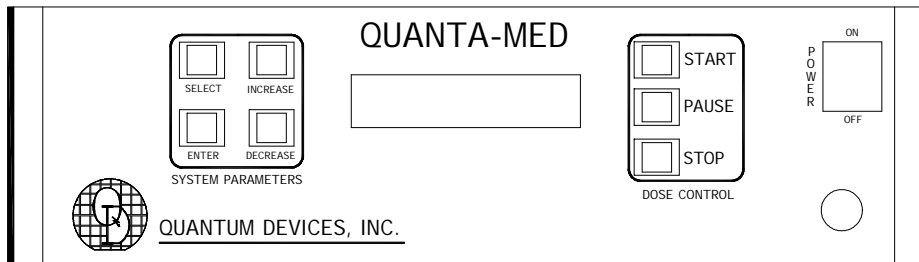


# QB-QUANTA-MED-688

## *Operation Manual*



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# Clinician's Operation Manual

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| <b>Warranty and Service Information</b>            |     |
| Proprietary Notice .....                           | i   |
| Limited Warranty .....                             | i   |
| Service and Support .....                          | i   |
| U.S Patents .....                                  | i   |
| <b>Warnings, Cautions &amp; Notes</b>              |     |
| Symbol Definitions .....                           | ii  |
| Warnings .....                                     | ii  |
| Cautions .....                                     | ii  |
| Notes .....  | iii |
| <b>Chapter 1: Introduction</b>                     |     |
| About the Manual .....                             | 1   |
| Theory of Operation.....                           | 1   |
| <b>Chapter 2: Intended Use and Device Features</b> |     |
| Intended Use .....                                 | 2   |
| Device Features.....                               | 2   |
| <b>Chapter 3: Controls and Features</b>            |     |
| QB-QUANTA-MED-688 Front Panel.....                 | 3   |
| Power Switch .....                                 | 3   |
| System Parameters Module.....                      | 3   |
| Dose Control Module.....                           | 3   |
| LCD Display .....                                  | 3   |
| Fuse replacement .....                             | 3   |
| <b>Chapter 4: Operating Instructions</b>           |     |
| Unpacking and Inspection.....                      | 4   |
| Procedure for Light Dose Delivery .....            | 4   |
| Pausing the System During Dose Delivery .....      | 5   |
| Stopping the System During Dose Delivery .....     | 5   |
| Changing Time Format .....                         | 5   |
| Viewing Previous Exposure.....                     | 5   |
| <b>Chapter 5: Maintenance</b>                      |     |
| Calibration.....                                   | 6   |
| Storage .....                                      | 6   |
| Cleaning and Disinfecting.....                     | 6   |
| Preventative Inspection.....                       | 7   |
| <b>Chapter 6: Specifications</b>                   |     |
| Power Requirements .....                           | 8   |
| Dimensions .....                                   | 8   |
| Environmental Specifications .....                 | 8   |
| <b>Chapter 7: Contact Information</b>              |     |
| Contact Information .....                          | 9   |

## Warranty & Service Information

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### Proprietary Notice

Information contained in this document is copyrighted by Quantum Devices, Inc. (QDI) and may not be duplicated in full or part by any person without prior written approval of QDI. Its purpose is to provide the user with adequately detailed documentation to efficiently install, operate and maintain the device supplied. Efforts have been made to keep the information contained in this document current and accurate as of the date of publication or revision. However, no guarantee is given or implied that this document is error free or that it is accurate regarding any specification.

### Limited Warranty

QDI warrants each new device to be free from defects in workmanship and materials under normal use for a period of one (1) year from the date of shipment. QDI's sole obligation under this warranty will be to repair or replace, at its option, products that prove to be defective during the warranty period. The foregoing shall be the sole warranty remedy. Except as set forth herein, seller makes no warranties, either expressed or implied, including the implied warranties of merchantability and fitness for a particular purpose. No warranty is provided if the product is modified without the express written consent of QDI. The seller shall not be liable in any event for incidental or consequential damage. This warranty is not assignable.

### Service Support

Repairs of QDI's devices under warranty must be made at QDI's factory. There are no customer serviceable parts for this device. If the device needs repair, contact QDI (See Chapter 7 of this manual for contact information). When calling have the device's model and serial number ready.

