manufacturers determine band width using 10% points (or some other significant points). Thus, if 10% points are used, determine the bandwidth that corresponds to 10% by using the Dale radiometer curve and divide your answer by the new band width. See the section *Units of Measure*.

Therefore, unless there is a correspondence of all factors mentioned above between radiometers from different manufacturers, it is difficult to compare readings either directly or by conversion of units.

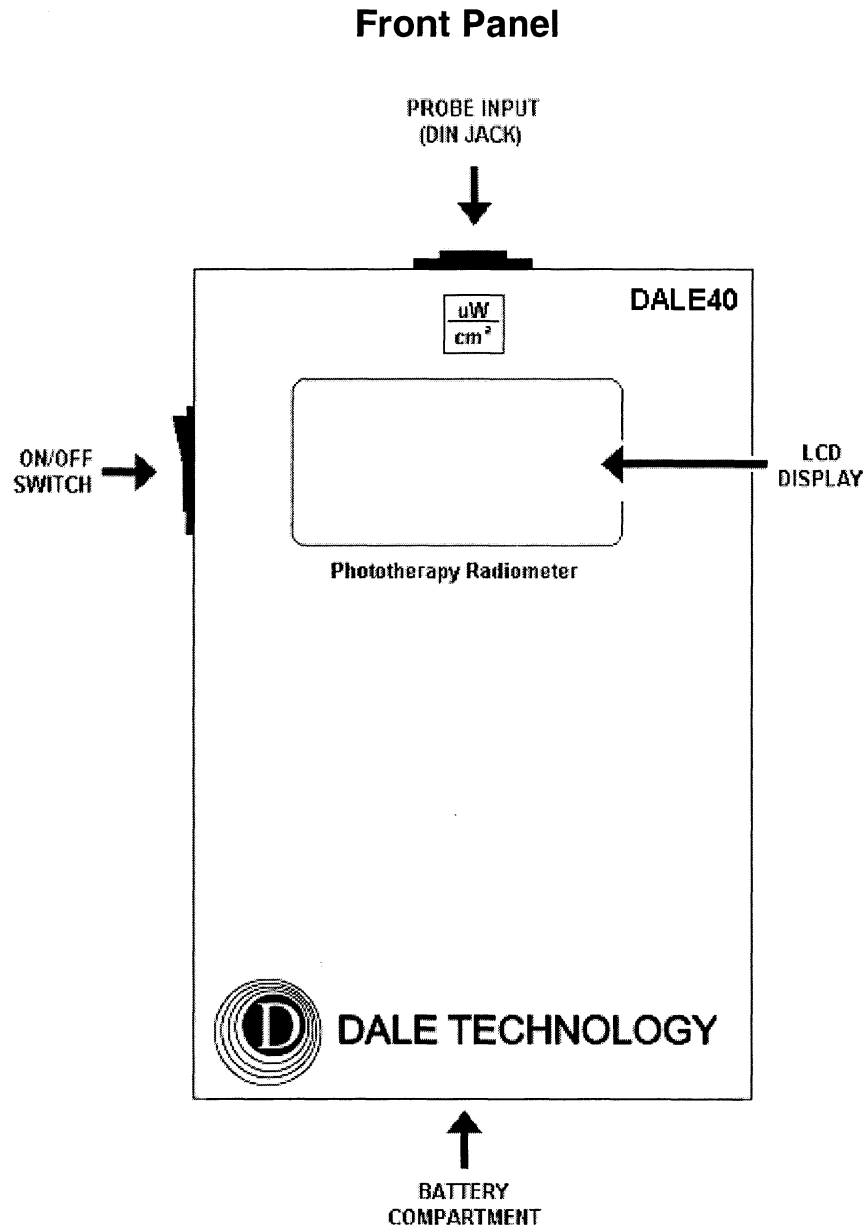


Figure 1-1: Radiometer Front Panel

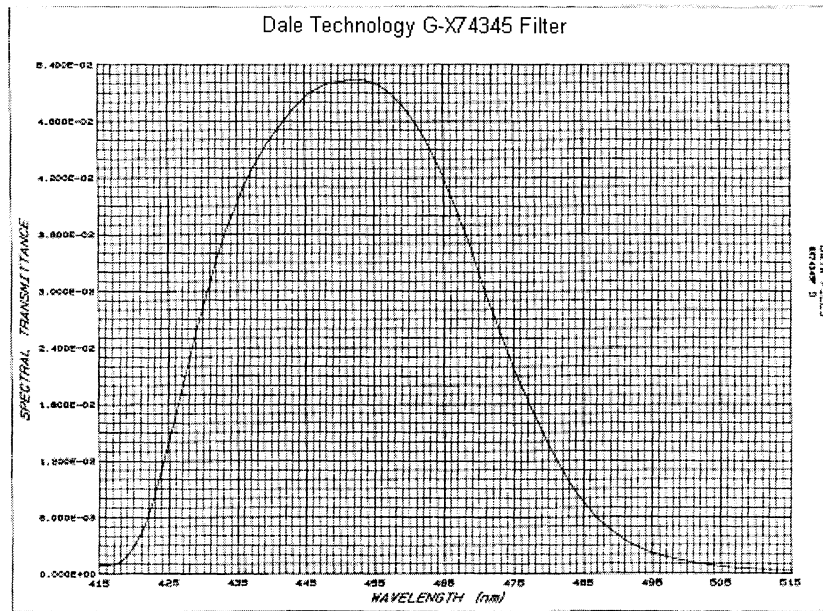


Figure 1-2: Wavelength/Response chart

Units of Measure

There are two commonly used units of measurement in phototherapy radiometry for irradiation (flux density across a spectral bandwidth):

- Microwatts per square centimeter ($\mu\text{W}/\text{cm}^2$).
- Microwatts per square centimeter per nanometer ($\mu\text{W}/\text{cm}^2/\text{nm}$).

The DALE40 Phototherapy Radiometer reads power in $\mu\text{W}/\text{cm}^2$. This unit of measurement was chosen because it represents the spectral power perceived by the photodetector. Conversion from one unit to another can be accomplished using the following formulas:

$$\mu\text{W}/\text{cm}^2/\text{nm} = \mu\text{W}/\text{cm}^2 / \text{bandwidth (nm)}$$

e.g.

$$4 \mu\text{W}/\text{cm}^2/\text{nm} = 4 \times 44 = 176 \mu\text{W}/\text{cm}^2$$

$$480 \mu\text{W}/\text{cm}^2 = 480 / 44 = 10.9 \mu\text{W}/\text{cm}^2/\text{nm}$$

$$\text{DOSAGE (irradiance-hrs)} = \text{irradiance } (\mu\text{W}/\text{cm}^2/\text{nm}) \times \text{Time (hrs)}$$

For example, if an irradiance of $320 \mu\text{W}/\text{cm}^2$ is given to a newborn baby for three hours, the baby receives a dosage of $4 \times 3 = 12$ irradiance-hrs.

Operating Procedures

