

LuminUltra GeneCount[®] Q-8 Q-16 qPCR Non-Touch Screen Version

For Windows[®] - based Software

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0. Introduction

This manual includes installation instructions, operating instructions, maintenance procedures and other technical information for the GeneCount® Q-8/Q-16 qPCR Touch Screen device.

Please read and understand this document before operating the unit. Failure to do so could result in personal injury or damage to equipment. Please consult your local representative if you do not understand the information in this manual, or if you need additional information.

Our team strives to improve and update existing information based on user feedback. Newest versions and information are available for download from the website my.luminultra.com and from sales@LuminUltra.com.

Note:

Very important information is contained within this manual and it should be carefully read before first use of the instrument. Failure to operate instrument according to the instruction could result in damage or abnormal functioning of the instrument.

Warning

The warning messages indicate caution when completing operation of a certain step. If the instrument is not used in the manner prescribed by the manufacturer, the protection provided may be compromised.

1. Safety

During operation, maintenance and repair of this instrument, the following basic notes must be observed. In case of failure to follow these measures or the warnings or notes indicated herein, the basic protection provided by the instrument, its safety criteria of design and manufacture, and its predicted use range would be impaired.

LuminUltra Technologies Ltd. shall not be liable for the consequences of the client's disregard for the safety requirements documented in this manual, or the use of plasticware and other laboratory supplies not provided by LuminUltra Technologies Ltd. or its subsidiaries.

1.1 Grounding Considerations

To avoid an electric shock, the input power cable of the instrument must be properly grounded. This instrument uses a 10A 3-pin grounded plug. It is for use with a grounded power receptacle and is a safety feature. If the plug cannot be inserted into the receptacle the receptacle must be fixed by a qualified electrician to maintain the safety function of the plug and the protection it provides.

1.2 Risk of Electric Shock

Operators are not allowed to disassemble instrument protection, replace components, or make internal adjustment without authorization. If necessary, it must be completed by certified professional maintenance personnel. In the event work is required to be performed the device must be disconnected from all power sources.

1.3 Power Supply Considerations

Before connecting to the mains and switching the instrument on, make sure the voltage is consistent with the instrument's requirements of 110-240V AC (16V DC) and up to 9A current draw. The rated load for the power socket must not be less than the instruments maximum load of 144W.

1.4 Power cord considerations

The instrument is supplied with a power cable, always use the supplied cable when operating the instrument. If the power cable is damaged it should be replaced with a new one of the same specifications. The power supply wire should be treated with care; do not place objects on the wire and do not place the wire in high traffic areas. If the power cord near a hot surface, add protection to prevent the insulation from being damaged.

1.5 Plugging and unplugging your device

At insertion and withdrawal of power cable, the back of the plug shall be firmly held with the hand. The plug must be completely and tightly inserted into the socket and must not be removed by pulling the cable.

1.6 Placement of instrument

This instrument should not be positioned in a place where it is difficult to cut off the power supply.

When not in use, the power should be switched off. If the instrument is not going to be used for a long time, the power should be switched off, the power plug withdrawn and the instrument covered with soft cloth or plastic film to prevent dust or foreign bodies entering the machine.

1.7 Notes during operation

During test, cares shall be taken to prevent liquid from dropping onto the instrument. The castoff used in tests, such as consumables, reagent, and so on, should be treated as required, and should not be thrown away or poured down the drain.

During test, if there are hazardous substances, user must be trained before using. Hazardous substances, which has been used, should be handled, and stored according to direction for use. Please consult and follow all regulations as required by the local authority having jurisdiction. User who operate the instrument, must be trained, and has relevant quantification.

Warning 

If any of the following should occur, you should immediately switch off the power supply, withdraw the power plug from the power socket, and contact the supplier to effect a repair: Repairs can only be carried out by suitably qualified engineers.

- Liquid gets inside the instrument.
- The instrument is rained upon or water is spilled over it.
- The instrument works abnormally, generates an abnormal sound, or generates a strange odour.
- The instrument is dropped, or its casing is damaged.
- There is an obvious change in the function of the instrument.

Warning 

When operating or performing work on the device, all relevant PPE guidelines should be followed taking special care to protect oneself and others from potentially contagious material.

1.8 Warning Signs

- Hot Surface warning Label



Warning 

When "HOT SURFACE!" is pasted in the instrument, it means that the metal part (module) near this sign shall not be touched with any part of the body during the operation of the instrument or a period of time immediately after the operation of the program to avoid burns!

