isospark®

Site Preparation Guide

isoplexis

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Revision History

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Rev. 1.2

IsoSpark Site Preparation Guide

Contents

Introduction

Congratulations on the purchase of your IsoSpark instrument. This document will guide you through the process of receiving, installing and getting training on your new IsoSpark If you have any questions or concerns during this process, please contact IsoPlexis technical support at:

support@isoplexis.com

475-221-8402

Installation and Training Workflow

The installation and training process will follow these steps:

1. Scheduling: Your Field Service Engineer (FSE) and Field Application Scientist (FAS) will both contact you to choose installation and training dates. The installation will take three days and the training will take three days. These do not need to happen the same week.
2. Shipping and Receiving: Your FSE will provide you with instrument shipment tracking info. When the instrument arrives, you will ensure the crate is not damaged (see page 5). Your FAS will provide you with shipment tracking info for the training reagents kit. When you receive the training reagents, please place them in appropriate storage (see page 5).
3. Site Preparation: You will review the items on the "Site Preparation Checklist" on page 4 and make sure that the site is ready. One week before the installation date, your FSE will have a phone meeting with you and will collect a completed and signed Site Preparation Checklist.
4. Installation: On the week of the actual installation, you will move the instrument to the install site and your FSE will install the instrument.
5. Training: On the week of the instrument training, your FAS will come on site and will train your team on how to use the instrument.

Site Preparation Checklist

Your FSE will contact you a week before installation to ensure that all items on this checklist have been reviewed and are ready. Please return a completed and signed checklist to your FSE a week before your scheduled installation date. We also ask that you include pictures of your setup with the following:

- Bench space where IsoSpark will be installed
- Regulator set pressure (30-70psi)
- Supply line tubing (OD 1/8", ¼", 5/32", or 4mm)

In the event that the site preparation checklist is not complete by the time of install, the installation may need to be rescheduled.

Completed	Initials	Site Preparation Requirement
☐		Shipping and Receiving (see page 5)
☐		Safety (see page 5)
☐		Bench space and clearance (see page 6)
☐		Environmental (see page 8)
☐		CO_2 (see page 9)
☐		Electrical (see page 11)
☐		Data transfer method setup (see page 13)

Customer Representative Name _____

Customer Representative Signature _____

Date_____

Shipping and Receiving

Crate Size and Weight

Your Isospark instrument will come in a crate on a pallet of the following size and weight

Height	Length (depth)	Width	Weight
81.3 cm (32”)	101.6 cm (40”)	96.5 cm (38”)	86 kg (190 lbs)

Inspecting the Shipment

When your IsoSpark arrives please inspect the crate for exterior damage and other evidence of rough handling. If you suspect rough handling, please immediately notify IsoPlexis and document the damage and evidence.

NOTE: Please do NOT open the crate and be prepared to provide adequate space for storage until the installation date. Your instrument is shipped in a special crating system. Your IsoPlexis Field Service Engineer is the only one authorized to open the crate and unpack the instrument.

Receiving Reagents

Your training kits will arrive separately from the instrument. When you receive them, please check the contents against the packing list and store the regents as specified.

Safety

Customer Responsibilities

The following safety equipment and protection from hazards must be available at the installation site: Protection from any sources of hazardous chemicals, radiation (for example, lasers, radioisotopes, radioactive wastes, and contaminated equipment), and potentially infectious biological material that may be present in the area where the service representative will work.

- Eyewash
- Safety shower
- Eye and hand protection
- Adequate ventilation, including vent line/fume hood, if applicable
- Biohazard waste container, if applicable
- First-aid equipment
- Spill cleanup equipment
- Applicable Safety Data Sheets (SDSs)

Supported BioSafety Levels

IsoPlexis does not install, service, or repair instruments in areas designated BioSafety Level 3 (BSL-3) or BioSafety Level 4 (BSL-4).

Disposing of Waste

WARNING! CHEMICAL HAZARD. Refer to Safety Data Sheets (SDSs) and local regulations for handling and disposing of plastic consumables. Follow local municipal waste ordinances for proper disposal provisions to reduce the environmental impact of plastic consumables.

WARNING! CHEMICAL HAZARD. Before handling chemicals, refer to the Safety Data Sheet (SDS) provided by the manufacturer, and observe all relevant precautions.

WARNING! CHEMICAL HAZARD. All chemicals in the instrument, including liquid in the lines, are potentially hazardous. Always determine what chemicals have been used in the instrument before changing reagents or instrument components. Wear appropriate eyewear, protective clothing, and gloves when working on the instrument.