If you need to ship the device, pack the device and accessories carefully to prevent shipping damage. All accessories should accompany the device.

### U.S. Patents



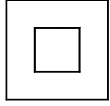
Protected by U.S. Patents: 5,278,432 5,728,090 5,660,461 and 5,012,609 other patents pending.

## Warnings, Cautions & Notes

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| KEYWORD | DEFINITION   |
|---------|--|
| WARNING | Tells you something that could hurt the patient or hurt the operator |
| CAUTION | Tells you something that could damage the device                     |
| NOTE    | Tells you other important information                                |

### Symbol Definitions

| SYMBOL   | DEFINITION                   |
|--|------------------------------|
|   | For alternating current only |
|   | Type BF Equipment            |
|  | Class 1 Device               |

### Warnings

**WARNING!** Federal law (USA) restricts the use or sale of this device by, or on the order of, a physician.

**WARNING!** Do not use this device in the presence of flammable anesthetics.

**WARNING!** Do not use this device in the presence of magnetic resonance imaging (MR or MRI) equipment.

**WARNING!** Emitted visible energy from the LED head has a central wavelength of 688nm. Even though, the emitted energy is incoherent and considered safe, extended direct eye contact should be avoided

### Cautions

**CAUTION!** Do not autoclave or immerse light source in liquid.

## **Warnings, Cautions & Notes (cont.)**

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**CAUTION!** This device is intended for use by persons trained in professional health care. The operator must be thoroughly familiar with the information in this manual before using the device.

**CAUTION!** Do not use this device if the integrity of the mains protective earth conductor can not be verified

### **Notes**

**NOTE!** This (Equipment and/or system) is suitable for use in all establishments other than domestic and those directly connected to low voltage power supply network which supplies buildings used for domestic purposes.

**NOTE!** Operation of this device may be adversely affected in the presence of strong electromagnetic sources, such as electrosurgery equipment.

**NOTE!** Operation of this device may be adversely affected in the presence of computed tomograph (CT) equipment.

**NOTE!** Operation of this device may be adversely affected if used in areas where high moisture or precipitation is present.

**NOTE!** There are no customer serviceable parts in this device. If service is required please contact QDI.

## **Chapter 1: Introduction**

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### **About the Manual**

The Operation Manual provides installation, operation, and maintenance instructions for health-care professional and other users trained in the application or use of photodynamic therapy drug-device combinations.

### **Theory of Operation**

Photodynamic Therapy (PDT) is a cancer treatment modality involving administration of a localized photosensitive dye, which upon activation with light destroys cells. The photosensitive dye is preferentially taken up and/or retained by malignant tissue. Subsequently the sensitized tissue is locally exposed to light of the appropriate wavelength, causing cell death. The high-powered QB-QUANTA-MED light source offers reliability, repeatability and the appropriate wavelength to achieve maximum results in PDT applications. The unit provides an increased emission size which allows the user to cover a larger surface area (without sacrificing output power) than other light sources commonly used with PDT.

## **Chapter 2: Intended Use and Device Features**

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### **Intended Use**

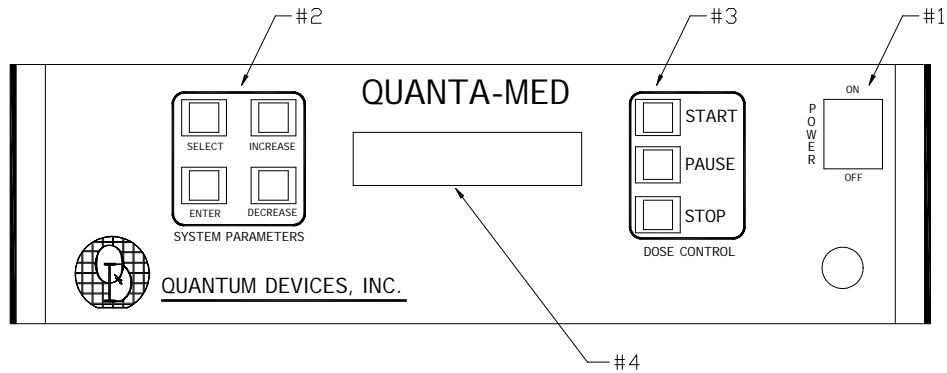
The Quanta-Med 688 light delivery system is a solid state, non-thermal, wavelength specific source designed to be used in the photodynamic treatment of multiple skin cancers in conjunction with benzoporphyrin derivative monoacid ring A [BPD-MA (verteporfin)]. The solid state illumination head can be placed directly on the skin lesions. Several heads can be used and thus allows photodynamic therapy to be performed on more than one tumor at a time.