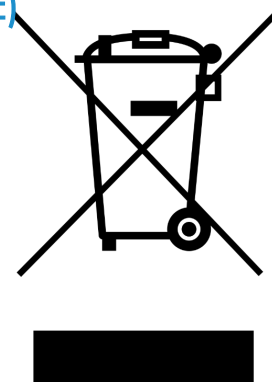
1.9 Waste Electrical and Electronic Equipment (WEEE)

For product recycling instructions and more information, please go to:

<https://www.luminultra.com/environmental-compliance/>

WEEE is to be shipped to the LuminUltra address listed below and WEEE is to be stated on the packing slip and/or packaging. Ship to:

LuminUltra Technologies
C/O NUNNER Logistics BV
Gerstdijk 24
5704 RG Helmond
The Netherlands



2. Maintenance of Instrument

If there is any stain on the surface of the instrument, it can be cleaned with a lint-free cloth and low strength bleach solution. Heat conducting oil medium is not allowed in the module hole of this instrument.

The drawer should be closed in time after the normal storage and use of the instrument to prevent dust accumulation.

Warning

- When cleaning the instrument, the power should be turned off.
- The instrument surface should not be cleaned with corrosive cleaning agents.
- The instrument module includes precise optics. Dust, foreign matter and residue should be avoided.

2.1 Information to the User

FCC Part 15, Class "A" Limits

Supporting test records reside with the manufacturer. The device complies with Part 15 of the FCC Rules. Operation is subject to the following conditions:

1. The equipment may not cause harmful interference.
2. The equipment must accept any interference received, including interference that may cause undesired operation.

Changes or modifications to this equipment not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment.

This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications.




Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

The following techniques can be used to reduce interference problems:

1. Disconnect the equipment from its power source to verify that it is or is not the source of the interference.
2. If the equipment is connected to the same outlet as the device experiencing interference, connect the equipment to a different outlet.
3. Move the equipment away from the device receiving the interference.
4. Reposition the receiving antenna for the device receiving the interference.
5. Try combinations of the above.

2.2 Manual Precautionary labels

Read all labels and tags attached to the instrument. Personal injury or damage to the instrument could occur if not observed. A symbol on the instrument is referenced in the manual with a precautionary statement.

	<p>This symbol indicates a safety alert. Obey all safety messages that follow this symbol to avoid potential injury. If on the instrument, refer to the instruction manual for operation or safety information.</p>
	<p>This symbol indicates an aperture from which potentially harmful light is emitted. Do not peer into the LED light aperture/s.</p>
	<p>This symbol indicates a potentially hot surface. Avoid touching the marked surface.</p>

3. Overview

This is a user's guide for using LuminUltra GeneCount qPCR with Windows[®]-based software.



3.1 Parts required

- GeneCount qPCR instrument unit
- AC adapter and power cord
- USB cable
- A Windows[®] - based PC

3.2 Key parameters

Instrument Electrical Class	Class III
Capacity (# of wells)	4, 8, 16
Channels (# of Fluorophores per well)	4 (1. FAM/SYBR Green; 2. JOE/HEX/VIC/TET; 3. ROX/Texas Red; 4. CY5/LIZ/Cy5.5)
Multiplex capability	Up to 4 targets per well
Minimum detection threshold	4 copies
Dynamic range	>1.0E9
Signal Interface	USB 2.0
Instrument Light Source	(1) LED white light
Instrument Operating Temperature	10 - 40°C (-50 – 104°F), 80% max. relative humidity (noncondensing)
Instrument Storage Temperature	-40 - 60°C (-40 – 140°F), 80% max. relative humidity (noncondensing)
Excitation source	High endurance LED
Detector	Ultra-low- light CMOS Bio-imaging chip
Thermal system	Solid-state, Peltier-based
Tube/plate formats	0.2mL, 4 or 8-tube strip
Reaction volume	10uL – 60uL
Filters:	4 sets exchangeable*, **
Excitation Range:	460nm – 670nm
Emission Range	510nm – 720nm
DNA probes supported:	DNA binding dyes (e.g. SybrGreen), hydrolysis probes (e.g. TaqMan probe) and hybridization probes (e.g. FRET probes).
Temperature Uniformity	< +0.2°C
Temperature control resolution	+0.1 °C
Temperature Ramp Rate	6.5°C/s heating; 4°C/s cooling
Dimension	247mm (L) x 187mm (W) x 135mm (H)
Weight	2.4Kg
Power supply	16VDC, 144W, (Class I adapter provided that accepts 100V-240VAC, 50/60Hz)

*: Wavelength characteristics can be modified by changing filter modules.

