Infinity MTx Platform

User Guide





Table of Contents

Chapter 1. Product Information

Chapter 2. Methods

2.1 User	Interface Overview	10
	2.1.1 Touchscreen Controls	10
	2.1.2 Keyboard	10
	2.1.3 User Screens	11
2.2 Softv	vare	11
	2.2.1 User Profiles	11
	2.2.2 Getting Started	12
	2.2.3 Managing User Profiles	12
	Creating a New Operator (Administrator Only)	12
	Creating a New Password	12
	Disabling an Operator (Administrator Only)	12
	Changing Passwords (Administrator Only)	13
	2.2.4 Administrator Settings	13
	Protocol Information: Payload, Cell Type, and Activation Time	14
	Instrument Name	14
	Date and Time	14
	2.2.5 General Settings	15
	User Guide	15

Table of Contents

Chapter 2. Methods Continued

Protocols	16
Creating Protocols	16
View Protocols	17
Run History	17
Backup Data	17
About	18
Shut Down	18
2.3 Experimental Setup and Guidelines	18
2.3.1 General Recommendations	18
Additional Required Equipment and Materials	19
2.3.2 Optimizing Microfluidic Transfection	19
Infinity™ Optimizer MPA	19
Selecting Gap Size	20
Selecting Instrument Pressure	20
Additional Experimental Parameters	20
2.3.3 Preparing Cells	21
Determining Required Cell Number	21
Sample Calculations	22
Preparation of Materials	23
Preparation of Cells for Transfection	23
Guidelines for Payload Quality and Quantity	23
Controls	24
2.3.4 Handling the Infinity™ MPA	25
Loading Samples	25
Collecting Samples	26
2.4. Creating and Running Protocols	26
2.4.1 Running a Protocol (Operator only)	26
2.4.2 Overview of Run Screen	27
2.4.3 Run in Progress	28
2.4.4 Modifying an Existing Protocol from the Run	29
2.5 Instrument Maintenance	29
2.5.1 Cleaning and Maintenance Guidelines	29
2.5.2 Cleaning Procedures	30
Appendix A: Specifications	31
Appendix B: Troubleshooting	32
Appendix C: Instrument Error Codes	34
Appendix D: Safety	36
Appendix E: Documentation and Support	43

1.1 Product Description

The Infinity MTx[™] cellular engineering platform is a benchtop device that employs a novel, microfluidics-based technology to efficiently deliver a wide range of gene-engineering payload types (DNA, RNA, and proteins) and sizes (>10kb) into mammalian cells, including primary and stem cells with high survival and post-transfection expansion rates. The Infinity technology is compatible with standard cell culture basal media. There is no need for specialized buffers, cell-specific buffer optimization, or chemical additives.

The Infinity[™] technology directs the flow of cells (suspended in media with diverse payloads) though microfluidic channels, where cells pass under a chevron ridge, forming a uniform compression gap with the opposing channel wall and extending across the channel width. This change in channel size leads to rapid cellular compression, causing a fleeting loss of intracellular fluid and a subsequent decrease in cell size. Within milliseconds, the target payload is actively transported into the cell by convective flow of media upon re-expansion. This process is known as volume exchange for convective transfer (VECT).

Unlike standard electroporation that delivers a high electric field to the biological sample, the Infinity microfluidic technology is a gentle, mechanoporation method. Throughout this process, cells experience a uniform and physiological event with no pH change, heat generation, or any other process that negatively impacts cell health. The result is an increased yield of transfected cells.

The Infinity MTx[™] platform features software designed in compliance with 21 CFR Part 11 guidelines. The software's user-friendly interface enables fine-tuning of protocol parameters specific to payload and cell type.

The InfinityTM microfluidic processing assemblies (MPAs) are single-use and include eight separately run processing units. With this flexible format, experiments can be performed using any (or all) of the eight processing units with up to 1.5×106 cells per unit in a volume of 30 - 90 µL.

CellFE offers two types of single-use microfluidic processing assemblies:

• The Infinity[™] Optimizer MPA is made up of processing units containing different gap sizes and is used to identify optimal operating parameters for a specific workflow (see page 20).

• The Infinity[™] MPA consists of processing units containing a single gap size, and is used for standard transfection protocols once optimal parameters have been established.

System Features

- **Small footprint** The instrument's compact design allows it to fit inside a biological safety cabinet (BSC) or atop a laboratory bench. The MPA is a closed unit consumable with filtered air inlet and outlet ports.
- **Flexible** Allows for the delivery of a wide range of payloads in order to transfect even the most challenging mammalian cell types.
- Customizable— Open-access system allows for parameter optimization.
- **Easy to use** Intuitive user interface, easy to create and edit protocols, and access run history.

Key Benefits

- Gentle on cells Healthy cells require shorter recovery.
- **Exceptional performance –** High yields of transfected cells with high proliferative capacity.
- Simple, streamlined workflow Easy to optimize.
- Cell-friendly processing No specific media, buffers, or chemical additives required.

1.2 Products

1.2.1 Infinity MTx[™] Platform

The Infinity MTx platform consists of the Infinity MTx instrument, the Infinity MTx accessories kit, and an Infinity MPA kit. Upon initial purchase of the Infinity MTx instrument, users receive an Infinity Optimizer Kit of their choosing (see section 1.2.4 for more information on Optimizer Kits).

Product Name	Reference Number
Infinity MTx™ Platform with Infinity™ Optimizer Kit A	00000701
Infinity MTx™ Platform with Infinity™ Optimizer Kit B	00000702
Infinity MTx™ Platform with Infinity™ Optimizer Kit C	00000703

1.2.2 Infinity MTx[™] Instrument

Front Panel



1. Touchscreen

Located on the front-facing window of the instrument, it allows for easy use of the software.

2. Barcode Scanner

Located beneath the CellFE logo on the front-side of the instrument.

3. Sample Loading Tray

Compatible with the Infinity Microfluidic Processing Assembly (MPA).

Back Panel



1. Air Vents

Used to vent circulated air for instrument cooling.

2. Compressed Air Inlet

Compatible with 1/4" NPT Pressure line tubing fitted with a push-to-connect (PTC) fitting.

3. Air Intake Fan

Provides cooling for internal electrical components.

4. Power Connection Port

110-240V power cable.

5. Power Switch

Used to power the instrument on and off.

6. USB-A Connection Port

Allows the operator to insert a USB 2.0 or higher for the following purposes:

- 1. Export data as a CSV file.
- 2. Attach an external mouse or English language keyboard to the instrument.

