

User Guide

LightDeck MINI System



Please see the test cartridge package insert for test-specific information.



5603 Arapahoe Avenue, Suite 1
Boulder, CO 80303 • 303-952-2905
www.LightDeckDx.com

Software version 1.0 or greater

Contents

Symbols	iii
Introduction	1
Description.....	1
Principle of Operation	1
Safe Usage and Handling Precautions	2
Precautions	2
Biohazards and Waste	2
Electrical Hazards.....	2
Laser Warnings	3
Other Safety Warnings	3
LightDeck MINI Overview	4
Installation.....	4
LightDeck MINI Front, Back, and Bottom Views	4
Instrument Label.....	5
LightDeck MINI Specifications.....	5
Calibration.....	5
Navigation.....	5
Import Lot-Specific Calibration Data with New Cartridge Lots	6
RUN TEST	7
Start instruments and software	7
Test Procedure	7
Read cartridge	8
VIEW DATA	10
Maintenance and Cleaning	12
How to Clean Outside Surfaces.....	12
Troubleshooting	12

Symbols



Consult instructions for use



Serial number



Batch code/lot number



Catalog number



Use by YYYY-MM-DD



Temperature limit



Caution, consult accompanying documents



Biological risk/Biohazard



Electrical hazard



Manufacturer



Date of manufacture



Do NOT recycle. In compliance with European Directive 2002/96/EC on waste electrical and electronic equipment (WEEE), this equipment must not be disposed of as unsorted municipal waste. Instead, it must be collected separately in accordance with local recycling regulations. Presence of the symbol indicates that compliance must be adhered to for this device on waste electrical and electronic equipment (WEEE).



DC electrical power rating

Introduction

Introduction

The LightDeck MINI System (hereafter referred to as LightDeck MINI) is used in conjunction with LightDeck test cartridges. Please refer to the test cartridge package insert for test-specific information.

The LightDeck MINI and test cartridges are manufactured by MBio Diagnostics, Inc. (dba LightDeck Diagnostics), based in Boulder, CO, USA.

Disclaimers

1. LightDeck Diagnostics shall not be liable for malfunctions and damage resulting from installation, relocation, remodeling, or LightDeck MINI repair done by vendors other than those specified by LightDeck Diagnostics.
2. LightDeck Diagnostics shall not be liable for malfunctions and damage of LightDeck Diagnostics products due to the use of products of other manufacturers not supplied by LightDeck Diagnostics.
3. LightDeck Diagnostics shall not be liable for malfunctions and damage resulting from negligence of precautions and operating methods contained in this manual.
4. LightDeck Diagnostics shall not be liable for malfunctions and damage resulting from use under environmental conditions outside the range of conditions required for proper use of this product (e.g., power supply, installation environment) described in this manual.
5. LightDeck Diagnostics shall not be liable for malfunctions and damage resulting from natural disasters such as fires, earthquakes, and floods.

The LightDeck MINI is used with LightDeck test cartridges to perform immunoassays.

Description

The LightDeck MINI is an automated fluorescence analyzer. The LightDeck MINI is run by software on a computer that is connected to the LightDeck MINI. The user interface on the computer guides you through the test procedure. Results are displayed at the end of the test and may be viewed, exported, or printed.

Principle of Operation

Planar waveguides with a printed microarray are assembled into disposable plastic cartridges. Each spot in the microarray measures a biomarker or built-in control. Light is focused through an integrated lens to create an evanescent field just above the surface of the waveguide. This evanescent field excites only the fluorescent dye that is bound by the capture antibody on the waveguide. At the end of the test, a laser turns on to excite bound dye. A camera reads fluorescence signal and software converts signal to quantitative concentrations of biomarkers. The result is displayed on the screen in $\mu\text{g/L}$.

Safety Information

Safe Usage and Handling Precautions

This section contains safety precautions which must be followed for safe operation of the LightDeck MINI .

Precautions



Before using the LightDeck MINI, read this User Guide to ensure correct operation.



Observe the precautions. Failure to do so may result in injuries, cause property damage, or produce incorrect results.



The LightDeck MINI is to be operated by personnel trained for its intended use and correct operation.

Biohazards and Waste



Wear appropriate Personal Protective Equipment (e.g., wear gloves, lab coat, and eye protection). Follow biohazard procedures when handling samples and cleaning the LightDeck MINI.



