

RainDrop[®] Sense Operator's Manual



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Contact

RainDance Technologies, Inc.
749 Middlesex Turnpike
Billerica, MA 01821
Fax: (978) 528-6090 (support)
Web: www.raindancetech.com/support
Email: customercare@raindancetech.com

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CHAPTER 1

Foreword

This chapter covers the following topics:

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About this Manual

This manual is designed to serve the operators of the RainDance Technologies[®], Inc. (hereafter called “RainDance”) RainDrop[®] Sense instrument. All material operating instructions, product illustrations, screen graphics, troubleshooting, error messages, and other relevant information are contained in this manual. It is the operator's responsibility to ensure that all safety instructions in this manual are strictly applied.

Where there is any conflict between the RainDance Software End User License Agreement included in the software, and the terms and conditions of sale, the order of precedence shall be as follows: (1) the RainDance Software End User License Agreement and (2) the terms and conditions.

Intended Use

For Research Use Only. Not for use in Diagnostic Procedures.

RainDance Technologies RainDrop Sense is the detection instrument that enables identification and counting of target molecules in each picoliter droplet following PCR amplification. Together the RainDance Source and RainDrop Sense instruments make up the RainDrop Digital PCR System delivering quantitative results.

Data Entry and Collection

RainDance requires that you do not enter health information identifiable to a particular person, or other information that is subject to regulatory or contractual protection, into any RainDance instrument. Such information is not protected from disclosure to service or other personnel and, as noted below, may be included in information provided to RainDance for purposes of servicing or evaluating the performance of your instrument.

Further, by requesting service of your RainDance instrument, you give RainDance consent to access and use data stored in your RainDance instrument. RainDance uses the data to troubleshoot and service the instrument in response to your service requests. RainDance also may aggregate data collected from your instrument in response to service requests with similar data from other customers and may use the aggregated data to improve instrument performance.

Your instrument from RainDance is enabled with an automatic email functionality that allows RainDance to receive performance data from the instrument from time to time without your knowledge. You may choose to disable that functionality. Disabling that functionality prevents the instrument from sending such data to RainDance. The data collected with this automatic email functionality consists of the number of samples processed, the success rate of the samples processed, data specific to the performance of your instrument, and data that is

entered by your operators. RainDance collects this data solely so that it may better understand and improve instrument performance. By allowing the functionality to remain enabled, you give RainDance permission to use the automatic email functionality.

Design Change Disclaimer

- Due to design changes and product improvements, information in this manual is subject to change without notice. RainDance reserves the right to change the product design, including illustrations, screen shots, and diagrams, at any time without notice to anyone, which may subsequently affect the contents of this manual.
- RainDance assumes no responsibility for any errors that may appear in this manual. RainDance will make every commercially reasonable effort to ensure that this manual is up-to-date and corresponds with the shipped RainDrop Sense Instrument.
- The depictions of the workstation screens in this manual are representative only. Depending on the hardware and software versions of the system, minor differences may appear between the actual displays and those shown in this manual.

Reproduction Disclaimer

You may make a reasonable number of copies of this manual for internal use only and only for use in connection with the RainDrop Sense Instrument. Except as provided by the previous sentence, neither this manual nor any part of it may be reproduced, photocopied, or electronically transmitted in any way without the advanced written permission of RainDance.

RainDance Support

If you have any difficulty running the RainDance Source instrument, contact your RainDance Support representative. [Chapter 7](#) of this manual includes a list of problems and possible solutions. The information given is general. Some applications may require additional procedures or equipment modification. Contact RainDance Support via email: support@raindancetech.com, Monday through Friday, excluding holidays.

Microsoft Windows Familiarity

- The supplied Instrument Control Software (ICS) is designed for the Microsoft® Windows® Embedded 7 operating system and uses the standard Windows interface. This manual assumes that you are familiar with these standard techniques: clicking the mouse, highlighting an item, right-clicking, dragging, using the keyboard, interacting with dialog boxes, keyboard commands, selection techniques, and other Windows basics.
- If you require assistance with these aspects of the software user interface, refer to the Microsoft Windows documentation.

Notes, Warnings, and Cautions

The symbols described in this section are used throughout this document to draw your attention to specific situations involving safety and proper use of the equipment. Symbols found on the instruments are listed in [Chapter 11: “Symbol Glossary.”](#)

Notes

Notes are set apart from the body of the document with either the word **Note** or **Important**. They are meant to draw your attention to reminders and information that is important to successful operation of the RainDrop Sense Instrument.

Note: A Note indicates a useful piece of information.

Important: An Important note is similar to a regular Note, except that it is meant to communicate greater weight to the issue at hand.

Warnings

Warnings are represented by a red triangle with an exclamation point inside of it. Warnings are reserved for situations that indicate the possibility of personal injury if the instructions are not followed.



Warning: A Warning indicates a potentially hazardous situation that, if not avoided, could result in serious personal injury or death to you or others. Warnings are set within boxed rules and indented.

Cautions

Cautions are represented by a blue triangle with an exclamation point inside of it. They indicate that you must follow a particular procedure in order to correctly operate the RainDrop Sense Instrument and to avoid any possible damage to the equipment or loss of consumables.



Caution: Do not operate the System in a manner other than specified in this manual. Doing so could damage the instrument or produce erroneous results.



Caution: RainDance service representatives are trained in the safe operation of the RainDrop Sense Instrument, including accessing those areas reserved for trained service representatives.

Biohazard Safety Warnings

A biohazard warning indicates that the user must use precautions, for example, gloves, when handling biological samples, to prevent any infections or hazards that can be caused by them.



Warning: Follow your laboratory's procedures and regulations when handling biohazardous materials.



Warning: RainDance suggests that users be professional and conscientious and take the appropriate safety measures when preparing, handling, and disposing of any biohazardous samples or waste.



Warning: When working with biohazardous samples, or waste, *always* follow standard universal safety procedures (lab coats, safety glasses, gloves, mask, etc.).

In addition, users should take precautions in accordance with local, state, and national requirements.

Laser Safety Warnings

The RainDrop Sense, classified as a Class 2 System, contains a Class 3B laser and Class 2 barcode laser. Avoid direct exposure to the Class 3B laser radiation when the unit is open and interlocks are defeated. Only a qualified service person should remove the cover or attempt to service this device, due to possible eye injury.

A laser warning indicates that the user must use precautions when operating the instrument to avoid injury from the lasers.



Warning: A Class 3B laser is hazardous if the eye is exposed directly, but diffuse reflections such as those from paper or other matte surfaces are not harmful. The AEL for continuous lasers in the wavelength range from 315 nm to far infrared is 0.5 W. For pulsed lasers between 400 and 700 nm, the AEL is 30 mW. Other limits apply to other wavelengths and to ultrashort lasers. Protective eye wear is typically required where direct viewing of a class 3B laser beam may occur. Class-3B lasers must be equipped with a key switch and a safety interlock.

In addition, users should take precautions in accordance with local, state, and national requirements.

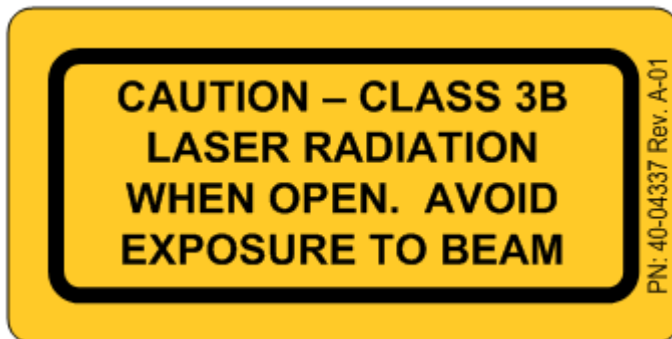


Figure 1-1: Laser Safety Warnings

Safety Information

Electrical Safety Warnings



Warning: This equipment is operated with hazardous voltages that can shock, burn, or cause death. To reduce the possibility of electrical shock, do not remove any fixed panels. Ensure that all service to the system is performed only by qualified RainDance service personnel.



Warning: Remove the wall plug before servicing the equipment. Never pull cords to remove the power cord from the outlet. Grasp the power cord plug and pull it from the outlet to disconnect it.



Warning: Do not operate the equipment with a damaged power cord.



Warning: Ensure that there is easy and adequate clearance to the power cord so that it can be disconnected in the event of a problem.



Warning: Position the power cord so that it cannot be tripped over, walked on, rolled over, crimped, bent, pinched, or accidentally pulled from the wall outlet.



Warning: Connect the equipment only to a grounded outlet.



Warning: This instrument is not disconnected from the AC power source (mains) as long as it is still connected to the wall outlet, even if the instrument is turned off. The primary means of disconnecting the instrument is to remove the plug from the wall outlet. Do not locate the instrument such that access to this plug is difficult.

Mechanical Safety



Warning: The RainDrop Sense instrument weighs approximately 65 lbs (29 kg). To avoid injury and damage to the instruments, do not move it without assistance from RainDance Technologies.



Warning: The potential for serious injury to hands or fingers exists as a result of rotating or clamping motion. Watch your hands and fingers when opening and closing the cover. Keep your hands away from moving parts.

To move the instrument to another location, contact RainDance Support.

Gas Pressure Safety

Do not exceed a maximum input pressure of 120 psi.

Product Labels

Figure 1-2 shows the RainDrop Sense product label.

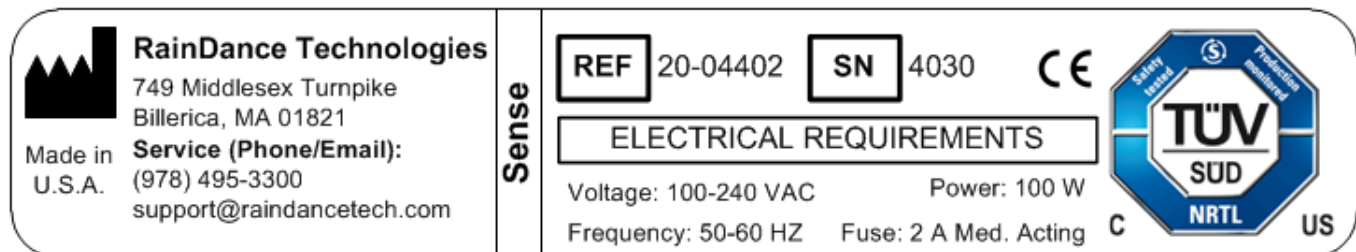


Figure 1-2: RainDrop Sense Product Label

Safety Interlock

The RainDrop Sense is equipped with an automatic safety interlock, which prevents it from operating unless its door is properly closed.

Packing and Transport

RainDance provides initial shipping and installation. If you are considering moving the RainDrop Sense instrument within your laboratory, refer to [Chapter 3](#) for the space requirements. Do not move the instrument without assistance from RainDance Technologies.

CHAPTER 2

Introduction

This chapter covers the following topics:

System Overview	page 2-2
RainDrop System Major Components	page 2-2
RainDrop Sense Major Components	page 2-3
RainDrop Sense Layout	page 2-4
RainDrop Carrier and Drive Oils	page 2-4
RainDrop Sense Barcode Reader	page 2-5
RainDrop Sense Chip	page 2-6
Handling the Sense Chip	page 2-6
RainDrop Sense Chip Compression Plate	page 2-7
Specifications	page 2-8

System Overview

The RainDance RainDrop[®] System comprises two instruments: the RainDance Source and the RainDrop Sense.

RainDrop System Major Components

- RainDance Source Instrument
- RainDrop Sense Instrument
- Two Instrument Control (IC) Workstations (computers), one for each instrument
- Two Instrument Control (IC) Monitors, one for each instrument
- Instrument Control Cables and Peripherals
 - IC Workstation Power Cables
 - IC Monitor Power Cables
 - IC Keyboards
 - IC Mouses
 - IC Network Cables
 - IC USB Cables
 - IC FireWire Cable
- Instrument Control Software (ICS)
- RainDrop Analyst II Software



Figure 2-1: RainDrop System Major Components

RainDrop Sense Major Components

Figure 2-2 shows the major components of RainDrop Sense instrument.

Instrument control workstation monitor

Instrument control workstation

RainDrop Sense instrument



Figure 2-2: RainDrop Sense Major Components

RainDrop Sense Layout

Figure 2-3 shows the RainDrop Sense layout and oil reservoir fill ports.

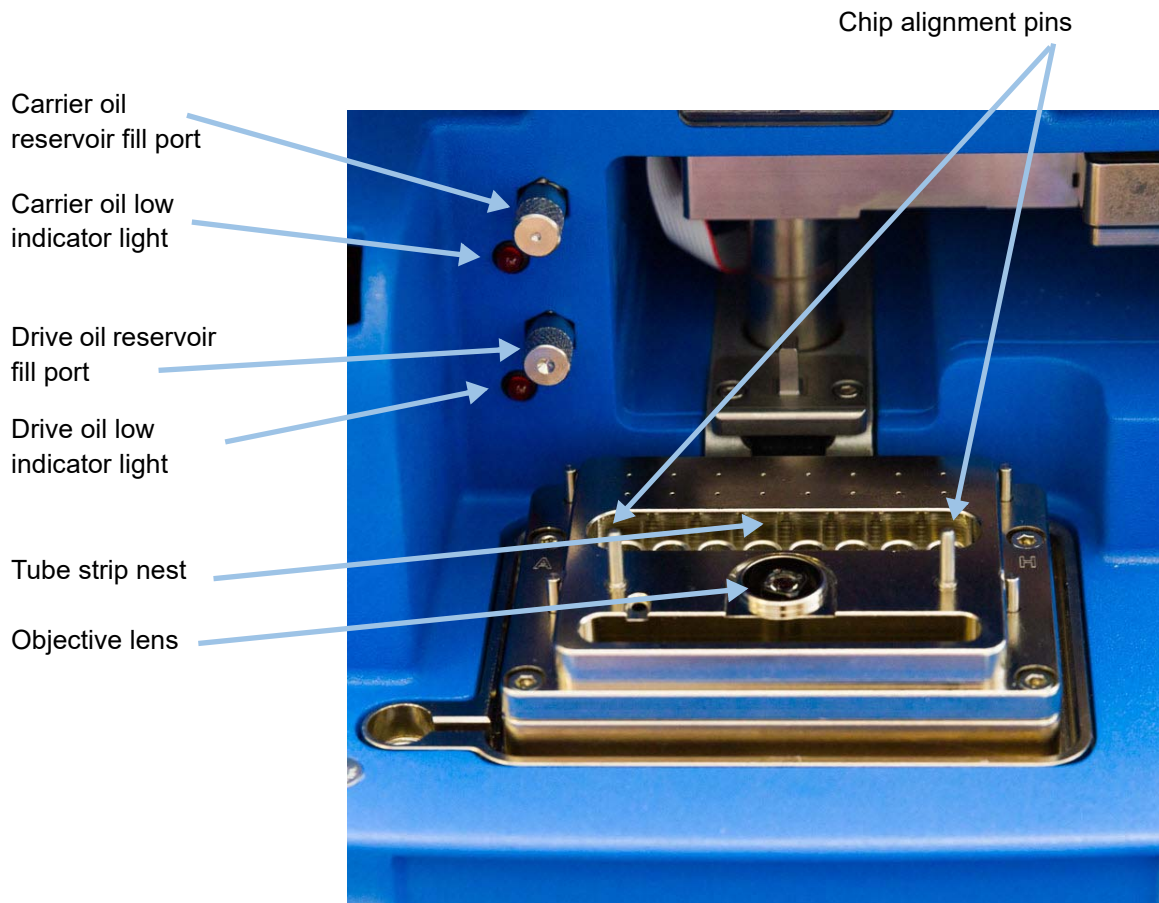


Figure 2-3: RainDrop Sense Layout

RainDrop Carrier and Drive Oils

Aqueous samples are encapsulated within each droplet on the Source instrument, surrounded by an immiscible carrier oil. The droplets are stabilized with surfactants allowing for robust manipulation both on and off the chip. Precise control of carrier and drive oil flow rates on the Sense instrument allows for control of droplet spacing. Use only RainDance-supplied oils to avoid damage to the RainDrop System. The carrier oil and drive oil ports can be filled with the oil provided in the Carrier Oil Syringe.

RainDrop Sense Barcode Reader

The barcode reader is used to scan barcodes that identify the various components used in the RainDrop Sense (see [Figure 2-4](#)). The following lists the components to be scanned:

- RainDrop Sense Chip(s)
- RainDrop Carrier Oil
- Tube Strips (May have a user-generated barcode. Scanning tube strips is optional.)
- Items bearing a user-generated barcode for sample tracking (within the limits of supported barcode formats)



Figure 2-4: RainDrop Sense Barcode Reader

Scanning Barcodes

Scan items as follows:

1. Click **Scan** in the ICS software. The red scanner light pulses for 10 seconds.
2. Hold the barcode on the item in front of the barcode reader. When the scanner reads the barcode, it automatically fills in the barcode information. The ICS accepts a barcode in the 2D Data Matrix format, which allows up to 96 characters of text. You may hear a subtle beep tone from the instrument when the barcode is accepted. If the scanner does not read the barcode, the ICS software displays a message and allows you to enter the barcode manually.

RainDrop Sense Chip

The RainDrop Sense Chip is placed into the instrument on top of the PCR tube strip. As part of the Sense process, the chip punctures the tube strip caps and transfers the emulsified sample through its lanes where the Sense instrument identifies and counts the droplets.