1.2.3 Accessories Kit

The Infinity Accessories Kit contains the materials needed to connect the instrument to power and to a pressurized air source. The compressed air supplied to the instrument must range from 100 to 120 psi.

The kit includes the following components:

- Power cable
- 1/4 IN Tubing (10 ft)
- 1/4 IN PTC to 1/4 NPT (2 included)
- 1/4 IN Air Female to 1/4 NPT
- 1/4 IN Air Male to 1/4 NPT
- 1/8 IN Quick Disconnect to 1/4 NPT

1.2.4 Infinity[™] Optimizer Kit

Upon purchase of the Infinity MTx instrument, users receive an Infinity Optimizer kit. The Optimizer kit is used to determine which gap size will optimize the yield of transfected cells. Each kit contains four Infinity Optimizer MPAs and each Optimizer MPA contains a series of four increasing gap sizes with two processing units per gap size, allowing eight samples to be run independently. Infinity Optimizer kits can be purchased separately as well.

Product Name	Gap Size (µm)	Reference Number (REF)
Infinity™ Optimizer Kit A	5.2, 5.4, 5.6, 5.8	CP000930
Infinity™ Optimizer Kit B	6.0, 6.5, 7.0, 7.5	CP000931
Infinity™ Optimizer Kit C	8.0, 9.0, 10.0, 11.0	CP000932

1.2.5 Infinity[™] MPA Kits

The Infinity MPA kit contains four MPAs of the same gap size. Eight samples can be run independently.

Product Name	Gap Size (µm)	Reference Number (REF)
Infinity™ MPA Kit 5.2	5.2	CP000918
Infinity™ MPA Kit 5.4	5.4	CP000919
Infinity™ MPA Kit 5.6	5.6	CP000920
Infinity™ MPA Kit 5.8	5.8	CP000921
Infinity™ MPA Kit 6.0	6.0	CP000922
Infinity™ MPA Kit 6.5	6.5	CP000923
Infinity™ MPA Kit 7.0	7.0	CP000924
Infinity™ MPA Kit 7.5	7.5	CP000925
Infinity™ MPA Kit 8.0	8.0	CP000926
Infinity™ MPA Kit 9.0	9.0	CP000927
Infinity™ MPA Kit 10.0	10.0	CP000928
Infinity [™] MPA Kit 11.0	11.0	CP000929





- 1. Air Inlet and Outlet Ports Each port contains a filter membrane to keep the sterility of the sample throughout the process.
- 2. Processing Units Each Processing Unit can be run independently via the software. Each unit consists of a Sample Chamber, a Microfluidic Chip, and a Collection Chamber. Processing Units cannot be reused.
- 3. Sample Chamber Each Sample Chamber holds up to 90 µl of sample. MPA dimensions align with the dimensions of a standard multi-channel pipette, allowing the user to quickly fill all chambers.
- 4. Microfluidic Chip The Microfluidic Chip is located between the Sample Chamber and the Collection Chamber and is where the transfection process occurs. As pressure is exerted, cells flow at high speeds from the Sample Chamber through the chip into the Collection Chamber.
- 5. Collection Chamber The sample passes through the Microfluidic Chip into the Collection Chamber.
- 6. Lid The lid latch allows for reversible locking of the MPA. To open the lid, gently lift the lid latch upwards. After samples are loaded, close the lid by gently applying downward pressure to the lid latch.

1.3 Site Preparations for the Infinity MTx[™] Instrument

1.3.1 Physical Space Requirements

- The Infinity MTx instrument must be placed on a level laboratory bench or within a biological safety cabinet (BSC). Once the MPA lid is closed, the MPA is tightly sealed and can be removed from the BSC without compromising samples.
- The Infinity MTx instrument requires a space of at least 16.75" x 16.75" x 15.75" for operational clearance.
- The area surrounding the Infinity MTx instrument must be clear, and the ventilation slots must not be blocked to allow for adequate air flow.
- The Infinity MTx instrument weighs 40 pounds (18.1 kg) and must be placed on a surface that can support its weight.

CAUTION: Ensure at least 6" of clearance behind the Infinity MTx instrument so that vents are not blocked, and so that the user can access the power switch and rear connections. Ensure there is enough space to prevent connection lines and cables bending more than 45°.

1.3.2 Electrical Requirements

Select a location capable of providing a 110/240 VAC, 5.9/2.7A, Frequency 50/60 Hz power input.

1.3.3 Infrastructure Requirements

The Infinity MTx instrument requires a compressed air source with pressure ranging between 100 and 120 psi.

If the facility has a compressed air connection available, ensure that the electrical and physical space requirements noted in this ducument are met. You may contact support@cellfebiotech.com for assistance in setting up the line from the available air source. Alternatively, an air compressor can be purchased and connected to the instrument.

The compressor requires the following:

- **Physical space:** 12" x 14" x 15" for operational clearance.
- Electrical: One 110/240 VAC, Frequency 50/60 Hz receptacle.

1.3.4 Safety and Environmental Considerations

- The Infinity MTx instrument is designed for indoor use only. Temperature, relative humidity, and altitude recommendations are provided in Appendix A: Specifications.
- During installation, personal protective equipment (PPE), including safety goggles or glasses, disposable gloves, and a laboratory coat should be utilized. Consult your safety officer for guidance.
- Do not turn on the primary air source or air compressor until attached to the Infinity MTx instrument.
- When disconnecting the tubing between the Infinity MTx instrument and air source, ensure the air source is turned off, the instrument is powered off, and the pressure within all components has been adequately released.



WARNING: Severe injury can occur if the instrument air line is disconnected before turning off the instrument, turning off the pressurized air supply, and depressurizing the line.

Chapter 2. Methods

2.1 User Interface Overview

2.1.1 Touchscreen Controls

lcon	Function		
Ŀ	Logout		
	Left: Open Tray Middle: Tray in Operation Right: Close Tray		
	Settings		
(-)	Back		

2.1.2 Keyboard

Users can interact with the instrument via the touchscreen. A keyboard (shown below) is provided on screens where text entry is required.



2.1.3 User Screens



NOTE: The user is automatically logged out after 10 minutes.

2.2 Software

2.2.1 User Profiles

There are two types of user profiles:

- 1) Administrator
- 2) Operator

Administrator privileges are detailed in the Administrator Settings section. Administrators cannot run protocols. Standard operators can run protocols, but do not have the rights to update settings.

2.2.2 Getting Started

The Administrator must log in and create a password to initiate use of the instrument.

• Select Operator \rightarrow Administrator \rightarrow Create a password \rightarrow Re-enter password.

NOTE: The username Administrator, cannot be changed.

NOTE: The password must include at least one letter and one number and be at least five characters long.

