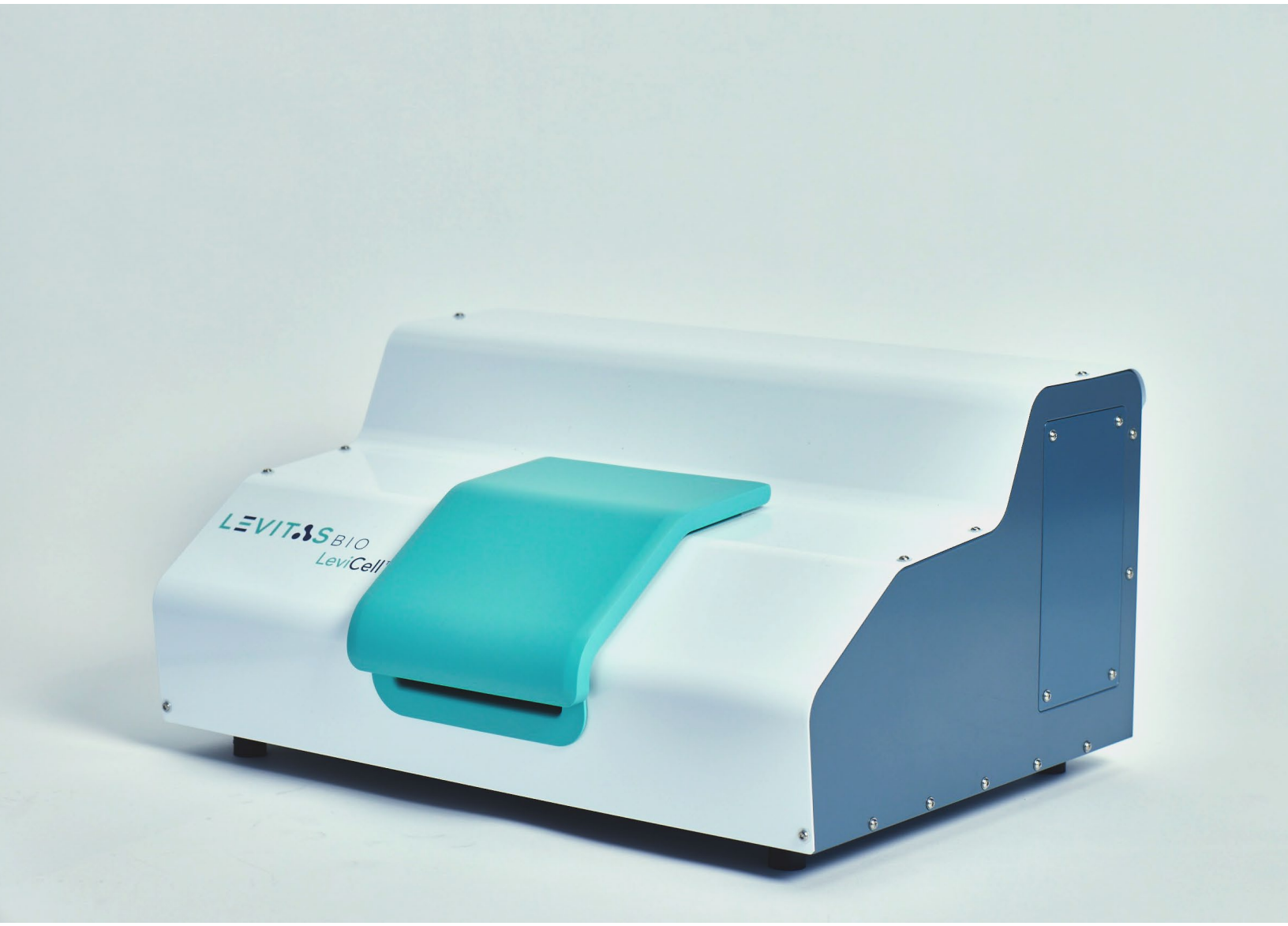
LEVITAS BIO™



LEVICELL-1.0 SYSTEM

DEMONSTRATION SYSTEM
INSTALLATION & RE-PACKING GUIDE

TABLE OF CONTENTS

SYMBOLS USED IN THIS GUIDE AND ON THE LEVICELL INSTRUMENT

Attention symbol. The associated message contains safety-related information.

