November 2022

# DML 3000 User Manual


For use with the *digene* ® Hybrid Capture® 2 DNA tests

IVD

CE

REF 5000-00031

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Sample to Insight

# Contents

# 1 Introduction

Thank you for choosing the *digene* Microplate Luminometer (DML) 3000. We are confident it will become an integral part of your laboratory.

Before using the instrument, it is essential that you read this user manual carefully and pay particular attention to the safety information. The instructions and safety information in the user manual must be followed to ensure safe operation of the instrument and to maintain the instrument in a safe condition.

## 1.1 About this user manual

This user manual provides instructions on using the DML 3000 to measure and analyze specimens in conjunction with the *digene* HC2 System Software. Use this user manual along with the other user manuals provided as part of the *digene* HC2 System Suite.

## 1.2 General information

### 1.2.1 Technical assistance

At QIAGEN, we pride ourselves on the quality and availability of our technical support. Our Technical Services Departments are staffed by experienced scientists with extensive practical and theoretical expertise in molecular biology and the use of QIAGEN products. If you have any questions or experience any difficulties regarding the DML 3000 or QIAGEN products in general, do not hesitate to contact us.

QIAGEN customers are a major source of information regarding advanced or specialized uses of our products. This information is helpful to other scientists as well as to the researchers at QIAGEN. We therefore encourage you to contact us if you have any suggestions about product performance or new applications and techniques.

For technical assistance, contact QIAGEN Technical Services.
Website: **support.qiagen.com**

When contacting QIAGEN Technical Services about errors, please have the following information ready:

- DML 3000 serial number, type, and version
- Error code (if applicable)
- Timepoint when the error occurred for the first time
- Frequency of error occurrence (i.e., intermittent or persistent error)
- Copy of log files

### 1.2.2 Policy statement

It is the policy of QIAGEN to improve products as new techniques and components become available. QIAGEN reserves the right to change specifications at any time. In an effort to produce useful and appropriate documentation, we appreciate your comments on this user manual. Please contact QIAGEN Technical Services.

## 1.3 Intended use of the DML 3000

The DML 3000 is intended to measure light that is emitted as a result of a chemiluminescent reaction. Assay results obtained using chemiluminescence technology in 96-well microplates are calculated and interpreted according to assay validation parameters.

### 1.3.1 Cybersecurity actions

1. Ensure that only authorized users have access to the computer in which the *digene* HC2 System Software was installed.
2. An antivirus (malware protection) software shall be installed on the computer where the user installs the application.
3. Only connect trusted hardware and devices to the computer in which the software is installed.
4. Ensure that any exported or printed data is stored appropriately.
5. Backup the file regularly to avoid hard disk failure or ransomware.

## 1.4 Requirements for DML 3000 users

The table below covers the general level of competence and expertise necessary for transportation, installation, use, maintenance, and servicing of the DML 3000.

**Table 1. Level of competence and expertise required in handling the DML 3000.**

| Task | Personnel | Level of competence and expertise |
|---|---|---|
| Transportation | Approved carrier | Appropriately trained, experienced, and approved by QIAGEN |
| Installation | Laboratory technicians or equivalent | Appropriately trained, experienced, and familiar with the use of computers and automation in general |
| Routine use | Laboratory technicians or equivalent | Appropriately trained, experienced, and familiar with the use of computers and automation in general |
| Maintenance | Laboratory technicians or equivalent | Appropriately trained, experienced, and familiar with the use of computers and automation in general |
| Service | QIAGEN Field Service employees or personnel trained by QIAGEN | Trained, certified, and authorized by QIAGEN |

## 1.5 Materials required

**Note**: Only use accessories supplied by QIAGEN.

- DML 3000
- Power Adaptor
- Power Cords (country specific)
- RS-232 Cable

## 1.6 Materials required but not provided

- Lumicheck Plate
- Personal Computer (PC)
- Laser Printer
- USB Printer Cable
- *digene* HC2 System Software

# 2 Safety Information

Before using the DML 3000, it is essential that you read this user manual carefully and pay particular attention to the safety information. The instructions and safety information in the user manual must be followed to ensure safe operation of the instrument and to maintain the instrument in a safe condition.

The following types of safety information appear throughout the *QIAGEN DML 3000 User Manual*.

**WARNING**

The term WARNING is used to inform you about situations that could result in personal injury to you or others.

Details about these circumstances are given in a box like this one.

**CAUTION**

The term CAUTION is used to inform you about situations that could result in damage to an instrument or other equipment.

Details about these circumstances are given in a box like this one.

The guidance provided in this manual is intended to supplement, not supersede, the normal safety requirements prevailing in the user's country.

Please be aware that you may be required to consult your local regulations for reporting serious incidents that have occurred in relation to the device to the manufacturer and/or its authorized representative and the regulatory authority in which the user and/or the patient is established.

**Note**: Operators of this instrument must be trained in both general laboratory safety practices and the safety requirements specific to the instrument. If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

## 2.1 Proper use

Maintain the instrument in good working order. If the instrument has been under adverse conditions such as fire, flood, earthquake, etc., contact QIAGEN Technical Services.

**WARNING** **Risk of personal injury and material damage**

Improper use of the DML 3000 may cause personal injuries or damage to the instrument.

The DML 3000 must only be operated by qualified personnel who have been appropriately trained.

**WARNING** **Risk of inaccurate test results**

The access door must be completely closed during microplate measurement to prevent ambient light from entering the DML 3000.

Ambient light could impact test results.

**WARNING** **Risk of personal injury**

Before lifting the DML 3000, position yourself at the back of the DML 3000. The weight distribution of the DML 3000 is heavier at the back than at the front.

To prevent injury, bend your knees and lift the DML 3000 slowly to compensate for this weight difference.

**CAUTION** **Risk of inaccurate test results**

Failure to properly maintain the DML 3000 may cause high background, a mechanical error, and/or irretrievable data loss. Make sure to perform the required maintenance procedures.

**CAUTION** **Damage to the instrument**

Insert the microplate in the DML 3000 so there is no interference from the microplate locator. If necessary, lift the plate mask 90 degrees to make sure there is no interference.

**CAUTION** **Damage to the instrument**

If the internal components of the DML 3000 are not secured, severe damage to the DML 3000 will result and the warranty will be voided.

**CAUTION** **Damage to the instrument**

Do not use solvents or abrasive cleaners to clean the DML 3000.

**CAUTION** **Damage to the instrument**

Do not touch the bottom surface of the optical head while removing the mask.

## 2.2 Electrical safety

Basic electrical hazard awareness is essential for the safe operation of any system. Elements of electrical safety include, but are not limited to, the following:

- Periodically inspect electrical cables in and on the instrument for signs of wear and damage.
- Do not disconnect any electrical connection while the instrument is powered ON.
- Only qualified personnel should perform electrical servicing.
- Use only the provided power cords and electrical accessories to protect against electric shock.
- Only connect the power cords to a properly grounded power source.
- Do not touch any switches or power source with wet hands.
- Power OFF the instrument before disconnecting the alternating current (AC) power cord.
- Power OFF and unplug the instrument prior to cleaning up any liquid spills.
- Replace all access covers before operating the instrument.

Refer to *digene HC2 System Software User Manual* for other warnings and precautions related to operating the DML 3000.

For best performance of the DML 3000, plug the DML 3000 into a surge protector or uninterruptible power supply (UPS) before plugging it into a grounded power source.

## 2.3 Environment

**WARNING** **Damage to the instrument**

In greater than 80% high-humidity environments, the DML 3000 must be powered ON at all times to prevent the buildup of internal condensation.

## 2.4 Biological safety

**WARNING** **Samples could contain infectious agents.**

Some samples used with this instrument may contain infectious agents. Handle such samples carefully and in accordance with the required safety regulations.

Always wear a suitable lab coat, disposable gloves, and protective goggles.

The responsible body (e.g., laboratory manager) must take the necessary precautions to ensure that the surrounding workplace is safe and that the instrument operators are not exposed to hazardous levels of toxic substances (chemical or biological) as defined in the applicable Safety Data Sheets (SDSs) or OSHA,* ACGIH† or COSHH‡ documents.

* OSHA: Occupational Safety and Health Administration (United States of America).
† ACGIH: American Conference of Government Industrial Hygienists (United States of America).
‡ COSHH: Control of Substances Hazardous to Health (United Kingdom).

## 2.5 Chemical safety

**WARNING** **Hazardous substances**

The products used with this instrument contain hazardous substances.

When working with chemicals, always wear a suitable lab coat, disposable gloves, and protective goggles. For more information, please consult the appropriate SDSs. These are available online in PDF format at **www.qiagen.com/safety**, where users can find, view, and print the SDS for each QIAGEN kit and kit component. For further information, see the instructions for use provided with the kit.

Venting for fumes and disposal of wastes must be in accordance with all national, state, and local health and safety regulations and laws.

## 2.6 Waste disposal

For more information about how to dispose of the DML 3000, see "Waste Electrical and Electronic Equipment (WEEE)" on page 45.

**WARNING** **Hazardous chemicals and infectious agents**

The waste contains samples and reagents. This waste may contain toxic or infectious material and must be disposed of properly. Refer to your local safety regulations for proper disposal procedures.

## 2.7 Mechanical hazards

**WARNING** **Risk of personal injury**

Keep hands free of moving parts. Do not reach into the DML 3000 while it is operating.

**WARNING** **Damage to the instrument**

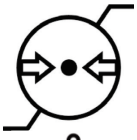
If the DML 3000 is powered ON, the optical head must remain in the home position while the access door is open.

Attempting to move the optical head when the DML 3000 is powered ON exposes the optical head to ambient light. Ambient light will damage the optical head.

## 2.8 Symbols on the DML 3000

The following symbols may appear in the user manual or on the packaging and labelling:

| Symbol | Location | Description |
|---|---|---|
|  | Inside the instrument above the plate carrier | Warning or caution sign |
|  | Inside the instrument above the plate carrier | Biohazard—the instrument may be contaminated with biohazardous material and must be handled with gloves |
|  | Type plate on the back of the instrument, instrument box label and the front cover of this user manual | CE mark for Europe |
|  | Type plate on the back of the instrument, instrument box label and the front cover of this user manual | The IVD Marking indicates that this instrument. is an *in vitro* diagnostic medical device |
|  | Type plate on the back of the instrument and instrument box label | Mark that indicates the instrument complies with applicable standards for electrical safety of laboratory equipment |
|  | Type plate on the back of the instrument and instrument box label | Mark of the United States Federal Communications Commission (FCC) |
|  | Type plate on the back of the instrument and instrument box label | C-Tick mark for Australia (supplier identification N17965) |

| Symbol | Location | Description |
|---|---|---|
|  | Type plate on the back of the instrument and instrument box label | RoHS mark for China that indicates the restriction of the use of certain hazardous substances in electrical and electronic equipment |
|  | Type plate on the back of the instrument and instrument box label | Waste Electrical and Electronic Equipment (WEEE) |
|  | Type plate on the back of the instrument and instrument box label | Serial number |
|  | Type plate on the back of the instrument, instrument box label and the front cover of this user manual | Legal manufacturer |
|  | Type plate on the back of the instrument and instrument box label | Consult instructions for use |
|  | Instrument box label | Fragile, handle with care |
|  | Type plate on the back of the instrument and instrument box label | Global trade item number (GTIN) |
|  | Type plate on the back of the instrument and instrument box label | Unique device identifier (UDI) |
|  | Instrument box label | Relative humidity |
|  | Instrument box label | Barometric pressure |
|  | Instrument box label | Temperature range |
|  | The front cover of this user manual | Material |

## 2.9 Additional symbols used in this user manual and instrument box label:

| Symbol | Location | Description |
|---|---|---|
| REF | Type plate on the back of the instrument, instrument box label and the front cover of this user manual | Catalog number |
| EC REP | The instrument box label and the front cover of this user manual | Authorized representative in the European Community |

# 3 General Description

The DML 3000 is highly sensitive with a broad dynamic range. It features a low background photon-counting PMT and measures light in the visible spectrum (350–650 nm).