2.2.3 Managing User Profiles

Operators can execute protocol runs, create new protocols, and update protocol related features. Operators cannot add users, change passwords, or update system settings.

Creating a New Operator (Administrator Only)

Only Administrators can add a new Operator:

System Settings → Administrator Settings → Operators → Add New → Create a unique operator username.

NOTE: Username must be at least three characters long.

Creating a New Password

Upon initial login, the new Operator must create a password:

• Select Operator \rightarrow Enter a password \rightarrow Re-enter password.

NOTE: Passwords expire every three months and Operators may not re-use their three most recently used passwords.

Disabling an Operator (Administrator Only)

• System Settings \rightarrow Administrator Settings \rightarrow Operators \rightarrow Select Operator \rightarrow Check

the Disable box.

Once disabled, an Operator's username will no longer appear on the Login Screen. However, it will remain in the system and can be reactivated by the Administrator at any time.

Changing Passwords (Administrator only)

- System Settings → Administrator Settings → Operators → Select Operator → Check the Reset Password box
- Upon next login, the Operator will be required to enter a new password and then confirm that password.

Idministrator	Administrator
perator Name	Disable
	Reset Password
	Last password change: YYYY-MM-DD
	Last login: YYYY-MM-DD
	Add
	Close

2.2.4 Administrator Settings

To navigate to Administrator Settings:

• Select Settings \rightarrow Administrator Settings.



Protocol Information: Payload, Cell Type, and Activation Time

The Administrator can create and delete payloads, cell types, and activation times. Operators can view and add these fields to Protocol Information for a specific run, but cannot update the fields themselves.



NOTE: All entries must be unique

Instrument Name

- System Settings \rightarrow Administrator Settings \rightarrow Instrument Name \rightarrow Enter up to 25 alphanumeric characters to identify the instrument.
- The instrument name is displayed on the right-hand side of the bottom menu bar.

Date and Time

- System Settings → Administrator Settings → Date and Time → Select the time by moving the clock hour or minute circles → Choose Time Format 24-hour or AM/PM → Select the date by clicking the corresponding day in the calender → Click Accept.
- The date and time are displayed on the right-hand side of the bottom menu bar on every screen.



Firmware Update

To perform a firmware update, insert a USB containing the update and follow the instructions on the screen:

System Settings → Administrator Settings → Insert USB → Firmware Update → Follow instructions on screen.

Software Update

To perform a software update, insert a USB containing the update and follow the instructions on the screen:

System Settings → Administrator Settings → Insert USB → Software Update → Follow instructions on screen.

2.2.5 General Settings

All users can access the following under Settings:

	User Guide	
	Protocols	
	Run History	
	Backup Data	
	About	
	Shut Down	
	ОК	
Ð		

User Guide

- Select User Guide \rightarrow Scan QR code \rightarrow Select Done to return to the Home Screen.
- The User Guide can also be accessed at: www.cellfebiotech.com/user-guide.



Protocols

Creating protocols:

 Select Protocols → Create → Enter protocol name → Select Accept → Select psi values for each Sample Chamber → Save.

NOTE: If using the same psi for all Sample Chambers, press "Select Ch Number to Apply PSI To All."

- Disable Sample Chambers that will not be used in protocol by toggling the Enabled field(s) to Disabled.
- Select Additional Protocol Information to add payload, cell type, and cell activation time (optional).

Edit: Protocol	Edit: Protect 4		
ch1 ck2 ch3 ch4 ch5 cx4 ch7 ch8 20 psi 20 psi	Protocol Information		
Trubled	Payload •		
	Cell Type		
	Activation Time		
	Cancel OK		

• Protocols can also be created once an MPA has been loaded into the instrument. Close the tray and click on **Create New Protocol**.



NOTE: The Infinity MTx software does not include default protocols. Protocols must be created before the start of a run.

NOTE: Only the Administrator can delete existing protocols.

View Protocols

Select Protocols → Click on desired row to view individual Sample Chamber pressure (psi) settings → Select Done.



Run History

• Select Run History \rightarrow Click on a row to expand to view Sample Chamber information \rightarrow Select More to view run messages and notes.

Run Date	Operator	Protocol	MPA	MPA ID	Notes	Message
24-01-04 16:23	Jane Doe	protocol 2		Test Device		Ch2 Leaking or Clogged
Status Pressure (ps) Used in this run 24-01-04, 15-55	Ch1 Ch2 Used LeakDrCLog 35 35 37 37 Jano Don	Ch3 Ch4 ged Used Used 35 40 20 20 20	Ch5 I Used 35 M	Ch6 Ch7 1 Used Used U 35 35 2 2 2	Ch8 Jsed 35 More	Ch2 Loaking or Classed
24-01-04 15:55	Jane Doe	protocol 2		Test Device		Ch2 Loaking or Clogged
				Export	Uone	

The information displayed in Run History includes run date/time, Operator, protocol name, MPA, MPA ID, notes, and any messages that appeared during the run.

Backup Data

Allows the user to export data in a .csv format via a USB port:

- Insert USB drive into the USB port located at the back of the instrument \rightarrow Select Settings \rightarrow Backup Data \rightarrow Press OK to continue or Cancel to cancel.
- Once backup has completed, press OK to return to the main screen.

CAUTION: Ensure that USB is free of viruses and/or malware prior to inserting into the instrument.

About

About allows the operator view the current software and firmware versions installed on the instrument.

Shut Down

Shut down allows the operator to shut down the instrument from the software. Once the instrument has been shut down, the operator must power off the instrument via the power button.

2.3 Experimental Setup and Guidelines

2.3.1 General Recommendations

- Optimization is recommended for new cell types, payloads, and changes in workflow parameters, and should be performed using the appropriate Infinity Optimizer MPA.
- For best results, use fresh, primary cells or cell lines at a low passage number.
- Culture conditions (media, supplements, culture vessel, seeding density, etc.) can impact transfection efficiency, cell health, growth, and expansion and should be optimized.
- Prepare an extra volume of sample to account for volume loss during handling. Ensure cell numbers are adjusted accordingly.

Additional Required Equipment and Materials

Equipment:

- Pressurized air source or external compressor
- Automated cell counter
- Centrifuge
- Flow cytometry or equivalent
- Cell culture plates, T flasks
- Pipette tips
- Serological pipettes
- Conical tubes

Materials:

- Cells
- High quality payload
- Dulbecco's-Phosphate Buffered Saline (DPBS) (to wash cells prior to transfection)

2.3.2 Optimizing Microfluidic Transfection

The Infinity MTx platform is designed to operate within specific parameters. The values and limits for each parameter are discussed below. For optimal yields of transfected target cells, use settings within the recommended range.