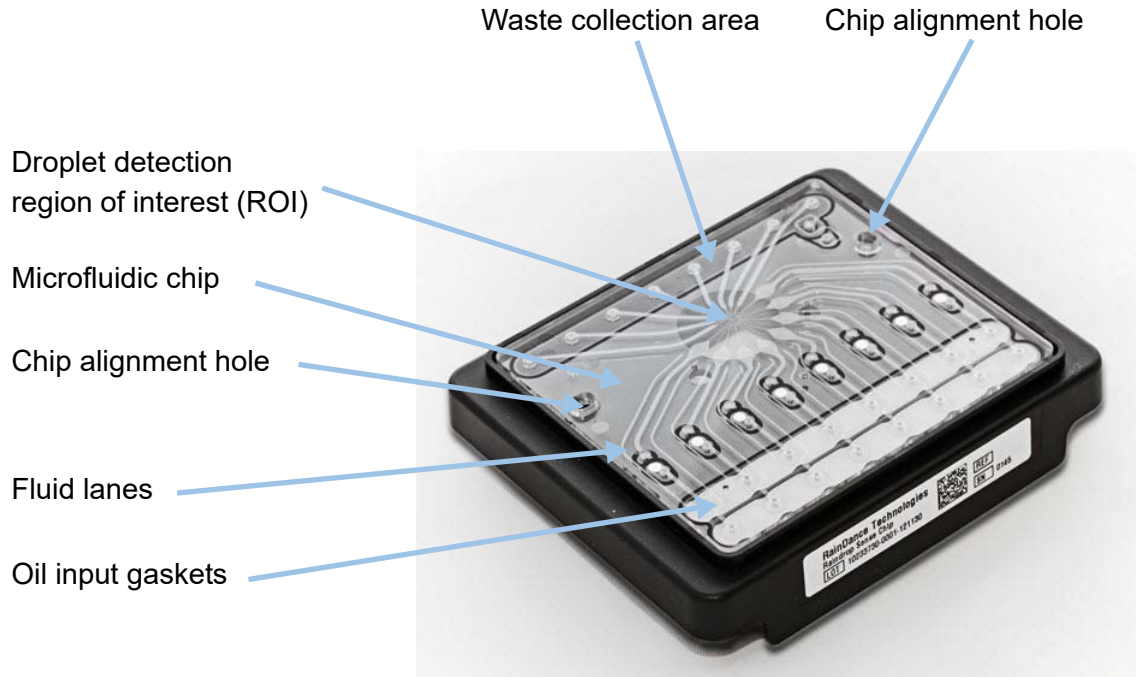


Figure 2-5: RainDrop Sense Chip

Handling the Sense Chip

Handle the Sense Chip as follows:

- Grasp the chip by its sides.
- Do not touch the clear microfluidic chip and its droplet detection region of interest.
- Save the bag the chip comes in for later disposal of the chip.

RainDrop Sense Chip Compression Plate

The RainDrop Sense Compression Plate is needed for smooth operation of the RainDrop Sense Instrument. Position the plate over the Sense chip prior to start of the run. When the plate is properly positioned, its RainDance logo should be facing you, the plate should be flat, and it should not be movable left to right or front to back.

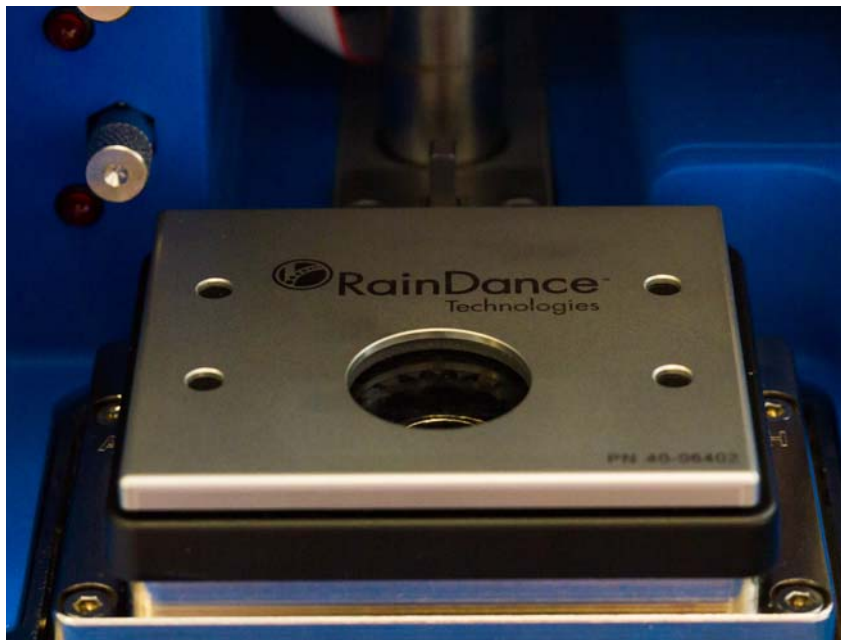


Figure 2-6: RainDrop Sense Chip Compression Plate

Specifications

Table 2-1 shows the specifications for the RainDrop Sense instrument. Table 2-2 shows the specifications for the Instrument Control (IC) Workstation.

Table 2-1: RainDrop Sense Hardware Specifications

Requirement or Specification	Description
Width	11 inches (27.9 cm) not including the IC Workstation
Depth	17 inches (43.2 cm)
Height	15 inches (38.1 cm)
Weight	~65 lbs (~29 kg)
Power Source (Electrical)	Voltage: 100 to 240 VAC, 35 W max 1 standard grounded outlet, within 6 feet (2 meters) of the instrument
Clearance	2 inches (5 cm) in rear
Fuses	2 fuses, 2 Amperes Medium Acting
Cable Connection	2 USB connections
Required compressed gas input pressure range	90-120 PSI (0.62 MPa – 0.82 MPa)
Capacity	8 lanes per chip
Maximum Sample Throughput per 8 hour shift	24 samples per shift in Standard Mode 56 samples per shift in Fast Mode
Detection Time	~8 lanes in 4 hours for Standard Mode (for 25uL sample) ~8 lanes in < 2 hours for Fast Mode (for 25uL sample)
Droplet Identification	Precise control of relative pressure and oil flow rate creates ideal spacing of the thermal cycled emulsion to allow for proper droplet identification and analysis.
Droplet Processing	Droplets are processed on a chip that has no moving parts or valves. Samples have minimal contact with either walls or air. In addition, one-time-only chip use prevents sample cross-contamination.

Table 2-2: Instrument Control (IC) Workstation Specifications

Requirement or Specification	Description
Instrument Control (IC) Workstation	
Power	Voltage: 100-240 VAC Dell Computer: 305 W max, 45 W min Standard grounded outlet within 6 feet (2m) of the instrument
Dimensions	Width: 7.5 inches (19 cm) Depth: 17 inches (43.2 cm) Height: 16 inches (40.6 cm)
Weight	~20 lb (~9 kg)
Clearance	2 inches (5 cm) in rear
Network Connection	TCP/IP connectivity (i.e., Internet) using a standard Ethernet connector. Instruments must be placed near an active Ethernet port so the computers can be networked. The Instrument Control Software has the ability to email notifications to customers if it is networked. In addition, RainDance has software that allows us, with customer permission, to access the computers to look at log files to assist in troubleshooting and to assess instrument performance. Without Internet access, support is compromised.
Instrument Control (IC) Monitor	
Power	Voltage: 100 to 240 VAC Dell Monitor: 75 W max, 35 W typical standard grounded outlet within 6 feet (2m) of the instrument
Dimensions	Width: 15 inches (38.1 cm) Depth: 10 inches (25.4 cm) Height: 19 inches (48.3 cm)
Weight	~12 lb (~5.4 kg)
Clearance	0.5 inches (1.2 cm) in all directions

Table 2-3: Operating Environmental Requirements

Requirement or Specification	Description
Laboratory Ambient Temperature Range	15-30°C
Ambient Temperature Fluctuation	<0.3°C per minute
Relative Humidity	5-85% RH, non-condensing
Atmospheric Pressure	101-81 kPa (1010-810 mbar) or sea level to 1800 m
Safety Compliance	IEC 61010-1:2010, the international safety standard for laboratory equipment, including USA (UL), Canadian (CSA), and European (CENELEC/EN) differences
Data Backup	RainDance suggests using a standard backup procedure for any computer system.

CHAPTER 3

Installation and Setup

This chapter covers the following topics:

Space Requirements	page 3-2
Connecting RainDrop Sense and Instrument Controller	page 3-3
Connecting Cables to the RainDrop Sense Instrument	page 3-3
Connecting Cables to the Instrument Controller	page 3-4
Gas Pressure Quality	page 3-6
Starting Up the RainDrop Sense Instrument	page 3-6
Relocating RainDrop	page 3-7

Important: Only trained and certified RainDance Service Representatives may remove the RainDrop[®] Sense instrument from its packaging and install it.

Space Requirements

The RainDrop[®] Sense instrument is designed to be placed on a standard laboratory bench. The Instrument Controller (IC) Workstation can be located on either the left or right side of the instrument.

Table 3-1: RainDrop Sense Dimensions (Including the IC Workstation)

Minimum Height (door open)	28 inches (71.1 cm)
Minimum Width, with the IC Workstation computer located under the bench top	36 inches (91.4 cm)
Minimum Width, with the IC Workstation computer located on the bench top	48 inches (121.9 cm)
Minimum Depth	36 inches (91.4 cm)
Bench Loading Weight	~92 lbs (~42 kg)

Note: Refer to the Pre-Site Guide for any additional installation details.



Caution: The RainDrop Sense instrument is sensitive to vibration and should be placed on a bench top that is free from vibration.

Gas Connectivity

Gas source should be located in proximity to the instrument because the gas supply connection is located on the back of the instrument. Use 4mm OD polyurethane tubing with an in-line shutoff valve. See [Appendix A](#) for information on suppliers.

Connecting RainDrop Sense and Instrument Controller

Before powering on the RainDrop Sense instrument and its IC Workstation, make sure all cables are properly connected as described in “[Connecting Cables to the RainDrop Sense Instrument](#)” on page 3-3 and “[Connecting Cables to the Instrument Controller](#)” on page 3-4.

Connecting Cables to the RainDrop Sense Instrument

The RainDrop Sense instrument has three cable connections (AC Power Cable and two USB) and a gas pressure connection as shown in [Figure 3-1](#).

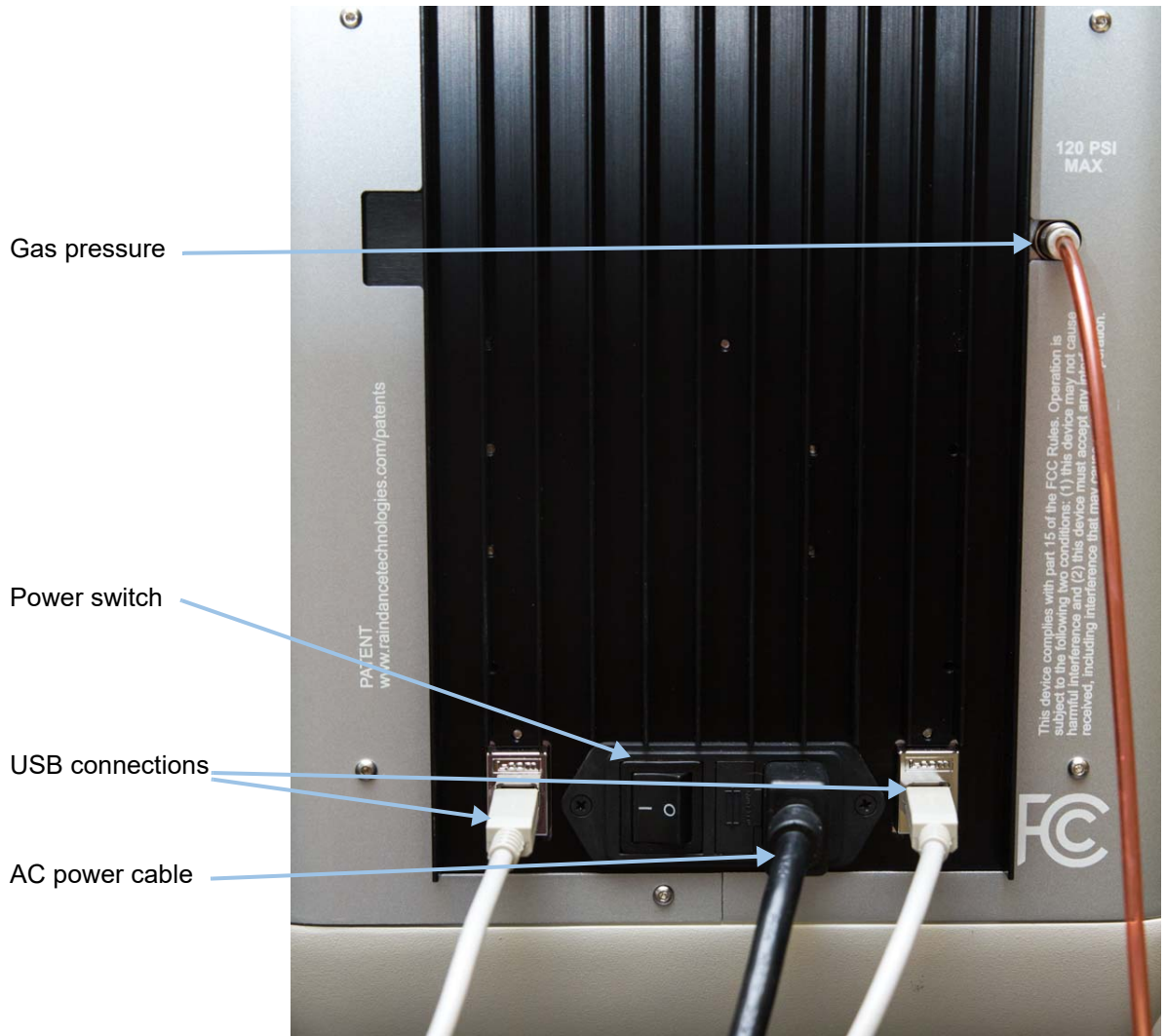


Figure 3-1: Cable Connections on RainDrop Sense

To plug cables into the back of the Sense instrument:

1. Plug one end of the AC Power Cable into the Power Cable Connection and the other end into a standard grounded wall outlet.

Important: The Detachable Main AC Power Cable for North America or other countries with 120 VAC 50/60 Hz supply voltage provided for the RainDrop Sense instrument is a 3-wire cord, 18AWG, 10A, 125VAC. Never substitute a Detachable Main AC Power Cable with a lower current or voltage rating.

2. Plug the two USB Cables into the USB Connections on the Sense instrument as shown in [Figure 3-1](#).

Connecting Cables to the Instrument Controller

The RainDrop IC Workstation has USB connections used for:

- The mouse
- The keyboard
- The RainDrop Sense instrument

Both the Source and Sense instruments connect to their IC Workstations in the same manner. The only difference is that the Sense instrument does not use a FireWire connection and has two USB connections. Use the following instructions for both.

[Figure 3-2](#) illustrates the USB cable connections on the IC Workstation.

Note: It is important that all the USB cables on the instruments are connected to USB ports on the workstations. Failure to connect the USB cable correctly can result in a loss of communication with the RainDrop instrument. In addition, the USB connections on your workstation may differ from those shown in [Figure 3-2](#).

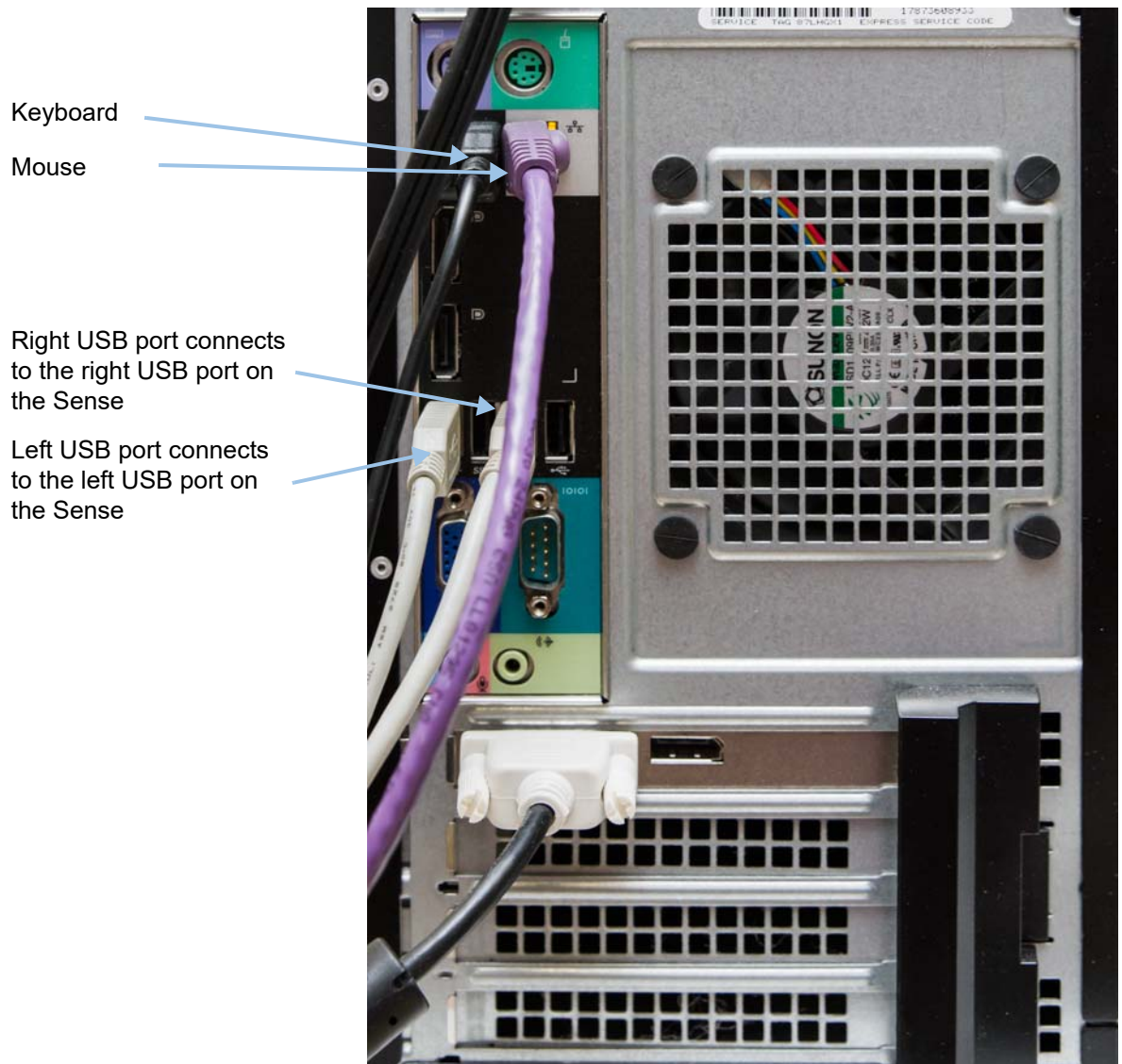


Figure 3-2: USB Cable Connections to the IC Workstation

1. With the IC Workstation turned off, plug the USB cables for the keyboard and mouse into the IC Workstation.
2. Plug the right USB output from the Sense instrument into the right USB in [Figure 3-2](#).
3. Plug the left USB output from the Sense instrument into right USB in [Figure 3-2](#).