Used test cartridges, pipette tips, and contaminated swabs or cloths used for cleaning equipment are potentially infectious waste and disposal must follow applicable local, state, or federal regulations.



When discarding the LightDeck MINI that may be contaminated with sample, disposal must follow applicable local, state, or federal regulations.

Electrical Hazards



Use only the power supply included with the LightDeck MINI. The power supply voltage applied to the equipment is AC90-264V – 2.5A, 50-60 Hz.



To avoid electrical shock, observe the following precautions:

- Avoid installation location where water may splash on the equipment.
- Plug the power cable into an outlet with a grounding receptacle.
- Make sure that all cables/cords have been properly connected.



When plugging the power supply in or removing it from an outlet, grasp the plug (not the cord) to prevent damage to the cord.



There are no user serviceable parts. Do not remove covers or other parts to avoid electrical shock or injury from moving parts.

Safety Information

Laser Warnings

The LightDeck MINI includes an embedded laser. The equipment complies with FDA performance standards for laser products except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007.

The LightDeck MINI is considered a Class 1 laser product per IEC 60825-1: 2007.



Do not open the LightDeck MINI. The LightDeck MINI has no user serviceable parts. Any unauthorized opening of the instrument can cause potential hazards, can expose hazardous laser radiation, and will invalidate warranty claims.



The LightDeck MINI is a Class 1 laser device. A light-tight enclosure and a safety interlock prevents the internal laser source from emitting laser light, should the test cartridge door be opened when a cartridge is not present.



If the enclosure is damaged, immediately stop using the LightDeck-MINI to prevent possible exposure to hazardous laser radiation.



Caution – Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

Other Safety Warnings



EXPLOSIVE HAZARD: Do not use flammable and explosive gas around the equipment.



Do not place fingers into the LightDeck MINI test cartridge door.



Test cartridges are single use only. Do not reuse test cartridges.



Only insert test cartridges manufactured by LightDeck Diagnostics. Do not insert damaged or used test cartridges into the LightDeck MINI.



Wear appropriate Personal Protective Equipment for the sample type being tested when using the LightDeck MINI.



Only connect the LightDeck MINI to a USB 2.0 or USB 3.0 port of a host computer. Use only the USB cable provided with the LightDeck MINI.

Overview

LightDeck MINI Overview

The LightDeck MINI ships in a custom-designed protective box. Use only these protective boxes if you must transport the components.

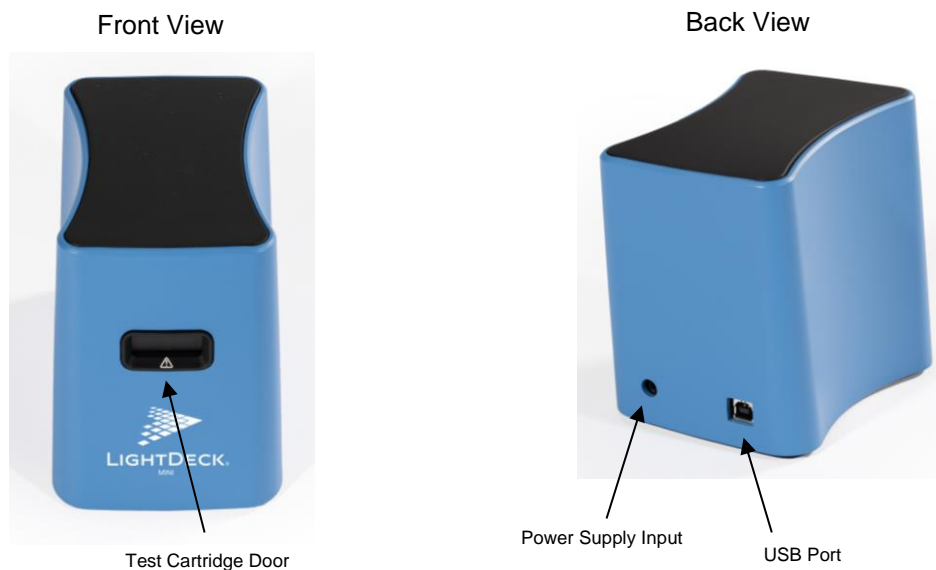
The following items are supplied with your LightDeck MINI:

1. LightDeck MINI
2. Power supply and cord
3. USB cable
4. 100 μ L fixed volume pipette
5. 30 disposable pipette tips
6. USB flash drive containing LightDeck-T software
7. User Manual