Operating temperature range

Operating humidity range

For information, contact

Catalog number reference

Serial number

Date of manufacture

Manufacturer of record (LevitasBio)

Do not reuse

SAFETY AND WARNINGS

ATTENTION: use the mains supply cords provided with the LeviCell system. Do not substitute a mains supply cord with inadequate rating (< 10 A current).

Use the LeviCell-1.0 system only as directed by LevitasBio. Use in a manner not specified by LevitasBio, especially including removal of any cover or portion of the enclosure, may create a risk of hazards.

The LeviCell instrument contains no user-serviceable parts. Do not remove any portion of the enclosure. The LeviCell system does not require any maintenance beyond the cleaning described in the section “Cleaning the LeviCell-1.0” below.

In the event of any fault, turn the instrument off using the rocker switch on the upper left of the rear panel, and disconnect the AC power plug from its outlet. Contact Technical Support at +1-408-663-4260 or **support@levitasbio.com**.

Do not obstruct access to the 24 V power supply plug leading into the instrument. It should be easily removable in an emergency.

To shut down the instrument in an emergency, disconnect the AC power plug leading to the 24V supply brick. Contact Technical Support at +1-408-663-4260 or **support@levitasbio.com**.

BIOSAFETY: when biohazardous samples are used in the LeviCell or are in use in the laboratory housing the system, all relevant precautions to work with those biohazardous samples must be followed, such as Universal Precautions.

Always consider any instrument in a BSL-rated laboratory to require handling as if contaminated to that BSL level.

In addition to contamination control features within the LeviCell-1.0 instrument, a primary safety feature that prevents contamination is the single-use designation of the cartridges. Do not attempt to reuse cartridges, as this may increase the risk of cross-contamination and exposure to any biohazard associated with the sample. If a cartridge is reused or a leak is suspected, contact Technical Support on +1-408-663-4260 or **support@levitasbio.com**.

Dispose of used cartridges according to your approved lab guidelines.

For indoor use only. The LeviCell-1.0 system is not designed for outdoor use and is not rated for resistance to precipitation. See the **Specification** section for details.

INSTALLATION INSTRUCTIONS

Destination preparation

The LeviCell arrives with all components packed within a large Pelican case.

1. First, ensure that the bench space where you will be installing the LeviCell is clear.
    a. The bench should be at least 24” (60 cm) deep
    b. The available width suggested is at least 48” (120 cm)
    c. There should be at least 18” (45 cm) vertical space available above the bench.

2. You will need access to 2 standard power outlets.

TIP: network connectivity is highly recommended, for access to image data and for remote technical support. Secured network access is not required for support (for example, your site’s guest Wi-Fi is sufficient).

Unpacking and assembling the LeviCell™ Demonstration System

The LeviCell system arrives with all components packed in a large Pelican case, containing the instrument unit, cartridges, levitation reagents, companion laptop and all necessary cables (see Figure 1).

Please ensure that you retain all of the packaging material as it will be used to return the instrument at the conclusion of the demo.