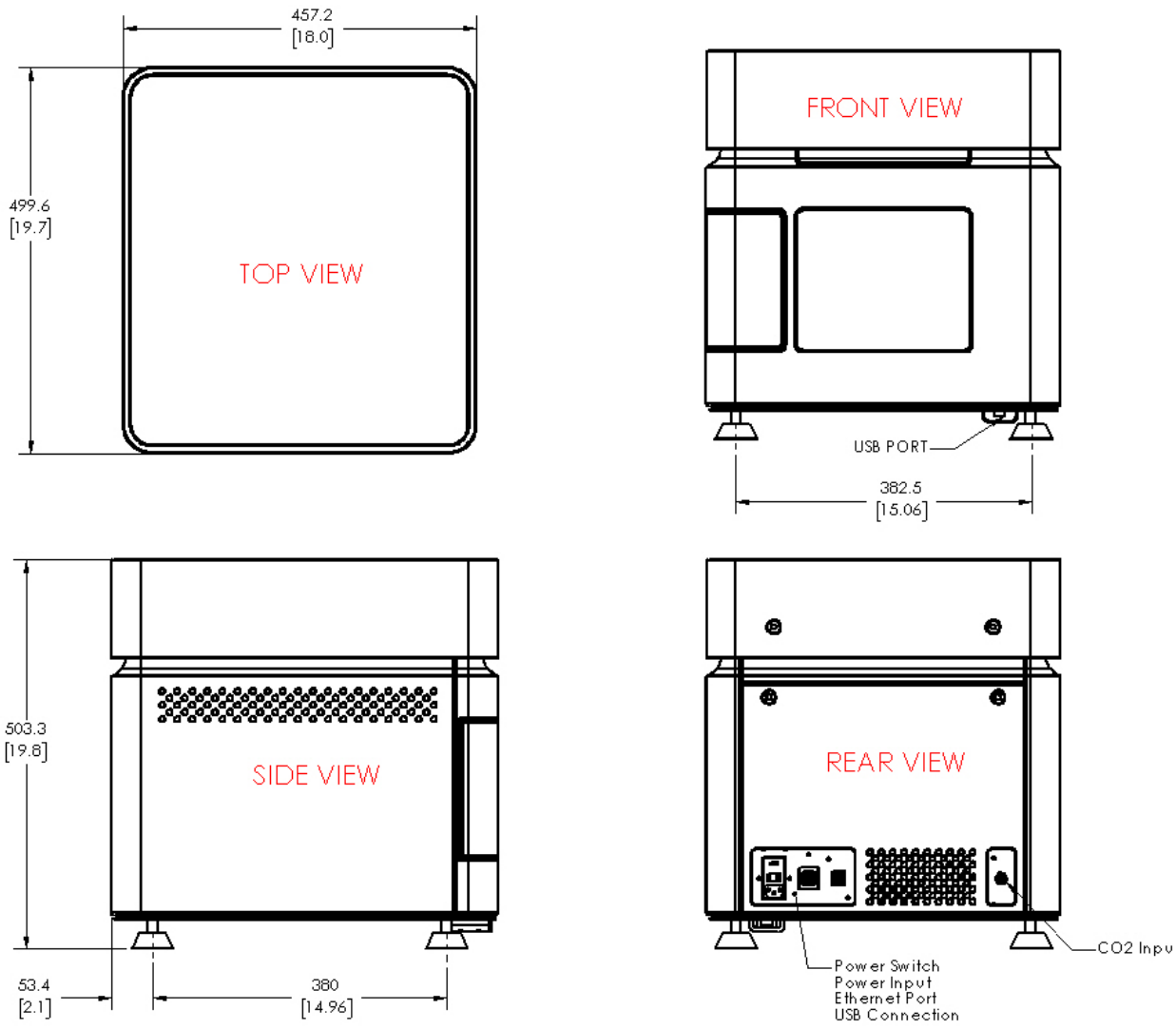
WARNING! CHEMICAL HAZARD. Waste produced by instruments can be hazardous and can cause injury or illness.

Bench Space and Clearance

The designated bench space for the IsoSpark must meet the following requirements:

Item	Requirement
Weight Capacity	90.7 kg (200 lbs.)
Width (horizontal space)	Instrument = 45.72 cm (18.0”) Service and Ventilation = 30.48 cm (12”) per side TOTAL = 106.68 cm (42”)
Depth (front to back)	Instrument = 49.96 cm (19.7”) Ventilation = 10 cm (4”) TOTAL = 59.96 cm (23.7”).
Height (vertical space)	Instrument = 50.33 cm (19.8”) Service and ventilation = 30 cm (12”) TOTAL = 80.33 cm (31.8”)

IsoSpark Dimensions



Dimensions are in millimeters [inches].