Transfection parameters must be optimized for all cell types, donors, and changes in experimental conditions. Gap size and sample process pressure should also be optimized to maximize the yield of transfected cells (transfection efficiency and viability).

Infinity[™] Optimizer MPA

The Infinity Optimizer MPAs are designed to help establish the optimal operational parameters required for a specific cell type, its phenotype, and activation state. Each Optimizer MPA has four gap sizes with two processing units per gap size. Use the Optimizer MPA to establish optimal operational parameters, both gap size and pressure (psi) setting.

Selecting Gap Size

The Infinity Optimizer MPA should be selected based on the average cell diameter in the sample. A given sample may have a wide or narrow cell diameter distribution depending on the activation state, passage number (cell lines), and overall cell health. See table below for general guidance on selecting the appropriate Optimizer MPA for the diameter of the cell of interest.

NOTE: Cell viability should be analyzed prior to transfection and should ideally be within 90-95%. Low starting cell viability may result in processing errors.

Infinity™ Optimizer MPA	Cell Diameter (µm)	Cell Type Examples	Sample Chamber #1 and 2	Sample Chamber #3 and 4	Sample Chamber #5 and 6	Sample Chamber #7 and 8
A	7-13	PBMC, T Cells, NK Cells, HSPC	5.2	5.4	5.6	5.8
В	13-22	Monocytes, Macrophages	6	6.5	7	7.5
С	23-30	ipsc, MSC	8	9	10	11

NOTE: For some cell types, a combination of two Optimizer MPA configurations may be required.

NOTE: "Cell Diameter" listed in the table are approximations and "Cell Types" are examples and may not correspond directly to a specific cell of interest.

NOTE: Cell diameter readings may vary depending on the method and instrument used.

Selecting Instrument Pressure

Pressure settings (psi) are controlled through protocol settings in the software. It is recommended to test psi ranges in increments of 5 or 10 psi to optimize processing pressure.

NOTE: The viability of a sample may decrease if psi settings are too high.

Additional Experimental Parameters

The following parameters can also be modified to further improve efficiencies and yields.

Using a single-gap size MPA:

1. Transfection medium:

For best results, a basal cell culture medium is recommended. Serum containing media and/or any other supplements from complete media may impact transfection efficiencies and should be optimized.

2. Cell density:

Cell densities should not exceed 50 x 10⁶ cells/mL.

3. Payload concentration (see page 23):

It is recommended to start with 10µg (for Cas9 RNP), 20µg (for 1kb mRNA,) and 10µg (for 3kb plasmid DNA) per mL of sample per Sample Chamber and titrate to determine the optimal payload concentration.

2.3.3 Preparing Cells

Experiments should be conducted using aseptic technique. For best results, use fresh, primary cells or cell lines at the lowest passage number.

Due to variations in levels of activation, growth of cells, and losses that can occur during sample preparation, it is recommended that cells be prepared in excess. A standard practice is to prepare 20–30% additional cells to account for experimental variation.

NOTE: When activating using magnetic beads, ensure that all beads have been removed. Residual magnetic beads may lead to clogging of the microfluidic channels.

Determining Required Cell Number

The total number of cells needed is calculated based on the number of experimental conditions (number of samples and controls) multiplied by the number of cells per sample chamber. The number of cells per chamber should not exceed 1.5 x 10⁶ cells. Cells can be resuspended to a density of up to but not exceeding 50 x10⁶ cells/mL. Volumes should not exceed 90µL.

NOTE: Low cell numbers may affect transfection efficiencies.

NOTE: Low starting volumes lead to a higher percentage loss of recovered volumes due to processing. To minimize total loss, volumes should be between 30-90µL.

Sample Calculations

Use the following example as a guideline to calculate the total number of cells required for an experiment and the volume of medium required to resuspend your cells. In the following example, one MPA is used with seven experimental samples, one positive control which is included in the MPA, two non-transfected negative controls and an additional, as overfill. A total of eight processing units and eleven samples will be used in the calculations below.

1. Total number of cells required:

- = Number of samples x total number of cells per chamber
- = 11 samples x 1.5x10⁶ cells per chamber = 1.65x10⁷ total cells required

2. Volume per Processing Unit:

- = Total number of cells / cell density
- = $1.5 \times 10^{\circ}$ cells / $50 \times 10^{\circ}$ cells/mL = 0.03 mL per Sample Chamber

3. Volume of medium required to resuspend harvested cells at desired cell density:

- = Actual total number of cells / desired cell density
- = 1.65×10^7 cells/ 50×10^6 cells/mL = 0.33 mL basal medium required

Table: Sample Chamber Parameters

Cell Density	Sample Volume	Number of Cells per Sample
(# of cells/mL)	(µL)	Chamber
≤ 50 × 10 ⁶	30 - 90	≤ 1.5 × 10 ⁶

Preparing Materials

- 1. Prepare DPBS to wash cells, basal cell medium for the transfection procedure, and complete medium for post-transfection cell culture by warming in a 37°C water/bead bath.
- 2. Thaw an aliquot of payload of interest.

NOTE: Do not allow media or buffer to undergo repeated temperature changes (from 4°C to room temperature).

Preparing Cells for Transfection (Suspension cells)

- Harvest the cells using a large bore serological pipette (10 mL). Fully and gently deaggregate cells to obtain a single cell suspension. Transfer to an appropriately sized tube, i.e., a 50mL conical tube.
- 2. Take an aliquot of cells and count the cells using a cell counter. For best results, cell viability should be 90-95%.
- 3. Centrifuge the cells at desired condition (i.e., 300 × g for 5 minutes at room temperature for human CD3 cells).
- 4. Discard the supernatant completely using a vacuum aspirator and aspirating tip.
- 5. Resuspend the cell pellets in 10mL of pre-warmed DPBS to wash off any remaining serum and/or other supplements from previous cell culture. Gently pipette the cells using a large bore 10mL serological pipette to dissociate cell aggregates.
- 6. Centrifuge the cells at desired condition (i.e., 300 × g for 5 minutes at room temperature for human CD3 cells).
- 7. Discard the supernatant completely using a vacuum aspirator and aspirating tip.
- 8. Calculate the volume of basal medium required to resuspend the total number of cells (see Sample Calculation on page 21).

NOTE: See Determining required cell number for sample calculation (page 20).

 Gently resuspend the cell pellet by pipetting with the calculated volume of pre-warmed basal medium to adjust to desired cell density. The cell density should not exceed 50x10⁶ cells/mL. NOTE: Avoid storing the cell suspension for more than 15-30 minutes at room temperature .