Figure 1. *Pelican case containing demonstration LeviCell system.*

3. Unpack the main unit
   a. Lay the case flat and open it – (see Figure 2).

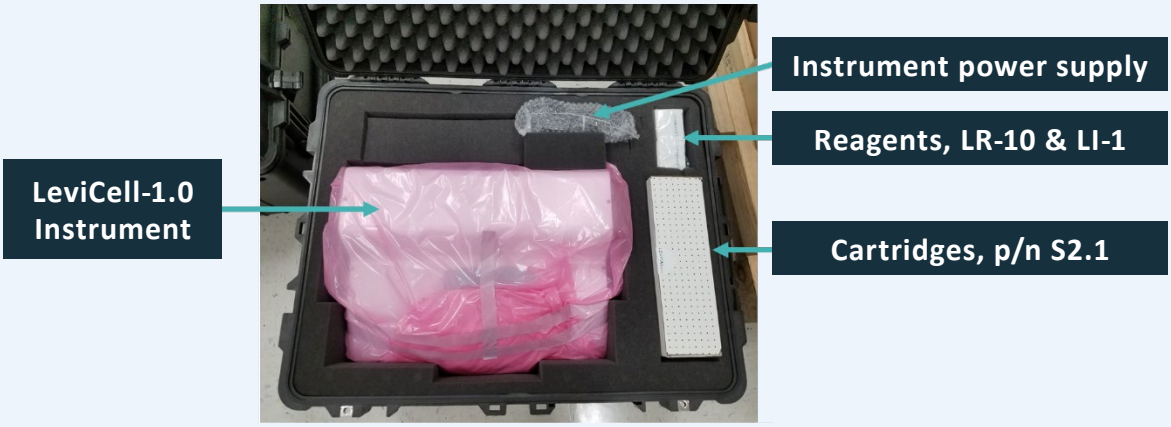


Figure 2. *System components in an open Pelican demonstration case.*

b. Remove the Cartridge and reagent cartons and set aside. (Note: the LI-1 Install Kit should be stored at 4 °C)

c. Lift the instrument unit out of the case and place on the bench. It is best to lift the instrument by reaching under the middle of the unit on the left and right sides, and lifting vertically out of the case.

Please retain the cartridge carton once contents are consumed! Return carton to the slot in the case - it adds stability when the system is returned.

ATTENTION: Do not lift using the sample door as a handle. Use safe lifting techniques: weight is 15 kg. Perform a 2-person lift if needed.

d. Once the instrument is on the bench, remove the antistatic plastic bag. Lift one end at a time to remove.

e. Carefully remove the bubble wrap from the cartridge access door and clamp arm on the instrument (see Figure 3).

Please retain the bag, for re-packaging upon return of the demo system – the case is perfect for storing all packaging materials.

Please retain the bubble wrap in the instrument case.

Figure 3. *Bubble wrap on cartridge access door.*

4. Check that the instrument power switch is in the Off (“O”) position. The power switch is on the upper left of the rear panel, as shown in Figure 4.

Figure 4. *Instrument power switch, shown in the OFF “ O “ position. Leave it OFF (“O”) until instructed.*

5. Locate and unpack the instrument power supply adaptor (Figure 2). Its connections are shown in Figure 5.

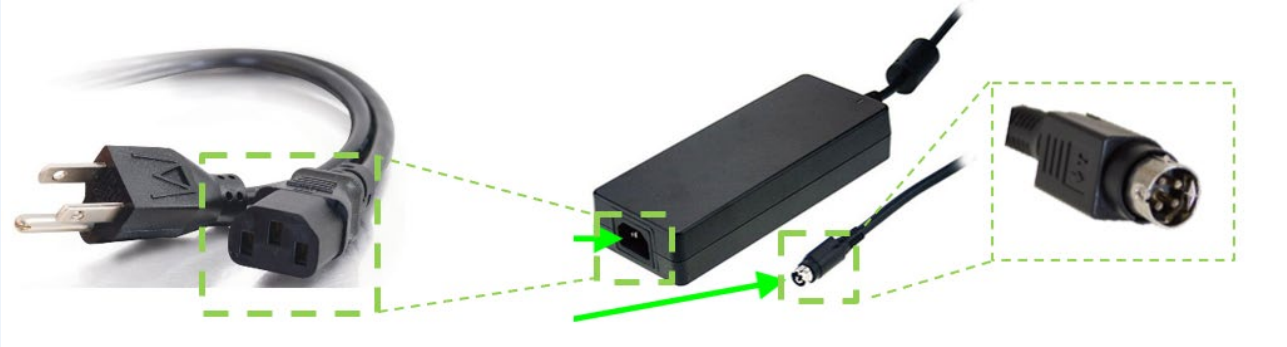


Figure 5. *Instrument 24V DC power supply adaptor.*
Inset: *Detail of connector at the end which connects to the main instrument enclosure.*