Gas Pressure Quality

You may use compressed argon or nitrogen. Ensure that the compressed gas system you use meets the following standards.

The input pressure must be regulated to a value, at the system, within the range of 90-120 psi.

In addition, the quality must meet the ISO/DIS8573 compressed gas quality standard, Class 2 for instrument quality gas, as follows:

Table 3-2: GasPressure Quality

Oil (ppm)	0.1
Water (dew point)	-40°F
Dirt (μ)	1.0

Starting Up the RainDrop Sense Instrument

Use the following startup sequence for the RainDrop Sense instrument:

1. With the RainDrop Sense and IC Workstation turned off, ensure that all the cables have been connected properly as described in [“Connecting Cables to the RainDrop Sense Instrument” on page 3-3](#) and [“Connecting Cables to the Instrument Controller” on page 3-4](#).
2. Turn on the IC Workstation (on the front of the workstation).
3. Log on to the Windows 7 operating system using the RDT account.
Note: Logging on using any other account results in ICS failures.
 - User name = RDT
 - No password
4. Turn on the RainDrop Sense instrument (located on the back of the instrument).
5. Wait 1 minute for the RainDrop Sense instrument to perform internal initialization. As the instrument initializes, the lights on the panel illuminate to indicate its status ([see Figure 3-3](#)).



Figure 3-3: RainDance LED Lights

6. Launch the Instrument Control Software (ICS) application as described in [Chapter 4](#).

[Table 3-3](#) lists the LED lights that indicate the status of the instrument.

Table 3-3: LED Lights Within the RainDance Logo

LED Name and Illumination Pattern	Meaning
Main Power LED (Solid)	Instrument is powered on.
All LEDs except Main Power are rotating on and off.	Instrument is operating normally.
All LEDs are flashing simultaneously.	Instrument has detected an error.
All LEDs are on.	Instrument is connected to the ICS.
All LEDs except Main Power are off.	Instrument is disconnected from the ICS.

Relocating RainDrop



Caution: The RainDrop Sense instrument weighs approximately 65 lbs (29 kg). To avoid injuries and damage to the instrument, do not move it without assistance from RainDance Technologies. If you want to move your instrument either within your laboratory or to another location, contact RainDance Technologies.

CHAPTER 4

Launching the Instrument Control Software (ICS)

This chapter covers the following topics:

Introduction	page 4-2
The Microsoft Windows 7 Login	page 4-2
Starting the ICS Application	page 4-2
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Introduction

The Instrument Control Software (ICS) application controls the operation of the RainDrop[®] Sense.

The Microsoft Windows 7 Login

The Instrument Control Workstation is configured with a single Microsoft Windows 7 Operating System login. Do not edit this account or add additional accounts. Failure to comply will result in ICS failures. The default login is an administrative account. The system differentiates between upper and lower case characters.

Note: Do not use the RainDance Support Windows Logon. This will result in ICS failure.

Starting the ICS Application

The startup sequence works as follows:

1. Power on each component of the RainDrop Sense in the following sequence:
 - Power on the IC Controller and log in to Windows.
 - Power on the RainDrop Sense. Wait one minute.
2. Click the ICS icon on your desktop:



Note: You can also start the ICS application by selecting Windows 7 Start Program Menu, and then selecting **Start > All Programs > RainDance Technologies > Launch ICS.exe**.

Note: The IC Workstation must be dedicated to ICS Operation. Use it only for RainDance designated application and software uses.

The Login window opens (see [Figure 4-1](#)).

Figure 4-1: Login Window

3. Enter your Login information in the appropriate fields. Enter the **Username** followed by the **Password** and then click **Login**. See [ICS Login Levels](#) for more information.

Note: Microsoft Windows 7 usernames are not case sensitive, but passwords are. In the ICS application, both usernames and passwords are case sensitive.

ICS Login Levels

The ICS application supports two levels of access to the ICS program: User and Administrator. The ICS application is configured with two default login IDs: one for User and one for Administrator. RainDance recommends that you change the default password on each of these accounts after initial use.

Table 4-1: ICS Default User and Administrator Login Information

Requirement or Specification	Description
User Login Username	User
User Login Password	user
Administrator Login User Name	Admin
Administrator Login Password	admin



Caution: After three failed attempts to login with the wrong password, the ICS application locks the account. You will not be able to login to your account. If this happens, you must contact someone in your facility with an Administrator account who can either unlock or reset your password. For details, see [“Resetting Password or Unlocking an Account”](#) on page 6-7.

Figure 4-2 shows the message for a failed login.

Invalid username, try again

Username

Password




Figure 4-2: Invalid Username Message

Changing the ICS Password

This section describes how to change an ICS password. RainDance recommends that you change the default User and Administrator passwords after initial use.

1. Select **Change Password** from the **Home** menu. The Change Password dialog opens (Figure 4-3).

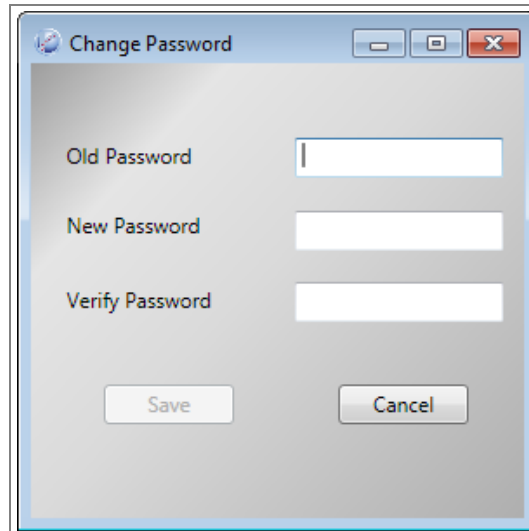


Figure 4-3: Change Password Window

2. Enter the old password in the **Old Password** field, the new password in the **New Password** field, and the new password again in the **Verify Password** field. Click **Save** when you are done to save the new password. Click **Cancel** to dismiss the dialog without saving your changes.

The ICS Account Types

Your account type defines the features you have access to (User and Administrator) within the ICS application.

Table 4-2: ICS Account Type

Feature	User	Administrator
Change Passwords	X	X
Export Instrument Files	X	X
View Runs	X	X
Maintenance Actions		X
Add New Users		X
Edit Users		X
Reset Passwords		X
Unlock Passwords		X
Start Runs	X	X
Stop Runs	X	X

The pull-down menu selections differ depending on your access rights; they are slightly different for a User and an Administrator account.

ICS Initialization

When you login to the instrument, the Initialization screen appears (see [Figure 4-4](#)).



Figure 4-4: Initialization Screen

From the Initialization screen, click **Start Initialization** to initialize the system. A progress bar shows the progress of the initialization.

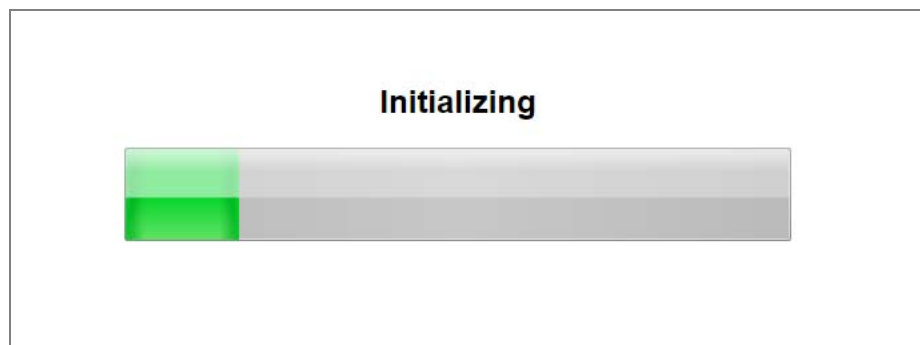


Figure 4-5: Initialization Progress Bar

If initialization fails, the following message appears:

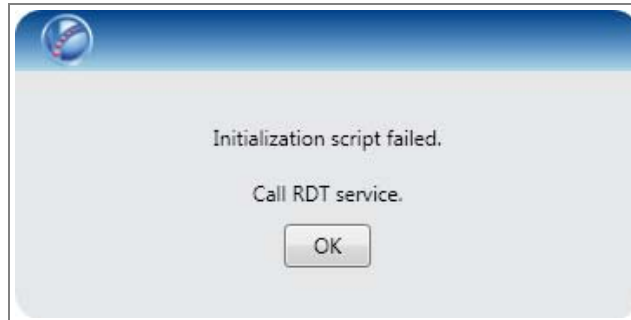


Figure 4-6: Initialization Failure Message

Click **OK** and contact RainDance Support. See [“RainDance Support” on page 1-3](#).

This error is often the result of starting ICS right after you turn on the instrument. RainDance recommends the following steps:

1. Exit the ICS.
2. Turn the instrument off.
3. Turn the instrument back on.
4. Wait 1 minute.
5. Start the ICS.

If the message appears again, restart the ICS.

If initialization is successful, the ICS home page is displayed (see [Figure 4-7](#)).

Note: All menu items are inactive until the initialization is finished.



Figure 4-7: Home Page

From the home page, you can Setup a Run (see [Chapter 5](#))

You can perform additional tasks by making selections from the drop down menus:




- View Runs (see [Chapter 6](#))
- Maintenance Actions (see [Chapter 7](#))
- Add New Users (Administrator only) (see [Chapter 6](#))
- Edit Users (Administrator only) (see [Chapter 6](#))

Status Indicators

A common set of status indicators appears throughout the system indicating the status of an item or process being performed. In general, the green check mark (✓) indicator means that everything is working as expected and you can proceed. The orange exclamation point (!) indicator is a warning that means that you can continue, but that some optional fields are blank. The red X indicator means there is a problem that needs to be resolved before you can continue.

Table 4-3 shows the status indicators and describes their meanings.

Table 4-3: Status Icons

Icon	Meaning
	Ready – If all icons are green check marks, the system is ready to start a run.
	Warning (Run Will Proceed) – If there is one or more orange exclamation point icons on the tabs, the run can start. These represent optional information.
	Error (Run Will Not Proceed) – If there is one or more red X icons on the tabs, there is an issue that may prevent the run from being performed.

Using Tabs in the ICS

There are two tabs in the ICS that appear after you click Setup a Run: Run Data and Run Info. To perform a run, you will need to complete some of the fields on each tab.

To ensure that all of the steps are completed correctly, RainDrop provides a System Status on the right side of the tabs to indicate the state of each of the required items. As you complete each step in the process the status icon for that step is updated. This section provides general information on what appears on the tabs and how to complete these processes.

Details on how to complete each of these processes is provided in [Chapter 5](#). Those descriptions assume you are familiar with how to use the tabs described here.

[Figure 4-8](#) shows an example of the Sense interface. The tabs required to complete the process are shown on the left side of the screen:

- Run Data
- Run Info

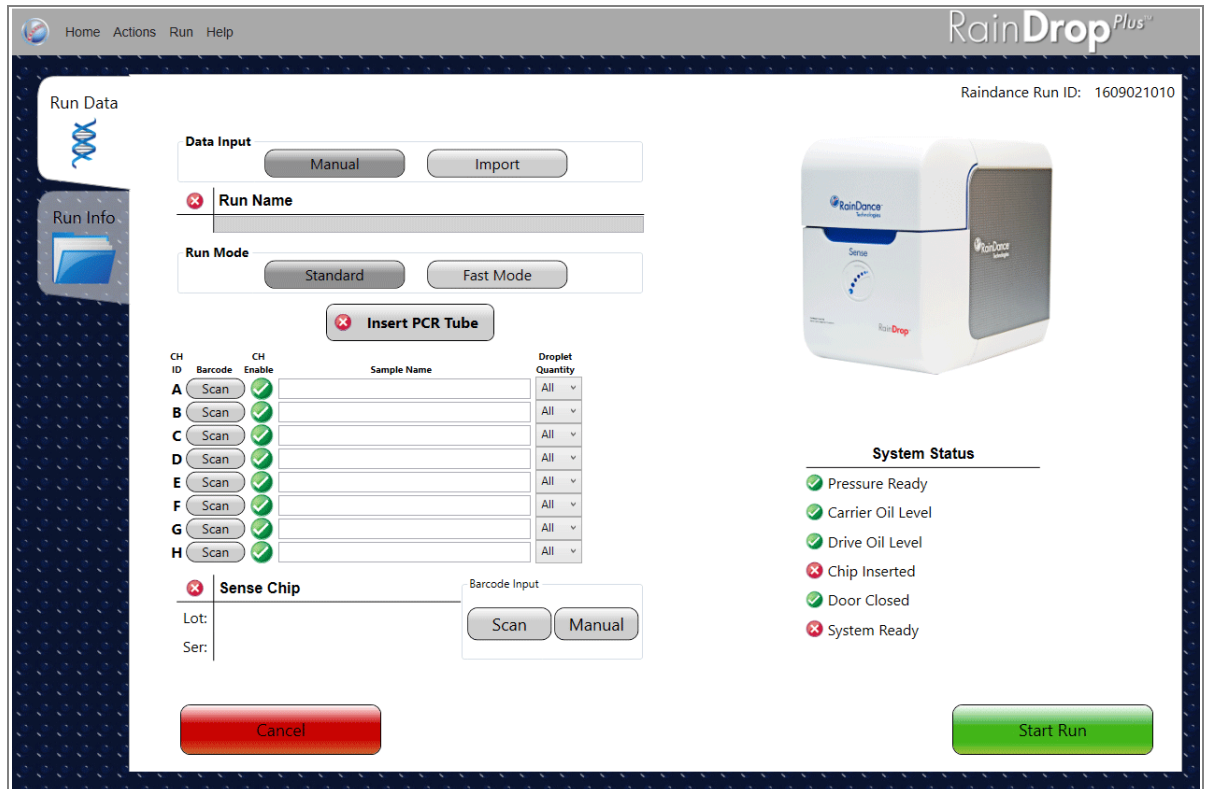


Figure 4-8: Sense Tabs

Only one tab is visible at a time. The selected (or active) tab has a white background and the inactive tab has a transparent background (Run Data is the active tab in Figure 4-8).

To prepare for a run on the Sense instrument, you must complete the following fields in the Sense ICS:

- **Run Data Tab:**
 - Run Name
 - Sense Chip barcode lot and serial number
 - At least one selected lane (indicated by a green check mark)
 - In addition, before you can proceed with the run on the Sense instrument, you must have clicked the **Insert PCR Tube** button to indicate that you have inserted the closed tube strip into the instrument.
 - Select Standard or Fast Mode detection.
- **Run Info Tab:**
 - Carrier Oil field and Drive Oil field and only if the instrument is out of one of those oils

As you complete each tab, the software updates the System Status for various items. If the green check mark is displayed, the item is ready to go. If an orange exclamation point is displayed, it means that optional fields are blank. If a red X is displayed, there are errors or missing data required for the run (see [Table 4-3](#)).

For a description of the meaning of the Status Indicators used on the tabs and throughout the system, see [“Status Indicators” on page 4-10](#).

Navigating Through the Tabs

You can switch back and forth between the two tabs at will. Click the tab name to move to a tab.

Canceling a Process

The Run Data tab has a red **Cancel** button in the lower left corner ([Figure 4-8](#)). If you click **Cancel** while a run is active, the application asks you to confirm that you want to cancel.

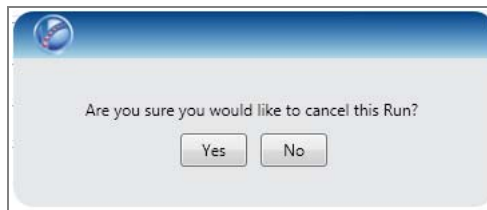


Figure 4-9: Cancel Confirmation

When you click **Yes**, the information you entered when you started the process is deleted, the run is canceled and you are returned to the RainDrop main screen.

Completing a Process

When you have completed each step to prepare for a run, review the System Status indicators. Ideally, all the status indicators will be green check marks, although you can still continue with orange exclamation points since they indicate only that optional fields are blank. The process cannot be started if there is even one red X (error indications) on any of the tabs.

When you are satisfied that the steps for the process are complete, click **Start Run** on the bottom right side of the **Run Data** tab. This starts the process on the RainDrop Sense instrument.

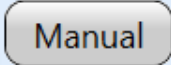
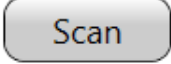


Figure 4-10: Start Run Button

Using Scan Buttons

The ICS allows you to scan barcodes to enter information into various text fields. There are two types of Scan buttons available in the system as shown in [Table 4-4](#).

Table 4-4: Scan Buttons

Button	Description	Use
	Manual Scan Button	The instrument requires that you manually enter a barcode.
	Scan Button	The system allows you to scan any type of barcode.

Clicking either type of scan button activates the barcode reader on the system and allows you to scan the barcode.

If you scan the wrong type of barcode, an error message appears. ICS will not accept an invalid barcode.

Alarms, Log, and Status Tabs

The Alarms, Log, and Status tabs are displayed on the bottom of the screen (see [Figure 4-11](#)). Each of these tabs is described below.



Figure 4-11: Example of Screen Showing Alarms, Log, and Status Tab at Bottom

The **Alarms** tab is displayed by default. Click **Log** or **Status** to display that tab.

- **Alarms Tab** – This tab lists instrument errors that exist in the system. If an error appears, the system is in a warning or error state. Different errors occur during the setup of the instrument. If an error does not clear when you close the door and click **Start Run**, check [“Troubleshooting” on page 7-8](#). If the issue is still not resolved, contact support@raindancetech.com for assistance.
- **Log Tab** – This tab is used for service purposes. It is used to check on the system automation.
- **Status Tab** – This tab is used for service purposes. It is used to determine the status of the instrument at different points during operation.

CHAPTER 5

Performing a Sense Run

This chapter covers the following topics:

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Gathering Supplies	page 5-2
Starting a Sense Run	page 5-3
Completing the ICS Setup	page 5-9
Checking the Status Indicators	page 5-9
Completing the Run Data Tab	page 5-11
Completing the Run Info Tab	page 5-14
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Introduction

Perform the operations described in this chapter on the RainDrop[®] Sense instrument. This procedure requires a number of consumables (available from RainDance Technologies[®] and other manufacturers).

Note: For the list of required consumables, see [“RainDrop Consumables and Equipment” on page A-1](#).

This chapter describes how to start a run on the RainDrop Sense instrument. Some of the steps involve preparing the physical components of the system and some of them take place within the RainDrop ICS.

For detailed information the ICS software, see [Chapter 4](#) and [Chapter 6](#).