Microplates are loaded at the front of the DML 3000. The individual microplate wells are sequentially moved beneath the opening of the detector and then individually measured. A step motor moves the microplate in the Y-direction to present the microplate wells to the detector. A separate stepper motor moves in the X-direction over the microplate.

An internal microprocessor is used to control the basic functions and communications with the *digene* HC2 System PC via a standard RS-232 serial port. The performance specifications of the DML 3000 are summarized in Table 2.

**Table 2. Performance specifications of the DML 3000.**

| Performance measure | Specification |
|---|---|
| Spectral sensitivity range | 350–650 nm |
| Dynamic range | 10 to 5 x $10^{6}$ RLU |
| Cross-talk | Less than 4.0 x $10^{-5}$ RLU |

The most important physical parameters for measuring a microplate are the following:

- Reflectivity of the light spectrum measured at the detector
- Absorbency of the light between adjacent microplate wells
- Homogeneity and reproducibility of the parameters of the detector
- Physical dimensions and properties, such as the flatness of the surface
- Accuracy and reproducibility of all physical dimensions


Figure 1. Front view of the DML 3000

## 3.1 LED status light

There are three light-emitting diode (LED) status lights on the front panel of the DML 3000: red, yellow, and green. All three lights illuminate briefly after powering ON the DML 3000.

The red LED status light indicates the DML 3000 is not operational. The yellow LED status light remains lit, unless the DML 3000 is performing a function as directed by the software. The green LED status light indicates the DML 3000 is powered ON.


**Figure 2. View of the LED status lights. (1): Red Led status light (2): Yellow Led status light (3): Green Led status light**

## 3.2 Access door

The access door is on the top of the DML 3000. It allows access to the plate mask and plate carrier. To open the door, lift the lower front edge.

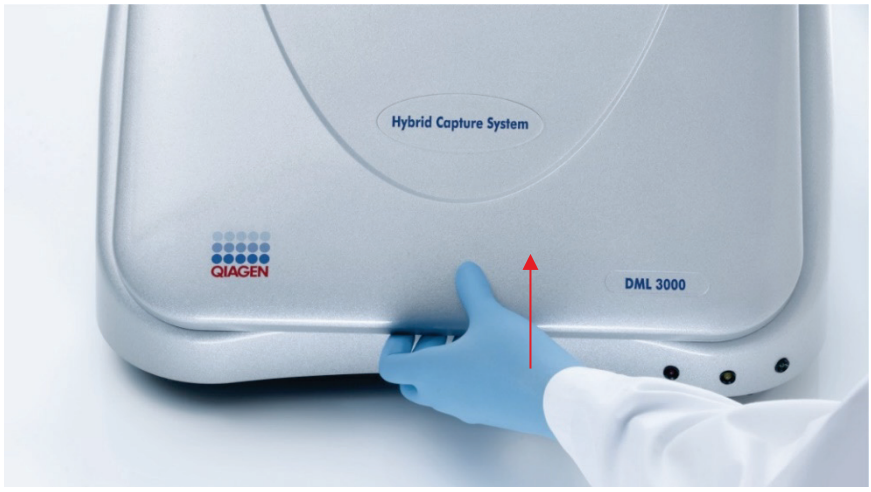



**Figure 3. Opening the access door of the DML 3000**

## 3.3 Gas actuator lift arm

The gas actuator lift arm supports the access door when it is opened and allows the access door to close evenly and smoothly.

**Figure 4. View of the gas actuator lift arm**

## 3.4 Optical sensor

An optical sensor in the front-center of the DML 3000 detects if the door is open or closed.

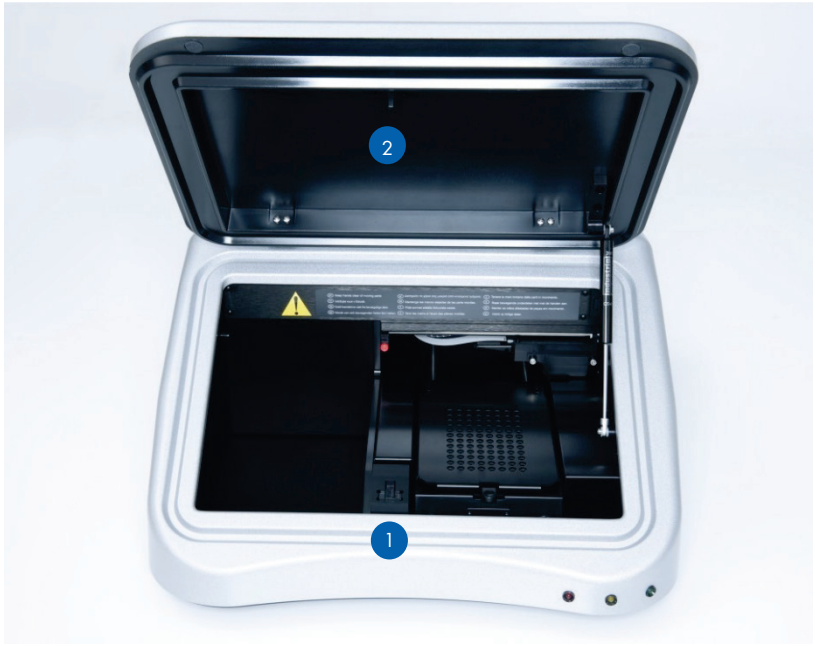



**Figure 5. View of the optical sensor when the access door is opened. (1): Optical sensor (2): Flag**

If the access door is not completely closed, the optical sensor does not detect the flag and the *digene* HC2 System Software reports an open door error.

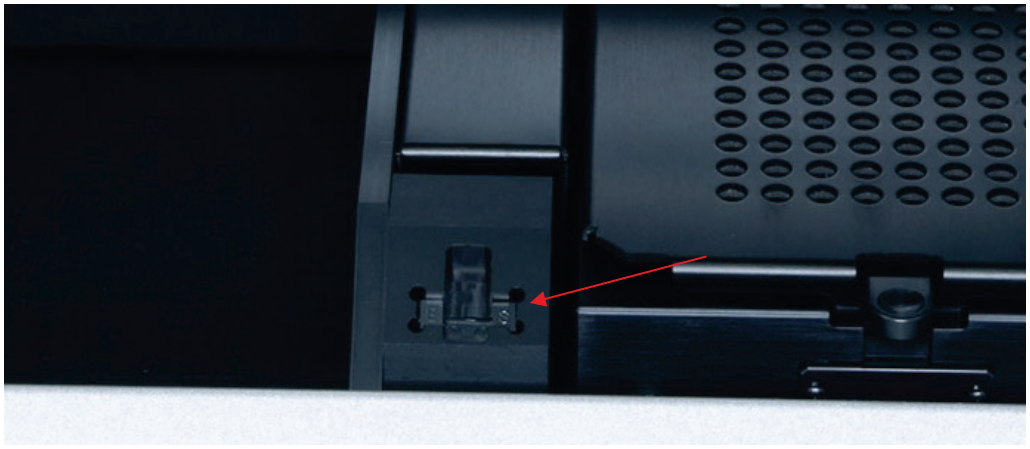


Figure 6. Close-up view of the optical sensor

## 3.5 Optical head

The optical head measures the chemiluminescence of each microplate well. The optical head has an optical mask and an optical mask retainer. The optical mask isolates one microplate well from the other microplate wells so that the DML 3000 can measure only that one microplate well. The optical mask retainer maintains the position of the optical mask.

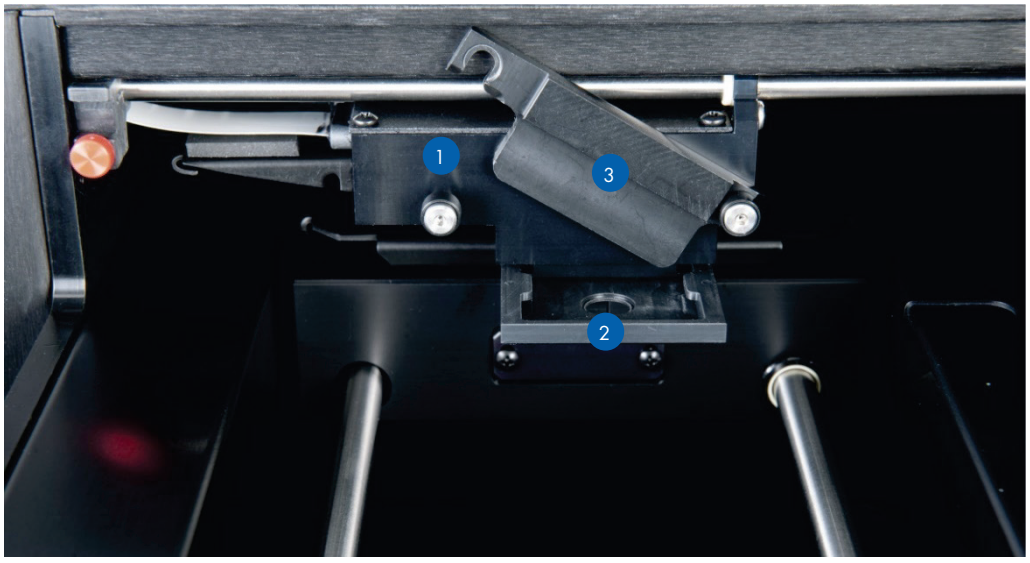



Figure 7. Close-up view of the optical head. (1): Optical head (2): Optical mask (3): Optical mask retainer

## 3.6 Plate carrier

When a 96-well microplate is placed in the DML 3000 for measurement, the plate carrier keeps the microplate positioned securely against the plate mask. The spring-loaded base of the plate carrier pushes the microplate up into the plate mask for a tight fit. Once the microplate is placed inside the plate carrier and the plate mask is closed, the springs provide a light upward pressure to secure the microplate in place.

The A1 corner is located in the back-right location. The A1 label acts as a visual aid to help properly position the microplate.

## 3.7 Plate mask

The plate mask is a metal cover with 96 holes aligned to the wells of a microplate. The plate mask is designed to minimize cross-talk between microplate wells.

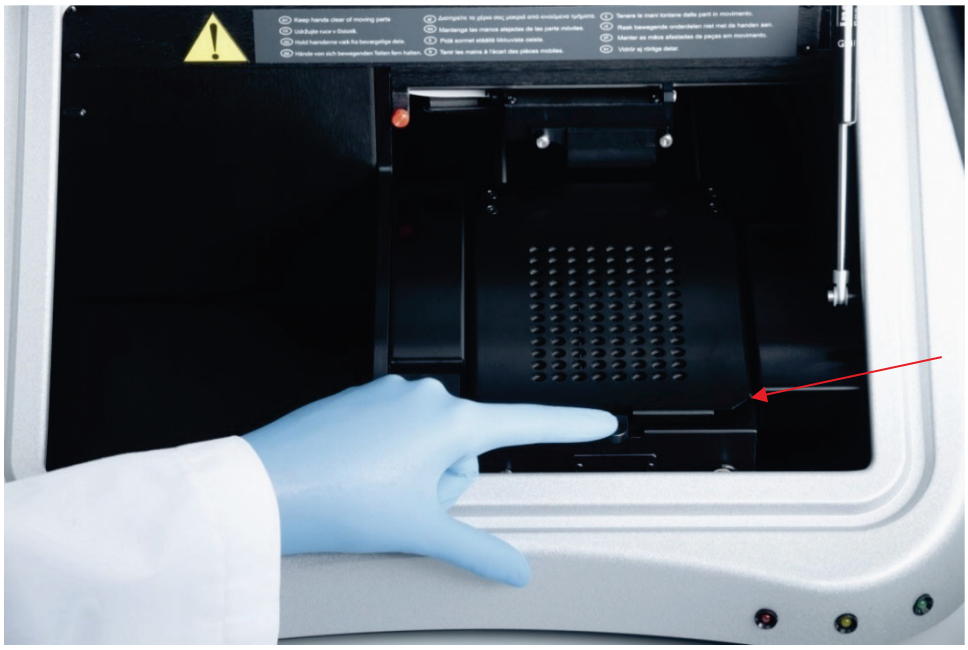


**Figure 8. View of the plate mask when the access door is opened**

## 3.8 Plate mask release latch

The plate mask release latch is used to open the plate mask, which opens approximately 90 degrees.