**: We support 1 – 4 channels in different configurations.

3.3 Set up the instrument

3.3.1 Step 1

After installing the software (see step-by-step software guide in the next page). Please visit www.luminultra.com/software/ to download and install software from LuminUltra's web site). Connect instrument with Windows[®] - based PC via included USB cable. Power up the instrument using the included AC adapter. In some models, there is a main power switch in the back. Please flip it to the on position.

Figure 1. PDx 16 USB and power connections

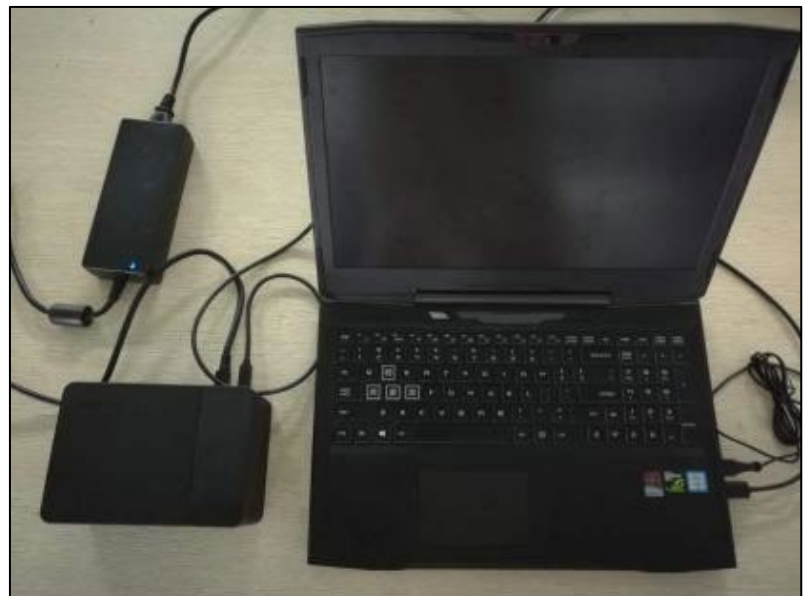


3.3.2 Step 2

Start the software, by launching the GeneCount .exe. file downloaded. The software should recognize the instrument Hardware automatically. There is no need to install a driver as Windows[®] should already have the driver necessary to connect to GeneCount device.²

3.3.3 Step 3

Open the instrument lid and place the test tubes filled with sample and reagent mix. We support 0.2ml standard qPCR tubes. Make sure the top lid of the tube is transparent and flat. Close the instrument lid when done



¹ We required Windows[®] 10 with Office 2010 or later installed to support print report function.

² We use the USB HID device interface for GeneCount. This is the same USB HID for keyboard and mouse

4. Step by step software guide

4.1 Installing the GeneCount software

Please visit www.luminultra.com/software/ to download and install software from LuminUltra's web site).

If the file is one compressed file, please decompress it first. If you do not have a compress/decompress utility installed on your computer, go get one at: <http://www.7-zip.org>. It is free.

Name	Type	Compressed size	Password ...	Size	Ratio	Date modified
Installer	Windows Installer Package	5,552 KB	No	5,959 KB	7%	2020-05-07 8:50 AM
setup	Application	252 KB	No	772 KB	68%	2020-05-07 8:50 AM



Once the file is decompressed, just copy the folder to any directory in your PC. The folder should look like this, see below, when opened. The executable file is the file "GeneCount.exe".

Next, the installer will open up a box as shown below. Follow the installer prompts to complete the set up:

4.2 Launching the software

When the GeneCount PC software is launched, after a brief delay for device initialization, the front page will display as shown in Figure 1.