6. Connect the 24V DC power supply to the instrument unit

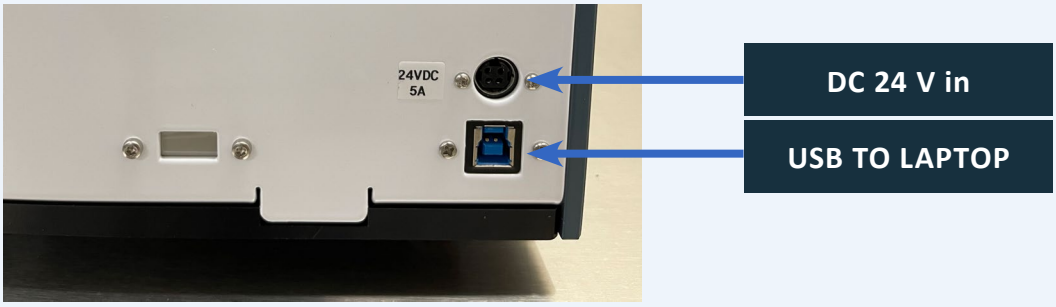


Figure 6. *Rear connector sockets on instrument.*

a. Connect the 24 V power supply's circular connector (see inset in Figure 5) to the instrument socket labelled "Power input" in Figure 6. Note the alignment notch in the outer metal ring and corresponding slit in the power input.

ATTENTION: when positioning the instrument, do not obstruct access to the 24 V power supply plug leading into the instrument. It should be easily removable in an emergency.

b. Verify that the instrument power switch (Figure 4) is still in the OFF position.

c. Plug the mains supply cable (C13) into the AC input of the power supply adaptor, then plug the mains plug into a power outlet.

ATTENTION: use the mains supply cords provided with the LeviCell system. Do not substitute a mains supply cord with inadequate rating (< 10 A current).

7. The main instrument unit is ready. We will now connect the laptop.
8. Take the laptop out of its containing bag, and place near the instrument.
9. Plug the laptop's power adaptor (figure 7).

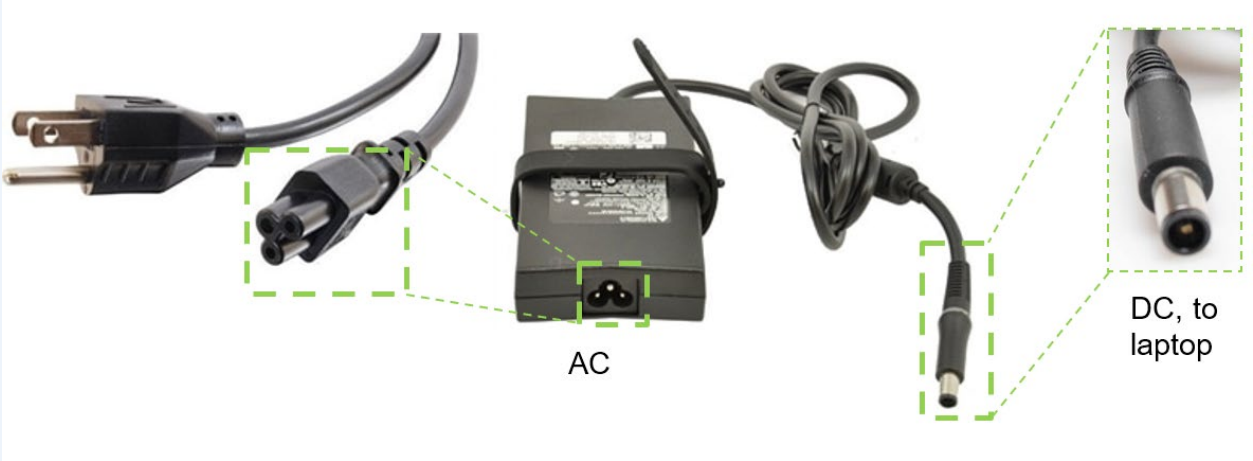


Figure 7. *Close-up of the laptop cables and connectors.*

Ensure you retain all of the packaging material as it will be used to return the instrument at the conclusion of the demo.

10. Start up the laptop and log in

- User name: LeviCell
- Password: Levitas2020

11. Connect the Bluetooth mouse to the laptop by turning it on using the On/Off Switch (see figure 8).

Figure 8.