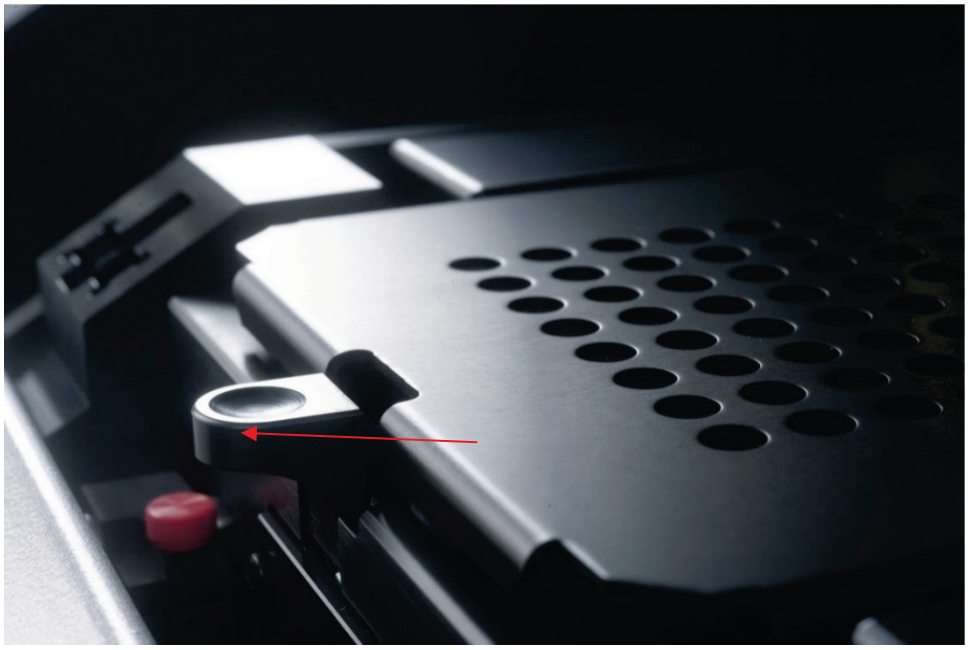


**Figure 9. View of the plate mask release latch**

## 3.9 Microplate locator

The back-right corner of the plate carrier has a microplate locator that retracts when the plate mask is open to allow the microplate to be placed in the plate carrier. When the plate mask is closed, the microplate locator aligns the microplate properly in the X–axis and Y–axis.

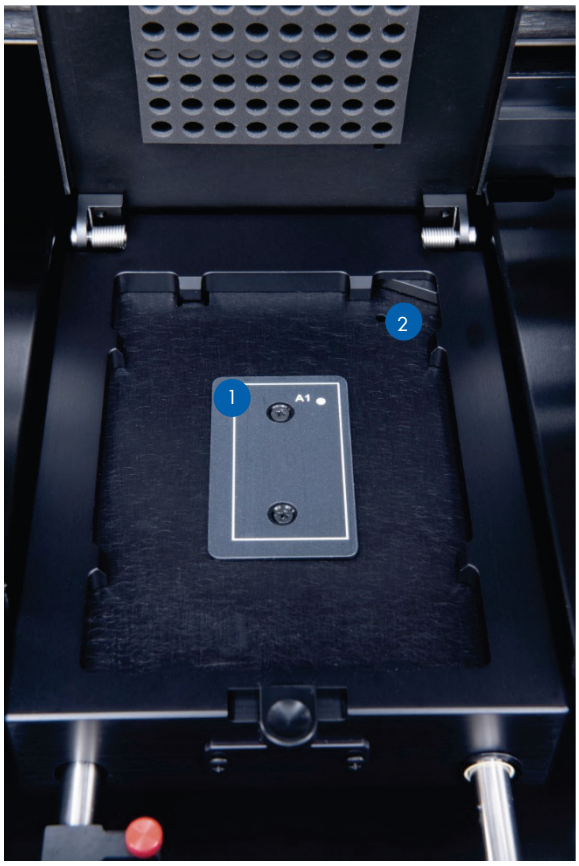



**Figure 10. View of the microplate locator. (1): Microplate locator (2): A1 orienting corner**

## 3.10 Detector

The DML 3000 uses a single PMT to measure chemiluminescence of the microplate wells on a 96-well microplate. It leverages both photon-counting and current-measurement modes to optimize the dynamic range of the DML 3000.

A light detector using a PMT can be characterized by the following parameters:

- Background signal
- Efficiency
- Sensitivity
- Dynamic range
- Linearity
- Spectral response

### 3.10.1 Background signal

The background signal can be divided in two components:

- A constant (baseline) component
- A statistically variable (noise) component that is different for each individual measurement

The background signal in the photon-counting mode is automatically checked at the start of each microplate measurement. In the current-measurement mode, used at high RLU levels, the background level is subtracted from each reported measurement.

### 3.10.2 Efficiency

Efficiency is the response (detector output signal) versus the input signal (light intensity). Efficiency is the gradient of RLU versus gradient of light intensity.

### 3.10.3 Sensitivity

Sensitivity is related to both background signal and efficiency. Sensitivity is directly proportional to efficiency and the background signal is inversely proportional (higher background results in lower sensitivity).

Sensitivity describes the lowest intensity of light that can be detected as different from background. Sensitivity is usually measured using the amount of a luminescent substance the DML 3000 is able to detect and clearly distinguish from background noise.

### 3.10.4 Dynamic range

Dynamic range is the relationship between the lowest and the highest signal that the detector is able to quantify. The dynamic range for the DML 3000 is 10 to 5 x $10^6$ RLU.

### 3.10.5 Linearity

Linearity describes the change of output signal, the RLU, related to the change of input signal (i.e., light intensity). The detector is linear if the change of output signal is of the same factor as the input signal change. For example, if light intensity is doubled, the output signal should also double.

### 3.10.6 Spectral response

Spectral response describes the relationship between the efficiency of the PMT versus the wavelength of light measured. The photomultiplier tube used has a spectral response of 350–650 nm.

### 3.10.7 Understanding cross-talk

Cross-talk is the amount of light that is measured in one microplate well that is emitted from a neighboring microplate well. In contrast to the parameters of the detector, cross-talk is not a parameter of the detector itself.

Cross-talk is related to the construction of the optical path between the detector and the microplate surface, especially how this path is shielded against detecting light from adjacent specimens. It is very much dependent on the microplate design and material itself and not solely a DML 3000 parameter.

## 3.11 Transport locks

The transport locks are used to secure the internal components of the DML 3000 when the instrument is being transported.

The DML 3000 is shipped from QIAGEN with the transport locks in the home position. The foam-block insert secures the plate carrier and optical head during transport. The transport locks are only used for transport when the foam-block insert is not available.

If the transport locks are not in the home position, see "Moving the transport locks to the home position" on page 31 for additional instructions.

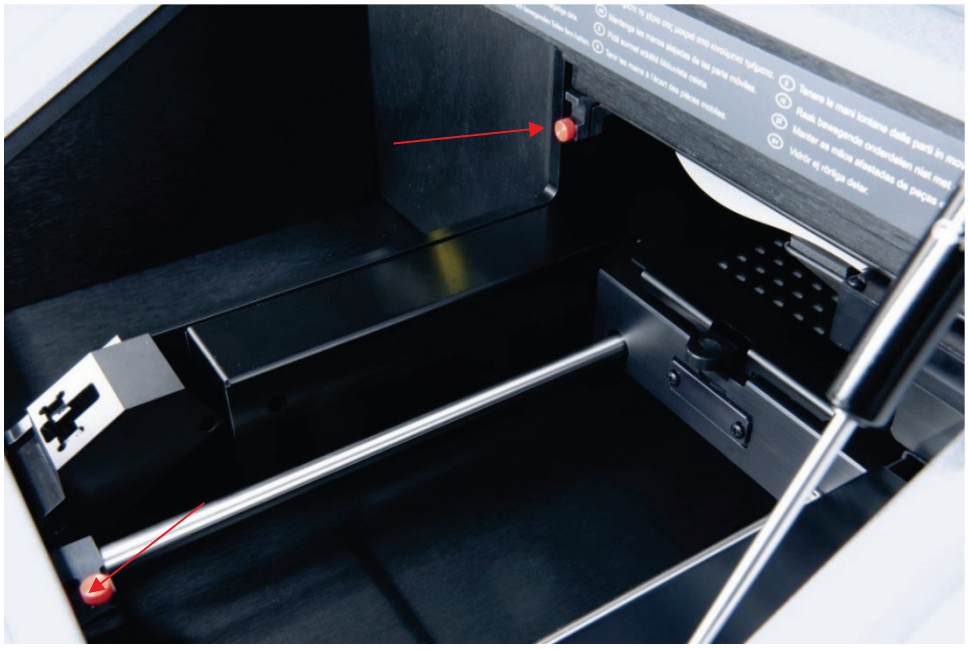


**Figure 11. View of the transport locks in the home position**

The transport locks must be used prior to transporting the DML 3000. See "Securing the DML 3000 using the transport locks" on page 33 for additional instruction.

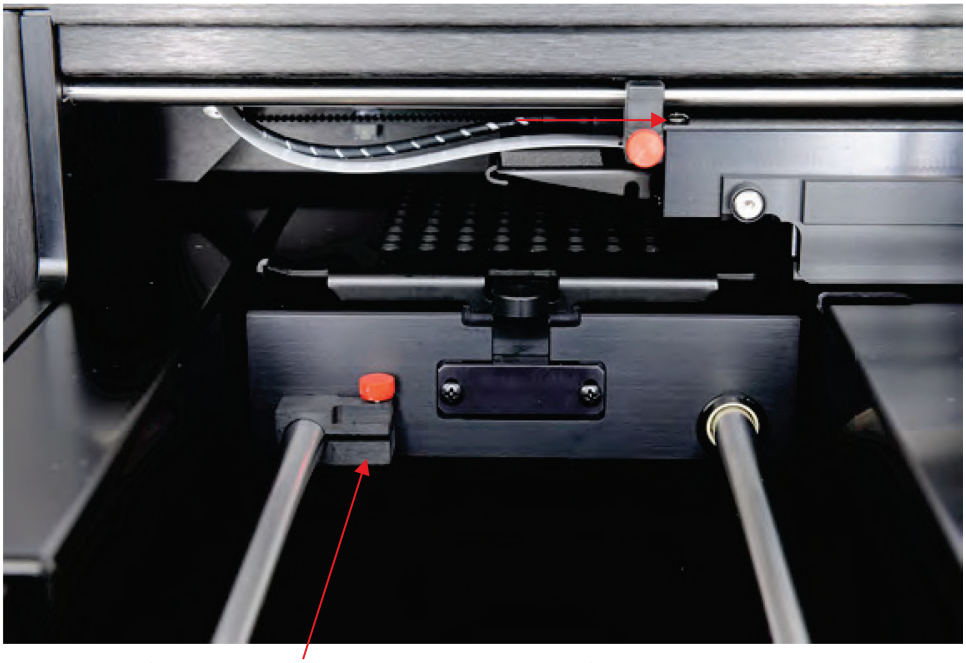


**Figure 12. View of the transport locks in the secured position and ready for transport**

## 3.12 Power connection port and power switch

Located at the back-left of the DML 3000, the power connection port is where the power adapter plugs into the DML 3000. The power switch powers the DML 3000 ON and OFF.