- 10. (Optional) Take an aliquot of cells and count the cells using a cell counter to record the actual cell number right before transfection.
- 11. Aliquot cells into separate tubes and mix with desired payload at desired concentrations (see payload guidelines below for more information). Always ensure cells are in suspension by pipetting gently up and down to resuspend before transferring sample to the MPA Sample Chamber and immediately process them using Infinity MTxTM. Delay in this process may cause cell settlement, which may lead to undesirable results due to non-uniform cell density and payload concentration throughout the process.

Controls

High-quality controls play an integral role in the successful optimization of gene-editing conditions.

Positive controls:

• As a recommendation, use an appropriate construct with a GFP (green fluorescent protein) reporter to determine transfection efficiency.

For plasmid payloads:

Below are the recommended control features of a GFP plasmid control:

- A strong viral promoter (CMV or equivalent) to ensure the highest possible expression level.
- A size of <10 kb.
- High purity with an A260/A280 value greater than 1.8. Lower values can result in lower transfection efficiencies.
- Low endotoxin levels of <10 EU/µg. Use plasmids purified through anion-exchange chromatography to avoid endotoxin contamination. The presence of endotoxins is detrimental to cell health and transfection efficiency.

Negative controls:

For post-transfection analysis, assess transfection efficiencies and viability compared to non-transfected cell samples. Below are the recommended controls:

- 1. Cells with payload: Not used in transfection run, but in post-transfection analysis.
- 2. Cells only, no payload: Not used in transfection run, but in post-transfection analysis. Transfection control should be added to the MPA.

2.3.4 Handling the Infinity[™] MPA

Loading Samples

1. Remove the MPA from its sterile packaging inside of a biosafety cabinet (BSC).

NOTE: If the MPA is removed from its pouch outside of the BSC or if it was used in previous experiments, sterilize the outside of the MPA by wiping with a alcohol swab before placing it in the BSC. Do not spray the MPA with ethanol or allow inlet and outlet filters to get wet.

- 2. Resuspend cell sample by pipetting gently to create a homogeneous mixture. Once the cell sample and payload have been mixed, immediately transfer to the MPA.
- Open the lid of the MPA and transfer the appropriate amount of sample into the appropriate Sample Chamber using a 100 or 200 µL micropipette tip. Sample Chambers are numbered from left to right, 1-8.

NOTE: Samples should be pipetted at the bottom of the chamber.

- 4. Repeat steps 2 and 3 for all samples.
- 5. When all samples have been loaded, the MPA lid can be closed. The lid will snap when properly sealed.
- 6. See Section 2.4 for instructions on how to load the MPA into the instrument and run a protocol.

NOTE: Store MPA in a sterile environment if processing units remain unused.



Collecting Samples

• Using a micropipette, insert the pipette tip into the Collection Chamber so that it reaches the lowest point of the chamber. Transfer transfected samples from the Collection Chamber to a cell culture plate that contains pre-warmed complete medium for cell culture and downstream analysis.

2.4 Creating and Running Protocols

2.4.1 Running a Protocol (Operator only)

From the Home Screen, select the Open Tray icon → Load MPA into the tray → Select the Close Tray icon → Choose from the Select Protocol dropdown or create a new protocol → Choose desired protocol.



- (Optional) The following information can be added and later viewed in Run History:
 - Additional Protocol Information: Add payload, cell type, and activation time.
 - Scan to Log: Add additional information from any barcode (1D or 2D) labels. For example, users can record what media they used for the experiment by simply scanning barcode labels from culture media bottle.
 - Enter protocol notes: Add additional notes.

• From the Run Screen, select Start to run a protocol \rightarrow Select OK to confirm the run or Cancel to return to the run screen.

When Run is complete:

- Select Open Tray to remove the MPA → Select Close Tray to close tray and return to Home Screen.
- Once the tray is closed, the run notes and messages will be saved to Run History.

NOTE: Sample Chambers can be enabled and disabled on the Run Screen before initiating a run. These changes will not be saved as part of the protocol for future use. However, this data will be accessible in the Run History.

NOTE: Information added on the Run Screen will not be saved to the protocol.

NOTE: Stop can be selected at any time during a run to manually terminate the run. Selecting stop can result in the loss of a sample that was already in process.

2.4.2 Overview of Run Screen



1. Enable or Disable – Sample Chambers can be enabled or disabled via the toggle button.

2. Enter protocol notes – This box displays notes added before, during, or after a run. It also includes information recorded from the "Scan To Log" function.

3. Scan to log – This button initiates the barcode scanner and saves the barcode number to the Run Notes section.

4. Additional Protocol Information – This button displays payload, cell type, and cell activation time.

5. Run Messages – This box displays any error messages that have occurred during a run. This dialog box appears only after a run is completed.

2.4.3 Run in Progress



When the run is in progress, the Sample Chamber being processed is highlighted in **yellow**. The highlight changes to **green** when the Sample Chamber has successfully been processed. (pictured above)

If the process fails for a given sample, the highlight changes to **red**. A failed run will be accompanied by an error message located in the Run Messages box. For information on error messages, refer to Appendix C: Instrument Error Codes.

After the run is complete, the Run Messages box will appear on the left side of the screen.

If an error occurs, error messages will be displayed in the Run Messages box.



2.4.4 Modifying an Existing Protocol from the Run

Protocols can be modified by editing a protocol on the Run Screen. However, it is recommended to create a new protocol under Settings before initiating the experiment to minimize the amount of time the samples are in the Sample Chambers. Modified protocols can be saved and accessed under Settings on the Protocols screen.

To modify a protocol on the Run Screen:

- Change one or all of the psi settings by selecting a psi button.
- Disable Sample Chambers by toggling the Enabled button to Disabled. The name of the protocol will change to Protocol Name – MODIFIED.
- Select the Start button
- Once a confirmation popup appears, select Yes to save the new protocol or No to continue to run the modified protocol unsaved.
- Once a Confirm Run window appears, select OK to run the protocol or Cancel to make further changes.



NOTE: Disabling a Sample Chamber alone will not lead to a protocol being modified. A psi value must be changed. After changing any of the psi settings, disabling or enabling of Sample Chambers will be saved as part of the modified protocol.

2.5 Instrument Maintenance

2.5.1 Cleaning and Maintenance Guidelines

CAUTION: Proper cleaning and maintenance of the Infinity MTx instrument is required in order to maintain optimal performance.