### **Device Features**

1. Self contained QUANTA-MED 688 Source/Control console includes the Power Source for the Illuminating Head, a Thermoelectric cooled fluid loop, and the associated electronic interface for control and monitoring of all salient operational parameters.
2. High Energy non-thermal, wavelength specific solid state Illuminating Head reduces exposure time and runs cool to the touch.
3. All system controls are conveniently located on the front panel for ease of set up and delivery of required light dosimetry.
4. Large area back lit Liquid Crystal Display (LCD) for ease of setup and monitoring the operation of the Illuminating Head and all of the control parameters during and after exposure.
5. The control console has been designed for single unit tabletop deployment or multiple unit rack mounting configurations.

## Chapter 3: Controls and Features

### QB-QUANTA-MED-688 Front Panel



#### 1. Power Switch

Toggleing the power switch will turn the power ON and OFF

#### 2. System Parameters Module

The system parameters module consists of four buttons, select, increase, decrease, and enter. These buttons allow for set up of dose delivery.

#### 3. Dose Control Module

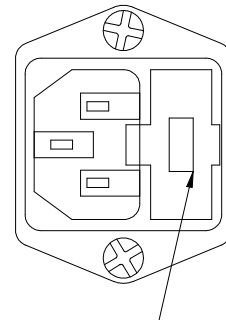
The three buttons in this module allow you to start, pause, and stop a light dose delivery.

#### 4. LCD Display

Displays menu items and status of the device.

### Fuse Replacement

In the event a fuse change is needed, locate the combination power cord receptacle/ fuse holder on the rear panel. Remove the power cord from the receptacle. Next pull out the tray located to the right of the receptacle that houses the fuses (pictured). Remove the suspect fuse(s), and replace them with new fuses making sure that they are the same voltage and amperage. Slide the tray back to the close position, making sure that it is properly closed.



Fuse Drawer

## Chapter 4: Operating Instructions

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### Unpacking and Inspection

Open the carton and check each item in the box. Make sure that you have everything listed on the packing list. There should be one or more of the following items.

#### **1. QB-QUANTA-MED-688 Control Console, and Light Source**

Consisting of all the necessary controls to operate the QB-Quanta-Med-688.

#### **2. Control Console Power Cord**

Used to provide power to the QB-Quanta-Med-688.

### Procedure for Light Dose Delivery

1. Secure the QB-QUANTA-MED-688 light source to the patient
2. Turn power button to on.
3. Allow for Self-Test to Complete, and Quanta-Med-688 display to appear.
4. Press the select button on the front panel to enter the menu sequence. Continuous pressing of the select key will scroll through the menu items. Items that you should see include Light intensity (mw/cm<sup>2</sup>), Light dose (J/cm<sup>2</sup>), Exposure time, Time format (viewed in HOURS:MIN:SEC or Seconds), and view previous exposure.
5. To Choose Light Intensity Desired
  - Press the select button until "Light Intensity" menu item appears.
  - Press the increase or decrease button until you have reached the desired power setting.(holding button down will increase scroll speed)
  - When desired setting is flashing on the LCD display press the enter key.
6. Choose Light Dose Desired
  - Press the select button until "Light Dose" menu item appears.
  - Press the increase or decrease button until desired setting is reached. (holding button down will increase scroll speed)
  - When desired setting is flashing on LCD display press the enter key.
7. To view exposure time
  - Press the select button until the "Exposure Time" menu item appears
  - This displays the exposure time needed to achieve the light dose desired (Chosen in steps 5 and 6).

## **Operating Instructions (Cont.)**

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8. When all parameters are set press the start button to start the dose delivery.