Installation

1. Unpack the LightDeck MINI and place it on a level, stable surface. Inspect for any obvious signs of damage. Report any damage immediately.
2. Install the software from the USB flash drive supplied with the LightDeck MINI.
 1. Insert the USB flash drive in the computer.
 2. Double click on the installation file.
 3. Follow the installation procedure as directed by the software.
 4. Plug in the power sources for the computer and LightDeck MINI.
 5. Attach USB cable from the LightDeck MINI to the computer.
3. Before using, allow the LightDeck MINI to equilibrate to the surrounding temperature for at least 30 minutes. Operating temperatures depend on the test cartridges, but are typically 50– 104 °F, 10 – 40 °C.

LightDeck MINI Front and Back Views



Overview

Instrument Label

LightDeck MINI Specifications

Detection system	Fluorescence immunoassay instrument
Cartridge	Compatible with test cartridges manufactured by LightDeck Diagnostics
Electrical power rating	+12DC / 2.5A max
Wall Power	AC90-264V – 2.5A, 50-60 Hz.
Laser classification	Laser Class 1 (per IEC 60825-1)
Operating temperature	Specific to test cartridges, typically 50– 104°F, 10 – 40°C
Operating relative humidity	25 – 65%, non-condensing
Storage temperature	0 – 45°C
Storage humidity	5 – 95%, non-condensing
Altitude	0-2000 m
Weight	3.5 pounds, 1.5 kg
Physical dimensions	4.4 (W) x 5.9 (H) x 6.1 (L) inches 112 (W) x 150 (H) x 155 (L) millimeters

Calibration

The LightDeck MINI is factory calibrated. No user calibration or verification required.

Software Interface

The Home Screen lets you navigate to modules to run sample or quality control tests, to view stored sample results or QC data, or import cartridge definition files.



RUN TEST
Measure new sample

RUN TEST: Test samples

VIEW DATA
Review sample measurements

VIEW DATA: Review stored data

IMPORT
Import cartridge definitions

IMPORT: A lot-specific cartridge definition file must be uploaded for each new lot of reagent. It contains calibration information.

INFORMATION
Application information

INFORMATION: Application information and legal

Import Lot-Specific Calibration Data with New Cartridge Lots

Each test cartridge lot is factory calibrated. Lot-specific calibration data must be loaded from the USB flash drive that is included with each box of test cartridges. If the file is missing, you will get a message to load the calibration data from the USB flash drive. Alternatively, calibration data can be downloaded from the internet by following the prompts in the LightDeck-T software.

1. Turn on the computer
2. Start LightDeck-T software by double clicking the LightDeck-T icon on the desktop to launch the software.
3. Import the calibration file
4. Select IMPORT.
5. Navigate to the USB drive. Double click the xxx.cdf.xml file. Alternatively, select INTERNET to download the file.
6. Select "Update Now" to import the calibration information.

The LightDeck-T software will import the cartridge definition file and calibration information. Do not remove the USB drive until the screen shows "Completed successfully."

Run Test

RUN TEST

This section tells you how to run a test or QC test. The examples show screen shots for a LightDeck MC + CYN Test Cartridge.

If cartridges were refrigerated, allow to warm to room temperature for at least 15 minutes.

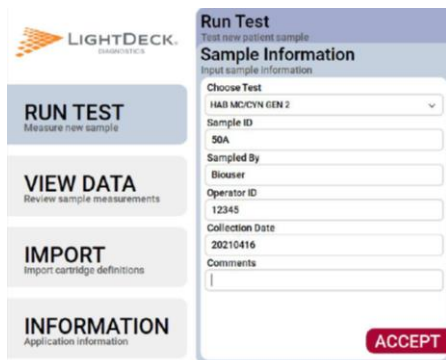
Start instruments and software

1. Turn on the computer
2. Start LightDeck-T software
3. Double click the LightDeck-T icon on the desktop to launch the software.

Test Procedure



Click the RUN TEST button.



Enter sample information.

- Choose a test from the drop-down menu.
- Enter Sample Information
- Click ACCEPT to load your inputs.



Open the pouch. Remove the test cartridge.

- Avoid touching the clear plastic on the bottom of the test cartridge.
- Label the test cartridge with a sample ID.