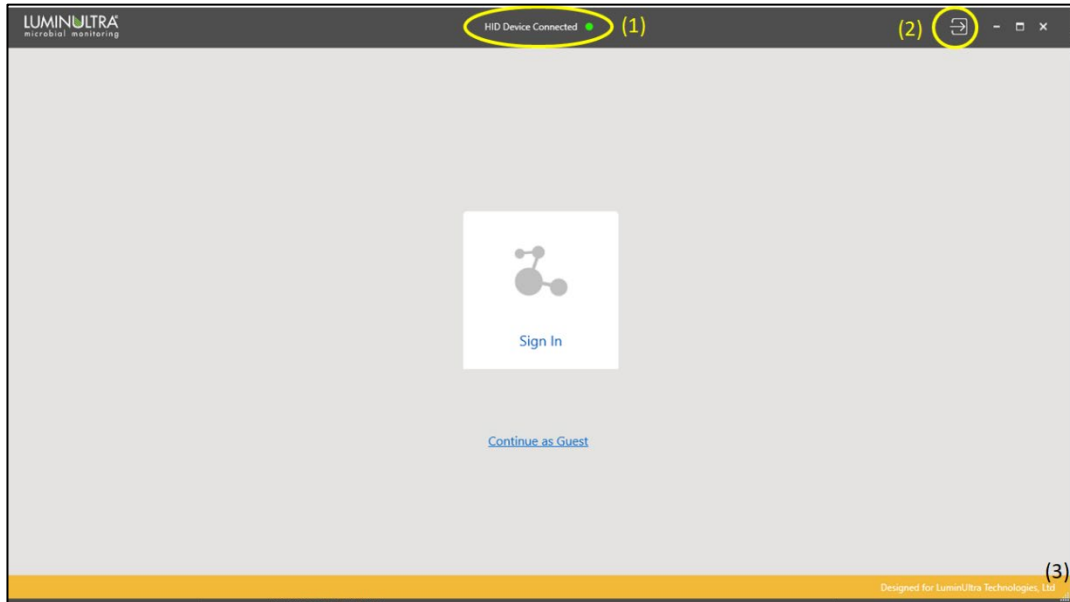


Figure 1 GeneCount software front page

Several notable features are marked in Figure 1. Marker (1) is an indicator of whether the GeneCount USB device is found. If found, a message “HID Device Connected” is shown along with a green dot. We call it HID, because the GeneCount instrument uses USB HID device class.

4.2.1 The home button

Marker (2) is the home button. At any time of running this software, click this button to return to this front page.

4.2.2 Resizing the window

Marker (3) is the place to drag to resize the GeneCount software windows.

4.3 The setup page – name setup

Click on the “Setup” button will take us to the setup page (Figure 2). Here we can set up the experiment. Here we can name the experiment and all the samples in the wells. We can also name and select the fluorescence channels for qPCR fluorescence reading.

A default date-coded experiment name is given on this page when we first enter. Feel free to change it to something you choose.

4.3.1 Samples and qPCR set up

The software automatically detects the number of reaction wells the connected instrument can support. Each reaction well can be associated with a sample. In this page, the user can enter a

name for each sample. If a sample well name field is left empty (white spaces), it is considered that the sample does not exist for that well.

Enter in experiment name and all sample data in the corresponding coordinates by double clicking the appropriate box (Marker 1).