Gathering Supplies

To start a run on the RainDrop Sense instrument, have the following equipment and supplies available:

- Gloves, nitrile or latex
- Sense Chip, P/N 30-06086
- Sense Chip Compression Plate, P/N 30-06423
- Drive Oil, shipped in syringes, P/N 30-07117
- PCR tube strip containing emulsion generated on the RainDance Source instrument and following thermal cycling
- For Standard Mode detection, standard PCR Tube Strip Caps (P/N 40-06087)
- For Fast Mode detection, High Speed Caps (P/N 40-08286)

Starting a Sense Run

This procedure assumes you have prepared your sample and that you have assembled all the necessary equipment and supplies. It also assumes that you have completed thermal cycling the sample. It shows you how to start a run on the RainDrop Sense instrument.

1. Launch the ICS software for the Sense instrument and log in.



Figure 5-1: Login Screen

2. Click **Start Initialization**.

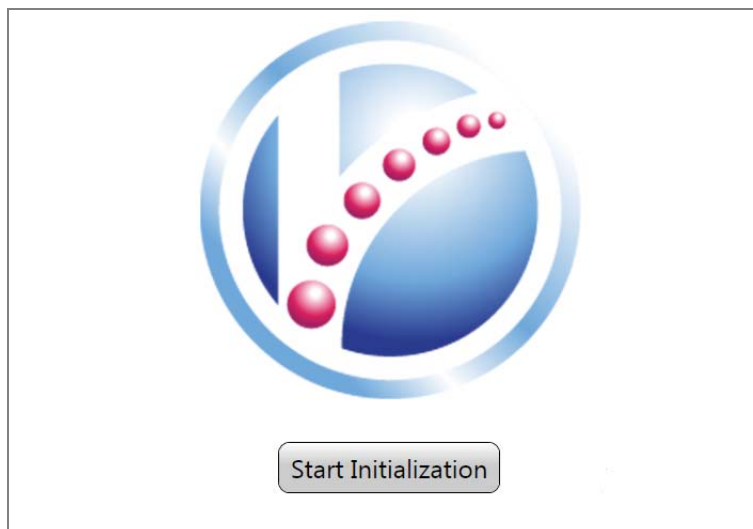


Figure 5-2: Initialization Screen

When you click **Start Initialization**, the system automatically prepares the instrument for normal operation. It sets valves and pressures and turns the laser in the barcode reader off. In addition, it homes the motion control subsystem. Initialization takes approximately four minutes.

Note: If initialization fails, the ICS returns to the **Initialization** screen after about fifteen minutes. Contact RainDance Support for assistance. See [“RainDance Support” on page 1-3](#).

3. Click Setup a Run.

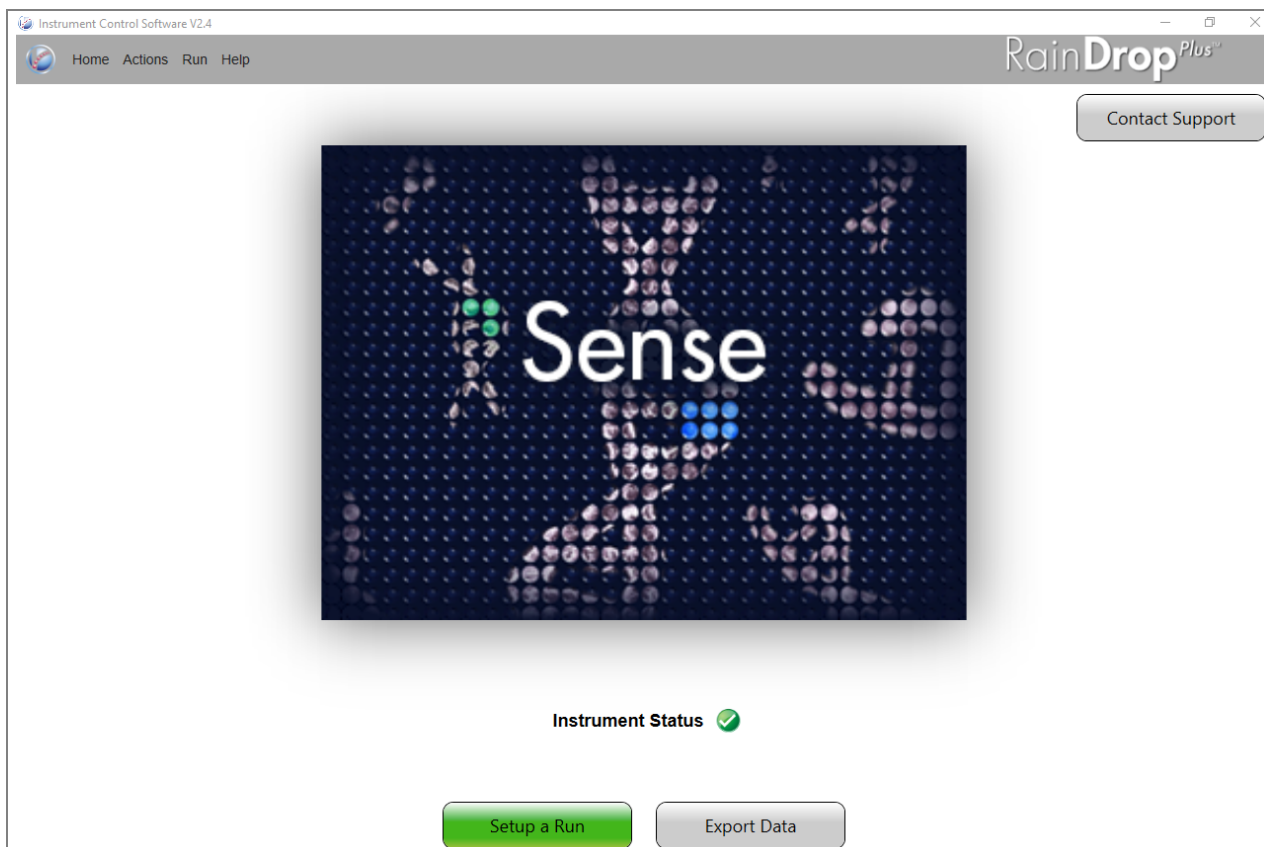


Figure 5-3: Instrument Status and Setup a Run Screen

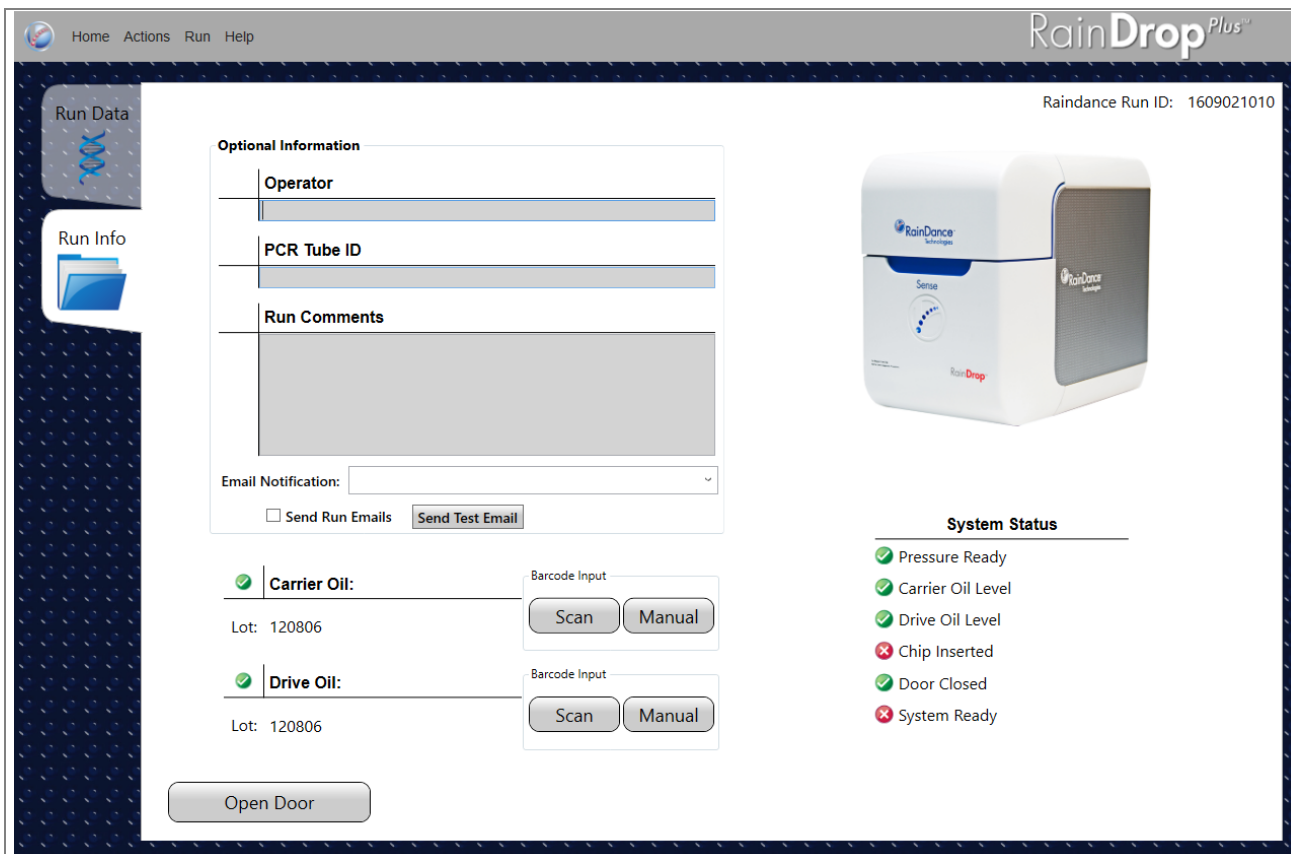
4. Select the **Run Info** tab.

Figure 5-4: Run Info Tab

5. On the **Run Info** tab, click **Open Door**. The door on the Sense instrument unlocks allowing you to lift it to the upright, open position.
6. If running in Fast Mode, use High Speed Caps. Following thermal cycling, carefully remove the domed caps (Axygen) and replace with High Speed Caps. Rock the caps back and forth to seat properly, then press into place. Ensure the cap is secured and the strip is tightly covered.

A properly covered PCR tube strip has:

- A flat cap all the way across
- Its tab oriented to the left (over number 1 on the tube strip)

An improperly covered PCR tube strip has:

- A bump or buckle
- A loosely fitting cap
- Its tab to right (over number 8 on the tube strip)

A bump in the cap

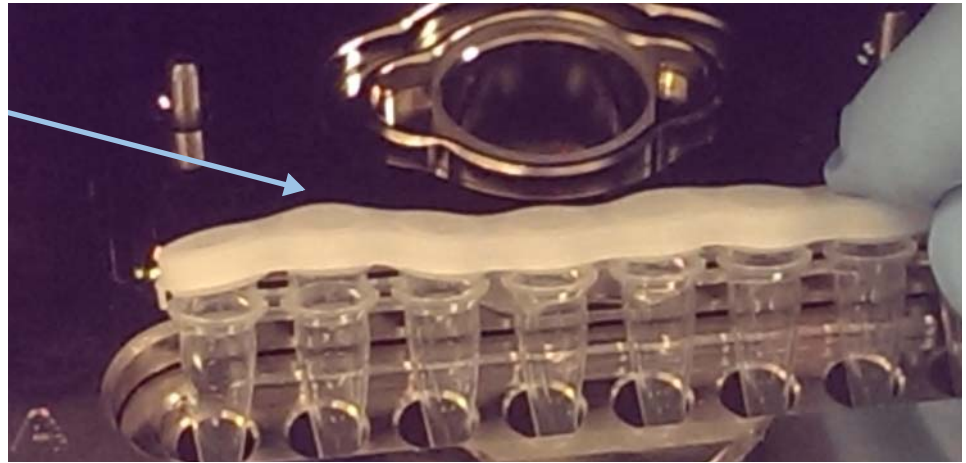


Figure 5-5: Improperly Covered PCR Tube Strip

7. Lift the door to the fully open position.



Figure 5-6: Sense Door in Fully Open Position

8. Insert a tube strip into the tube strip nest (see Figure 2-3). Orient the tabbed end to the left.

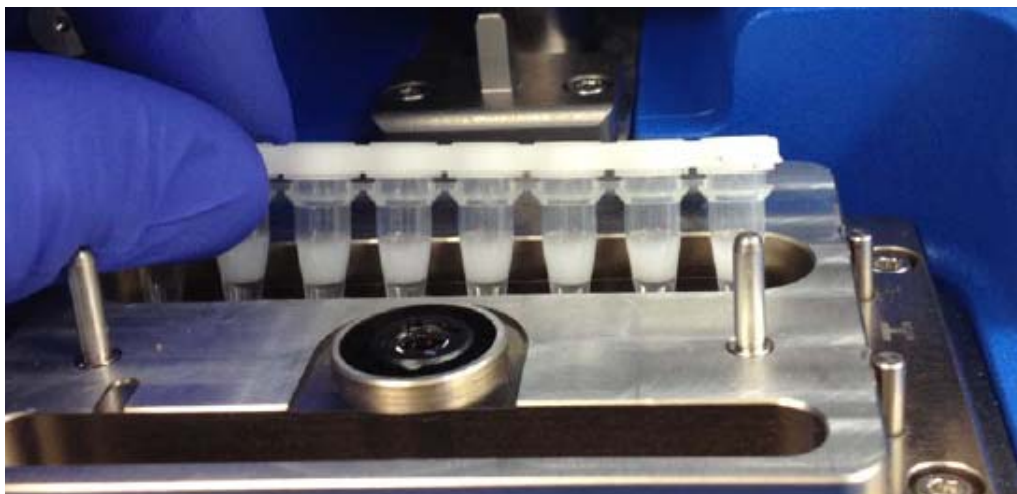


Figure 5-7: Insert a Tube Strip

9. Remove a Sense Chip from its packaging; for more information on the chip, see [see “RainDrop Sense Chip” on page 2-6](#). Handle the Sense Chip as follows:
 - With gloved hands, grasp the chip by its sides.
 - Do not touch the clear microfluidic chip and its droplet detection region of interest.
 - Save the bag the chip comes in for later disposal of the chip.
 - Do not touch the objective lens.
10. Scan the chip by clicking **Scan** in the ICS software. The red scanner light pulses for 10 seconds. Hold the Sense Chip in front of the barcode reader. If the scanner reads the barcode, it automatically fills in the barcode information. The ICS accepts a barcode in the 2D Data Matrix format, which allows up to 96 characters of text. You may hear a subtle beep tone from the Sense instrument.

If the scanner does not read the barcode, the ICS software displays a message and allows you to enter the barcode manually. To do so, click the **Manual** button and enter the barcode numbers from the label of the chip. In manual format, the ICS accepts 99 characters of text.
11. Insert the chip into the Sense instrument. Orient the Sense Chip over the alignment pins and ensure that the pins are coming through the alignment holes on the chip. Do not insert it at an angle. The instrument is designed so that the Sense Chip punctures the caps of the tube strip. Do not apply pressure to the chip after inserting it. It is important that the instrument is able to make a seal and then puncture the tube caps. The Sense instrument will not allow you to proceed until the chip is oriented properly.



Figure 5-8: Inserting a Sense Chip

12. Locate the Chip Compression Plate; for more information on the plate, see [see “RainDrop Sense Chip Compression Plate” on page 2-7.](#)
13. Place the Chip Compression Plate over the Sense chip as shown in [Figure 5-9.](#) When the plate is properly positioned, its RainDance logo should be facing you, the plate should be flat, and it should not be movable left to right or front to back.



Figure 5-9: Placing the Chip Compression Plate

After you insert the Chip Compression Plate, you are done setting up the physical components.

14. Close the door on the Sense instrument.

Completing the ICS Setup

Before starting a run on the Sense instrument, you must complete a number of setup steps. The steps ensure that the instrument is ready for operation and provide data about the run. They include:

- Check the status of various components.
- Complete the Run Data.
- Complete the Run Info.

Checking the Status Indicators

Status indicators tell you about the readiness of the instrument.

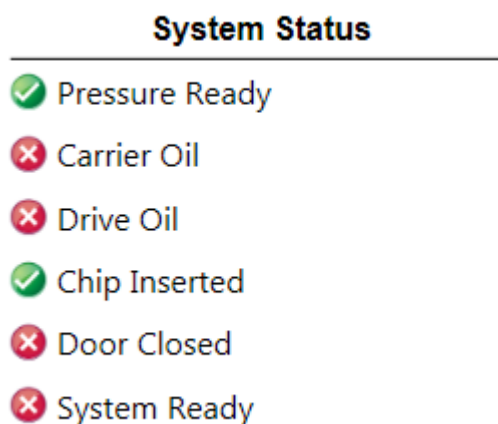


Figure 5-10: System Statuses

Observe the status indicators in the software.

Table 5-1: System Status Indicators

Indicator	Meaning
Pressure Ready	Indicates the status of the instrument gas pressure. When the pressure is sufficient, the ready indicator is displayed.
Carrier Oil	Indicates the status of the carrier oil reservoir. When there is sufficient oil to complete a run, the ready indicator is displayed. A valid carrier oil lot number is required for the green check mark to be displayed.
Drive Oil	Indicates the status of the drive oil reservoir. When there is sufficient oil to complete a run, the ready indicator is displayed. A valid drive oil lot number is required for the green check mark to be displayed.

Table 5-1: System Status Indicators

Chip Inserted	Indicates the presence of the Sense Chip. When the Sense Chip is present and inserted properly, the ready indicator is displayed. Note: You must scan the chip prior to use; otherwise, the instrument will not detect it. If you have scanned the chip before inserting it and it is still not detected, wiggle the chip and try again.
Door Closed	Indicates the status of the instrument door. When the door is properly closed, the ready indicator is displayed.
System Ready	Indicates the overall status of the instrument. When all the requirements of the instrument are present and ready for a run, the ready indicator is displayed.

In addition to satisfying the Status Indicators, in order to start a run you must also have:

- Scanned or input the barcode number from a Sense Chip
- Clicked **Insert Tube Strip** to affirm that you have inserted the tube strip

Completing the Run Data Tab

The **Run Data** tab opens after you click **Start Run** on the startup screen and contains the details about the contents of the run. You can enter this information manually or you can import it from a file you saved on the Source instrument.