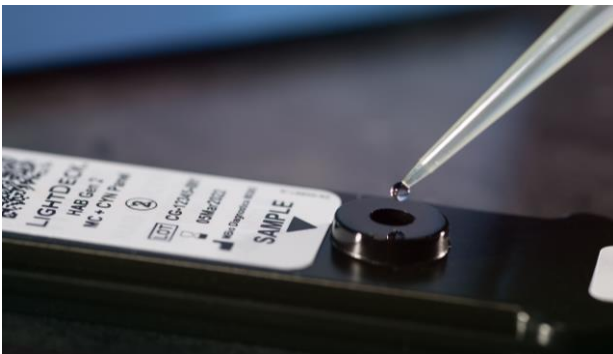
Caution: A desiccant sachet should also be in the pouch. Discard the cartridge if the desiccant sachet is not present.

Run Test



Add sample to reagents.

- Add **100 µL** sample to the microtube containing dried reagents.
- Mix by aspirating and dispensing 10 times until the reagents are fully rehydrated and well mixed with the sample.
- When using the pipette depress the plunger fully before aspirating.



Add sample to cartridge

- Dispense **100 µL** combined sample and reagents into the sample port of the test cartridge.

Read cartridge



Open cartridge door.

- Click **READY** to open the test cartridge door.

Tip: The door will automatically close after 30 seconds, so click Ready when you are ready to insert the test cartridge. If the door closes, just click Ready again.

Run Test



Insert the cartridge.

- Insert the test cartridge.

The LightDeck MINI reads the test cartridge bar code and populates the rest of the Sample Information.



Test Processing

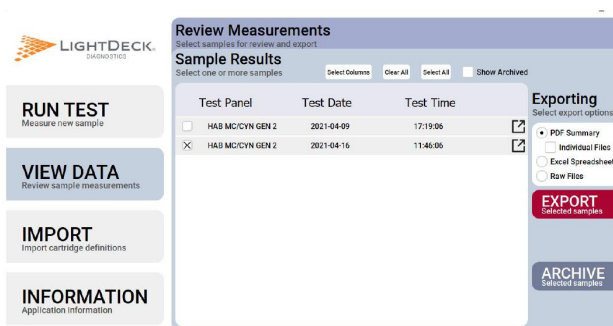
The rest of the test is automatic. For most test cartridge types, the processing time is 10 minutes.



Test Complete

Results are displayed.

Click DONE to release the cartridge and remove it from the LightDeck MINI.



Export Test Results

If a PDF report for the sample is desired, click VIEW DATA, select samples to export, and click EXPORT.

Review Results

Review Results

This section tells you how to view results, create reports, and archive samples.

Click [VIEW DATA](#)

Review Measurements
Select samples for review and export

Sample Results
Select one or more samples

Select Columns Clear All Select All Show Archived

	Test Panel	Test Date	Test Time	
<input type="checkbox"/>	HAB MC/CYN GEN 2	2021-04-09	17:19:06	↗
<input checked="" type="checkbox"/>	HAB MC/CYN GEN 2	2021-04-16	11:46:06	↗

Exporting
Select export options

- PDF Summary
- Individual Files
- Excel Spreadsheet
- Raw Files

EXPORT
Selected samples

ARCHIVE
Selected samples

Select PDF Summary to export data as .pdf files. Select Excel Spreadsheet to export data in a spreadsheet format.

You may configure the table to show multiple columns. Click on Select Columns, then click on the field, and then click on the arrow to move it.

Select Result Table Columns (Max 5)

Available Columns:

- Collection Date
- Comments
- Operator ID
- Patient ID
- Sample ID
- Test Date/Time

Used Columns:

Result Field	Displayed Header
Test Panel	Test Panel
Test Date	Test Date
Test Time	Test Time

OK CANCEL

Review Results

Select Raw Files to export the six .png files and one .res file that is associated with the sample measurement.

Overview

The table gives a summary of samples that have not been archived.

Click on the Box and Arrow icon to show the details associated with the sample.

The default order in the table is the most recent test first. Click on the column header to sort in ascending or descending order. For example, if you use “QC” as part of your naming convention, you can sort by Sample ID to group QC samples together.

Click Show Archived at the top of the table to show archived samples in the summary table.

