SphereFlash® Colonies Software
Instructions for Use

Automatic Colony Counter / Inhibition Halos Measurement

Contents

INDICATION OF THE INTRODUCED MODIFICATIONS

If it's the first time that you use SphereFlash, please read the entire document carefully.

If it's not the first time that you use SphereFlash and you use it before, in the table below you can read the indication of the introduced modifications

Revision	Description of change
10	Update section 1.2.1
	Update section 3 Update
	Appendix G Update Warning
	notes format

1. INTRODUCTION

Thank you for choosing the SphereFlash®. We are confident that this instrument will become an integral part of your laboratory.

Before using the SphereFlash®, it is essential that you read these Instructions for Use carefully. Following the instructions and safety information in these Instructions for Use will ensure safe operation and maintain the system in a safe condition.

1.1. Intended use of the SphereFlash®

The SphereFlash® is an automatic colony counter that meets all the requirements that may be required in a modern microbiology laboratory.

With its SphereFlash® Colonies LITE Software, it performs colony counting simply and reliably thanks to its world-class software and its patented built-in lighting system.

For more demanding users the software can be upgraded to the SphereFlash® Colonies PRO Software to increase its capabilities, e.g., setting user's permission levels, LIMS connectivity, worksheets, barcode reading, reporting, audit trail, or CFR21 Part 11.

With the optional SphereFlash® Halos PRO Software, the SphereFlash® unit can be transformed to measure inhibition halos, accepting various circle approximation criteria to obtain the corresponding diameters of virtual circle areas.

In all versions, the lighting is done through LEDs that are oriented to the internal wall of a moving spherical chamber. The result is an unprecedented uniform and reflection-free illumination in a colony counter device.

The moving sphere closes the chamber and prevents the area in which the Petri dish is located from any external light. It avoids any reflection or interference from external light, creating a luminous atmosphere without reflections from the walls of the Petri dish or the colonies. For the transparent media, the light by transmission is also available in all versions.

1.2. General Information

1.2.1. Scope of delivery

The delivery includes the following items:

a. SphereFlash$^{®}$ instrument
b. AC Adaptor
c. Power cord
d. USB 3.0 Type-A interface cable
e. Calibration disk
f. Verification disk for Colonies
g. Verification disk for Halos
h. DVD with the Application Software Instructions for Use (Basic and Advanced)
i. Centering device (Ø 87-91 mm)

1.2.2. Technical Assistance

At Scigiene we pride ourselves on the quality and availability of our technical support. Our Technical Service Department is staffed by experienced technicians with extensive practical and theoretical expertise in the use of Scigiene products. If you have any questions or experience any difficulties regarding the SphereFlash$^{®}$ or Scigiene products in general, do not hesitate to contact us.

Scigiene customers are a major source of information regarding advanced or specialized uses of our products. This information is helpful to other customers as well as to the researchers Scigiene. We encourage you to contact us if you have any suggestions about product performance or new applications and techniques.

For technical assistance, please contact your sales representative at Scigiene.

1.2.3. Policy Statement

It is the policy of Scigiene to improve products as new techniques and components become available. Scigiene reserves the right to change the specifications of products at any time.

To produce useful and appropriate documentation, we appreciate your comments on these Instructions for Use. Please contact Scigiene Technical Service with any feedback.

1.2.4. Requirements for SphereFlash® users

Table 1 covers the general level of competence for the use and servicing of the SphereFlash®.

Task	Personnel	Training and experience
Routine use	Laboratory technicians or equivalent	Training in techniques for laboratory instrument operation
Servicing	Scigiene Service Specialists only	Trained, certified, and authorized by Scigiene

2. SAFETY INFORMATION

Before using the SphereFlash®, it is essential that you read these Instructions for Use carefully. Following the instructions and safety information in these Instructions for Use will ensure safe operation and maintain the system in a safe condition.

The following types of safety information appear throughout the SphereFlash *Instructions for Use.*

WARNING	The term WARNING is used to inform you about situations that could result in **personal injury** to you or other persons. Details about these circumstances are given in a box like this one.