Home Actions Run Help

RainDrop^{Plus}

Raindance Run ID: 1609021010

Run Data

Run Info

Data Input

Manual Import

Run Name

Run Mode

Standard Fast Mode

Insert PCR Tube

CH ID	Barcode	CH Enable	Sample Name	Droplet Quantity
A	Scan	✓		All
B	Scan	✓		All
C	Scan	✓		All
D	Scan	✓		All
E	Scan	✓		All
F	Scan	✓		All
G	Scan	✓		All
H	Scan	✓		All

Sense Chip

Barcode Input

Lot: Ser:

Scan Manual

System Status

- ✓ Pressure Ready
- ✓ Carrier Oil Level
- ✓ Drive Oil Level
- ✗ Chip Inserted
- ✓ Door Closed
- ✗ System Ready

Cancel Start Run

Figure 5-11: Run Data Tab

Only the following fields on the **Run Data** tab are required for the run to proceed:

- Run Name
- Sense Chip barcode lot and serial number
- At least one selected lane (indicated by a green check mark)

Your lab procedures determine how much of the optional information is necessary for your specific situation.

In addition, before you can proceed with the run, you must have clicked the **Insert PCR Tube** button to indicate that you have inserted the closed tube strip into the instrument.

Table 5-2: Run Data Fields

Field Name	Meaning
Run Name	The name of the run. Run name is required and can contain up to 20 characters. This is required.
Lanes A - H	The identifiers for each tube (or lane) on the chip. These fields are not required. The lane letter identifiers are hard-coded and cannot be edited.
Lane Description	The text description that you enter. This is not required.
Sense Chip Lot & Serial Number	The identifiers for each Sense Chip. This information is automatically completed when you scan the chip and is required.

Run Filenames

When the ICS saves data at the end of a run, it uses the information you enter in the fields in the above table to name the file. It creates one file per lane in a folder named for the Run ID, as follows:

The filename for one lane of a run looks like this:

```
<Run ID>-<Lane Letter>-<Lane Description>.fcs  
For example: 1302181535-A-ExampleDescription.fcs
```

The Run ID is the numeric run number from the upper right corner of the ICS screen. It appears on both the Run Data tab and the Run Info tab. See [“Handling Data” on page 5-19](#) for more information.

Entering the Run Data

Enter the run data as follows:

1. Type the name of the run into the **Run Name** field.
2. All lanes are selected by default. Deselect any lanes you are not using. At least one lane must be selected in order for the run to proceed.
3. If necessary, enter lane information in one of the following ways:
 - Type the name for the lane manually. When you enter the name manually, the field limits entry to 99 characters.

- Scan the barcode from a printout. To do so, place the printout in front of the barcode reader and click **Scan** next to the correct lane. When you enter the name using the scanner, the field limits entry to 96 characters.
 - Import the lane information as described in [see “Completing the Run Tabs Using the Import Function” on page 5-15.](#)
4. Select the number of droplets you want from the Droplet drop-down.
 5. Click **Insert PCR Tube** to confirm that you have inserted the tube strip into the instrument.

Note: The Sense Chip field should already display the information you scanned earlier in [see “Starting a Sense Run” on page 5-3.](#)

Completing the Run Info Tab

The fields on the Run Info tab contain information about the run. The only fields on this tab that are required are the Carrier Oil and Drive Oil fields and only if the instrument is out of one of these types of oil.

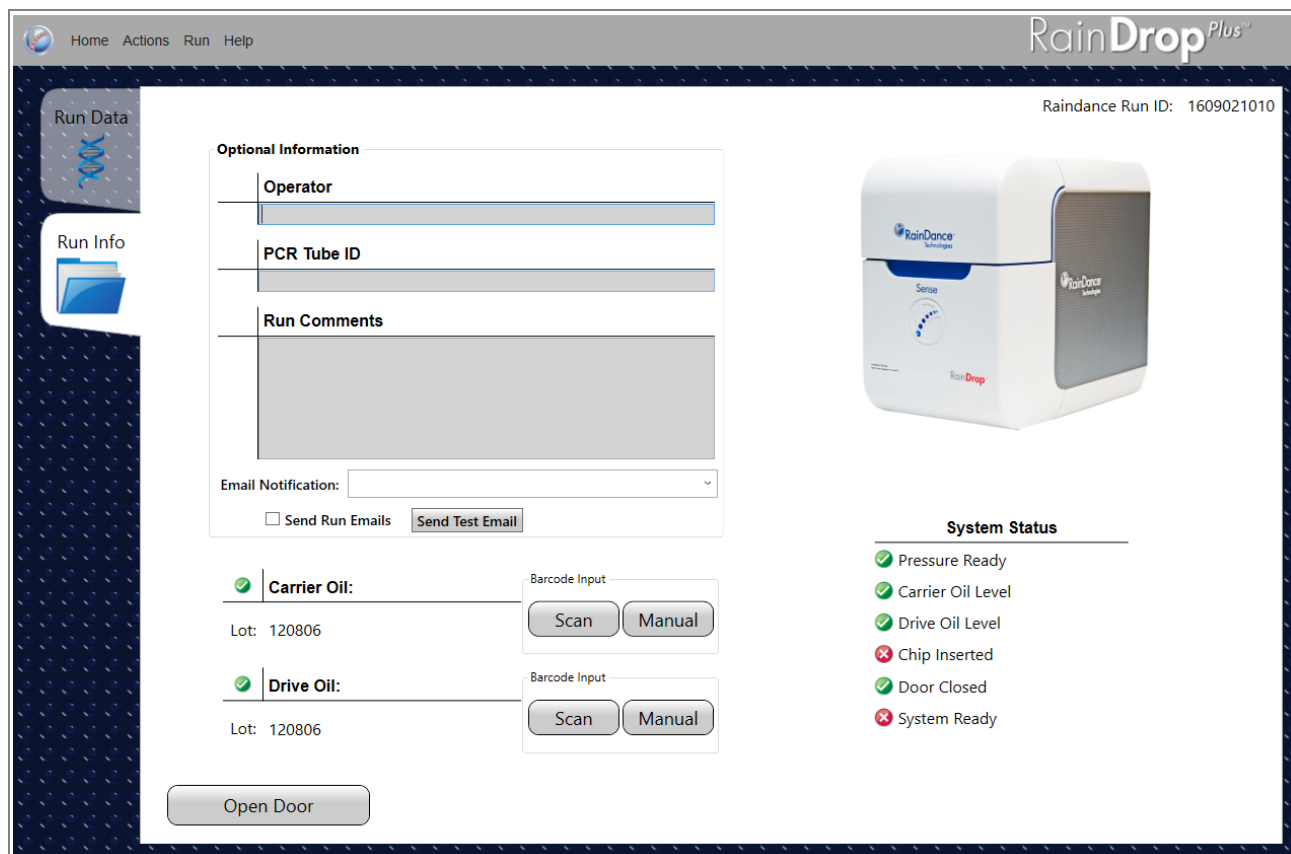


Figure 5-12: Run Info Tab

Your lab procedures determine how much of the information is necessary for your specific situation. Enter the run information as follows:

Table 5-3: Run Info Fields

Field Name	Meaning
Operator	The name of the person performing the run.
PCR Tube ID	The identifier of the sample to be run.
Run Comments	Any detailed descriptive information you want stored with the run information.

Completing the Run Tabs Using the Import Function

To complete the run tabs using the import function:

1. Click **Import** at the top of the **Run Data** tab. The import works only with XML files generated by the Source instrument. The page displays a list of runs.
2. Locate the file to import and click on it.
3. ICS imports only the following fields:
 - On the Run Data tab:
 - Run Name
 - Lane information
 - On the Run Info tab:
 - Operator
 - PCR Tube ID
 - Run Comments
4. Complete any other of the optional fields, as needed.

Using Email Notification

The RainDrop Sense instrument is located in a lab space which may be a distance from your desk or usual work area. Email Notification allows you to receive messages when a run is finished, so that you do not have to continually check the instrument. Select **Send Run Emails** on the Run Info tab. If email addresses have been entered by an Administrator, they appear in the Email Notification field. You can leave these addresses as is, edit them, or add to them. Notifications are sent to those addresses.

Note: Email notification does not support text messaging.

Setting Up Email Notification (Administrator)

Setup Email Notification as needed. You do not have to edit these settings for each run. You can establish email settings and then not change them unless you need to change who is notified at the end of a run.

To enter email addresses:

1. Select **Setup Email** from the **Actions** menu. The **Email** dialog opens.
2. Enter email addresses in the **Email Notification** field, separated by semi-colons. These email addresses will appear on the Run Info tab by default.
3. Select **Send Run Emails**, if you want this to be the default action.

4. Click **Save** to save the new addresses. Click **Close** to dismiss the dialog.

Email Messages

Email messages contain the following information:

Table 5-4: Email Message Data

Field Name	What is reported
RainDance ID	The serial number of the instrument
Run Name	The name the user entered in the Run Name field prior to beginning the run. If the user does not enter a Run Name, this lists a name provided by the RainDrop Sense instrument.
Description	The comments entered by the user at run time, if any
Start Time	The date and time the run was started
End Time	The date and time the run ended
Sample Info	For each sample, it lists: Lane, Sample Description, Droplets, CV (coefficient of variance), Read Length, and Status
Total Samples	The number of samples attempted
Samples Successful	The number of samples that successfully ran without errors
Samples Failed	The number of samples that generated an error, including any samples not processed because the run was stopped because of a prior/fatal error
Errors	All errors encountered during the run

Performing the Run

After you have entered the required run data, you are ready to begin the run.

1. Click the **Start Run** button. The screen displays information about the Sense run in progress as shown in the following image.

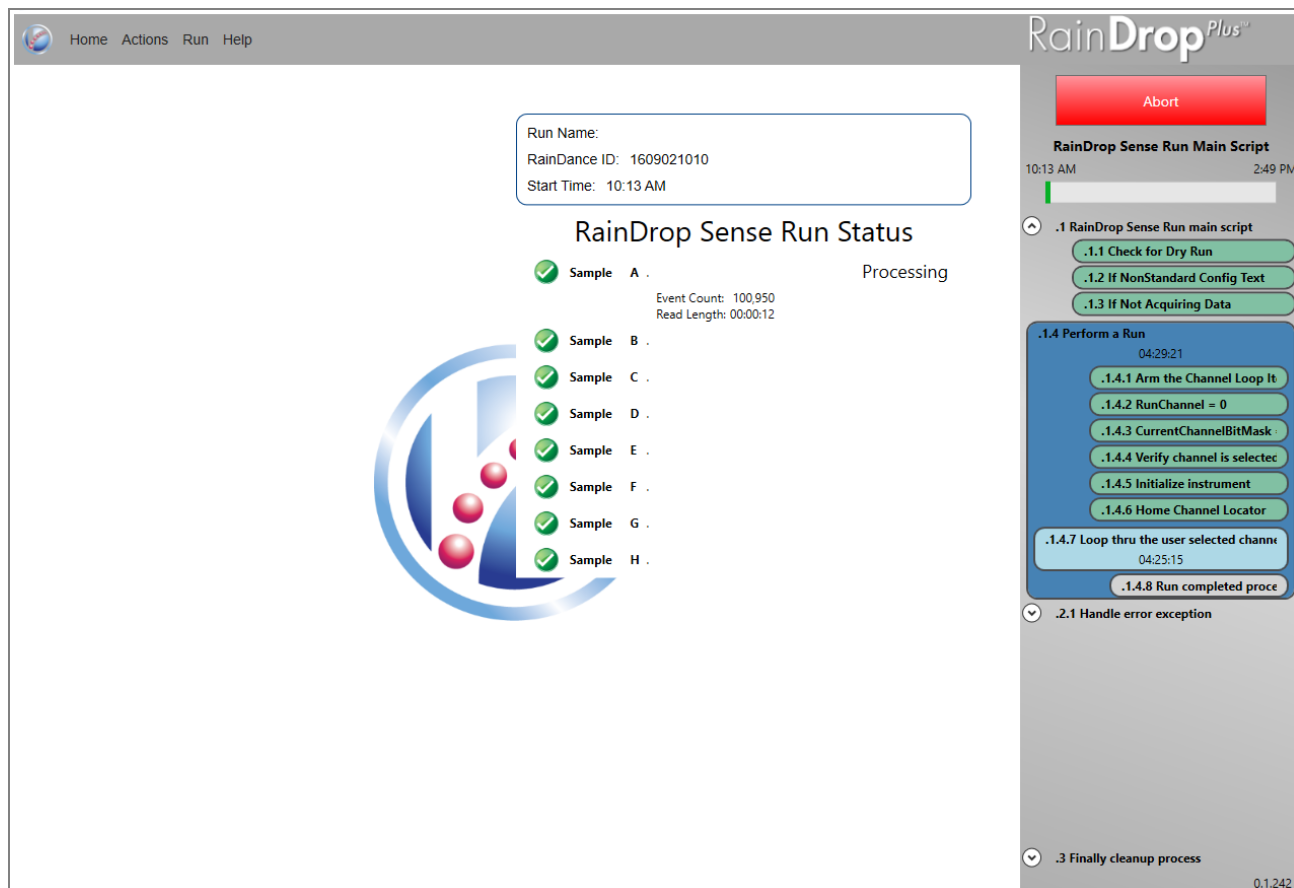


Figure 5-13: Sense Run Screen

The center of the screen displays information about which sample is being processed. The right side of the screen displays information about the progress of the run.

2. When the sample is done, the door unlocks automatically.
3. Lift the door to its full open position.
4. To minimize the potential for contaminating the lab environment with the amplicon, return the used chip to the bag it came in and discard it in a solid waste disposal container.

The ICS displays the Run Complete screen.

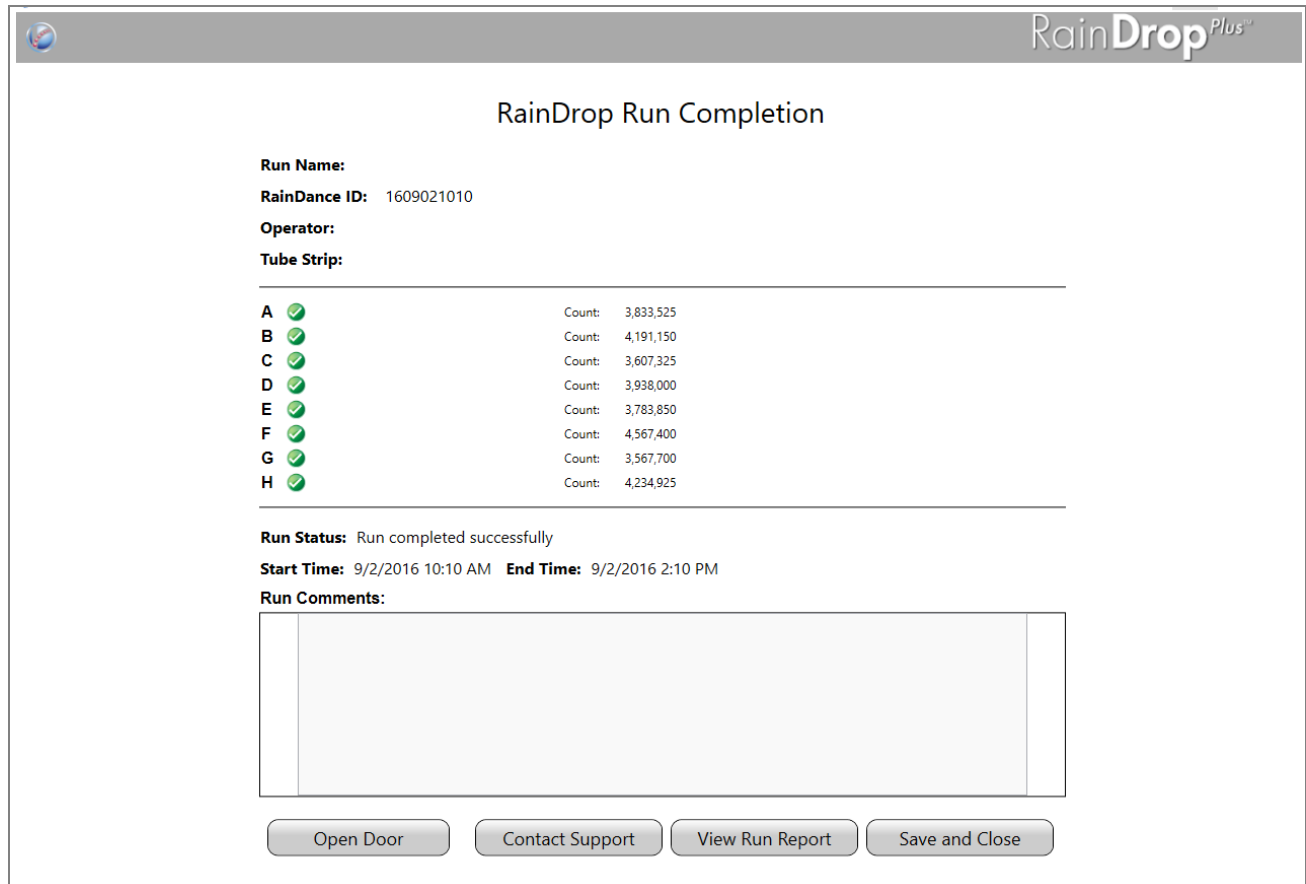


Figure 5-14: Sense Run Complete Screen

5. Click **View Run Report** to review the run data.
6. Click **Save and Close**. ICS saves the data from the run in a file in FCS format, which can be read by the RainDrop Analyst software.

Note: As stated above, the instrument door unlocks after the run is complete. If you accidentally close the door and still need access, click **Open Door** to open it.

Canceling a Run

If you want to stop a run after you have started filling out the Run Data tab, but *before* clicking Start Run, click **Cancel**. This brings you back to the Instrument Status and Setup a Run Screen (see [Figure 5-3](#)) and blanks out any data you have entered for this run.

If you want to stop a run *after* clicking Start Run, click the **Abort** button. This brings you to the Run Completion screen.

Handling Data

The data from Sense runs is collected on the hard drive of the ICS Workstation. Files are stored in folders on the D drive named for their runs within a RainDance folder as follows:

```
D:\RainDance\RunLogs\<<RunID>
```

The <RunID> is displayed in the upper right corner of the ICS screen on both the Run Data tab and the Run Info tab.

The Run ID is built on the date and time as follows: YYMMDDHHMM. In the above image, the number 1302181529 represents 3:29 pm on February 18, 2013. The Sense ICS creates the folder when you click **Start Run**.