12. Connect the instrument to the laptop

- **a.** Plug in the USB cable (see Figure 9) “B” type connector to the port labelled “USB input” on the main instrument unit (to identify the instrument port, see Figure 6).
- **b.** Plug the “C” end of the USB cable from the instrument to the only USB Type-C port on the laptop.

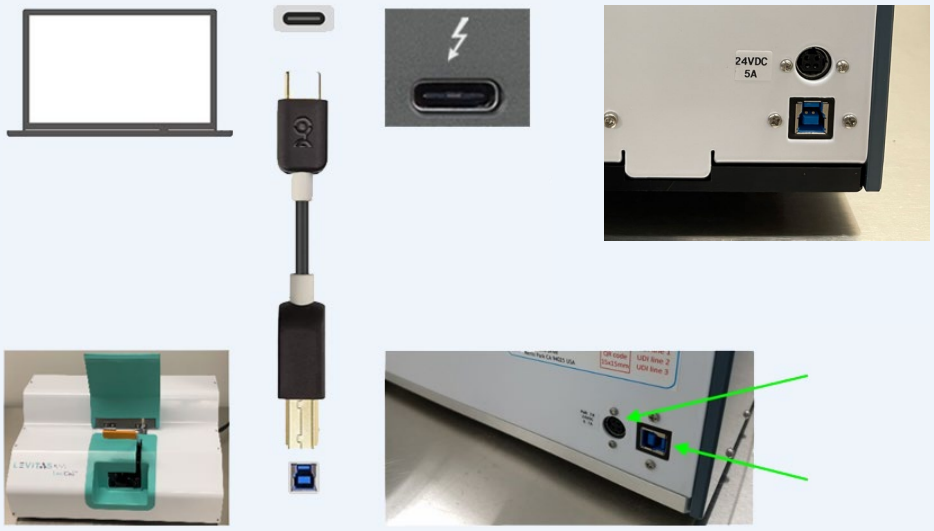


Figure 9.

13. Connect the barcode scanner to any of the USB-A ports on the laptop.

14. Blank cartridge: to protect the pneumatic interface, the LeviCell-1.0 instrument is shipped with a blank testing cartridge loaded – see Figure 10. **DO NOT DISCARD!**