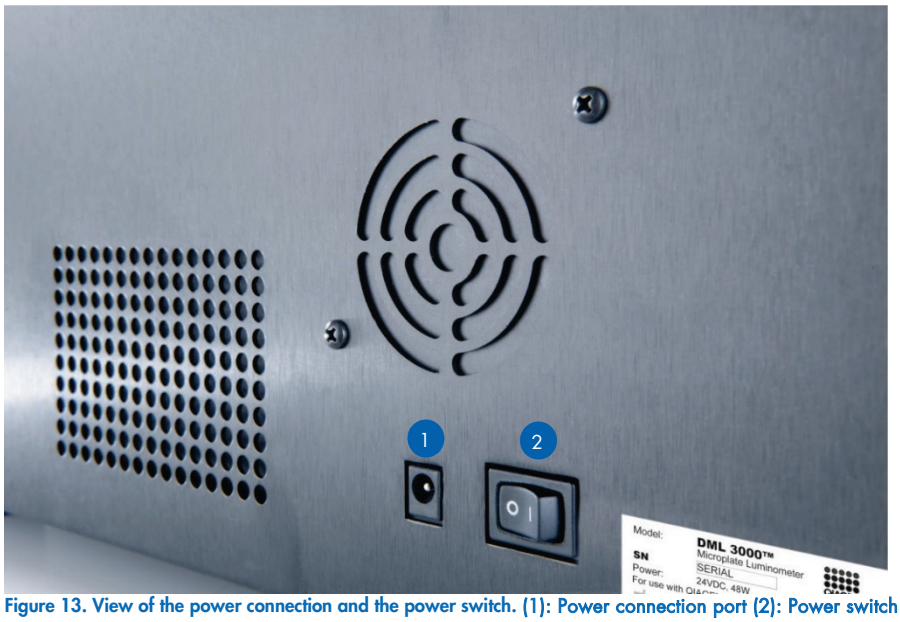



**Figure 13. View of the power connection and the power switch. (1): Power connection port (2): Power switch**

## 3.13 Power cord

The power cord connects to the power source at one end and the power adapter at the other. For the best performance of the DML 3000, connect the power cord to a surge protector or an UPS.

**Figure 14. View of the power cord**

## 3.14 Power adapter

The power adapter connects to the DML 3000 power connection port at one end and to the power cord at the other end.

Important: Only use the power adapter provided with the DML 3000. Use of a power adapter other than the one provided with the DML 3000 voids the warranty.

**Figure 15. View of the power adapter**

## 3.15 USB-to-Serial converter

The USB-to-Serial converter is an external expansion COM port module that converts a USB port on the *digene* HC2 System PC to two 9-pin serial COM ports for serial connectivity. A USB converter will need to be used if a Rapid Capture® System (RCS) or laboratory information system (LIS) is connected to the same *digene* HC2 System PC as the DML 3000. The USB-to-Serial converter is optional and supplied with the Personal Computer Country Kit.


**Figure 16. View of the USB-to-Serial converter**

# 4 Unpacking Procedures

| | |
|---|---|
| **WARNING**  | Risk of personal injury<br>Before lifting the DML 3000, position yourself at the back of the DML 3000. The weight distribution of the DML 3000 is heavier at the back than at the front.<br>To prevent injury, bend your knees and lift the DML 3000 slowly to compensate for this weight difference. |

The DML 3000 must be unpacked from its shipping container. Place the box on an even surface. One person should be able to unpack the DML 3000 and lift it from the packing box.

**Note**: Keep the original shipping bag, box, and foam inserts for future shipping requirements.

1. Cut the tape along the shipping box top to the sides of the box.
2. Open the shipping box flaps.
3. Remove the unpacking instructions.
4. Remove the accessories kit.
5. Inspect the packaging carefully to make sure all components and accessories are present:
   - 5a. DML 3000
   - 5b. Power adapter
   - 5c. Power cord
   - 5d. RS-232 cable

   If any of these items are missing, contact your local QIAGEN representative or QIAGEN Technical Services.
6. Place your hands under the back of the DML 3000.
7. Bend your knees and lift the DML 3000 and packing foam out of the box.


**Figure 17. Removing the DML 3000 from the shipping box**

8. Set the DML 3000 on a level surface.

9. Remove the packing foam from either side of the DML 3000.

**Figure 18. View of the packing foam removed from around the DML 3000**

10. Remove the tape on the plastic shipping bag.
11. Remove the DML 3000 from the plastic shipping bag, discard the 2 desiccant bags in the plastic shipping bag, and place the plastic shipping bag into the shipping box.


**Figure 19. View of the DML 3000 in plastic shipping bag**

12. Open the DML 3000 access door. Locate the foam-block insert on the right side of the DML 3000.

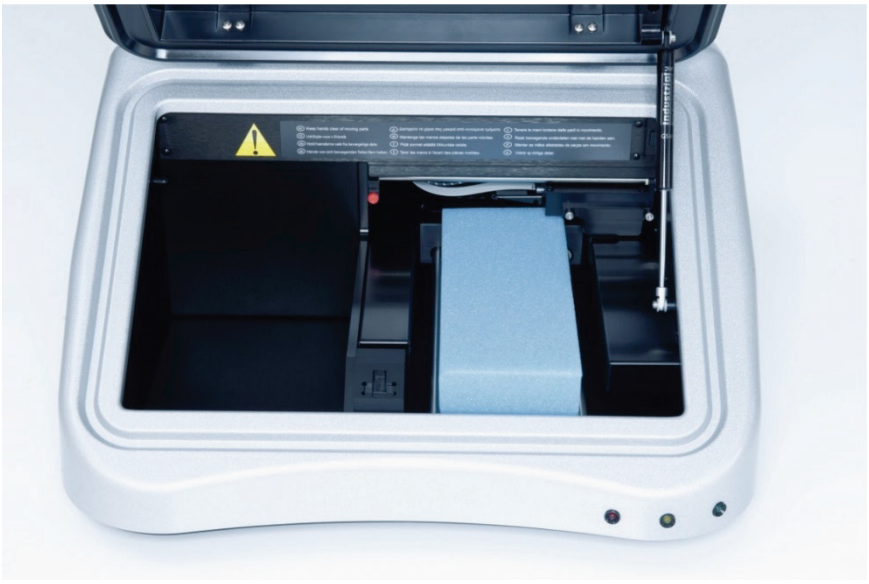


**Figure 20. View of foam-block insert inside the DML 3000**

13. Remove the foam-block insert from the DML 3000, and place it in the shipping box.

    Make sure that the transport locks are in the home position. See “Transport locks” on page 18 for additional information.

14. Store the box, plastic bag, and foam-block insert for later use.

# 5 Installation Procedures

## 5.1 System delivery and installation

A person who is familiar with your laboratory and computer equipment should be present during the installation.

The unpacking and installation of DML 3000 must be performed by a certified QIAGEN Field Service Specialist.

The following items are delivered:

- DML 3000 instrument
- *DML 3000 User Manual*
- Workstation
- *digene* HC2 System Software (will be installed by QIAGEN Field Service during initial set up)

## 5.2 Site requirements

The installation of the DML 3000 must adhere to the space and positioning requirements in Table 3 and the following requirements:

Place the instrument on a firmly secured benchtop. Locate it away from other vibration-sensitive instruments such as an analytical balance. Place the instrument on a level, stable surface near a grounded electrical outlet. Allow at least 7.5 cm (3 in.) of clearance on all sides of the instrument for proper ventilation. While operating, make sure that the DML 3000 platform does not touch other objects. For power requirements and technical data, see "Appendices," page 44. The DML 3000 type plate is located on the right side of the back panel next to the power switch. The type plate contains the DML 3000 serial number which is required to set up the DML 3000 in the *digene* HC2 System Software.

**Table 3. Space and positioning requirements in the installation of the DML 3000.**

| Requirement | Specification |
|---|---|
| Space for the instrument, including the *digene* HC2 System PC, keyboard, and printer | Approximately 153 cm (60 in) wide, 64 cm (2 in) deep, and 64 cm (25 in) high |
| Clearance behind the DML 3000 required to allow for adequate heat dissipation and accessibility to the power button. | A minimum of 20 cm (8 in) clearance.<br>Place the DML 3000 so that the power cord can be easily unplugged from the rear panel. |
| Weight on top of DML 3000 | No weight is allowed on top of the DML 3000. |

## 5.3 Connecting the components

1. Locate the following components:

- Power adapter
- Power cord
- RS-232 cable

2. Plug the power adapter into the power connection port.

   **Note**: The power connection port is located on the right side of the back panel.

   **Important**: Only use the power adapter provided with the DML 3000. Use of a power adapter other than the one provided with the DML 3000 voids the warranty.

Figure 21. Close-up view of power connection port

3. Plug the power cord into the power adapter, and then plug the power cord into a grounded power source.
4. Plug the RS-232 cable into the RS-232 port on the back of the DML 3000. Tighten the lock screws.

Figure 22. Close-up view of the RS-232 port

5. Plug the other end of the RS-232 cable into the serial port of the *digene* HC2 System PC, and tighten the lock screws.

   **Note**: Refer to *digene HC2 System Software User Manual* for the correct COM port to use with the *digene* HC2 System PC.

**Note**: If a RCS or LIS is used on the same computer as the DML 3000, then a USB-to-serial converter will be required. The USB-to-Serial converter is supplied with the Personal Computer Country Kit. Refer to *digene HC2 System Software User Manual* for the correct COM port to use and setting up the connections.


**Figure 23. Example of the DML 3000 with the *digene* HC2 System PC**

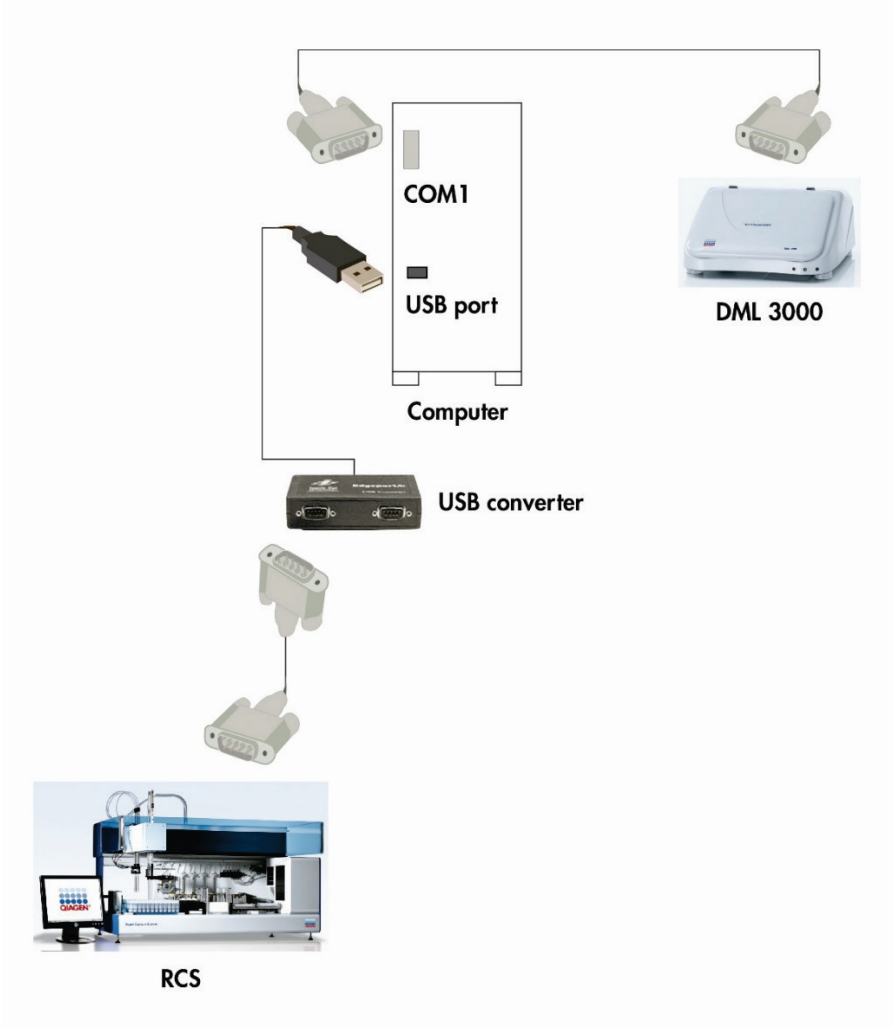



Figure 24. Diagram of connecting a DML 3000 with an RCS.