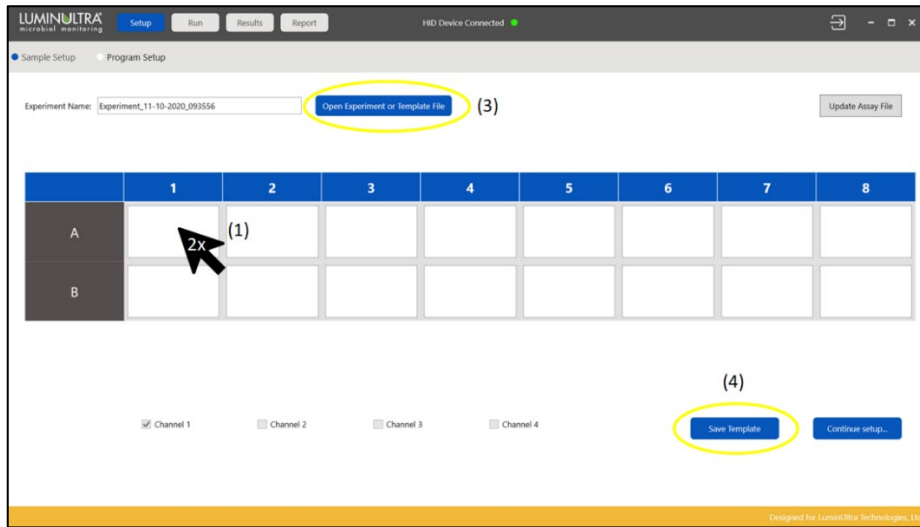


Figure 2 The setup page – name setup

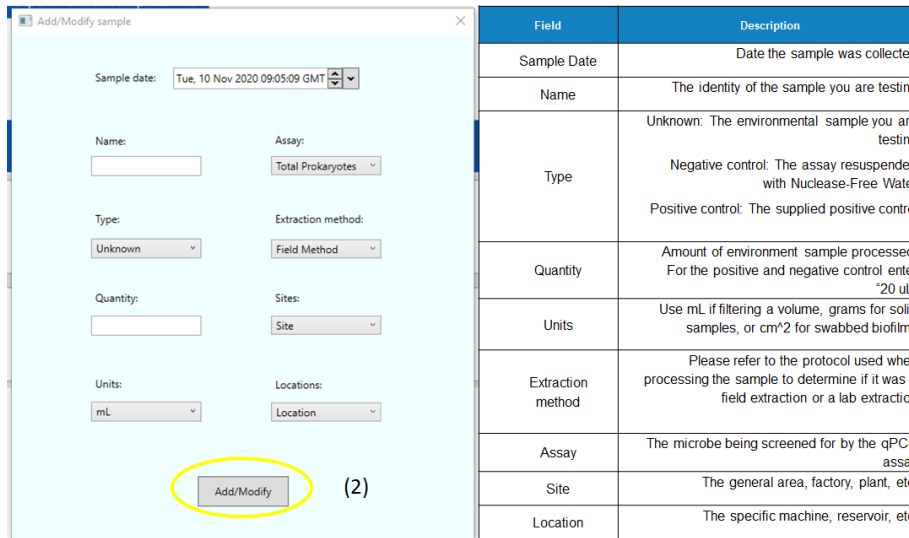


Figure 3 The setup page – Add/Modify Sample

Add sample information into each field according to the provided chart and press "Add/Modify" (Marker 2).

4.3.2 Saving template

At this step, we can also save the settings to a template file (Marker 4). So next time when we perform a similar experiment, we can just load the template file instead of manually entering all the information again.

4.3.3 Open existing experiment for template file

We can also load an existing experiment file or template file by clicking on the “Open experiment file” button (Marker 3).

When this step is done, we can click on the “Next step” button to continue setting the thermal cycling program

4.4 The setup page – cyclers setup

Here we can setup the thermal cycler program. Each assay has pre-set cycling conditions specified by LuminUltra and do not need to be changed. After reviewing press the “Start” button to begin the run (Marker 1)

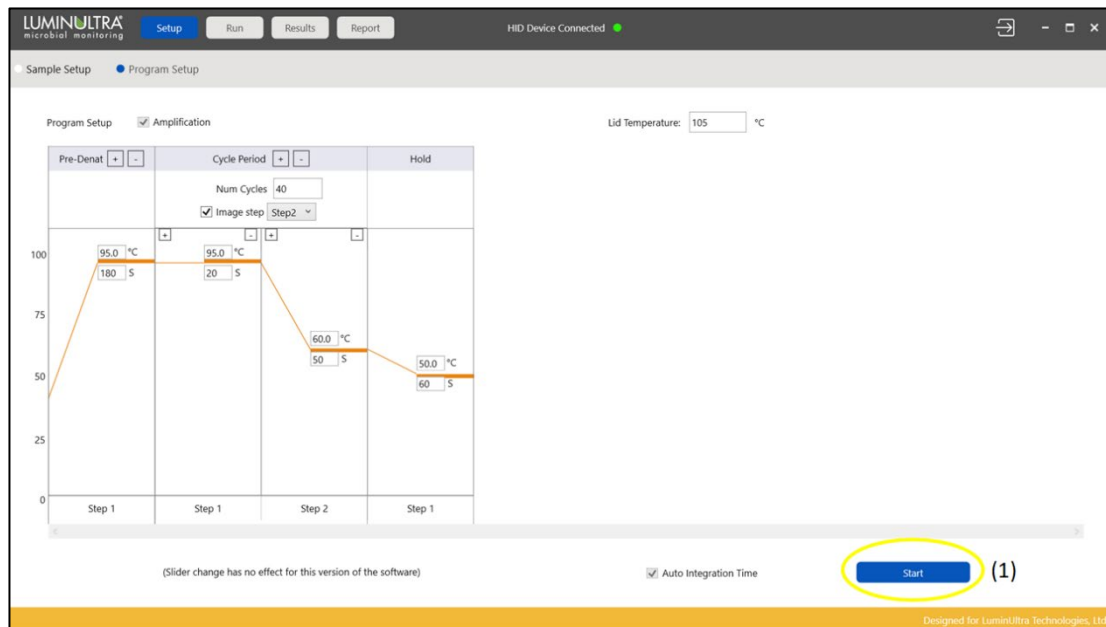


Figure 4 - Cycling Condition Review

5. Running the experiment and monitor status

In the setup page – cycler setup, when we are satisfied with all the settings and loaded the samples, we can start running the experiment by click the “Start...” button.