- DO NOT employ cleaning agents that can create potential hazards due to reactions with the equipment or materials contained within it.
- DO NOT perform any cleaning while the Infinity MTx instrument is powered. Turn off the instrument and the air compressor, and ensure that the instrument is depressurized before performing cleaning and maintenance.
- The Infinity MTx instrument must be decontaminated and cleaned in each of the following scenarios:
 - a) if hazardous materials are spilled and come into contact with the instrument.

b) before scheduling service, repair, maintenance, trade-in, disposal, or relocating the instrument.

- Regular cleaning as outlined in the section below should be performed once a week in addition to cleaning immediate spills as required.
- Before employing any cleaning or decontamination techniques that deviate from CellFE's recommendations, users should verify with CellFE that the proposed methods will not cause damage to the equipment.

NOTE: Only utilize the cleaning and maintenance methods outlined in this section. The user must ensure adherence to the following guidelines to guarantee warranty and service agreements:

2.5.2 Cleaning Procedures

Clean the surfaces of the Infinity MTx instrument using a slightly damp cloth or disposable paper towel. Do not use organic solvents or harsh chemicals. The instrument should be cleaned with a 70% ethanol solution.

In the case of a non-hazardous liquid spill inside of tray or on the instrument, wipe the spill with a dry paper towel. In the case of a spill that could pose a biological hazard, utilize proper personal protective equipment (laboratory coat, safety glasses, and gloves) and abide by your laboratory's standard operating procedure to clean the biological hazard.

For any other repairs or services, contact CellFE Technical Support at support@cellfebiotech. com.

WARNING: Do not perform any repairs or services by yourself or with a third-party vendor.

Appendix A: Specifications

Input Voltage:	100 – 240 VAC, Frequency 50/60 Hz
Protective Earthing:	Class I
Minimum Input Pressure:	90 psi
Maximum Input Pressure:	120 psi
Minimum Output Pressure:	5 psi
Maximum Output Pressure:	90 psi
Altitude:	Up to 2,000 meters above sea level
Operating Temperature:	15°C to 30°C (59 to 86°F)
Maximum Relative Humidity:	80% for temperatures up to 31°C decreasing
	linearly to 50% relative humidity at 40°C
Degree of Protection:	IPx0
Instrument Type:	Benchtop Unit, for indoor use only
Max Device Dimensions:	11.75" X 11.75" X 10.63"
Device Weight:	40 pounds (18.1 kg)

Appendix B: Troubleshooting

Observation	Possible Cause	Recommended Action
Sample not processed or only partially processed and / or error message R-007 appeared.	The sample cell number is too high.	Reduce the number of cells or cell density.
	The initial cell viability is too low.	Improve the cell viability by optimizing cell culture or removing dead cells before processing.
	The payload concentration is too high. The sample may be too viscous.	Reduce the payload concentration. Use a highly purified, high-quality payload.
	The sample contains impurities (magnetic beads etc.)	Remove any cell culture components such as magnetic beads that can clog channels.
	Instrument failure (pump etc.)	Contact Technical Support.
	MPA gap size is too small, and/or the psi is too high.	Optimize gap size and pressure setting.
Sample not processed or only partially processed and / or error message such as R-006 appeared.	The system may have timed out because the flow rate was too fast. The cell number is too low, the MPA gap size too large, and/or the psi is too high.	Increase the number of cells per sample to increase the volume. Check the cell diameter and use the Infinity Optimizer MPA to optimize for gap size. Reduce psi.
	The sample was not loaded.	Make sure the sample was loaded.

Observation	Possible Cause	Recommended Action
Low or no transfection	Gap size selection or pressure is not optimized.	If the cell size is smaller than original optimization, repeat with Optimizer MPA. Choose a gap size that will apply 40- 55% compression. The cell culture or cell activiation may be sub-optimal.
	No payload or payload quality is not ideal.	Check the quality of payload and optimize for payload concentration. Use a positive GFP control.
	Payload design is not appropriate.	Check the design of payload. Use a positive GFP control.
	Cell status (quiescent cells).	Perform cntrol delivery to confirm the proper delivery. Quiescent cells may not respond to specific payload types.
Low viability	Gap size is too small or psi setting is too high.	Repeat optimization with an appropriate Optimizer MPA. The cell culture or cell activation may be sub-optimal. Cells may be over-activated.
	Payload toxicity.	Check the payload and solvent quality. Repeat optimization with an appropriate Optimizer MPA.
	Cell quality or cell state (fragile cells).	Contact Technical Support.
For further assistan support@cellfebio	ce with troubleshooting, conta tech.com	ct Technical Support at

Appendix C: Instrument Error Codes

This section describes error messages that may be displayed by the software during operation.

MPA has passed It is recommended to use MPAs before expiration	
	on date.
expiration date. However, users can use at user's own risk.	
Would you like to	
continue?	
This MPA has been One or more of eight Processing Units have prev	viously been
used before. used. If there are unused sample chambers, use	ers can
Would you like to choose to continue. Note: A Processing Unit is sin	ngle-use
continue? and will be disabled after use.	
Scanner Hardware failure. Contact Technical Support.	
malfunction	
Scan failed. Re-scan. If the problem persists, contact Technic	cal Support.
Please try again.	
A-005 System error Hardware failure. Contact Technical Support.	
Tray error Check for obstruction of the tray. If problem per	rsists,
contact Technical Support.	
NFC reader error Reboot instrument. If problem persists, potential	hardware
failure - contact Technical Support.	
NFC write error The MPA cannot be tracked. However, this will n	not impact
the run. If problem persists, contact Technical Su	upport.
No MPA detected Check to make sure that the MPA was inserted in	into the tray.
If problem persists, contact Technical Support.	
This error may not This message will appear after an error message	e is triggered
be indicative of unintentionally. In most cases, the sample will he	ave been
channel status processed. Check the Collection Chamber for s	successful
transfer. If the sample was not processed, run th	e protocol
again.	
All channels have Use a brand new MPA.	
been used. MPA	
cannot be run.	
NFC Reader Try inserting MPA again. If problem persists, cont	act
Timeout Technical Support.	