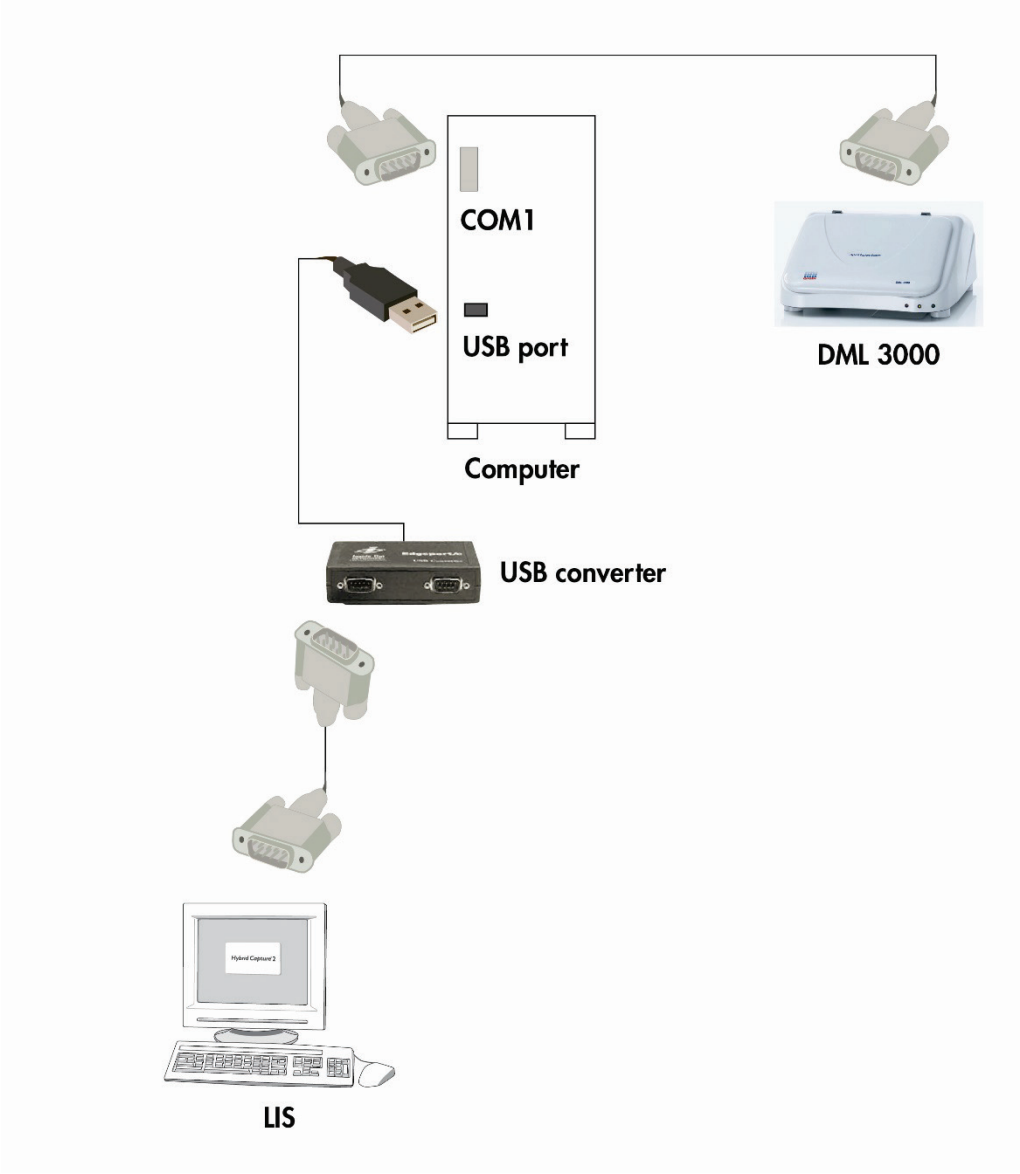



Figure 25. Diagram of connecting a DML 3000 with a LIS.

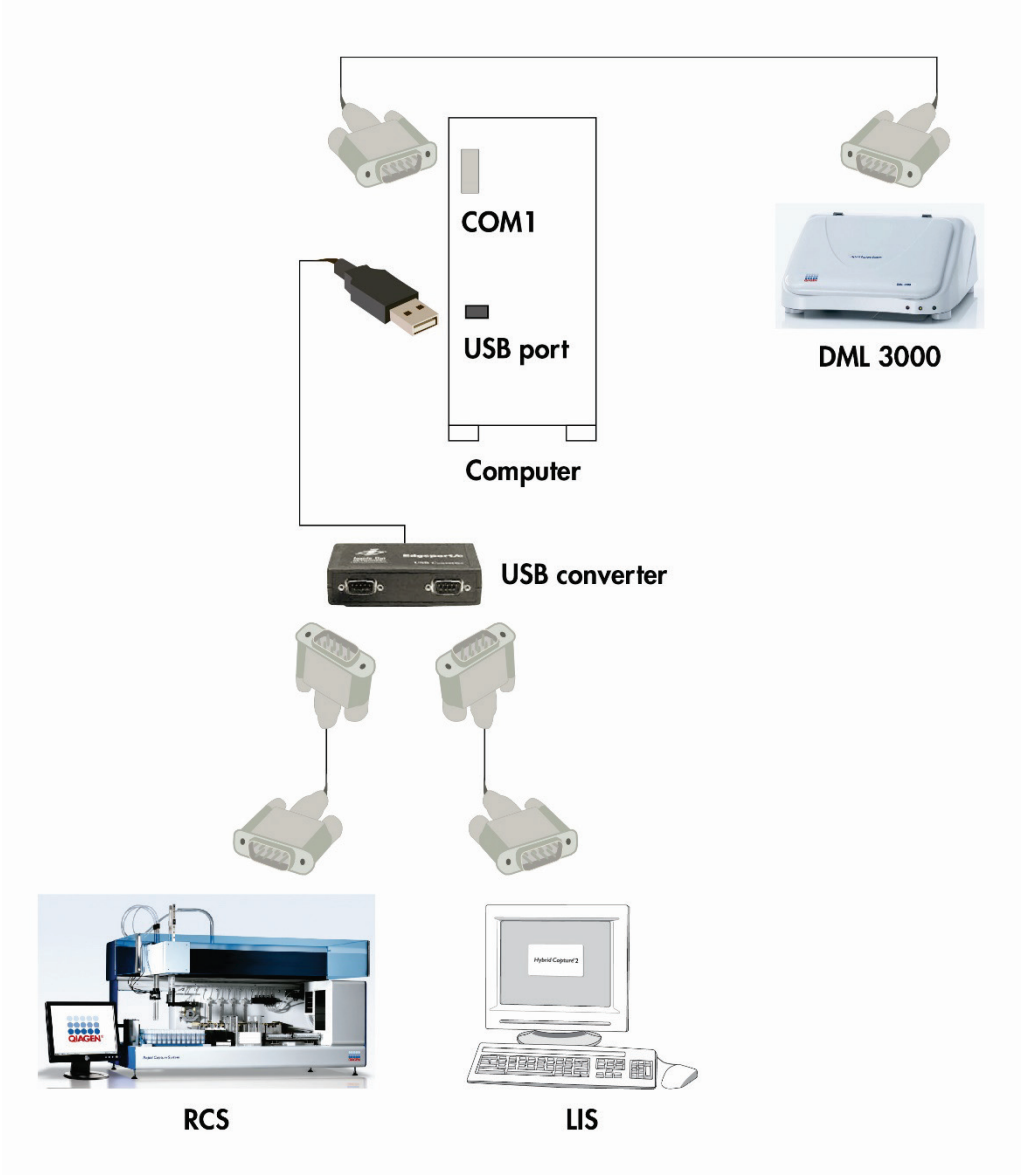



Figure 26. Diagram of connecting a DML 3000 with a RCS and a LIS.

# 6 General Operation

Note: The LumiCheck Plate is used to evaluate the stability of the DML instrument and monitor the instrument performance by periodically testing the functions of the DML instrument.

The DML 3000 measures light in the visible spectrum (350–650 nm) and measures chemiluminescence from opaque microplates. It is optimally designed for the measurement of glow-type luminescence.

To measure a microplate using the *digene* HC2 System Software, the following is required:

- The DML 3000 is initialized and has established communication with the *digene* HC2 System PC.
- A plate layout exists in the *digene* HC2 System Software indicating the microplate wells to be measured. Refer to *digene HC2 System Software User Manual* for additional information.
- The microplate to be measured has been inserted into the DML 3000.
- A mechanical test has been performed.

## 6.1 Moving the transport locks to the home position

The transport locks must be located in the home position to operate the DML 3000. Use this procedure to move into the transport locks to the home position.

1. Open the access door.
2. Loosen the red thumb screws of both transport locks.
3. Slide the transport lock on the optical head guide rail all the way to the left and tighten the thumb screw.
4. Slide the transport lock on the left guide rail to the front of the DML 3000 and tighten the thumb screw.

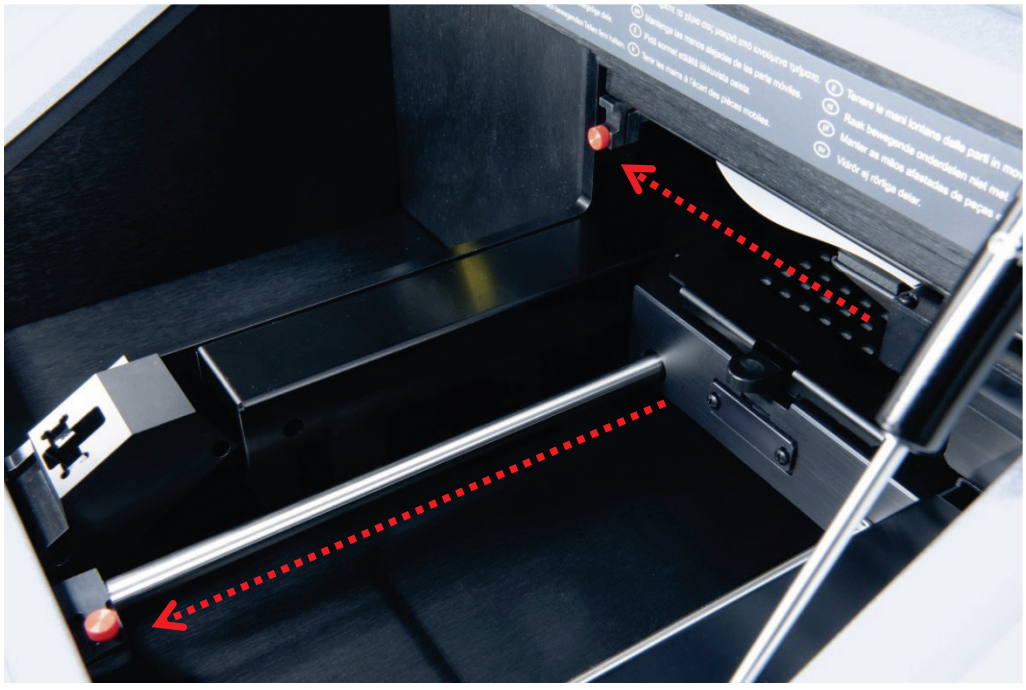


Figure 27. View of the transport locks in the home position.

## 6.2 Placing a microplate in the DML 3000

1. Open the access door.
2. Press the plate mask release latch to lift the plate mask.

| CAUTION | **Damage to the instrument** |
|---|---|
|  | Insert the microplate in the DML 3000 so there is no interference from the microplate locator. If necessary, lift the plate mask 90 degrees to make sure there is no interference. |

3. Insert the microplate with the A1 position, which has a notched corner, in the right-rear corner of the plate carrier.

   The microplate locator must retract, and the microplate must be flush against the plate carrier. Make sure the microplate is not resting on top of the microplate locator.