Before the instrument starts to execute thermal cycling program, it will automatically check to ensure the lid is closed and the main power is applied.

5.1 Running amplification program

When running normal qPCR amplification program, the amplification window will real time monitor the fluorescence signal from the samples. In addition, the Run-Amplification Curve page will also show the current run status and estimated remaining run time

5.1.1 Ct Threshold (1)

The threshold for determining Ct is expressed as the percentage of the saturating level of the amplification levels after normalization. The bigger this percentage, the more delayed the Ct values are.

5.1.2 Ct Low limit (2)

The minimum value of Ct is set through this parameter. This setting is helpful in determining the base fluorescence value for amplification curve analysis.

5.1.3 Normalize (3)

When displaying amplification curve, we usually normalize the fluorescence values. This will allow us to visualize Ct threshold value. This choice will not affect the result of the analysis.



Figure 5 – Results Analysis

6. Results

6.1 Samples:

- Detected: The sample has a detectable amount of genomic units. The limit of detection is different for every assay.
- Undetected: The sample has a genomic unit that is below the limit of detection (LOD).

6.2 Positive and Negative control reactions:

- Pass: The positive/negative controls have a Ct value that is within our acceptable range. All reagents are viable, and the reaction was set up correctly.
- Fail: The positive/negative controls have a Ct value that is outside our acceptable range.
 - Positive control fails: the positive control maybe degraded, the master mix may no longer be viable, or the reaction was set up incorrectly.
 - Negative control fails: There is a significant amount of contamination present which may have also contaminated the samples that were run.

6.3 Concentration:

For samples, the genomic unit concentration per unit will be displayed if the sample has a level above the limit of detection. This value is based on our standard curve and is calculated based on the original volume, mass, or surface area entered in the "Quantity" field of the individual sample and the volume of sample processed of the given extraction method.

7. Reports

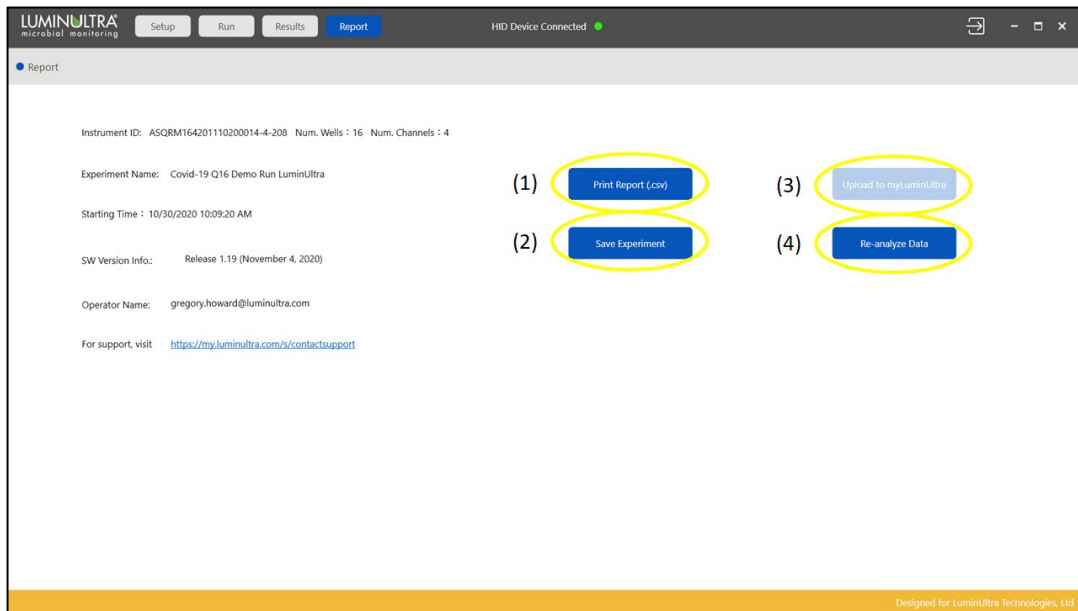


Figure 6. Save and export page

On the report tab you can export the experiment file as a .csv spreadsheet (Marker 1) and save it as a .json experiment file (Marker 2). If you have logged into a myLuminUltra account, you can also upload it to our cloud to review it using our "Test+Analyze" feature (Marker 3). If you have an older experiment you can also Re-analyze the data for upload (Marker 4).