ID-ERROR CODE	Description	Troubleshooting Recommendations
R-001	Pressurization error	Reinsert the MPA and run the protocol again. If the problem persists, contact Technical Support.
R-002	Timeout error	If this error occurs prior to the protocol run, run the sample again. It will be necessary to open and close the tray to return to Select Protocol to rerun the program.
		If this error occurs after a protocol run, check to see if the sample was processed and is in the Collection Chamber.
R-003	Timeout error	If this error occurs prior to the protocol run, run the sample again. It will be necessary to open and close the tray to return to Select Protocol to rerun the program. If this error occurs after a protocol run, check to see if the sample was processed and is in the Collection Chamber.
		If the problem persists, contact Technical Support.
R-004	Input pressure error	Make sure the Air Inlet connection is secure. Check that the air supply pressure is between 100 and 120 psi. If the prob- lem persists, contact Technical Support.
R-005	Process start error	Check to see if the sample is still in the Sample Chamber. Run the protocol again. If the problem persists, use a differ- ent MPA. If the problem persists, contact Technical Support.
R-006	Process start error	Check to ensure that a) the sample is loaded in the Sample Chamber or b) the sample volume is not less than the rec- ommended volume, 30ul . If the problem persists, contact Technical Support
R-007	Processing error	The flow path may have been obstructed by the sample. See Troubleshooting section or contact Tech Support.
R-008	Processing Timeout	If the sample has been partially processed, run the proto- col again. If the problem persists or if no sample has been processed, contact Technical Support.

Appendix D: Safety

Symbol	Explanation
CE	The CE mark symbolizes that the product conforms to all applicable European Community provisions for which this marking is required. Operation of the Infinity MTx Instrument is subject to the conditions described in this manual. The protection provided by the device may be impaired if the instrument is used in a manner not specified by the manufacturer.
o Intertek	This product conforms to UL 61010-1, CAN/CSA C22.2 No.61010-1 "Safety Requirements for Electrical Equipment for Measurement, Control, and Labo- ratory Use, Part I: General Requirements." Instruments bearing the ETL symbol are certified by ETL Product Services to be in conformance with the applica- ble safety standard for the US and Canada.
X	WEEE (Waste Electrical and Electronic Equipment) symbol indicates that this product should not be disposed of in unsorted municipal waste. Follow local municipal waste ordinances for proper disposal provisions to reduce the environmental impact of WEEE. This instrument meets European requirement WEEE Directive 2012/19/EU.
Ĩ	Read User Guide before using the Infinity MTx™ Instrument
\mathbf{A}	Potential biohazard.
<u>^</u>	Warning. If ignored, can cause serious adverse reactions (death) and potential safety hazards (injury).
Â	Caution, If ignored, can trigger adverse reactions for safe and effective use of the device
I	Indicates the ON position of the instrument power switch.
0	Indicates the OFF position of the instrument power switch.
	Indicates the fuse rating for the device when replacing the fuse use one of the same type and rating as marked on the label.
\sim	Indicates the AC power requirements of the device. Refer to the label to ensure that the facility can handle the requirements.
RUO	Research only use - "For Research Use Only. Not for use in diagnostic proce- dures."

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

The Infinity MTx instrument is designed to meet IEC 61010-1 Safety Standards. To ensure safe, reliable operation; Always operate the Infinity MTx instrument according to the instructions in this manual. Failure to comply with the instructions in this manual may create a potential safety hazard and will void the CellFE's warranty and void the safety standard certification. CellFE is not responsible for any injury or damage caused by use of this instrument when operated for purposes for which it is not intended. All repairs and service should be performed by CellFE Inc.

Caution

- This Infinity MTx instrument is not to be used for clinical investigation or clinical diagnostics.
- The Infinity MTx instrument contains no user-serviceable parts. Do not attempt to open the enclosure. Contact CellFE Technical Support in case of problems with the instrument.
- The Infinity MTx instrument contains a high voltage source. Do not attempt to open the enclosure.
- Do not operate the Infinity MTx instrument in case of damage to the tray, enclosure, power cord, pressure line, interface screen, or device carrier.
- Biological specimens should be handled and disposed of with appropriate precautions as though biohazardous, including compliance to OSHA blood-borne pathogens standard (21 CFR 1910.1030).
- The Infinity MTx instrument weighs 40 pounds (18.1 kg). Follow your institutional safety instructions for lifting heavy objects.
- Dispose of waste in accordance with federal, state, and local regulations. Prepare and use reagents and samples with appropriate good laboratory practice and caution.
 Wear appropriate personal protective equipment (e.g., lab coat, gloves, eye protection, disposable respirator).
- The Infinity MTx instrument is connected to a high-pressure air source. Before unplugging the air line from the Infinity MTx instrument, turn off the instrument and the source of compressed air, and ensure the source of compressed air has decompressed completely before proceeding.
- Turn off the instrument when not in use.
- Avoid spilling liquids on the Infinity MTx instrument. In case of spill, wipe clean with a lint-free dry wipe. Wipe may be wet with water or a dilute alcohol solution to clean residues.
- Ensure that the power supply input voltage matches the voltage available in your location.
- Set the main switch on the power supply unit to OFF before connecting the power cord to the wall outlet

- To avoid potential shock hazard, make sure that the power cord is properly grounded.
- Set the main switch to OFF, uplug the power cord, and secure the pipette station before moving the device.

Safety Directives

EU Directive 2014/35/EU – Low Voltage Directive IEC/EN/UL/BS 61010-1 – Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirement. CAN/CSA C22.2 No. 61010-1 – Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirement. IEC/EN/UL/BS 61010-2-081 - Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-081: Particular requirements for automatic and semiautomatic laboratory equipment for analysis and other purposes CAN/CSA C22.2 No. 61010-1 - Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-081: Particular requirements for automatic and semiautomatic laboratory equipment for analysis and other purposes

EU directives:

- Electromagnetic Compatibility Directive (EMC) 2014/30/EU
- Low Voltage Directive (LVD) 2014/35/EU
- Waste Electrical and Electronic Equipment (WEEE) Directive 2012/19/EU
- RoHS Directive 2015/863/EU (RoHS3)
- REACH Directive Reg. (EC) No 1272/2008
- Radio Equipment Directive (2014/53/EU).

Electromagnetic Compatibility (EMC)

Directive 2014/30/EU – European Union EMC Directive IEC/EN/BS 61326-1 – Electrical Equipment for Measurement, Control and Laboratory Use – EMC requirements – Part 1: General Requirements ICES – 003 – Information Technology Equipment (Including Digital Apparatus) ETSI EN 301 489-1 V2.2.3 (2019-11), ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard for ElectroMagnetic Compatibility ETSI EN 301 489-17 V3.2.4 (2020-09) ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonised Standard for ElectroMagnetic Compatibility

USA EMC Compliance Statement Class A Digital Device

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 their own expense.

Canada EMC Compliance Statement

CAN ICES-003(A) / NMB-003(A) This Class A device complies with Canadian ICES-003 Cet Clase A appareil est conforme à la norme NMB-003 du Canada.

RFID Reader

RFID module RED (Radio Equipment Directive) Contains pre tested transmitter module IC with the following #'s: DLP-RFID2 Manufactured by DLP Designs Inc.