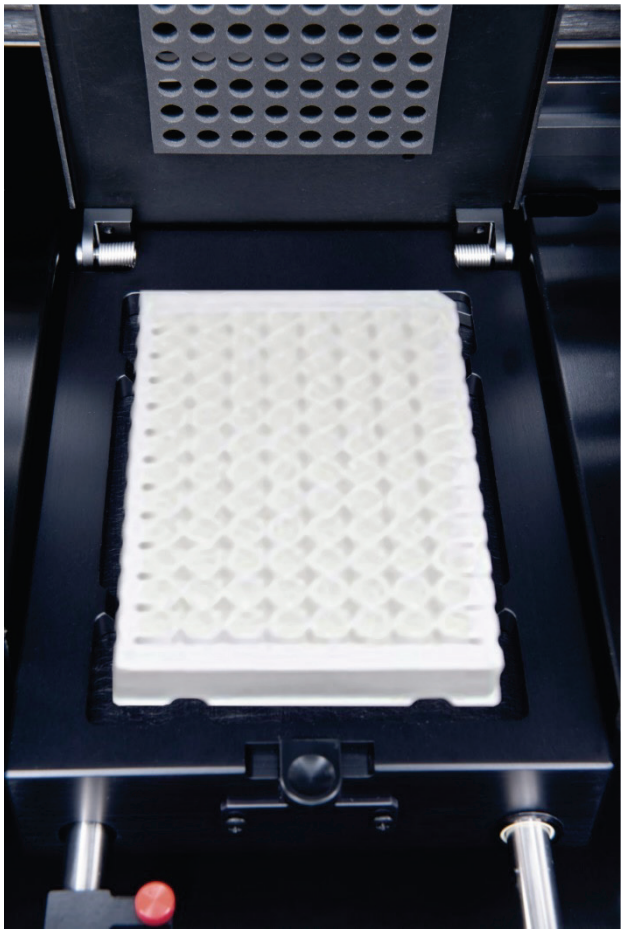


Figure 28. Example of the microplate in the plate carrier.

4. Close the plate mask.

5. Visually make sure that the holes of the plate mask align with the microplate wells.

| WARNING | **Risk of inaccurate test results** |
|---|---|
|  | The access door must be completely closed during microplate measurement to prevent ambient light from entering the DML 3000.<br>Ambient light could impact test results. |

6. Close the access door.

## 6.3 Securing the DML 3000 using the transport locks

Use the transport locks to secure the internal components of the DML 3000 during transport.

1. Loosen the red thumb screws of both transport locks.
2. Slide the transport lock on the optical head guide rail all the way to the right, and tighten the thumb screw.
3. Slide the transport lock on the left guide rail to the back of the DML 3000, and tighten the thumb screw.

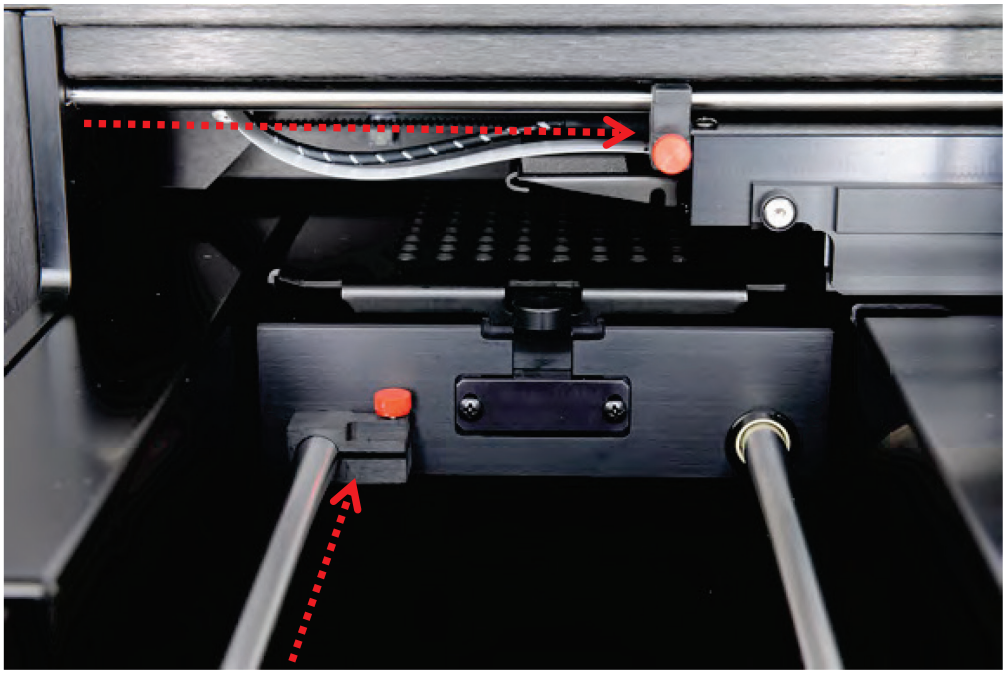


**Figure 29. View of the transport locks in the secured position.**

## 6.4 Repackaging and transporting the DML 3000

When repackaging the DML 3000 for shipping, the original packaging materials must be used. If the original packaging materials are not applicable, contact QIAGEN Technical Services. Make sure that the instrument has been properly prepared (see Maintenance) prior to packing and that is poses no biological or chemical hazard.

1. Exit the *digene* HC2 System Software.
2. Power OFF the *digene* HC2 System PC.

3. Power OFF the DML 3000.
4. Disconnect all the cables connected to the DML 3000.
5. Decontaminate the DML 3000. See "Decontaminating the DML 3000," on page 41 for additional instructions.
6. Open the access door.
7. Gently push the plate carrier to the back of the DML 3000.

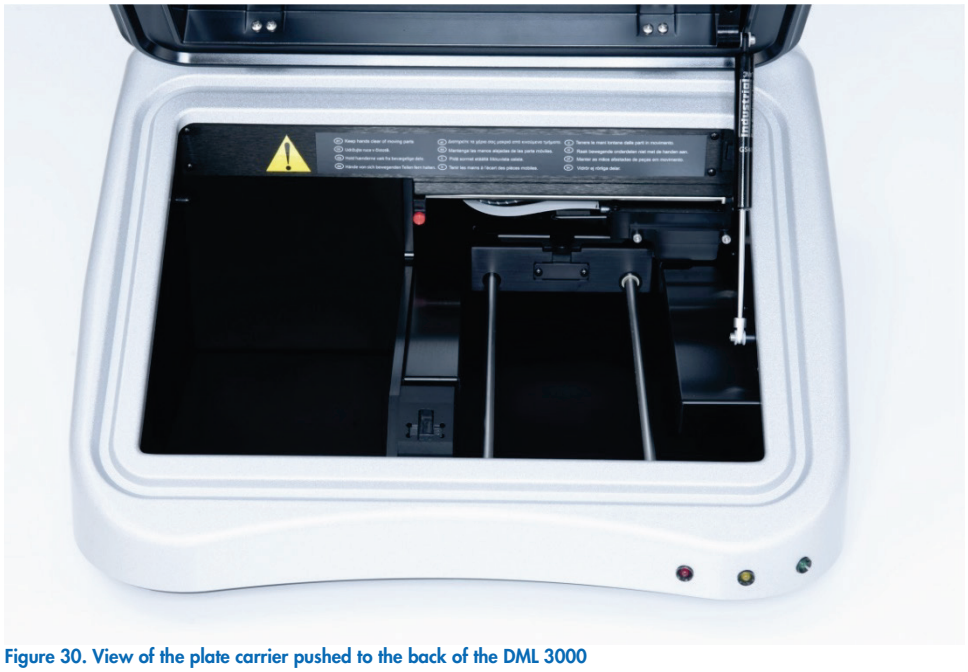


**Figure 30. View of the plate carrier pushed to the back of the DML 3000**

8. Place the foam-block insert into the space between the plate carrier guide rails. If a foam-block insert is not available, use the transport locks to secure the internal components of the DML 3000 during transport. See Figure 27 on page 32 for additional instructions.

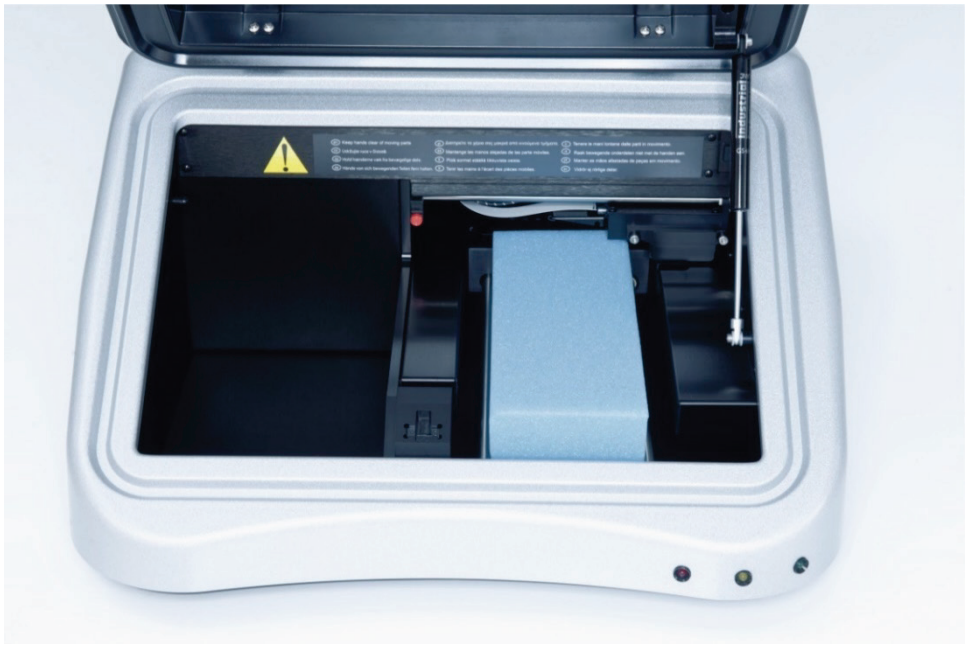


Figure 31. View of the foam-block insert in the DML 3000.

| CAUTION | **Damage to the instrument** |
|---|---|
|  | If the internal components of the DML 3000 are not secured, severe damage to the DML 3000 will result and the warranty will be voided. |

9. Once the internal components are secure, close the access door.
10. Place the DML 3000 in the plastic shipping bag.
11. Place the outside foam box inserts on the two sides of the DML 3000.
12. Place the DML 3000 in the original cardboard shipping box.


Figure 32. Example of placing the DML 3000 in the shipping box.

13. Place the RS-232 cable, power adapter, and power cord in the shipping box.

    **Note**: Do place the USB-to-Serial connector in the shipping box.

14. Tape the box securely. The DML 3000 is ready for transport.

# 7 Maintenance

The DML 3000 requires regular maintenance, as described in this section. Disconnect the DML 3000 from the power source before performing any maintenance procedure.

**Note**: Only use parts supplied by QIAGEN.

| | |
|---|---|
| **WARNING**  | **Risk of inaccurate test results**<br>Failure to properly maintain the DML 3000 may cause high background, a mechanical error, and/or irretrievable data loss. Make sure to perform the required maintenance procedures. |

## 7.1 Cleaning the DML 3000

The following tools and supplies are needed to clean the DML 3000:

- Latex or nitrile powder-free gloves
- 70% isopropyl alcohol
- Deionized or distilled water
- Foam-tipped applicators
- Low-lint paper towels
- 0.5% bleach (sodium hypochlorite) solution (0.5% NaOCl)
  Note: Industrial bleach contains 10% NaOCl while household bleach contains approximately 5% NaOCl. When using industrial bleach, prepare a 20:1 mixture of water to bleach. When using household bleach, prepare a 10:1 mixture of water to bleach. The final concentration should be 0.5%.

| | |
|---|---|
| **CAUTION**  | **Damage to the instrument**<br>Do not use solvents or abrasive cleaners to clean the DML 3000. |

### 7.1.1 Cleaning the exterior of the DML 3000

At least once per week, wipe the exterior of the DML 3000 with a low-lint paper towel moistened with 70% isopropyl alcohol or 0.5% bleach solution. If a 0.5% bleach solution is used, follow by wiping with a low-lint paper towel moistened with deionized or distilled water.

### 7.1.2 Cleaning the interior of the DML 3000

Once per month, clean all interior surfaces using a low-lint paper towel moistened with 70% isopropyl alcohol as described below. If necessary, use a foam-tipped applicator or cotton swab wrapped in a low-lint paper towel to get into hard-to-reach areas.