Upon completing the run, the Sense ICS creates one FCS file per lane within the Run ID folder. The filename for one lane of a run looks like this:

```
<RunID>-<Lane Letter>-<Lane Description>.fcs  
For example: 1302181529-A-ExampleDescription.fcs
```

The lane letter and lane description come from data you enter on the **Run Data** tab. See ["Completing the Run Data Tab" on page 5-11](#) for more information.

Exporting Data

The Export Data function allows you to search for previous runs and to save that run data to either the same or a new location. This allows you to move your FCS files from one location to another to make them available for use by other applications such as analysis software. To export data:

1. Launch the ICS as you normally do. See [“Starting the ICS Application” on page 4-2](#).
2. Click **Export Data**. The Export Data screen opens.

Search for previous runs and select run for export.

Start Date: 2/4/2013 12:00:00 AM End Date: 2/18/2013 11:59:59 PM Update List

Date/Time	Run Name	# Samples	Operator	RainDance ID
10:13:54 AM		6		1302071012
2:21:16 PM	EGFR858	8		1302071420

Selected Run: EGFR858 (1302071420)

Export Directory: D:\RainDance Browse

Export Close

Figure 5-15: Export Data Screen

3. Use the **Start Date** and **End Date** fields to specify a range for the data. Click **Update List** to tell ICS to display only data that fall between the dates you enter.
4. Select one or more runs by clicking on them. Use **Shift+Click** to select contiguous runs or **Ctrl+Click** to select non-contiguous runs.
5. Type the name of an **Export Directory** or click **Browse** to locate a folder for the export.
6. Click **Export**. When the export is done, ICS displays a message. Click **OK** to dismiss the message.

Moving Data Files

The data files created by the Sense instrument from just one run can easily exceed several gigabytes. You can use the Export process described above to locate your FCS files in a location that is accessible by your analysis software. In addition, RainDance offers the following instructions for moving your files when disk space becomes an issue on the ICS Workstation. Keep in mind that the network configuration at your location is unique. You may need to seek assistance from your in-house IT department to learn their recommendations.

Because RainDrop files are large, RainDance has several recommendations for managing your data files.

- Never attempt to move files while a run is in process.
- Move files at a time when network activity is at a minimum so that file transfer is as efficient as possible.
- Consider developing a file management protocol. The disk drive on the ICS is large, but not infinite. You may need to save files to an external storage device and remove some from the internal hard drive from time to time. Consult with your internal IT department to develop a strategy for managing large amounts of data.

To copy files using a flash drive:

1. Insert the flash drive into a USB port on the ICS Workstation.
2. Launch Windows Explorer and navigate to the D drive.
3. Open the **RainDance** folder on the D drive.
4. Open the **Run** folder whose data you want to copy.
5. Click the **Type** column to sort the data files by type. The only files you need to move to the computer running RainDrop Analyst II are the FCS files. They should appear at the top of the sorted list.
6. Select only the FCS files. Click and drag them to the flash drive icon within Windows Explorer.
7. When Windows Explorer is done copying the files to the flash drive, bring the drive to the computer running RainDrop Analyst.

To copy files over a network:

1. Launch Windows Explorer and navigate to the D drive.

2. Open the **RainDance** folder on the D drive.
3. Open the **Run** folder whose data you want to copy.
4. Click the **Type** column to sort the data files by type. The only files you need to move to the computer running RainDrop Analyst II are the FCS files. They should appear at the top of the sorted list.
5. Select only the FCS files. Right-click on the collection of files.
6. From the pop-up menu, select **Copy**.
7. Navigate to the network drive where you want to copy the files.
8. Locate the folder where you want to move the FCS files. Right-click and from the pop-up menu, select **Paste**.

CHAPTER 6

Managing the System

This chapter covers the following topics:

Introduction	page 6-2
Managing Users	page 6-2
Adding a New User	page 6-3
Editing a User	page 6-5
Deleting a User	page 6-7
Resetting Password or Unlocking an Account	page 6-7
Viewing Past Runs	page 6-8
Viewing Runs	page 6-8

Introduction

You must have a username and password before you can login to the ICS application. There are two types of user accounts: Administrator and User. [Chapter 4](#) provides detailed information on logins and account types.

Important: To manage users, you must be logged in with Administrator privileges.

This chapter describes several software management functions. These include:

- Managing Users
- Viewing Past Runs

Managing Users

The ICS software lets you manage user accounts from the Actions menu (see [Figure 6-1](#)).

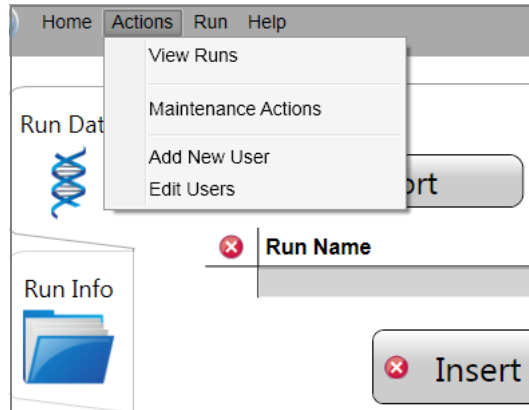
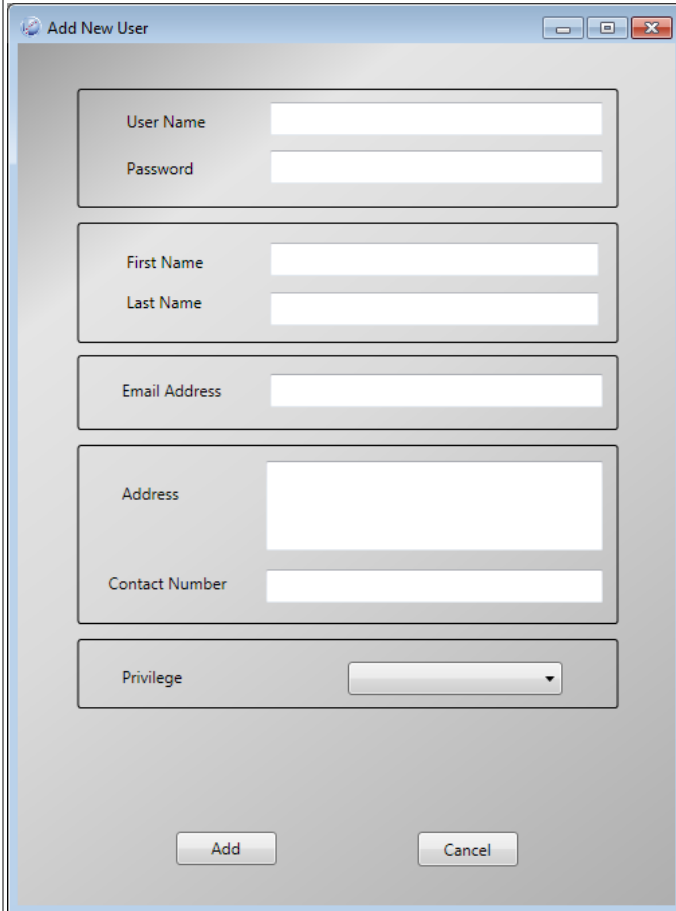


Figure 6-1: Actions Menu

Adding a New User

To add a new user:

1. From the **Actions** menu, select **Add New User** (see [Figure 6-1](#)).
The **Add New User** dialog opens (see [Figure 6-2](#)).



The screenshot shows a dialog box titled "Add New User". It contains the following fields and controls:

- User Name** and **Password** input fields.
- First Name** and **Last Name** input fields.
- Email Address** input field.
- Address** and **Contact Number** input fields.
- Privilege** dropdown menu.
- Add** and **Cancel** buttons at the bottom.

Figure 6-2: Add New User Dialog

2. Enter the information for the new user as required (see [Table 6-1](#)) and click **Add** to save it or **Cancel** to dismiss the dialog without saving your entries.

Table 6-1: Add New User Dialog

Field or Table Element	Description
User Name	Specifies the name you use to login. Case sensitive. Required.
Password	Specifies the password; any alphanumeric combination is acceptable. Case sensitive. Required.
First Name, Last Name	Specifies the user's first and last names. Required.
Email Address	Specifies the user's email address. Required.
Address	Specifies the user's address. Required.
Contact Number	Specifies the user's phone number. Required.
Privilege	Specifies the user's Privilege level (Admin or User) selected from a drop-down menu. Required.
Add, Cancel buttons	Adds the user information, or cancels the process. If added successfully, a confirmation window displays.

Editing a User

The Edit Users dialog allows a user with administrator privileges to edit the information for an existing user or remove an existing user from the database. An administrator can also add a new user from this dialog.

1. From the **Actions** menu, select **Edit Users** (see [Figure 6-1](#)). The Edit Users dialog opens (see [Figure 6-3](#)).

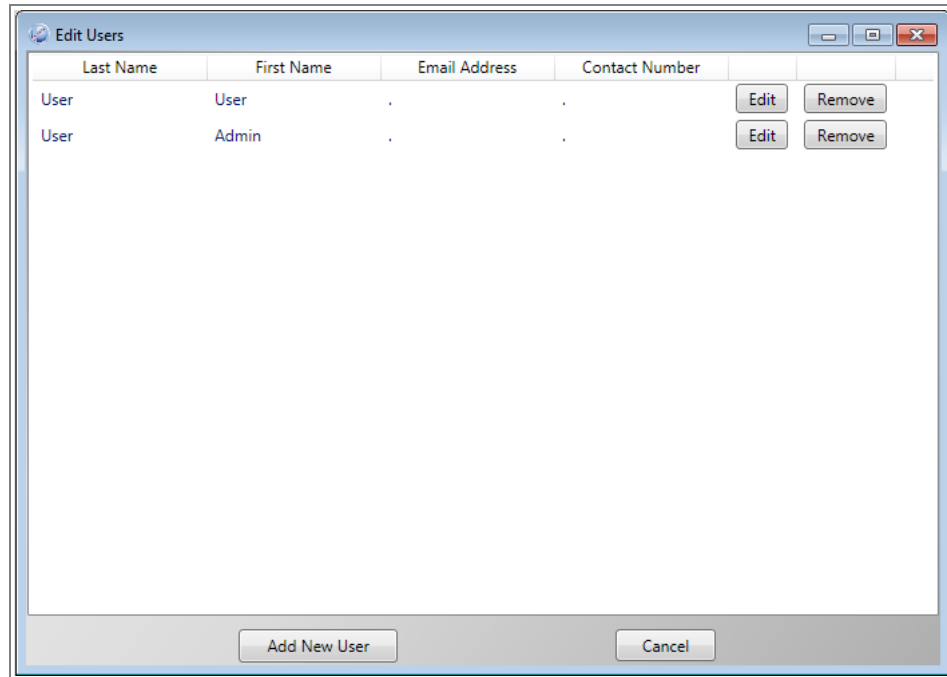


Figure 6-3: Edit Users Dialog Box

2. To edit the data for an existing user, click **Edit** in the row for that user. The **Edit User Information** dialog opens for the selected user (see [Figure 6-4](#)).

The screenshot shows a dialog box titled "Edit User" with a standard Windows-style title bar. The dialog is organized into several sections:

- User Name:** A text input field containing "User". Below it are two checkboxes: "Reset Password" and "Unlock Account", both of which are unchecked.
- First Name:** A text input field containing "User".
- Last Name:** A text input field containing "User".
- Email Address:** A text input field containing a single period ".".
- Address:** A large text input field containing a single period ".".
- Contact Number:** A text input field containing a single period ".".
- Privilege:** A text input field containing "User" and a dropdown menu also showing "User".
- Account Status:** A text input field containing "Active".
- Date Created:** A text input field containing "4/29/2010 8:16:04 AM".

At the bottom of the dialog are two buttons: "Save" and "Cancel".

Figure 6-4: Edit User Dialog Box

3. Editing user information is essentially the same as adding new user information. Edit the user information as required (see [Table 6-1](#)) and then click **Save**. Click **Cancel** button to dismiss the dialog without saving any changes.

Deleting a User

To delete a user:

1. Select **Edit Users** from the **Actions** menu (see [Figure 6-1](#)). The **Edit Users** dialog opens as in [Figure 6-3](#).
2. Click **Remove** in the same row as the user to be deleted. The system asks you to confirm that you want to delete the user. Click **Yes** to confirm or **No** to cancel the deletion.

Resetting Password or Unlocking an Account

After three failed attempts to login with the wrong password, the ICS application locks the account and you are not able to login. If this happens, you must contact someone in your facility with Administrator privileges who can either reset or unlock your password.

To reset an account:

1. Select the **Reset Password** check box in the **Edit User** dialog (see [Figure 6-4](#)). This changes the user's password to the **default password, abc123**.
2. To save the changes to the account, click **Save**. The application displays a message confirming that the changes have been saved.

To unlock an account:

1. Select the **Unlock Account** check box in the **Edit User** dialog (see [Figure 6-4](#)). This allows the user to login again with his/her original password.
2. To save the changes to the account, click **Save**. The application displays a message confirming that the changes have been saved.

Viewing Past Runs

This section describes how to view previous runs. It also describes how to generate and view reports and how to export run results.

Viewing Runs

Certain run parameters are saved by the ICS application. The ICS application lets you search for and view past run parameters by entering a specific Start Date and an End Date (inclusive) on which the run was completed.

To view a run report:

1. Select **View Runs** from the **Actions** menu (see [Figure 6-1](#)). The **View Run Report** window opens (see [Figure 6-5](#)).



Figure 6-5: View Run Report Window

2. Enter a date range to locate the run of interest and click **Search**. The default start and end dates are today's date, so if you want to see the run you just completed, you can just click **Search** without changing the date.

All runs that match the selected date range appear in a list below the white title bar.

3. Clicking or selecting a row in the list of runs opens the report for that run. This may take 2-5 seconds.

RainDance Technologies		
RainDrop Sense Run Report		
Run Name:	Test Build 2.1.2.9357	Operator:
RainDance ID:	1307031700	Tube Strip:
<hr/>		
A Passed		7,288,200 events
B Passed		7,217,725 events
C Passed		7,325,625 events
D Passed		6,911,875 events
E Passed		6,685,175 events
F Passed		6,446,775 events
G Passed		6,561,575 events
H Passed		7,915,100 events
<hr/>		
Start Time:	7/3/2013 5:00:34 PM	End Time: 7/3/2013 10:18:17 PM
Chip Lot:	12133710-0007-130508	Chip Serial Number: 0032
Carrier Oil Lot:	130112	Drive Oil Lot: 130423
Run Comments:		

Figure 6-6: Example of a Sense Run Report

Reports are divided into three sections. The first section contains:

- Run Name
- Operator
- RainDance ID (machine name)
- Tube Strip

The second section contains a summary of how the run performed. It includes:

- Channel Pass/Fail
- Sample Information

The last section lists the following:

- Start Time
- End Time
- Chip Lot
- Chip Serial Number
- Carrier Oil Lot
- Drive Oil Lot
- Run Comments

4. From the menu bar (see [Figure 6-7](#)) you can print the report or export it to various formats, such as a PDF file or an Excel file.



Figure 6-7: Report Menu

5. When you are done viewing the report, close it by clicking on the **Close** box in the upper right corner of the screen. You return to the **View Runs** window so you can view additional reports if necessary.

CHAPTER 7

Support, Customer Maintenance, and Troubleshooting

This chapter covers the following topics:

RainDance Support	page 7-2
RainDance Planned Maintenance	page 7-2
Customer Maintenance	page 7-2
Restarting the IC Workstation	page 7-2
Cleaning the RainDrop Sense	page 7-2
Refilling the Oil Reservoir	page 7-3
Service and Diagnostic Requirements	page 7-6
Powering Off the System	page 7-6
Powering On or Restarting the System	page 7-6
Restoring the System After a Failure	page 7-6
Support Agreement Information	page 7-6
Moving the System	page 7-7
Storing the System	page 7-7
Reinstalling/Updating ICS Application	page 7-7
Error Messages	page 7-7
Troubleshooting	page 7-8

Maintenance refers to non-technical procedures you must perform to keep the system working properly. *Service* refers to tasks that are intended to be performed only by a qualified RainDance-authorized service representative. The RainDrop[®] System comprises two instruments: RainDance Source and RainDrop Sense. The sections in this chapter describe them separately only when each instrument requires different maintenance or service.

RainDance Support

- RainDance Technologies[®] provides full support for their products.
- Some troubleshooting information is provided within this chapter (see “[Troubleshooting](#)” on page 7-8.). Additional self-service technical and troubleshooting information is available at www.raindancetech.com/support.
- To request technical assistance from RainDance support personnel, send an email to support@raindancetech.com.

RainDance Planned Maintenance

A Planned Maintenance (PM) schedule and tasks are designed to be performed by RainDance Support personnel. A number of PMs are conducted as part of the service contract agreement. Contact RainDance Support for a recommended PM schedule.

Customer Maintenance

This section lists the steps you should follow for proper maintenance of the RainDrop Sense system.

Restarting the IC Workstation

Good operating practice for any Windows operating system includes restarting the operating system on a weekly basis. To perform a shutdown, select the **Start** icon the lower left corner of the screen and select **Shut down**. When the system has completed its power off routine, reboot the Windows 7 operating system on the IC Workstation as described in “[Powering On or Restarting the System](#)” on page 7-6.

Cleaning the RainDrop Sense

There is no extraordinary routine maintenance required for the RainDrop instruments. Clean the chip dock of spills and residues as follows:

- Always use protective gloves.
- Use only a soft, lint-free towel to clean the chip dock; wet with either isopropanol or HFE-7100.
- For DNA decontamination, RainDance recommends using HFE-7100 or DNA-ExitusPlus.

- Keep cleaning fluids away from the objective lens.



Caution: Use caution while cleaning the chip dock, specifically in the area of the lenses of each instrument.

- DO NOT submerge the system in liquid or pour or spray liquid onto the system.
- Clean the IC workstation monitor window as described in its manufacturer's documentation.
- All technical maintenance or service must be performed by RainDance Support personnel.

Refilling the Oil Reservoir

The oil reservoir on the RainDrop Sense instrument must be refilled from time to time. You will know that it is time to refill the reservoir when the oil light on the front of the instrument glows red.



Caution: Never refill an oil reservoir unless the red light is illuminated. Failure to comply can result in an internal overflow and potential damage to the instrument.