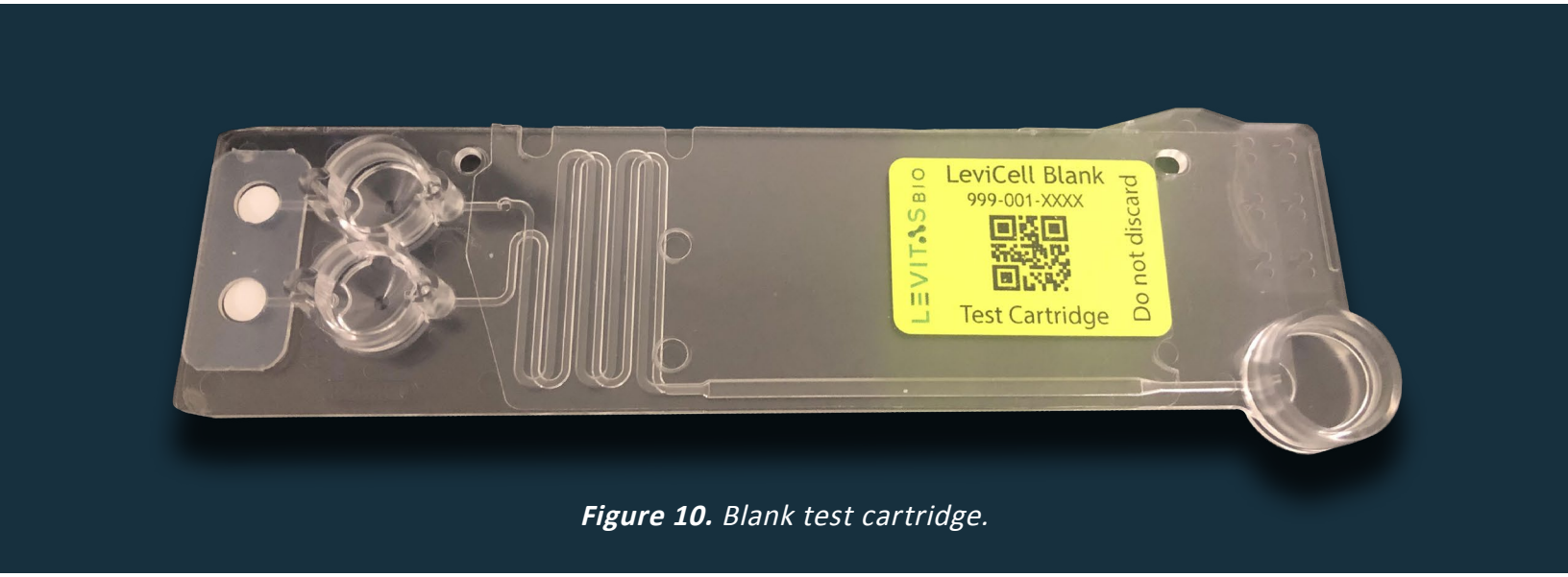


Figure 10. *Blank test cartridge.*

a. Load the blank testing cartridge into the instrument, engage the cartridge clamp and close the front cover whenever the instrument is not in use.

POWERING UP AND STARTING THE LEVICELL™ 1.0

1. Log into the laptop. The starting credentials are:

   a. User: LeviCell

   b. Password: Levitas2020

2. Once the laptop has finished booting up, turn on the instrument unit: flip the power switch to the ON " I " position as shown in Figure 4.

WARNING: Do NOT launch the Experiment Manager software prior to powering up the LeviCell instrument. This may cause system errors to occur.

3. Start the Experiment Manager software by double-clicking on the desktop icon.

NOTE: the application takes several seconds to start up, while establishing connections to instrument hardware components.

4. You will see the main activity selection screen for the Experiment Manager application (Figure 11). From here, Experiment Manager will guide you through the protocol, step by step. The options are:

   - **Small, Standard or Large Live Cell Enrichment.** These options each launch the main experiment protocol.
   - **System Tools.** This option provides a set of utilities including a System Check which is used for testing the instrument after shipment
   - **Exit.** This option closes the Experiment Manager front-end interface.

5. If you Exit from the Experiment Manager front-end interface, the back-end software interface will still be visible - see Figure 12. In the back-end software the user can:

   - Close the application by clicking on the “X” at the upper right.
   - Resume the Front-End interface by clicking the LevitasBio icon button

6. Refer to www.levitasbio.com/support for the latest user guides to perform the operational and performance qualification of the system.

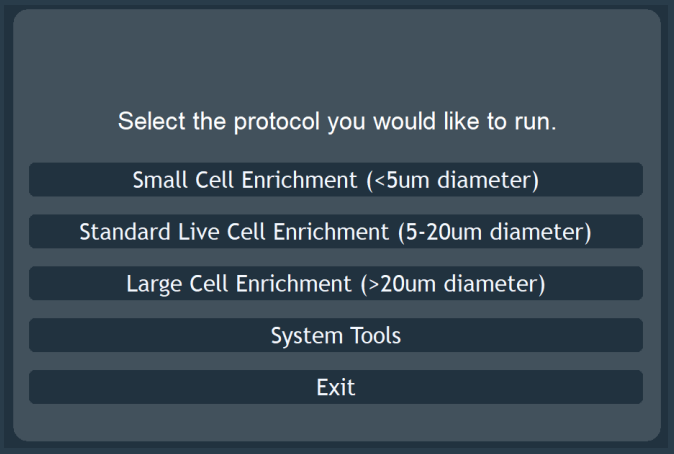


Figure 11. *Action selection screen to initiate protocols or tasks on the LeviCell instrument.*