If liquid has spilled inside the DML 3000 or liquid is visible on the plate mask or the underside of the plate mask, wipe up the excess liquid with a low-lint paper towel, and clean the interior of the instrument as described below.

| CAUTION | **Damage to the instrument** |
|---|---|
|  | If the DML 3000 is powered ON, the optical head must remain in the home position while the access door is open.<br>Attempting to move the optical head when the DML 3000 is powered ON exposes the optical head to ambient light. Ambient light will damage the optical head. |

1. Power OFF the DML 3000. Disconnect the power supply.

   **Important**: Do not attempt to clean the instrument or move the internal components while the instrument is powered ON.

2. Moisten a low-lint paper towel with 70% isopropyl alcohol, and wipe the top and bottom surfaces of the plate mask and the plate carrier.

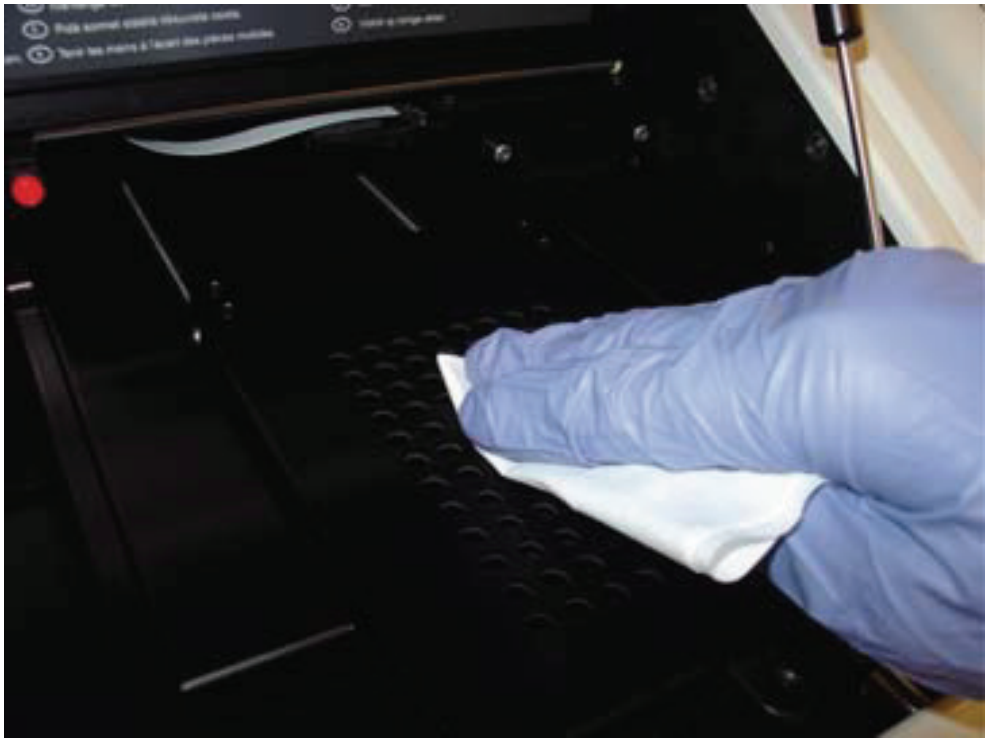


Figure 33. Wiping the top of the plate mask

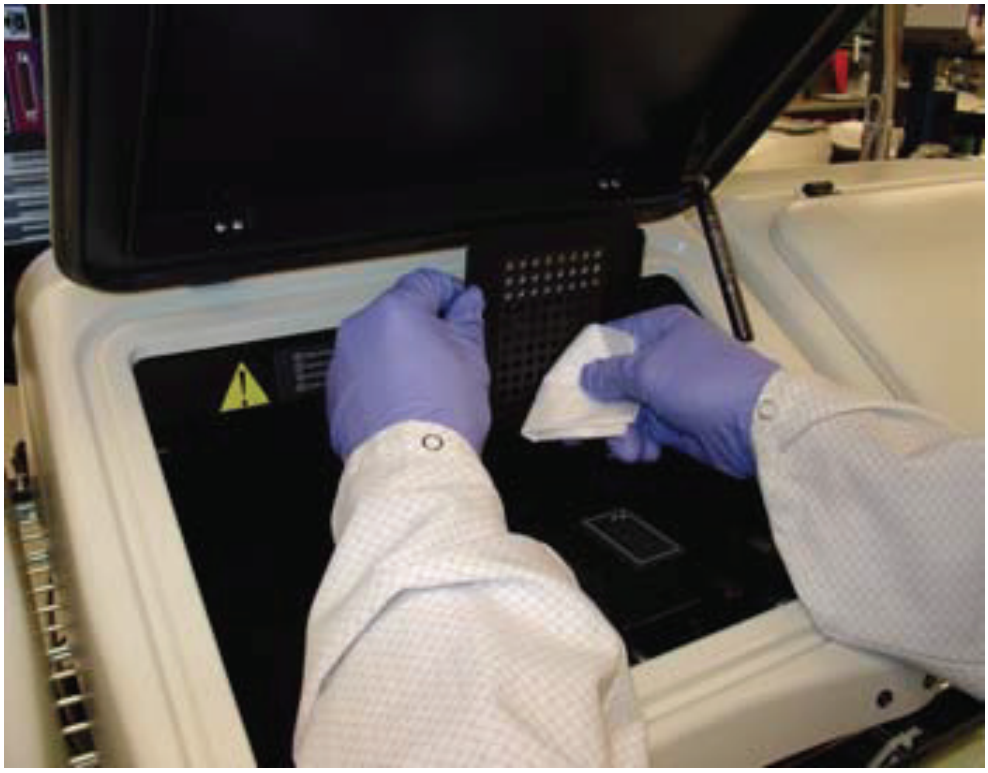


Figure 34. Wiping the interior of the plate mask

3. Clean each opening in the plate mask with a foam-tipped applicator or cotton swab wrapped in a low-lint paper towel moistened with 70% isopropyl alcohol.

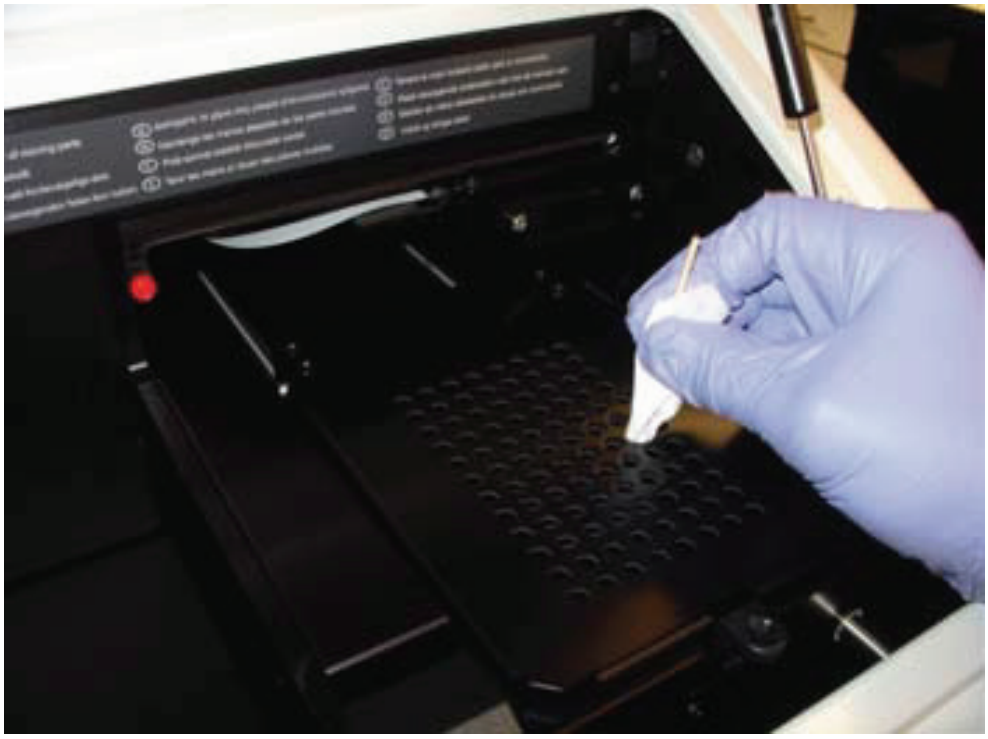


Figure 35. Cleaning the plate mask openings

4. Gently push the plate carrier to the back of the DML 3000.

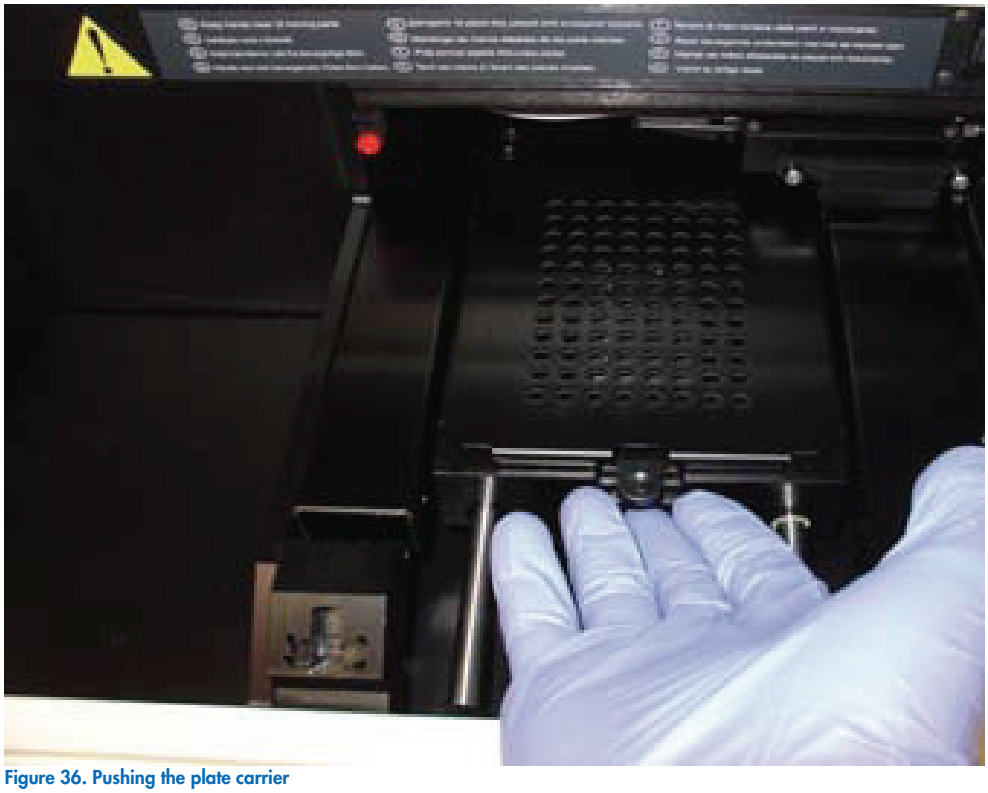


Figure 36. Pushing the plate carrier

5. Gently push the optical head from the home position toward the center of the instrument.

Figure 37. The optical head in the home position

Figure 38. The optical head in the centered position

6. Push up on the left side of the optical mask retainer to detach it from the left pin, and then pull the optical mask retainer to the left to detach it from the right pin.