Module Verification # SZCR2303000529ATV System Level testing :

ETSI EN 300 330:2017Ed.V2.1.1

short Range Devices (Srd); Radio Equipment In The Frequency Range 9 Khz To 25 Mhz And Inductive Loop Systems In The Frequency Range 9 Khz To 30 Mhz; Harmonised Standard Covering The Essential Requirements Of Article 3.2 Of Directive 2014/53/Eu

ETSI EN 301 489-1:2019 Ed.2.2.3

Electromagnetic Compatibility (EMC) Standard for Radio Equipment and Services; Part 1: Common Technical Requirements; Harmonised Standard for Electromagnetic Compatibility ETSI EN301489-3:2017Ed.V2.1.1

Electromagnetic Compatibility (EMC) Standard For Radio Equipment And Services; Part 3: Specific Conditions For Short-Range Devices (Srd) Operating On Frequencies Between 9 Khz And 246 Ghz; Covering The Requirements Of Article 3.1 (B) Of Directive 2014/53/Eu

Industry Canada

Contains transmitter module IC: 5675A-RFID2 Contient le module émetteur IC : 5675A-RFID2 This device complies with Industry Canada license exempt RSS standard(s). Operation is subject to the following two conditions:

(1) this device may not cause interference, and

(2) this device must accept any interference, including interference that may cause undesired operation of the device.

Cet appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes:

(1)l'appareil ne doit pas produire de brouillage, et

(2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Condition	Acceptable Range
Operating Environment	Temperature: 15 to 30°C (59 to 86°F)
	Humidity: 20 to 80% RH (noncondensing)
Storage and transport condi-	Temperature: -30 to 60°C (-22 to 140°F)
tions	Humidity: 20 to 80% RH (noncondensing)
Electromagnetic interference	Do not use this device in close proximity to sources of strong
	electromagnetic (EMC) radiation (for example, unshielded
	intentional RF resources), as EMC radiation might interfere with
	the proper operation of the device.

Environmental Requirements

Biological Hazard



WARNING! Potential Biohazard – The surface may be considered biohazard. Use appropriate decontamination methods when working with biohazards. The following references provide general guidelines when handling biological samples in a laboratory environment. • U.S. Department of Health and Human Services, Biosafety in Microbiological and Biomedical Laboratories (BMBL), 6th Edition, HHS Publication No. (CDC) 300859, Revised June 2020 www. cdc.gov/labs/pdf/CDC-BiosafetymicrobiologicalBiomedicalLaboratories-2020-P.pdf • Laboratory biosafety manual, fourth edition. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs) www.who.int/publications/i/item/9789240011311

This product complies with the safety requirements outlined in IEC 61010-2-081 for laboratory equipment. It may come into contact with biohazardous materials during use. To ensure safe biohazardous waste disposal and overall product safety, please adhere to the following guidelines:

- 1. **Biohazard Identification:** Always clearly label and identify any materials or specimens that may contain biohazardous agents in accordance with your organization's biohazard safety protocols and applicable regulations.
- 2. Material Safety Data Sheets (SDS or MSDS): Access and familiarize yourself with Material Safety Data Sheets (SDS or MSDS) for any chemical substances or biohazardous agents used in conjunction with this product. MSDS provides critical information on the properties and safety precautions associated with these materials. Ensure that all users are aware of the location of MSDS and how to interpret them.
- 3. Personal Protective Equipment (PPE): When handling biohazardous materials or substances identified in the MSDS, wear the appropriate personal protective equipment (PPE) as recommended by the MSDS and your institution's safety guidelines. This includes gloves, lab coats, safety goggles, masks, or other protective gear specified.
- 4. Biohazard Waste Containers: Use appropriate biohazard waste containers designed for the safe collection and disposal of biohazardous materials. These containers should be clearly labeled with biohazard symbols and warnings.
- 5. Decontamination: Ensure that all surfaces and equipment that come into contact with biohazardous materials are thoroughly decontaminated following your institution's established decontamination procedures.
- 6. **Disposal:** Dispose of biohazardous waste in strict accordance with local, national, and international regulations governing biohazardous material disposal, as specified in the MSDS and your institution's waste disposal protocols.
- 7. Emergency Response: Familiarize yourself with emergency response procedures pertaining to biohazardous materials, as outlined in the MSDS and your institution's safety guidelines.
- **8. Training:** It is essential that all individuals using this equipment receive proper training in biohazard safety practices, disposal procedures, and the utilization of MSDS.
- **9. Support:** For inquiries related to biohazard safety, disposal, and MSDS specific to this product, please contact the manufacturer at the address provided above. For information regarding safe disposal of materials please contact your local regulatory agency.

WEEE Directive Statement

Electronic and Electrical Equipment placed onto the market in Europe are marked with the crossed-out wheeled bin symbol to indicate that they are covered by the WEEE Directive (2012/19/EU), which imposes a number of obligations on producers of EEE including obligations relating to the financing of the take-back treatment and recycling of end of life equipment (WEEE).

To ensure proper disposal and recycling of this product, please follow the guidelines provided below:

1. End-of-Life Disposal: Do not dispose of this product with regular household waste. It is your responsibility to properly dispose of this product at the end of its life cycle.

- 2. Collection and Recycling: Contact your local authorities or recycling centers to find out about the designated collection points for electronic waste. In some regions, special collection facilities may be available for WEEE products.
- 3. Separation of Batteries: If this product is equipped with batteries, remove them before disposal and recycle them separately in accordance with local regulations.
- 4. Environmental Protection: By disposing of this product correctly, you are contributing to environmental protection and conserving natural resources.
- 5. Penalties may be applicable for incorrect disposal of this waste, in accordance with your national legislation.

For additional information on WEEE compliance and recycling options, please contact your local regulatory agency or the manufacturer at the address provided in this manual.

Proposition 65 warning

This product can expose you to chemicals including Nickel (metallic) which are known to the State of California to cause cancer or birth defects or other reproductive harm. For more information, visit www.P65Warnings.ca.gov.

Appendix E: Documentation and Support

Technical Support

Email: support@cellfebiotech.com.

Patents

Various features of this product and corresponding processes may be protected by United States patents and described in various patent publications listed below. This listing is intended to satisfy the virtual patent marking provisions of U.S. patent law. This listing may not be all inclusive as new patents are expected to be granted and new patent applications are expected to be filed. Furthermore, patents and patent publications may include corresponding foreign and continuation cases. By listing patents in this document, CellFE makes no admission that other patents do not apply. CellFE's patents can be viewed by visiting the link below:

• <u>https://www.cellfebiotech.com/patents/</u>

Authorized EU Representative

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