CAUTION	The term CAUTION is used to inform you about situations that could result in **damage to the instrument** or other equipment. Details about these circumstances are given in a box like this one.

The advice given in this manual is intended to supplement, not supersede, the normal safety requirements prevailing in the user's country.

2.1.   Proper use

WARNING/ CAUTION	**Risk of personal injury and material damage** Improper use of the SphereFlash® instrument may cause personal injury or damage to the instrument. The instrument must only be operated by qualified personnel.

CAUTION	**Damage to the instrument** Do not attempt to move the sphere by hand at any time; it may cause a failure on the sphere mechanism, and that failure will not be covered by Warranty.

CAUTION	**Damage to the instrument** Do not try to add or remove a Petri dish when the sphere is moving, although has been tested that there is no danger for the user by entrapment, the mechanism of the sphere could be damaged.

CAUTION	**Damage to the instrument** Avoid spilling water or chemicals onto the SphereFlash® instrument as well as onto its Host Computer. Damage caused by water or chemical spillage will void your warranty.

In case of emergency, switch off the SphereFlash® at the power button and unplug the power cord from the power outlet.

2.2. Electrical Safety

If the operation of the SphereFlash® is interrupted in any way (e.g., due to interruption of the power supply or a mechanical failure), first switch off the instrument using the power switch, then disconnect the electrical cord from the mains power outlet. Contact Scigiene Technical Service after such an incident.

WARNING 	**Electrical hazard** • Risk of electrical shock and energy hazard. All failures should be examined by a qualified technician. Please do not remove the case of the AC adaptor by yourself! • Adaptors should be placed on a reliable surface. A drop or fall could cause damage. • Please do not place the AC adaptor in places with high moisture or near the water. • Please do not place the AC adaptor in places with high ambient temperature or near a fire source. About the maximum ambient temperature, please refer to Technical Data. • Disconnect the AC adaptor from the AC power before cleaning. Do not use any liquid or aerosol cleaner. Only use a damp cloth to wipe it. • In case of replacement or a loosing of the AC adaptor or the mains power cord, these must be replaced only with the AC adaptors or power cords listed in Ordering Codes and provided by Scigiene.

To ensure safe and satisfactory operation for SphereFlash® routine use or after servicing:

• The line power cord connected to the AC Adaptor must be connected to a line power outlet that has a protective conductor (earth/ground).

• The instrument must not be operated with the cover removed.

• If liquid has spilled on the instrument or over the AC adaptor, switch it off, disconnect the AC adaptor from the mains power outlet, and contact Scigiene Technical Services.

If the SphereFlash® becomes electrically unsafe, prevent other personnel from operating it, and contact Scigiene Technical Service.

The instrument may be electrically unsafe if:

• The AC adaptor or the power cord appears to be damaged.

• The AC adaptor has been stored under unfavorable conditions for a prolonged period. For the storage conditions, please refer to Technical Data.

- A different AC adaptor is used other than the one provided by Scigiene.

- A different mains power cord is used other than the one provided by Scigiene.

WARNING	Risk of electric shock
	In case of replacement or a loosing of the AC adaptor or the mains power cord, these must be replaced only with the AC adaptors or power cords listed in Ordering Codes and provided by Scigiene.

2.3.   Environment

Operating conditions

See Technical Data for a list of the operating conditions, storage conditions, and transport conditions.

WARNING	Explosive atmosphere
	The SphereFlash$^{®}$ is not designed for use in an explosive atmosphere.

WARNING	Risk of overheating
	Slits and openings that ensure the ventilation of the SphereFlash$^{®}$ must not be covered.

2.4.   Biological safety

Use safe laboratory procedures as outlined in publications such as Biosafety in Microbiological and Biomedical Laboratories, HHS:

http://www.cdc.gov/od/ohs/biosfty/biosfty.htm

WARNING ⚠️	**Samples containing infectious agents** Some samples used with the SphereFlash® may contain infectious agents. Handle such samples in accordance with the required safety regulations. The responsible person(s) (e.g., laboratory manager) must take the necessary precautions to ensure that the workplace is safe and that the instrument operators are suitably trained and not exposed to hazardous levels of infectious agents, as defined in the applicable Safety Data Sheets (SDSs) or OSHA [1] ACGIH [2] or COSHH [3] documents. Venting of fumes and disposal of wastes must be in accordance with all national, state, and local health and safety regulations and laws.