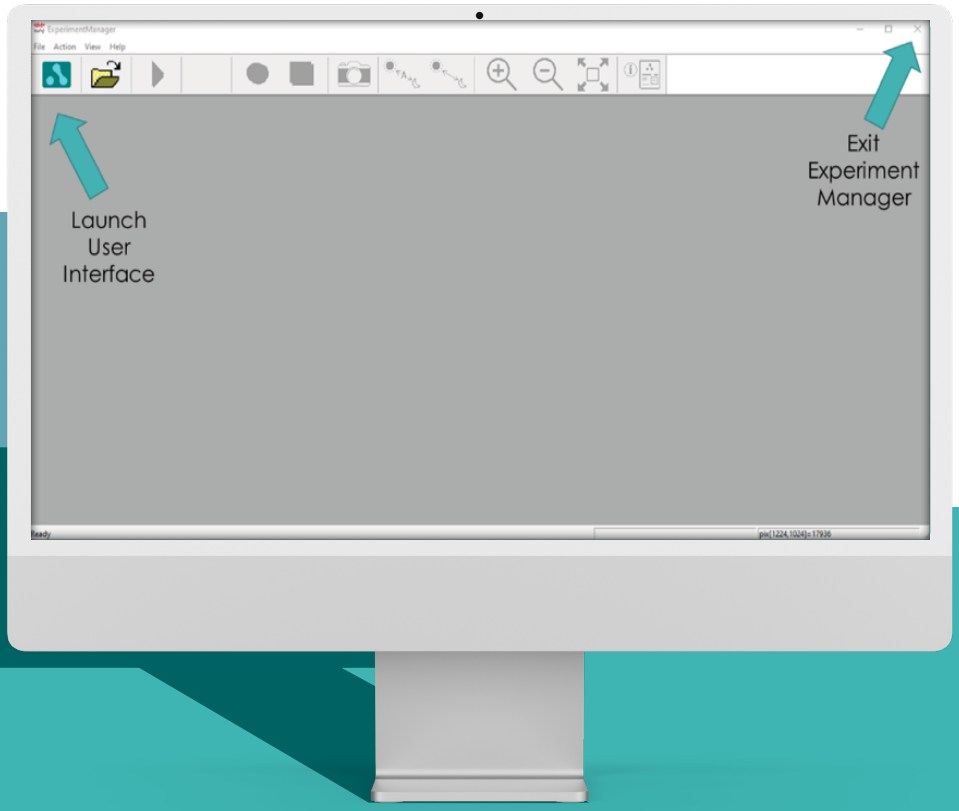


Figure 12.
Experiment Manager software back-end interface, highlighting some key controls.

LEVICELL SHUTDOWN

LevitasBio does not recommend leaving the instrument on overnight. Initiate shut down with the following steps:

1. Insert the blank testing cartridge (Figure 10) into the instrument. Engage the cartridge clamp and close the lid.
2. Select “Exit” in the main action selection screen.
3. Close the Experiment Manager back-end application.
4. Turn off the power to the instrument using the power switch at the upper left of the rear panel.

CLEANING THE LEVICELL-1.0

In the event of a spill or contamination, the exterior and cartridge loading area of the LeviCell-1.0 may be cleaned using a cloth or wipe pre-wetted with mild cleaning agents such as the following:

- Detergents in aqueous solution
- Up to 80% ethanol
- Up to 80% isopropyl alcohol
- Diluted bleach (sodium hypochlorite up to 1 % w/v, aqueous)

Use standard precautions for any cleaning agents.

DO NOT USE the following cleaning agents on the LeviCell-1.0 instrument, as damage to finishes may occur:

- aggressive organic solvents such as acetone, methanol, or aromatic compounds (e.g., toluene)
- strong acids
- abrasive compounds

RE-PACKING THE LEVICELL-1.0 AT THE END OF YOUR DEMO

Now that your demonstration is complete, and please prepare the system for return or onward shipment by following the instructions below.

A checklist is provided with your instrument to assist in this procedure.

1. If you would like to remove any confidential data, check the following locations:

    a. D:\ImageData\<daily folders to remove>
    b. D:\ImageData\RunLogs\<logs to remove>
    c. Don’t forget to Empty the Recycle Bin after deleting.

2. Log out of any online accounts such as email which you used during the demo.
3. Follow the usual shutdown instructions:

    a. Insert the blank testing cartridge (Figure 10) into the instrument and close the clamp and door.
    b. Select “Exit” in the main action selection screen. Stop live imaging if it is active (click the green “Play” arrow shown in Figure 12).
    c. Close the Experiment Manager back-end application.
    d. Turn off the power to the instrument, using the power switch at the upper left of the rear panel.