In addition, the instrument must be located on a bench free of vibration creating equipment such as centrifuges and compressors and away from sources of sunlight, heat, draft, and electronic noise. See Environmental below.

Environmental

The area where the IsoSpark is operated must meet the following environmental requirements

Item	Requirement
Altitude	Between sea level and 2000 m (6500')
Humidity	20-80% RH, non-condensing
Operating Temperature	15°C to 30°C (59°F to 86°F) Note: The room temperature must not fluctuate more than 2°C over a 2-hour period.
Vibration	The bench should be free of contact with equipment that causes vibration such as centrifuges, compressors, freezers, and pumps.
Heating and Cooling	Instrument must not be in direct sunlight or adjacent to or below heating and cooling ducts.
Pollution	The IsoSpark is intended to be used in commercial laboratory environments. The instrument must be placed away from any vents that could expel particulate matter.

CO_2

The IsoSpark instrument requires a clean, consistent, regulated supply of CO_2 in order to operate. CO_2 is used both to maintain ambient CO_2 in the incubation chamber and as a pressurized gas to move liquid reagents and cleaning solutions. Failure to provide proper and adequate CO_2 will lead to failed runs and loss of data.

Item	Requirement
Quality	99.5% pure or above
Consumption	A single run will consume up to 9 lbs of CO_2 (≈79 ft^3 or ≈2250 L at room temp)
Tank	The tank should not contain a syphon tube. Do not use liquid CO_2. See the CO_2 Supply Options section below.
Shut-Off	There should be a manual shut-off valve easily within reach of the instrument.
Pressure	The instrument requires 30 to 70 PSI. A low-pressure regulator should be installed at the instrument. Contact IsoPlexis for a recommendation if required.
Supply Line	A flexible plastic (Nylon, Polypropylene, Polyurethane) supply line should bring the CO_2 to where the IsoSpark will be placed. Supported outer diameters include 1/8”, 1/4", 5/32” and 4 mm OD.

CO_2 Supply Options

Option	Description	Benefits and Details
A. "House" Gas	Gas at high volume is stored at the customer's site. House gas must be available at the location of the IsoSpark at the pressure specified on page 9.	Tanks are not handled and placed near the IsoSpark by lab personnel
B. Large tank (~200 lbs of CO_2)	These CO_2 tanks are typically delivered & placed near the IsoSpark by a gas supplier. Tanks dimensions approximately 53 cm (21") in diameter, 155 cm (61") tall. IsoPlexis can supply a regulator. Product code ISOREG-01	Monitoring the number of completed IsoSpark runs is required to maximize CO_2 usage efficiency Tanks must be replaced approximately every 22 IsoSpark runs.
C. Standard tank (50 lbs of CO_2)	Tanks dimensions approximately 25 cm (10") in diameter, 140 cm (55") tall. IsoPlexis can supply a regulator. Product code ISOREG-01	Monitoring the number of completed IsoSpark runs is required to maximize CO_2 usage efficiency Tanks must be replaced every 5 IsoSpark runs. Tanks must be handled and placed near the IsoSpark by lab personnel
Option B and C can be configured in a single or multiple tank configuration	When configured in a single tank setup (ISOREG-01), usage must be monitored, and tanks replaced as described above. When configured in a multiple tank setup (ISOREG-02), usage must still be monitored but not as closely. When primary tank is emptied it will automatically switch to the secondary tank providing uninterrupted supply of CO_2 to the IsoSpark. When the IsoSpark is not in the process of a run, the empty tank must be replaced to provide reserve capacity for future runs.	Continuous CO_2 delivery is provided by the reserve capacity of a multiple tank configuration. Monitoring of the tanks is still required but not as critical compared to a single tank configuration.

Electrical

WARNING! For safety, the power outlet used for powering the instrument must be accessible at all times. In case of emergency, you must be able to immediately disconnect the main power supply to all the equipment.

Item	Requirement
Voltage	100-240 V AC (±10% of nominal voltage)
Frequency (Hz)	50/60 Hz
Rated Current (A)	6 Amps via building code compliant 15A circuit
UPS	**Recommended**: Customer supplied 1.5-kVA uninterruptible power supply. Contact IsoPlexis for recommendation if required.
Cord	Use an Isoplexis supplied detachable power supply cord, to connect the system to the wall or UPS

Electromagnetic Capability

The IsoSpark is suitable for use in electromagnetic environments within the limits shown in the table, below.