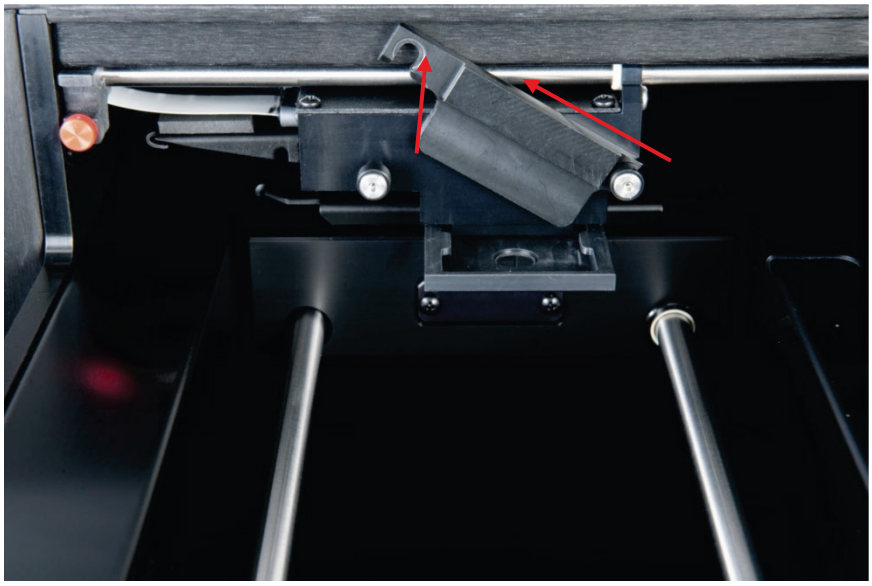


Figure 39. Removing the optical mask retainer

| CAUTION | **Damage to the instrument** |
|---|---|
|  | Do not touch the bottom surface of the optical head while removing the mask. |

7. Place your fingers on both sides of the optical head, grasp the optical mask, and gently pull the optical mask toward you to remove it.

Figure 40. Removing the optical mask.

8. Clean the optical mask and optical mask retainer with a low-lint paper towel moistened with 70% isopropyl alcohol.
   **Note**: If heavy reagent residue is present, the optical mask and optical mask retainer may be soaked for 30 minutes in 70% isopropyl alcohol to dissolve the reagent residue.
   **Note**: Some abrasion marks may be on the underside of the optical mask. This is normal. The optical mask is lightly spring loaded and contacts the plate mask and black metal shelf during normal operation.
9. Rinse the optical mask and optical mask retainer with deionized or distilled water.
10. Allow the optical mask and optical mask retainer to air dry completely before returning to the instrument.
11. Once dry, align the optical mask with the optical head and gently guide the optical mask into the optical head.
    A light click will be heard when the optical mask is correctly positioned in the optical head.
12. Once dry, position the optical mask retainer just above the pins on the optical head. Push the retainer to the right to snap the optical mask retainer securely to the right pin of the optical head. Then push down on the left side of the optical mask retainer to snap it onto the left pin.
13. Moisten a low-lint paper towel with 70% isopropyl alcohol, and thoroughly wipe the black metal shelf to the right of the centered optical head. Allow the black metal shelf to air dry completely.
14. Moisten a low-lint paper towel with 70% isopropyl alcohol, and wipe the two steel guide rails and the interior floor. Allow the guide rails and the floor to air dry completely.
15. Moisten a low-lint paper towel with 70% isopropyl alcohol, and wipe the inside of the access door and all other visible interior surfaces not previously cleaned. Allow to air dry completely.
16. Gently push the optical head all the way to the right to return the optical head to the home position.
    Failure to move the optical head to the home position will not harm the instrument, but will cause a loud grinding noise upon powering ON the instrument. The optical head will move to the home position upon powering ON the instrument.
17. Connect the power supply.
    The instrument may now be powered ON.

## 7.2 Decontaminating the DML 3000

To decontaminate the DML 3000, clean the interior of the instrument. See “Cleaning the interior of the DML 3000” on page 36 for additional instructions. Once the cleaning is complete, wait at least 10 minutes before wiping the interior of the instrument with a low-lint paper towel moistened with deionized or distilled water.

# 8 Troubleshooting

This section provides information about what to do if an error occurs when using the DML 3000.

If further assistance is required, contact QIAGEN Technical Services using the contact information below:

Website: **support.qiagen.com**

When contacting QIAGEN Technical Services about an error with the DML 3000, note the steps leading up to the error and any information appearing in any dialog boxes. This information will help the QIAGEN Technical Services solve the problem.

When contacting QIAGEN Technical Services about errors, please have the following information ready:

1. DML 3000 serial number, type, and version
2. Software version (if applicable)
3. Timepoint when the error occurred for the first time
4. Frequency of error occurrence (i.e., intermittent or persistent error)
5. Detailed description of the error situation
6. Photo of the error, if possible
7. Copy of log files

This information will help you and your QIAGEN Technical Service Specialist to deal most efficiently with your issue.

**Note**: Information about the latest software and protocol versions can be found at **www.qiagen.com**. In some cases, updates may be available for addressing specific problems.

### Hardware and software errors

| Error | Possible cause | Comments and suggestions |
|---|---|---|
| DML 3000 is not responding | • Miscommunication between the *digene* HC2 System PC and the DML 3000<br>• A faulty cable connection between the *digene* HC2 System PC and the DML 3000<br>• Use of an incorrect serial port<br>• The software setting for "Instrument Type" is incorrect | 1. Click "OK" in the dialog box or press "Enter" on the keyboard.<br>2. Power OFF the DML 3000.<br>3. Check all the cable connections by disconnecting and reconnecting the cables. Make sure the correct COM port is used for the connections. Refer to *digene HC2 System Software User Manual* for additional information.<br>4. Check the serial cabling from the DML 3000 to the computer and make sure the connection is tight.<br>5. Correct the "Instrument Type" setting in the *digene* HC2 System Software. Refer to *digene HC2 System Software User Manual* for additional information.<br>6. Power ON the DML 3000. |

### Error and warning messages

| Error | Possible cause | Comments and suggestions |
|---|---|---|
| "Communications Failed" message | • A faulty cable connection<br>• The transport locks are not positioned correctly | 1. Power OFF the DML 3000.<br>2. Check all the cable connections by disconnecting and reconnecting the cables.<br>3. Make sure that both transport locks are not in the transport positions. See "Transport locks" on page 18 for additional information.<br>4. Power ON the DML 3000.<br>5. Make sure the green LED status light is lit. |
| "Door is Open" message | This error occurs when the access door is open. | Close the access door and restart the measurement of the microplate. |
| "Erratic Results" message | • The DML 3000 is powered ON but has not warmed up<br>• High background condition | 1. If the DML 3000 is not powered ON at all times, allow the DML 3000 to warm up for at least an hour prior to microplate measurement.<br>2. Measure the empty microplate mask. |
| Rattling noise or "Mechanical Failure" message | This error may be caused by the plate mask not being secure while the microplate is in the DML 3000. | 1. Power OFF the DML 3000.<br>2. Open the access door.<br>3. Reseat the microplate in the plate carrier.<br>4. Close the plate mask.<br>5. Power ON the DML 3000.<br>6. Click the "Cancel" button.<br>7. Remeasure the microplate. |
| Grinding noise or "Mechanical Failure" message | This error may be caused by the buildup of reagent residue on the plate mask, optical mask, or guide rails. | Clean the DML 3000. See "Cleaning the interior of the DML 3000," page 36, for additional instructions. |
| "Background too high, measurement cancelled" message | This error may be caused by the presence of fluorescing contamination, causing the background to be out of range. | Clean the DML 3000. See "Cleaning the interior of the DML 3000," page 36, for additional instructions. |

# 9 Appendices

## 9.1 Technical Specifications

For power and operating environment requirements for the *digene* HC2 System PC and printer, refer to the documentation provided by the manufacturer.

### 9.1.1 Environmental conditions – operating conditions

| | |
|---|---|
| Power requirements (Power Adapter) | 100–240 V AC, 50–60 Hz, 1.5A |
| Power Requirements (DML 3000) | 24 Vdc, 48W |
| Main supply voltage fluctuations | Voltage fluctuations are not to exceed 10% of the nominal supply voltage |
| | |
| Air temperature | 15–30°C (59–86°F) |
| Relative humidity | 10 to 85% (non-condensing) |
| Pollution degree | 2 |
| Altitude | Up to 2000 m (6500 ft) |
| Place of operation | For indoor use only |

### 9.1.2 Transport conditions

| | |
|---|---|
| Air temperature | –20°C to 60°C (–4°F to 140°F) in manufacturer's package |

### 9.1.3 Storage conditions

| | |
|---|---|
| Air temperature | –20 to 40°C (–4 to104°F) in manufacturer's package |

### 9.1.4 Mechanical data and hardware features

| | |
|---|---|
| Dimensions (h x w x d) | 26.1 x 49.3 x 51.0 cm (10.3 x 19.4 x 20.0 in.) |
| Height of DML 3000 with access door open | 51 cm (20 in.) |
| Weight | 10 kg (22 lbs.) |

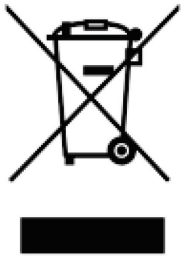
## 9.2 Legal

### 9.2.1 Waste Electrical and Electronic Equipment (WEEE)

This section provides information about disposal of waste electrical and electronic equipment by users.

The crossed-out wheeled bin symbol (see below) indicates that this product must not be disposed of with other waste; it must be taken to an approved treatment facility or to a designated collection point for recycling, according to local laws and regulations.

The separate collection and recycling of waste electronic equipment at the time of disposal helps to conserve natural resources and ensures that the product is recycled in a manner that protects human health and the environment.



Recycling can be provided by QIAGEN upon request at additional cost. In the European Union, in accordance with the specific WEEE recycling requirements and where a replacement product is being supplied by QIAGEN, free recycling of its WEEE-marked electronic equipment is provided.

To recycle electronic equipment, contact your local QIAGEN sales office for the required return form. Once the form is submitted, you will be contacted by QIAGEN either to request follow-up information for scheduling collection of the electronic waste or to provide you with an individual quote.

### 9.2.2 FCC Declaration

The ''United States Federal Communications Commission'' (USFCC) (in 47 CFR 15. 105) declared that the users of this product must be informed of the following facts and circumstances.

This device complies with part 15 of the FCC: Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This Class B digital apparatus complies with Canadian ICES-0003.

The following statement applies to the products covered in this manual, unless otherwise specified herein. The statement for other products will appear in the accompanying documentation.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules and meets all requirements of the Canadian Interference-Causing Equipment Standard ICES-003 for digital apparatus. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that the interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected
- Consult the dealer or an experienced radio or television technician for help.

QIAGEN is not responsible for any radio television interference caused by unauthorized modifications of this equipment or the substitution or attachment of connection cables and equipment other than those specified by QIAGEN. The correction of interference caused by such unauthorized modification, substitution, or attachment will be the responsibility of the user.

## 9.3 DML 3000 Maintenance Log

Use this log to record routine maintenance of the DML 3000 according to your laboratory's policies and procedures.

**As needed and weekly maintenance of DML 3000**

| Task | Initial/Date | Initial/Date | Initial/Date | Initial/Date | Initial/Date | Initial/Date |
|---|---|---|---|---|---|---|
| **As Needed** | | | | | | |
| Wipe down the plate carrier and plate mask | | | | | | |
| Archive the data | | | | | | |
| **Weekly** | | | | | | |
| Wipe down the exterior of the instrument | | | | | | |

**Monthly maintenance of DML 3000**

| Task | Initial/Date | Initial/Date | Initial/Date | Initial/Date | Initial/Date | Initial/Date |
|---|---|---|---|---|---|---|
| Clean the plate mask, plate mask openings, and the plate carrier | | | | | | |
| Clean the optical mask and optical mask retainer | | | | | | |
| Clean the black metal shelf | | | | | | |
| Clean the guide rails and the remaining interior surfaces of the instrument | | | | | | |

# 10 Ordering Information

| Product | Contents | Cat. no. |
|---|---|---|
| **DML 3000** | The DML 3000 is a luminometer that automates amplified chemiluminescent signal detection and results reporting for *digene* Hybrid Capture 2 DNA Tests. | 5000-00031 |
| **Related Products** | | |
| **Lumicheck Plate** | Tool used to monitor the performance of the *digene* microplate luminometer (DML). | 6000-5013 |
| **HCS Laser Printer** | Printer uses to print the results. | 9023211 and 9023212 |
| **USB Printer Cable** | Cable used to connect the Printer to the PC | 9023213 |
| ***digene* HC2 System Software** | Software used to provide results | 9024226 and 9024228 |

# 11 Document Revision History

| Date | Changes |
|---|---|
| R1, November 2022 | Initial release for IVDR compliance |