1. Place a 9-volt battery in the rear compartment, insuring proper polarity.
2. Attach the photodetector probe to the unit by aligning the pins and screwing tightly. When removing the probe, do not pull or bend cord. (Use metal surfaces only.)
3. Turn the power switch ON. With the probe away from all lights, the reading on the LCD display should be 000.
4. Cleaning Instructions: Cleaning should be carried out normally according to regular hospital practices. A germicidal surface cleaner is recommended for the exterior surfaces of the meter body. Lens tissue should be used to wipe the lens receptor.

NOTES: If "LO BAT" is displayed, battery replacement is required. Inaccurate readings may be caused by dirty probe lenses.

Specifications

Effective Spectral Range: 429-473 nm (maximum response at 453 nm)

Range: 0-1999 $\mu\text{W}/\text{cm}^2$

Resolution: 1 $\mu\text{W}/\text{cm}^2$

Power: One 9 V battery (transistor). When battery is due for replacement, "LO BAT" will appear (service = 150 hours).

Linearity: $\pm 3\%$ full scale

Operating Temperature: 0-50°C (32-122°F)

Electrical Accuracy: $\pm 3\%$

Radiometer Accuracy: Within $\pm 5\%$ full scale

Weight: 250 g (9 oz)

Dimensions: 80 mm x 38 mm x 145 mm (3.1" x 1.5" x 5.7")

Receptor Type: Silicon photocell.

**All specifications are subject to change without notice.*

Service

The DALE40 Phototherapy Radiometer should be returned to Dale Technology if repairs are required. Before shipping the unit, call our customer service representatives at the number provided below for assistance. Pack the unit carefully; insure it for the full retail value and return it to:

DALE TECHNOLOGY
Service Department
5200 Convair Drive
Carson City, NV 89706

Tel: 775.883.3157
Fax: 775.886.6320
Toll Free: 800.265.7586



DALE TECHNOLOGY

Dale Technology
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