4. Clean the exterior of the instrument and computer, especially high-touch areas such as the keyboard and mouse.

Suitable cleaning agents are listed in Cleaning the LeviCell-1.0 above.
Use standard precautions for any cleaning agents.

5. Place the carton which contained cartridges into the slot in the Pelican case, along with any unused cartridges. Even empty, this helps keep the case contents securely in place.
6. Reverse the installation operations, starting with removing the cables: that is step 14 in the setup instructions above.
7. Additional packing information is available as a video (LevitasBio Support will share this), and by contacting LevitasBio Technical Support – see **Contact Information**.
8. Once the system is ready for pickup, please confirm with LevitasBio. You will receive prepaid shipping labels for the case.

TROUBLESHOOTING

Contact LevitasBio Technical Support to receive a helpdesk ticket number or hyperlink to start a remote support session.

STEP	ISSUE	REASON	SOLUTION
Launch software	Software reports communication errors	• Power not on • Loose connector • Internal fault or blown fuse	A. Check power cable and that the power supply is on. Check that the DC supply cable clicks into place when connected B. Unplug and re-seat both ends of the USB cable from the PC to the instrument C. Disconnect from AC supply and contact support
Entering Experiment Info	Scanned barcode ID has an additional character	The GS1 data standard for 2D barcodes includes a check digit	No action required
Software launch or workflow imaging	“Pylon” Camera Error	A. Loose connection at USB port to PC A. Windows communication error to USB ports	A. Seat USB connector fully in port and ensure cable is not strained or bumped B. Turn off instrument, restart PC, turn on instrument and restart software

LEVICELL SYSTEM SPECIFICATIONS

SPECIFICATION	VALUE
Number of sample inputs	1
Number of output fractions	2
Levitation magnets	Rare earth permanent magnets
Separation flow rate	100 µL/min
Imaging modes	Brightfield (transmitted illumination) Two fluorescence channels: • Excitation 470 nm, Emission 524 nm (e.g. Calcein, FITC • Excitation 560 nm, Emission 628 nm (e.g. PI, Cy 3.5)
Imaging resolutions	Approximately 2 microns
OPERATIONAL	
DC power input to instrument (from supplied AC-DC adaptor)	24 V, maximum current 5.1 A
Input voltage to DC power adaptor	100-240 VAC, universal
AC supply current drawn	1.4A at mains voltage 115VAC; 0.7A at mains voltage 230VAC (Standard wall circuit)
Main enclosure dimensions	475 mm wide x 340 mm deep x 240 mm high (19” x 13” x9”)
Instrument weight	15.3 kg (33.6 pounds)
Laptop Operation system	Windows 10, Professional, 64 bit

Over-voltage protection	105 ~ 135% rated output voltage. Protection type: shut down o/p voltage, re-power on to recover
Ingress protetcion rating	Not rated (no protection claimed)
ENVIROMENTAL	
Operating ambient temperature	15 °C - 27 °C
Operation relative humidity	20% RH - 80% RH ambient, non-condensing
Pollution degree of the intended enviroment	Pollution Degree 2 (normal indoor laboratory environment)
Altitude	Sea level to 1,700 m (5,500 feet)
For indoor use only	Not designed for outdoor use. Not designed for use in wet locations.
Shipping environment	5 °C to 50 °C, RH 5% - 99%, non condensing

CONTACT INFORMATION

Technical Support Phone Number:

+1-408-663-4260

Technical Support Email Address:

support@levitasbio.com

Company Website:

www.levitasbio.com

Company Shipping Address:

LevitasBio
1505 Adams Drive, Suite D
Menlo Park, CA 94025

LEGAL

For Research Use Only. Not for use in diagnostic procedures.

The LeviCell instrument, developed by and manufactured for LevitasBio, Inc., is For Research Use Only. Not for use in diagnostic procedures. The LeviCell instrument or its associated cartridges and reagents may not be used for any other purpose, including, but not limited to, use in drugs, in vitro diagnostic purposes, therapeutics, or in humans. LevitasBio products may not be transferred to third parties, resold, modified for resale, or used to manufacture commercial products without prior written approval of LevitasBio, Inc.

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