As guidance, follow the requirements in the "Environment" section of this document. Additionally, the IsoSpark mains power quality and power frequency should be typical of commercial laboratory environments. An uninterruptible power supply (UPS) is recommended (see the "Electrical" section of this document). Major sources of electromagnetic noise, including refrigerators or microwaves, should be used no closer than 30 cm (12 inches) to any part of the IsoSpark, including cables specified by IsoPlexis. The IsoSpark must not be used in areas with intense electromagnetic disturbances. Intense electromagnetic disturbances may be caused by high frequency RF equipment, such as diathermy devices and other high frequency surgical devices. If abnormal performance is observed, additional measures may be necessary, including moving the IsoSpark or orienting it, such that electromagnetic disturbances are reduced.

EMC standard or test method	Immunity Test Levels
EN 55011:2009+A1:2010	Class A
IEC/CISPR 11:2009+A1:2010	Class A
IEC 61000-4-2 Electrostatic Discharge	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
IEC 61000-4-3 Radiated RF EM fields	3 V/m

IEC 61000-4-8 Rated power frequency	30 A/m 50 Hz or 60 Hz
IEC 61000-4-4 Electrical fast transients/bursts	± 2 kV 100 kHz repetition frequency
IEC 61000-4-5 Surges Line-to-ground	± 0.5 kV, ± 1 kV, ± 2 kV
IEC 61000-4-6 Conducted disturbances induced by RF fields	3V 0.15 MHz – 80 MHz 6V in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz
IEC 61000-4-11 Voltage dips	0 % U_t: 0.5 cycle
	0 % U_t: 1 cycle And 70 % U_t: 25/30 cycle Single phase: at 0

WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of the IsoSpark could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas), including major sources of electromagnetic noise, such as refrigerators or microwaves, should be used no closer than 30 cm (12 inches) to any part of the IsoSpark, including cables specified by IsoPlexis. Otherwise, degradation of the performance of the IsoSpark could result.

WARNING: Use of the IsoSpark adjacent to other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally. Do not stack equipment on the IsoSpark.

WARNING: The IsoSpark has been tested for radiated RF immunity only at selected frequencies, and use nearby of emitters at other frequencies could result in improper operation.

WARNING: The electromagnetic emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). The IsoSpark must not be used in a residential environment (for which CISPR 11 class B is normally required).

Data Transfer and Management

The IsoSpark system requires transfer of raw data from the IsoSpark instrument to an external PC for analysis through the IsoSpeak software. IsoPlexis supports three methods of data transfer off of the IsoSpark.

- USB removable media
- Ethernet to local network
- Ethernet directly to IsoSpeak analysis workstation

In all three cases the instrument may be configured to automatically upload image data to a specified location during run time. **Each Single Cell chip requires approximately 15 GB of data and each CodePlex chip requires approximately 7 GB of data.**

It is recommended the customer understand the options provided prior to device installation, so the field engineer present may assist with setup.

Once connection to a desired device is established, the user is free to specify the exact path the IsoSpark will upload to.

Restrictions and Considerations

- IsoPlexis does not support customer administration of the IsoSpark.
- IsoPlexis does not support installation of third-party software on the IsoSpark.
- IsoPlexis does not support updating of third-party software components on the IsoSpark.
- IsoPlexis recommends only connecting the IsoSpark to local networks.

Data Transfer Methods

USB removable media

Data may be transferred to removable media via USB. This method requires no network connection or special configuration. IsoPlexis only supports this option with the flash drive provided; Alternate third-party drives may impair instrument function and are used at the user's own risk.

Ethernet to local network

Data may be transferred to a network share location. This method requires no special instrument configuration. However, IsoPlexis can provide IT technical assistance if required. Upload speed may be limited by the quality of the network attached network connection. **IsoPlexis recommends only connecting the IsoSpark to local networks.** The following needs to be provided by the user.

- Network connection
- SMB file share
- Network credentials
- IP Address or Hostname of share

Ethernet directly to IsoSpeak analysis workstation

Similar to the network share method, the IsoSpeak laptop may be directly used as a server upload location. **However, this method requires configuration of instrument settings by an IsoPlexis technician.** This can be completed at installation by your FSE. IsoPlexis offers an optional network cable and USB ethernet adapter.

Related Documents and Support

Document	Pub. No.	Description
IsoSpark User Manual	704-00086-01	Describes the IsoSpark hardware and firmware and provides information on preparing, maintaining, and troubleshooting the system.
IsoSpeak User Manual	795-00018-01	Describes the use of the IsoSpeak software for data preprocessing and analysis.

Visit IsoPlexis.com/support for the latest in services and support, including:

Customer and technical support:

- Product FAQs
- Product documentation, including:
    - User guides, manuals, and protocols

Note: For SDSs for reagents and chemicals from other manufacturers, contact the manufacturer.

Limited product warranty:

For warranty information please contact IsoPlexis at support@isoplexis.com