Carrier oil reservoir
fill port

Carrier oil low
indicator light

Drive oil reservoir
fill port

Drive oil low
indicator light

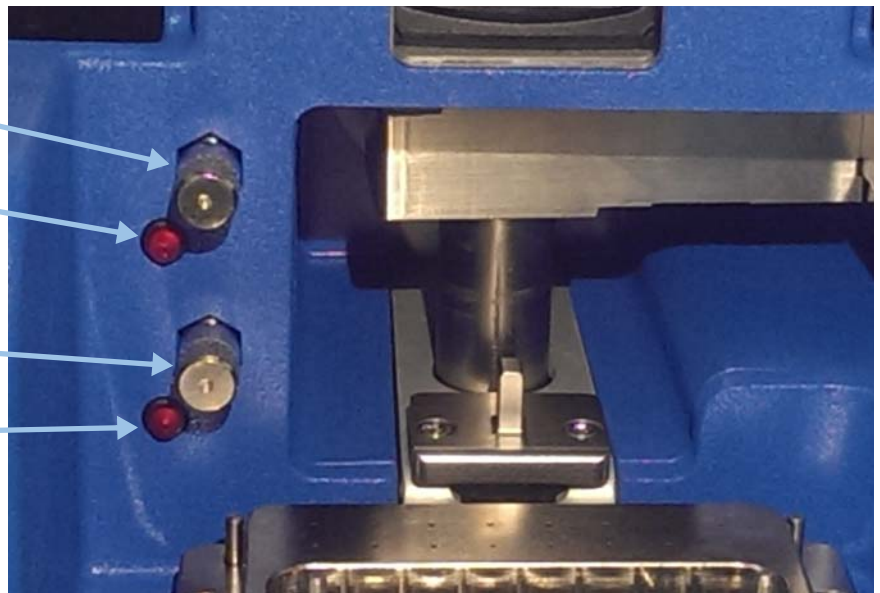


Figure 7-1: RainDrop Sense Oil Reservoir Fill Ports

To refill the oil reservoir:

1. Obtain a pre-measured syringe of oil (P/N 30-07117).
2. Scan the barcode on the oil syringe. Refer to [“Scanning Barcodes” on page 2-5](#) for more information on how to scan.
3. Remove the cap from the tip of the syringe.
4. Place a gloved finger over the end of the syringe to ensure that it does not squirt oil while you are moving it.



Figure 7-2: Gloved Finger over Syringe

5. Unscrew the cap that covers the oil reservoir fill port and place it in a safe place.

6. Place the tip of the syringe over the fill port and begin to turn the entire syringe clockwise. The syringe screws onto the fill port to create a tight fit.



Figure 7-3: Syringe Connected to the Fill Port

7. Continue to turn the syringe until it fits snugly.



Caution: Do not overtighten the syringe onto the fill port.

8. Press the end of the syringe and inject its contents until the syringe is empty.
9. Unscrew the empty syringe and discard it in a lab-approved solid waste stream. When you are done refilling the reservoir, the oil low indicator light turns off.
10. Replace the cover on the fill port. Do not overtighten.

Service and Diagnostic Requirements

- The system checks its status at start-up automatically. The ICS application prevents runs when it detects a system failure or not ready condition.
- The hardware is designed to facilitate field replacement of subsystems and/or subsystem components as required.
- There are no user serviceable parts inside the RainDrop instrument. For safety reasons, those components have limited access.
- All technical maintenance or service is provided by RainDance Support.

Powering Off the System

Follow this sequence to turn the system off:

1. Exit the ICS application. Wait 10 seconds.
2. Power off the instrument by turning off the switch on the rear of the instrument.
3. Power off the IC Workstation by selecting the **Start** icon and then selecting **Shut down**.
4. Press the **Power** button on the monitor to turn it off.

Powering On or Restarting the System

Refer to “[Starting the ICS Application](#)” on page 4-2.

Restoring the System After a Failure

In most cases, the RainDrop instruments automatically reset after a failure. You can start subsequent runs without manual intervention.

Note: Never start another run until the root cause of the failure is identified and resolved.

Support Agreement Information

For detailed information on Support Agreements, go to www.raindancetech.com/support and click on the **Support Agreement** link.

Moving the System



Warning: The RainDrop Sense instrument weighs approximately 65 lbs (29 kg). To avoid injury and damage to the instruments, do not move them without assistance from RainDance Technologies.

To move the instrument to another location, contact RainDance Support.

Storing the System

- For short term storage (less than 30 days) of the instruments:
 - Remove any RainDrop Chips and PCR tube strips from the instruments.
 - Leave the Carrier Oil and Drive Oil from the last run in the instruments.
 - Close the door.
 - Power off the instruments.
- For long term storage of the instruments contact RainDance Support.

Reinstalling/Updating ICS Application

The ICS application is installed and tested during installation. You are not required to perform any installation or maintenance of ICS. Any new version of ICS that is user-installable includes instructions for installation. If the ICS application files lose their integrity for any reason (for example, they get accidentally moved or deleted), you can re-install the ICS application after contacting RainDance.

Error Messages

For current error messages and actions, refer to www.raindancetech.com/support.

Troubleshooting

The following table lists some problems that you may observe while working with the RainDrop Sense instrument. The table is divided into three columns as follows:

- Observed Problem
- Possible Cause
- Corrective Actions and Comments

Table 7-1: Troubleshooting the RainDrop Sense Instrument

Observed Problem	Possible Cause	Corrective Actions and Comments
<p>There is a red X on the Instrument Status and Setup a Run screen.</p>	<p>The gas pressure is not connected or is not adequate.</p>	<p>Ensure that the gas pressure cable is connected properly and that the gas pressure is sufficient. Click Start Run. A dialog box opens listing the reason(s) the run cannot start. If you continue to have problems, check the Alarms Tab first; see Alarms, Log, and Status Tabs on page 4-14. Then contact RainDance Support. See RainDance Support on page 1-3.</p>
<p>The ready indicator next to the Chip Inserted System Status displays a red X even after I insert a chip.</p>	<p>The instrument does not detect a properly inserted chip. The chip is not inserted properly, may not be seated well, or is not aligned with the chip alignment pins.</p>	<p>The chip sensor will not detect the chip if there is an error in the barcode name. If you have entered the barcode try scanning the chip, then placing it in the instrument. Shut down the software and instrument, then restart the instrument, wait 1 minute, and restart the software and scan the barcode again, then place it in the instrument. If the chip is still not recognized, try another chip and contact RainDance support. See RainDance Support on page 1-3.</p>

Table 7-1: Troubleshooting the RainDrop Sense Instrument

<p>The ICS does not display droplets during a run or displays an unstable pattern of droplets.</p>	<p>You have under-filled one or more sample wells. This means that there is less than 25 μL in the problematic well. The lane will fail.</p>	<p>The sample in that lane is lost. Deselect the corresponding lane on the Sense run.</p>
<p>One of the lanes fails, displays erratic droplet formation, or uneven droplet spacing.</p>	<p>Sample may be improperly sheared, may have too much DNA, or may have contaminants such as fibers that interfere with droplet formation. Refer to the <i>RainDrop Assay dPCR Guidelines</i> for information in preparing the sample.</p>	<p>The sample is lost. Make sure the DNA is properly sheared. Try diluting the sample and generating droplets. Filter materials through a 0.2 micron filter to remove debris and contaminants.</p>
<p>There is a white sheen on the tube strip when I remove it from the instrument and there is liquid in the tube strip nest and the emulsion is not in the tube as expected.</p>	<p>Inspect the tube strip to see if there is a hole in the bottom of one of the tubes. This is a rare, but known, manufacturing defect and the sample may have leaked out of the tube.</p> <p>The run may time out after 50 minutes or it may finish properly.</p>	<p>Visually inspect tube strips before using them.</p> <p>The sample is lost in tube strip nest and is unrecoverable. In addition, you must contact RainDance Support (see RainDance Support on page 1-3) to clean the instrument to ensure that the tube strip sensor is working properly.</p>
<p>The ICS displays unstable droplet generation, a lower than expected number of droplets, or the lane fails.</p>	<p>The sample was improperly pipetted and either is mixed with too much air or is a bead on the side wall of the sample input well.</p>	<p>Sample may be lost. When you pipette sample, ensure that you place the tip at the bottom of the well to avoid leaving the sample on the wall of the sample input well.</p>

Table 7-1: Troubleshooting the RainDrop Sense Instrument

<p>One of the lanes does not display any droplets. In addition, the run may stop prematurely if emulsion is not detected.</p>	<p>Emulsion is not detected because the emulsion sensor is tripped. This may be due to one of the following: --the tube strip is dirty --the tube strip contains writing in the conical area --the tube strip was partially filled prior to your using it --there is a static problem that pulls the emulsion down the side of the tube --tube strip is not installed properly</p>	<p>The sample is lost. In some cases, you may be able to recover the sample. Contact RainDance Support (see RainDance Support on page 1-3) for more information.</p>
<p>The ICS displays a message telling me that the chip I inserted has been used before.</p>	<p>You are attempting to run a chip that has already been run.</p>	<p>You must use a new chip for each run.</p>
<p>The ICS displays a message telling me that the barcode for samples is invalid.</p>	<p>You are attempting to use a barcode format (for samples) that is not supported by the barcode reader.</p>	<p>You must use a supported barcode format or manually enter the barcode information for samples. The ICS accepts a barcode in the 2D Data Matrix format, which allows up to 96 characters of text.</p>
<p>I am not receiving emails, even though I have entered an email address.</p>	<p>You have entered an invalid email address. The system does not detect undelivered emails.</p> <p>There may be a connectivity issue with your network.</p>	<p>If you are not receiving email messages at the end of the run, check the email addresses you have entered for accuracy.</p> <p>Check with your IT department to be sure you are properly connected.</p> <p>When setting up a run, ensure that the Send Run Emails check box is selected.</p> <p>Click the Send Test Email button to see if you have solved the problem.</p>

Table 7-1: Troubleshooting the RainDrop Sense Instrument

I tried to fill the oil reservoir before the oil light came on.	It is possible to overfill the oil reservoir and to spill oil into internal areas of the instrument. You may not notice it, even when you have done this.	For this reason, do not refill the oil reservoir until the oil light comes on.
There is dirt, debris, or oil residue on the instrument.	The instrument has not been properly cleaned.	Clean the instrument according to the instructions in Cleaning the RainDrop Sense on page 7-2 .
<p>The sample has evaporated. The sample volume in one or more wells is reduced or totally gone. The droplet count is lower than expected.</p> <p>The tube strip or the tube strip cap was deformed during thermal cycling and resulted in a leak into the PCR tube strip nest of the Sense.</p>	The tube strip cap was not seated properly or the tube strip was not covered within 30 minutes of Source run completion.	<p>Ensure that the tube strip cap is seated properly. It should be even along the entire length of the tube strip. An extra cap is supplied in each kit; if you find one that does not fit properly, discard it and use another.</p> <p>Do not reuse tube strip caps. Caps are pierced by the Sense instrument as part of the process. Pierced tube strip caps allow evaporation and introduce the potential for cross contamination.</p> <p>Clean the PCR tube strip nest on the Sense instrument. Use the recommended cleaning protocol. See Cleaning the RainDrop Sense on page 7-2.</p>
One lane or the entire run has failed.	There may be dirt, debris, scratches, or smudges on the imaging region of interest on the Sense Chip.	<p>Handle chip as recommended in Handling the Sense Chip on page 2-6.</p> <p>Keep the chip dock clean as described in Cleaning the RainDrop Sense on page 7-2.</p>

Table 7-1: Troubleshooting the RainDrop Sense Instrument

<p>The Alarms tab or Log tab displays an error message. The ICS displays an error message in a dialog box.</p>	<p>A known error has occurred. The ICS may suggest a way for you to deal with the error.</p>	<p>Follow the instructions provided by the error message. If no instructions are provided, verify that the instrument has power and verify that all cable connections are secure. See Connecting RainDrop Sense and Instrument Controller on page 3-3. Contact RainDance Support if the problem is not resolved. See RainDance Support on page 1-3.</p>
<p>The ready indicator next to the Chip Inserted System Status displays a red X even after I insert a chip.</p>	<p>The instrument does not detect a properly inserted chip. The chip is not inserted properly, may not be seated well, or is not aligned with the chip alignment pins.</p>	<p>The chip sensor will not detect the chip if there is an error in the barcode name. If you have entered the barcode try scanning the chip then placing it in the instrument. Shut down the software and instrument, then restart the instrument, wait 1 minute, and restart the software and scan the barcode again, then place it in the instrument. If the chip is still not recognized, try another chip and contact RainDance support. See RainDance Support on page 1-3.</p>
<p>There is a large leak from the PCR tube.</p>	<p>You are using an incorrect PCR tube strip, meaning that it is not an Axygen tube strip.</p>	<p>The sample is lost.</p>
<p>The ICS reports a minimal number of droplets being read. In addition, you may receive an email notification that includes failure information.</p>	<p>There is no sample in one or more lanes. The assay may be too dim for non-amplified droplets to be detected.</p>	<p>The lane or lanes will fail or timeout after 30 minutes. Multiplex your assay or reorder with a different quencher.</p>

Table 7-1: Troubleshooting the RainDrop Sense Instrument

Some of the expected lanes were not processed. The sample remains in the Sense Chip sample wells.	You did not select the lanes on the Run Data tab of the ICS (see Completing the Run Info Tab on page 5-14) that represent the lanes on the Sense Chip that contain sample.	The sample may be recoverable, but you cannot reuse the chip. Contact RainDance Support (see RainDance Support on page 1-3) for help recovering the sample. In addition, there is a risk of contaminating the work area with amplicon. See Cleaning the RainDrop Sense on page 7-2 .
The data does not appear where I expect it. The expected results appear in another lane or are not detectable at all.	You may have confused the lane name with the physical position of the sample in the tube strip.	The run proceeds as normal. Make a note of which samples have been switched and address this issue in downstream analysis. Use a multichannel pipettor in the future to reduce the risk of mixing up samples.
The Sense ICS displays a lower or higher than expected droplet count.	You have selected a droplet count, but the Sense Instrument is not delivering what you requested.	The run proceeds as normal. It is not always possible to achieve an exact number of droplets. The system is designed to produce a number of droplets higher than what you select to account for filtering losses.
The ICS displays a message telling me that the chip I inserted has been used before.	You are attempting to run a chip that has already been run.	You must use a new chip for each run.
The ICS displays a message telling me that the barcode for samples is invalid.	You are attempting to use a barcode format (for samples) that is not supported by the barcode reader.	You must use a supported barcode format or manually enter the barcode information for samples. The ICS accepts a barcode in the 2D Data Matrix format, which allows up to 96 characters of text.

Table 7-1: Troubleshooting the RainDrop Sense Instrument

<p>I am not receiving emails, even though I have entered an email address.</p>	<p>You have entered an invalid email address. The system does not detect undelivered emails.</p> <p>There may be a connectivity issue with your network.</p>	<p>If you are not receiving email messages at the end of the run, check the email addresses you have entered for accuracy.</p> <p>Check with your IT department to be sure you are properly connected.</p> <p>When setting up a run, ensure that the Send Run Emails check box is selected.</p> <p>Click the Send Test Email button to see if you have solved the problem.</p>
<p>I am not receiving a text message at the end of a run even though I have entered my phone number into the email field.</p>	<p>The RainDrop Sense instrument does not support text messages.</p>	<p>You must use a valid email address for email notification.</p>
<p>I tried to fill the oil reservoir before the oil light came on.</p>	<p>It is possible to overfill the oil reservoir and to spill oil into internal areas of the instrument. You may not notice it, even when you have done this.</p>	<p>For this reason, do not refill the oil reservoir until the oil light comes on.</p>
<p>There is dirt, debris, or oil residue on the instrument.</p>	<p>The instrument has not been properly cleaned.</p>	<p>Clean the instrument according to the instructions in Cleaning the RainDrop Sense on page 7-2.</p>

Table 7-1: Troubleshooting the RainDrop Sense Instrument

<p>The sample has evaporated. The sample volume in one or more wells is reduced or totally gone. The droplet count is lower than expected.</p> <p>The tube strip or the tube strip cap was deformed during thermal cycling and resulted in a leak into the PCR tube strip nest of the Sense.</p>	<p>The tube strip cap was not seated properly or the tube strip was not covered within 30 minutes of Source run completion.</p>	<p>Ensure that the tube strip cap is seated properly. It should be even along the entire length of the tube strip. An extra cap is supplied in each kit; if you find one that does not fit properly, discard it and use another.</p> <p>Do not reuse tube strip caps. Caps are pierced by the Sense instrument as part of the process. Pierced tube strip caps allow evaporation and introduce the potential for cross contamination.</p> <p>Clean the PCR tube strip nest on the Sense instrument. Use the recommended cleaning protocol. See Cleaning the RainDrop Sense on page 7-2.</p>
<p>The Alarms tab or Log tab displays an error message. The ICS displays an error message in a dialog box.</p>	<p>A known error has occurred. The ICS may suggest a way for you to deal with the error.</p>	<p>Follow the instructions provided by the error message. If no instructions are provided, verify that the instrument has power and verify that all cable connections are secure. See Connecting RainDrop Sense and Instrument Controller on page 3-3. Contact RainDance Support if the problem is not resolved. See RainDance Support on page 1-3.</p>

CHAPTER 8

Waste Management

This chapter covers the following topics:

Introduction and Disclaimer	page 8-2
Classification of Waste	page 8-2
Anticipated Typical Waste Stream Composition	page 8-3
Recommended Waste Stream Disposal	page 8-4

Introduction and Disclaimer

The waste stream from the RainDrop® platform includes fluorocarbon oil-emulsified aqueous samples and wetted solid materials (PCR tubes, chips, etc.). The following guidelines are intended to assist the customer in communicating with Environmental Health and Safety staff and/or commercial waste disposal service providers. The following guidelines are not definitive. The Customer is solely responsible for complying with applicable laws and regulations with respect to waste management and disposal.

Important: The Customer must dispose of all waste in accordance with all applicable environmental laws and regulations.

Classification of Waste

- Depending on applicable environmental laws and regulations, the waste stream may be treated as hazardous **chemical** waste.
- Depending on applicable environmental laws and regulations, the waste stream may **not** be classified as **mixed** hazardous waste.

Important: If the DNA sample is classified as infectious by the institution that operates the RainDrop, it is **not** considered the normal waste stream. Refer to the institution's EH&S regulations.

- The customer may be required to certify to the chemical waste disposal service provider that the normal waste stream is non-infectious.
- Consult applicable laws and regulations to determine if fluorinated materials present in the waste stream are regulated.
- Customers should consult with local authorities to determine specific state and local requirements.