EXPORT

- ① Click on the format for the export operation.
 - You can choose the fields to include in your spreadsheet.
 - Click PDF Summary for a summary table of the selected samples, similar to the table shown on the screen,
 - Click PDF Summary and Individual Files for a multi-page PDF with a report for each sample selected.
 - Click Excel Spreadsheet for an Excel file. Each row in the spreadsheet contains data associated with each sample.
 - Individual Files gives you a report for each sample.
- ② Click on the Select All box at the top of the table or on individual samples. Click EXPORT to create the reports or a spreadsheet.
- ③ Click on the ARCHIVE to hide them from the table. Files are always saved to a default location on the computer.

Maintenance and Cleaning

The LightDeck MINI is a maintenance-free instrument and has no user-serviceable parts. When encountering failures or damage, please contact Technical Support.



Do not open the LightDeck MINI for cleaning or servicing.

How to Clean Outside Surfaces

Use a soft cloth to clean the LightDeck MINI with a mild detergent, 70% solution of ethanol or isopropyl alcohol in water, or 10% bleach solution.



Do not directly spray the LightDeck MINI with cleaner.

Apply cleaning solutions to a cloth and then wipe the instrument.

Troubleshooting

When an error occurs, a dialog box appears displaying the error message, possible cause and solution. If you are unable to resolve the problem, please contact Technical Support.

Error Message	Reason Type	Action
The cartridge has expired	Cartridge shelf life exceeded	Discard expired cartridge. Run within expiration.
The cartridge contains an invalid barcode	Did not recognize the barcode	Re-run the sample using a new cartridge.
Unable to read the cartridge barcode	Barcode not read	Verify that barcode is not damaged and retry. If error persists, select a new cartridge.
The inserted cartridge is of an unknown test type	Cartridge Definition File not loaded	Load the Calibration Info for the cartridge lot using the USB drive provided in the test cartridge box.
Wrong Cartridge Inserted – Do you wish to proceed?	Cartridge inserted does not match requested test	Update sample information to indicate test type matching the cartridge type.
Calibration information needed	Instrument has no record of cartridge lot information	Load Calibration Info for that specific cartridge lot using the USB drive provided in the test cartridge box.
Unknown error processing the cartridge	General error	Must run a new cartridge. If the problem repeats, re-start the instrument.
Error connecting to hardware	Internal instrument communication	Restart the instrument. If problem persists, contact Customer Support.
Cartridge error	Internal control out of range	Re-run the sample using a new cartridge
Reference Spots Not Found	Reference internal control out of range	Re-run the sample using a new cartridge

Appendix

High background detected	Excessive background	Re-run the sample using a new cartridge if error repeats dilute sample prior to measurement with a new cartridge
Low Internal Positive Control	Flow control reading low	Re-run the sample using a new cartridge
High Internal Positive Control	Flow control reading high	Re-run the sample using a new cartridge
Reference Spot Not Found	Reagent pellet error	Re-run the sample using a new cartridge
Dried Reagents Not Added or Cartridge Not Punctured	Reagent pellet error or cartridge error	Re-run the sample using a new cartridge
Cartridge Hold Failure	Cartridge error	Re-run the sample using a new cartridge



HACH COMPANY World Headquarters
P.O. Box 389, Loveland, CO 80539-0389 U.S.A.
Tel. (970) 669-3050
(800) 227-4224 (U.S.A. only)
Fax (970) 669-2932
orders@hach.com
www.hach.com

HACH LANGE GMBH
Willstätterstraße 11
D-40549 Düsseldorf, Germany
Tel. +49 (0) 2 11 52 88-320
Fax +49 (0) 2 11 52 88-210
info-de@hach.com
www.de.hach.com

HACH LANGE Sàrl
6, route de Compois
1222 Vésenaz
SWITZERLAND
Tel. +41 22 594 6400
Fax +41 22 594 6499

FCC Supplier's Declaration of Conformity



47 CFR § 2.1077 Compliance Information

Product Name: MQ Reader
Description: Portable Lab Instrument – model # 90-00007
Responsible Party: MBio Diagnostics
5603 Arapahoe Ave., Suite 1
Boulder, Colorado 80303
U.S.A.
<http://mbiodx.com/technology/index.php>

This device complies with the following regulations:

47 CFR Part 15, Subpart A – Unintentional Radiators, Class A for Home or Commercial use

- 1. 15.107 Conducted emissions limits; general requirements**
- 2. 15.109 Radiated emission limits; general requirements**

FCC Compliance Statement -

This device complies with Part 15 of the FCC Rules. 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.

Signed  Date 1/8/2021
Printed Name Chris Myatt Title CEO