During the dose delivery procedure, pressing the select button continuously will show Dose Delivered, Remaining Time, Delivered Time, Light Intensity, and Light Dose.

### **Pausing the System During Dose Delivery**

To pause the system while delivering a dose simply press pause. Pressing pause in the middle of a dose delivery will shut off the LEDs and halt the system. Pressing start again will resume the dose delivery.

### **Stopping the System During Dose Delivery**

To stop the delivery, simply press the stop button. Pressing the stop button during a dose delivery will terminate the delivery, and send you back to the menu sequence.

### **Changing Time Format:**

The time format can be viewed from HOURS:MIN:SEC or Seconds.

- Press the select button until "Time Format" appears on the LCD
- Press the increase or decrease button to obtain desired format.
- When desired format is flashing press the enter key.

### **Viewing Previous Exposure:**

To view the previous exposure

- Press the select button until "View Previous Exposure" appears on LCD display.
- Press the enter button to view previous exposure parameters

## Chapter 5: Maintenance

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### Calibration

Calibration for this unit is required after 100 hours of run time. If the calibration alert appears instead of Quanta-Med-688 after the power on self-test, the unit needs to be sent back to Quantum Devices, Inc. to be re-calibrated.

### Storage

Whenever possible, the QB-QUANTA-MED-688 should be stored at room temperature in a dry place.

If it is necessary to store the device for an extended period of time, the unit should be packed in its original shipping container.

Storage Specifications are as follows

Temperature: -30° C to 55° C (-22° F to 131° F)

Relative Humidity: 10% to 95% (non-condensing)

### Cleaning and Disinfecting

| ITEM:           | HOW OFTEN:     | BY DOING THIS:   |
|-----------------|----------------|--|
| Lamp Head       | After each use | 1. Unplug unit from the outlet.<br>2. Wipe the surfaces of the lamp with a soft, clean cloth dampened in warm soapy water or 10% bleach solution. Use only a cloth that is dampened not wet.<br><br><b>CAUTION!</b> Do not allow liquid to enter any of the openings on the unit.            |
| Control Console | When necessary | 1. Unplug unit from the outlet.<br>2. Wipe the surfaces of the control console with a soft, clean cloth dampened in warm soapy water or 10% bleach solution. Use only a cloth that is dampened not wet.<br><br><b>CAUTION!</b> Do not allow liquid to enter any of the openings on the unit. |

## Chapter 5: Maintenance (cont.)

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### **Preventative Inspection**

Before each use, carefully inspect the device to make sure it does not appear damaged. When the device is operational, inspect the cooling fan on the rear panel to make sure it is functional and that there is quality airflow. Before operation the user should also check the lamp head to verify that protective glass housing the LEDs is intact.

## Chapter 6: Specifications

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### Power Requirements

**AC Line Input:**

|                |                    |
|----------------|--------------------|
| Auto-ranging   | 90-132/180-264 VAC |
| Line Frequency | 47 to 63 Hz        |

**Fuse Selection:**

|                |                                   |
|----------------|-----------------------------------|
| For 90-132VAC  | 6.3A, 250 Volt, Time-Lag, 5x20mm  |
| For 180-264VAC | 3.15A, 250 Volt, Time-Lag, 5x20mm |

### Dimensions

**Cabinet:**

|         |                     |
|---------|---------------------|
| Height: | 5.22 in. (132.6 mm) |
| Width:  | 19 in. (482.6 mm)   |
| Depth:  | 11.02 in. (280 mm)  |
| Weight  | 24 pounds           |

**LED Head:**

|           |                    |
|-----------|--------------------|
| Length:   | 2.4 in. (60.96 mm) |
| Diameter: | 1.6 in. (40.64 mm) |

**Head Cable:**

|         |                  |
|---------|------------------|
| Length: | 60 in. (1524 mm) |
|---------|------------------|

### Environmental Specifications

|                   |  |
|-------------------|--|
| Operating Temp:   | 15 - 35° C (59 - 95°F)   |
| Storage Temp:     | -35 - 55° C (-22 - 131° F)   |
| Relative Humidity | 10 - 95% (storage), non-condensing<br>15 - 95% (operating), non-condensing |

## Chapter 7: Contact Information

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### **In The United States or Canada Contact:**

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