Anticipated Typical Waste Stream Composition

During normal workflow operation, for every 96 samples run on the RainDrop Sense system, approximately 570 grams (20.11 oz) of waste is generated. The following approximate composition of the waste stream is expected if all consumables and waste reagents are combined into a single waste stream:

Table 8-1: Solids Appearing in Waste Stream

Material	Sense Waste Amount (wt %)
Fluorocarbon oil (from Carrier and Drive Oil)	15.3
Fluorosurfactant (from Carrier and Drive Oil)	0.4
Water	0.8
DNA, polymerase, DNTPs, buffer salts	Trace
Commercial polymers (for example, poly(etheretherketone), polyethylene, polycarbonate, polypropylene, COC)	83.4

Figure 8-1 and Figure 8-2 show images of solid waste.



Figure 8-1: Syringe

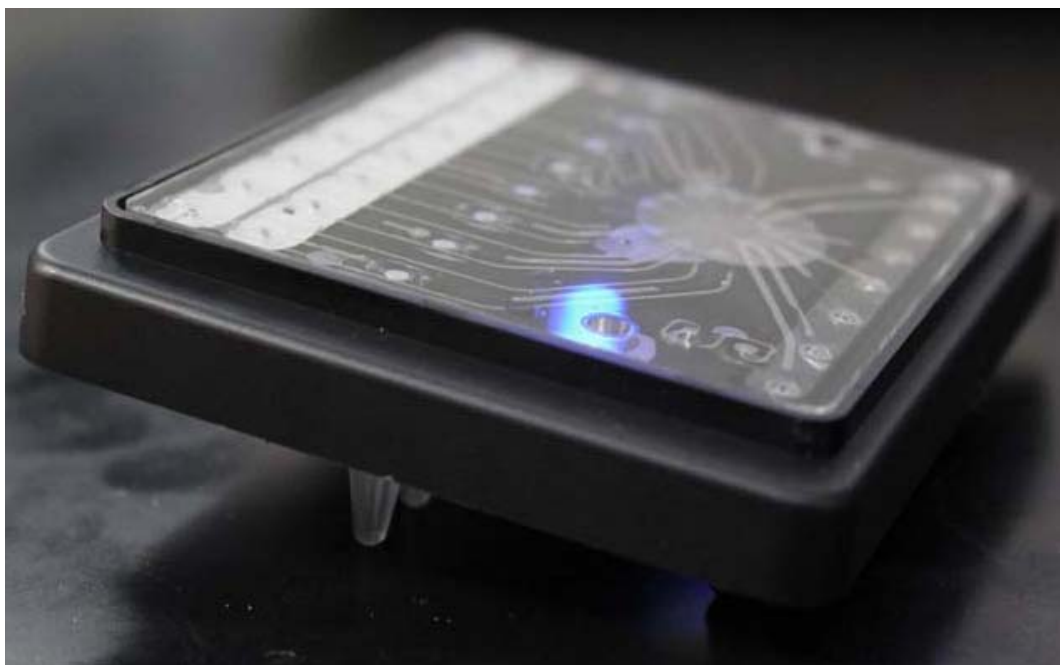


Figure 8-2: Spent Sense Chip with Tube Strip Attached

Recommended Waste Stream Disposal

- Depending on applicable environmental laws and regulations, the waste stream, which contains fluorinated chemicals, should be incinerated in an industrial or commercial facility in the presence of a combustible material.
- Combustion products will include hydrofluoric acid.
- The incineration facility must be capable of handling halogenated – particularly fluorinated – materials.
- Depending on applicable environmental laws and regulations, the non-infectious aqueous samples and the solid materials (chips, tube strips, and caps, etc.) do not need to be separated from the fluorinated oil.
- Depending on applicable environmental laws and regulations, all components can be collected in a single container, and the container can be incinerated as miscellaneous lab debris.
- Customers should consult with local authorities to determine specific state and local requirements.

CHAPTER 9

Customer Care Information

This chapter covers the following topics:

General Care Information	page 9-2
Consumables	page 9-2

General Care Information

RainDance's Customer Care group can help you with:

- Placing an order
- Expediting a shipment
- Contacting the proper personnel
- Inquiring about other special sales requests

To contact RainDance Customer Care, go to www.raindancetech.com/support or email customercare@raindancetech.com.

Contact RainDance Customer Care to:

- Order a RainDrop[®] System or other RainDance products
- Track a shipment
- Determine availability
- Check on installation
- Return products
- Issue a complaint or compliment
- Request training classes

Consumables

Order consumables from RainDance or your RainDance-authorized distributor. Use only RainDance products or RainDance-approved products in your RainDrop Sense instrument. RainDance shall not be liable for damage to or malfunction of the system that it deems was caused by the use of unauthorized materials.

CHAPTER 10

Regulatory Information

This chapter covers the following topics:

Sense Instrument Declaration of Conformity

page 10-2

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

Sense Instrument Declaration of Conformity

	Declaration of Conformity	No.: DOC-1005
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Product: RainDrop Sense	Manufacturer: RainDance Technologies 749 Middlesex Turnpike Billerica, MA, 01821 Telephone No. (978) 495-3300 http://www.raindancetechnologies.com/
Model No.: 20-04402	
Serial No.: 401X – and greater	

The undersigned hereby declares, on behalf of RainDance Technologies of Billerica, MA 01821, that the above-referenced product, to which this declaration relates, is in conformity with the provisions of:


Directives/Requirements:

Document No.	Title	Edition/DOI
2004/108/EC	OFFICIAL JOURNAL OF THE EUROPEAN COMMUNITIES COUNCIL DIRECTIVE ON ELECTROMAGNETIC COMPATIBILITY	22 March 2007
CFR Title 47	CFR TITLE 47 FCC PART 15 SUBPART B, CLASS A	Current
2006/95/EC	COUNCIL DIRECTIVE ON LOW VOLTAGE EQUIPMENT SAFETY	12 Dec 2006
ICES-003, Issue 4, Class A	SPECTRUM MANAGEMENT AND TELECOMMUNICATIONS POLICY INTERFERENCE-CAUSING EQUIPMENT STANDARD – DIGITAL APPARATUS	Issue 4/Feb-04
BSMI CNS-13438, Class A	TAIWAN BSMI (BUREAU OF STANDARDS, METROLOGY AND INSPECTION) – EMISSIONS TESTING FOR INFORMATION TECHNOLOGY EQUIPMENT: REQUIREMENTS FOR MEASUREMENTS ABOVE 1GHZ AND CONDUCTED EMISSIONS ON TELECOMMUNICATION PORTS	2006
VCCI V-4/2012.04, Class A	VOLUNTARY CONTROL COUNCIL FOR INTERFERENCE BY INFORMATION TECHNOLOGY EQUIPMENT (VCCI)	2012

Tests:

Document No.	Title	Edition/DOI
EN 61326-1	ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL AND LABORATORY USE – EMC REQUIREMENTS	2006
EN 55011:2009 +A1:2010	INDUSTRIAL, SCIENTIFIC AND MEDICAL EQUIPMENT — RADIO-FREQUENCY DISTURBANCE CHARACTERISTICS —LIMITS AND METHODS OF MEASUREMENT	31 August 2010
ACMA AS/NZS CISPR 11:2009 + A1:2010, Class A	INDUSTRIAL SCIENTIFIC AND MEDICAL (ISM) RADIO-FREQUENCY EQUIPMENT – ELECTROMAGNETIC DISTURBANCE CHARACTERISTICS – LIMITS AND METHODS OF MEASUREMENT	19/05/2010 Edition 5.1
EN 61000-6-1	ELECTROMAGNETIC COMPATIBILITY - GENERIC IMMUNITY STANDARD PART 1: RESIDENTIAL, COMMERCIAL AND LIGHT INDUSTRY	2001
EN 61000-4-2	ELECTROMAGNETIC COMPATIBILITY (EMC) PART 4: TEST AND MEASUREMENT TECHNIQUES – SECTION 2 ELECTROSTATIC DISCHARGE IMMUNITY TEST	1995-01
EN 61000-4-2	AMENDMENT A1 – ELECTROMAGNETIC COMPATIBILITY (EMC)	1998
EN 61000-4-2	AMENDMENT A2 – ELECTROMAGNETIC COMPATIBILITY (EMC)	2002
EN 61000-4-3	ELECTROMAGNETIC COMPATIBILITY (EMC) PART 4: TESTING AND MEASUREMENT TECHNIQUES – SECTION 3 RADIATED, RADIO-FREQUENCY IMMUNITY TEST	1995-02
EN 61000-4-3	AMENDMENT A1 – ELECTROMAGNETIC COMPATIBILITY (EMC)	1998
EN 61000-4-3	AMENDMENT A2 – ELECTROMAGNETIC COMPATIBILITY (EMC)	2001
EN 61000-4-3	ELECTROMAGNETIC COMPATIBILITY (EMC), PART 4: TESTING AND MEASUREMENT TECHNIQUES – SECTION 3 RADIATED, RADIO-FREQUENCY IMMUNITY TEST	2002
EN 61000-4-3	AMENDMENT A1 – ELECTROMAGNETIC COMPATIBILITY (EMC)	2002


Figure 10-1: Sense Instrument Declaration of Conformity

	Declaration of Conformity	No.: <u>DOC-1005</u>
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Document No.	Title	Edition/DOI
EN 61000-4-4	ELECTROMAGNETIC COMPATIBILITY (EMC) PART 4: TESTING AND MEASUREMENT TECHNIQUES – SECTION 4 ELECTRICAL FAST TRANSIENT/BURST IMMUNITY TEST	1995-01
EN 61000-4-4	AMENDMENT A1 – ELECTROMAGNETIC COMPATIBILITY (EMC)	2001
EN 61000-4-4	AMENDMENT A2 – ELECTROMAGNETIC COMPATIBILITY (EMC)	2001
EN 61000-4-4	ELECTROMAGNETIC COMPATIBILITY (EMC), PART 4: TESTING AND MEASUREMENT TECHNIQUES – SECTION 4 ELECTRICAL FAST TRANSIENT/BURST IMMUNITY TEST	2004
EN 61000-4-5	ELECTROMAGNETIC COMPATIBILITY (EMC) PART 5: TESTING AND MEASUREMENT TECHNIQUES – SECTION 5 SURGE IMMUNITY TEST	1995-02
EN 61000-4-5	AMENDMENT A1 – ELECTROMAGNETIC COMPATIBILITY (EMC)	2001
EN 61000-4-6	ELECTROMAGNETIC COMPATIBILITY (EMC) PART 6: TESTING AND MEASUREMENT TECHNIQUES – SECTION 6 IMMUNITY TO CONDUCTED DISTURBANCES, INDUCED BY RADIO FREQUENCY FIELDS	1996-03
EN 61000-4-6	AMENDMENT A1 – ELECTROMAGNETIC COMPATIBILITY (EMC)	2001
EN 61000-4-8	ELECTROMAGNETIC COMPATIBILITY (EMC) PART 4: TESTING AND MEASUREMENT TECHNIQUES – SECTION 8: POWER FREQUENCY MAGNETIC FIELD IMMUNITY TEST	1993-01
EN 61000-4-8	AMMEDMENT 1	2000
EN 61000-4-11	ELECTROMAGNETIC COMPATIBILITY (EMC), PART 11: TESTING AND MEASUREMENT TECHNIQUES - SECTION VOLTAGE DIPS, SHORT INTERRUPTIONS AND VOLTAGE VARIATIONS IMMUNITY TEST	1994-06
EN 61000-4-11	AMENDMENT A1 – ELECTROMAGNETIC COMPATIBILITY (EMC)	2001
EN 61000-4-11	ELECTROMAGNETIC COMPATIBILITY (EMC), PART 11: TESTING AND MEASUREMENT TECHNIQUES - SECTION VOLTAGE DIPS, SHORT INTERRUPTIONS AND VOLTAGE VARIATIONS IMMUNITY TEST	2004
IEC/EN 61010-1	SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL, AND LABORATORY USE - PART 1: GENERAL REQUIREMENTS	2010 (3 rd Edition)
IEC/EN 61010-2-081	SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL AND LABORATORY USE - PART 2-081: PARTICULAR REQUIREMENTS FOR AUTOMATIC AND SEMI-AUTOMATIC LABORATORY EQUIPMENT FOR ANALYSIS AND OTHER PURPOSES	2003
UL 61010-1	ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL, AND LABORATORY USE;PART 1: GENERAL REQUIREMENTS	R/2008 (2 nd Edition)
CAN/CSA C22.2 No. 61010-1	SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL, AND LABORATORY USE - PART 1: GENERAL REQUIREMENTS	R/2009
CAN/CSA C22.2 No. 61010-2-081	SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL, AND LABORATORY USE - PART 2-081: PARTICULAR REQUIREMENTS FOR AUTOMATIC AND SEMI-AUTOMATIC LABORATORY EQUIPMENT FOR ANALYSIS AND OTHER PURPOSES	R/2009
IEC 60825-1	SAFTY OF LASER PRODUCTS	2007-03

Continue next page...

Figure 10-1 (continued): Sense Instrument Declaration of Conformity

	Declaration of Conformity	No.: <u>DOC-1005</u>
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Test Provider:	<i>Compliance Worldwide, Inc., - 357 Main Street Sandown, NH 03873</i>
Reference:	<i>Test Report Number 101-13 (January 1-4, 15, 2013) and 499-12 (Month 06, 2013)</i>

Test Provider:	<i>TÜV SÜD America Inc., - 10 Technology Drive, Suite #2 Peabody MA 01960</i>
Reference:	<i>Technical Report No. DI1204828-001 (2013-02-26)</i>

The Technical Construction File required by this Directive is maintained at the corporate headquarters of: RainDance Technologies 749 Middlesex Turnpike, Billerica, MA 01821

 <hr/> Andrew D. Connerty - Director, Quality Assurance	<hr/> June 12, 2015 Date of Issue	<hr/> Billerica, MA Place of Issue
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




Figure 10-1 (continued): Sense Instrument Declaration of Conformity

CHAPTER 11

Symbol Glossary

The symbols in the following table are used on the RainDrop Sense instrument.

Table 11-1: Symbol Glossary

Symbol Name	Symbol Illustration	Definition
AC symbol		Alternating current
Ground symbol in circle		Protected earth (ground)
" " on Power Switch		ON
"0" on Power Switch		OFF
Fuse symbol		Fuse
Lightening bolt in triangle		Dangerous Voltage
Laser safety		A laser warning indicates that the user must use precautions when operating the instrument to avoid injury from the lasers.
Pinch point		Keep hands and fingers clear.

Appendix A

RainDrop[®] Consumables and Equipment

This chapter provides a list of customer-supplied consumables and equipment required to operate the RainDrop[®] System. [Table A-1](#) provides a list of consumables, their associated part numbers and other ordering information.



Caution: Where RainDance part numbers are indicated, use only RainDance-specified consumables to avoid damage to the instrument.

Table A-1: Part Numbers for Customer-Supplied Consumables

Customer-Supplied Consumable	Source/Part Number or Suggested Manufacturers
<p>RainDrop Consumable Kit - supports 96 samples</p> <p>Includes the following:</p> <ul style="list-style-type: none"> ● RainDance P/N 30-06085 (carton of 12 Source Chips plus 13 PCR Tube Strip Caps) ● RainDance P/N 30-06086 (carton of 12 Sense Chips plus 13 High Speed Tube Strip Caps) ● RainDance P/N 30-07117 Carrier Oil Syringe (3) 	<p>RainDance P/N 20-04410</p>
<p>RainDrop Consumable Kit - supports 480 samples</p> <p>Includes five (5) RainDance 20-04410 kits</p>	<p>RainDance P/N 20-04411</p>
<p>0.2 mL 8-Tube PCR Tube Strips, Clear</p>	<p>Axygen P/N PCR-0208-C</p>
<p>0.2 mL 8-tube PCR Tube Strips and Caps</p>	<p>Axygen P/N PCR-0208-CPC</p>
<p>0.2 mL 8-Tube PCR Tube Caps</p>	<p>RainDance P/N PCR-02CP-A</p>
<p>Gas Installation Kit (Refer to the Pre-Installation Site Prep Document No. LCN 50-07597)</p>	<p>RainDance P/N 20-07591</p>
<p>Gas Source with 4 mm O.D. polyurethane tubing with in-line shutoff valve</p>	<p>In the US:</p> <ul style="list-style-type: none"> ● http://www.grainger.com/Grainger/ATP-Tubing-1PBR5?Pid=search ● http://www.coleparmer.com/Product/PTFE_Tubing_2_48_x_4m_m_25_ft_pk/EW-06605-53 <p>In the EU:</p> <ul style="list-style-type: none"> ● http://www.smc.eu/portal/WebContent/digital_catalog/jsp/view_product_configurator.jsp?dc_product_id=49694&part_number=TU0425R1-20&basket_product_id=726514&load_content_from=save_product_link

Table A-1: Part Numbers for Customer-Supplied Consumables

Adaptor to attach 4 mm O.D. tubing to male ¼ inch adaptor on regulator	<p>In the US:</p> <ul style="list-style-type: none"> • http://www.coastpneumatics.com/KQF04-02.html
4 mm in-line shut off valves	<p>In the US:</p> <ul style="list-style-type: none"> • http://www.mcmaster.com/#catalog/119/444/=n4vr4p_scroll down to PN4764K45 <p>In the EU:</p> <ul style="list-style-type: none"> • http://www.smc.eu/portal/WebContent/digital_catalog/jsp/view_product_configurator.jsp?dc_product_id=25151
Gas tubing splitter (if running both instruments from same air tank)	<p>In the US:</p> <ul style="list-style-type: none"> • http://www.grainger.com/Grainger/LEGRIS-Union-Tee-1PEU3?cm_sp=IO--IDP--RR_VTV70300505&cm_vc=IDPRRZ1 <p>In the EU:</p> <ul style="list-style-type: none"> • http://www.smc.eu/portal/WebContent/digital_catalog/jsp/view_product_configurator.jsp?dc_product_id=88174

Additional Customer-Supplied Equipment

- Computer workstation for RainDrop Analyst, running Windows 7, 64 bit, with at least 8 GB of RAM (16 GB recommended).

For information about equipment and reagents used in assay development, refer to the *RainDance dPCR System Assay Guidelines*.

LCN 50-04344 Rev. B

Date of Issue: December 2016

RainDance Technologies, Inc.
749 Middlesex Turnpike
Billerica, MA 01821
Fax: (978) 528-6090 (support)
Web: www.raindancetech.com/support
Email: customer care@raindancetech.com



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