2.5.   Chemicals

WARNING ⚠️	**Hazardous chemicals** Some chemicals used with the SphereFlash® may be hazardous. Always wear safety glasses, gloves, and a lab coat. The responsible person(s) (e.g., laboratory manager) must take the necessary precautions to ensure that the workplace is safe and that the instrument operators are suitably trained and not exposed to hazardous levels of toxic substances (chemical or biological), as defined in the applicable Safety Data Sheets (SDSs) or OSHA, ACGIH or COSHH documents. Venting of fumes and disposal of wastes must be in accordance with all national, state, and local health and safety regulations and laws.

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[1] OSHA: Occupational Safety and Health Administration (United States of America).
[2] ACGIH: American Conference of Government Industrial Hygienists (United States of America).
[3] COSHH: Control of Substances Hazardous to Health (United Kingdom).

## 2.6.	Maintenance safety

CAUTION	**Damage to the instrument** Do not use spray bottles containing alcohol or disinfectant to clean the surface of the SphereFlash® instrument or its parts. Spray bottles should be used only to clean items that have been removed from the instrument.

WARNING	**Risk of electric shock** Do not try to open the AC adaptor; there are no serviceable parts inside. **Risk of personal injury and material damage** Only perform maintenance that is specifically described in this Instructions for Use.

## 2.7.	Waste disposal

Used consumables, such as sample tubes or bags, may contain hazardous chemicals or infectious agents. Such waste must be collected and disposed of properly in accordance with local safety regulations.

For disposal of waste electrical and electronic equipment (WEEE) see Technical Data.

2.8.   Symbols on the SphereFlash® instrument

Symbol	Location	Description
	Type plate on the back of the equipment	Waste Electrical and Electronic Equipment (WEEE), see Appendix C: Waste Electrical and Electronic Equipment (WEEE)
CE	Type plate on the back of the equipment	CE Mark, Declaration of Conformity, see EC Declaration of Conformity
FCC	Type plate on the back of the equipment	FCC Mark, see FCC Statement
	Type plate on the back of the equipment	China RoHS, see China RoHS Statement
SS	On the side overlay	USB 3.0 Device compliant

3. COMPUTER REQUIREMENTS

In order to install and run the SphereFlash® Software, the computer needed must meet or exceed the following requirements:

Processor	x64 architecture ≥2.5 GHz
Operating System	Microsoft 64-bit Windows 7, 8.1, 10, 11 (x64 platforms):

System type:	64-bit Operating System

Interface	1 free USB 3.0 compliant port:

RAM	8 Gigabytes
Free disk space	Application: 100 Megabytes
	Database: 10 Gigabytes (for 5000 results stored w/images)
Screen resolution	Full HD (1920 x 1080px) (recommended)
Screen size	24'' (recommended)
DVD reader	For the installation of the software[1]
Optional third-party applications	Microsoft Excel® 2007 or higher, 64bits (to open exported Excel files)
	A virtual PDF printer such as PDFCreator (to create PDF reports)
	Adobe Acrobat Reader DC® 2015 or higher (to digitally sign PDF reports)

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[1] Alternatively, you may transfer the files from the DVD to a USB memory stick in another computer, and then install the software onto the destination computer from the USB memory stick; see section 6.2.

4. GENERAL DESCRIPTION

4.1.　Features of the SphereFlash® instrument

1. Body of the instrument

2. Diffusing sphere for upper lighting (slides down when operated)

3. DC power input socket

4. USB 3.0 type A plug (computer interface)

5. Platform to integrate the centering device

A. Centering device
B. Lower lighting system (for transmission images)
C. Upper lighting lamps (for reflection images)
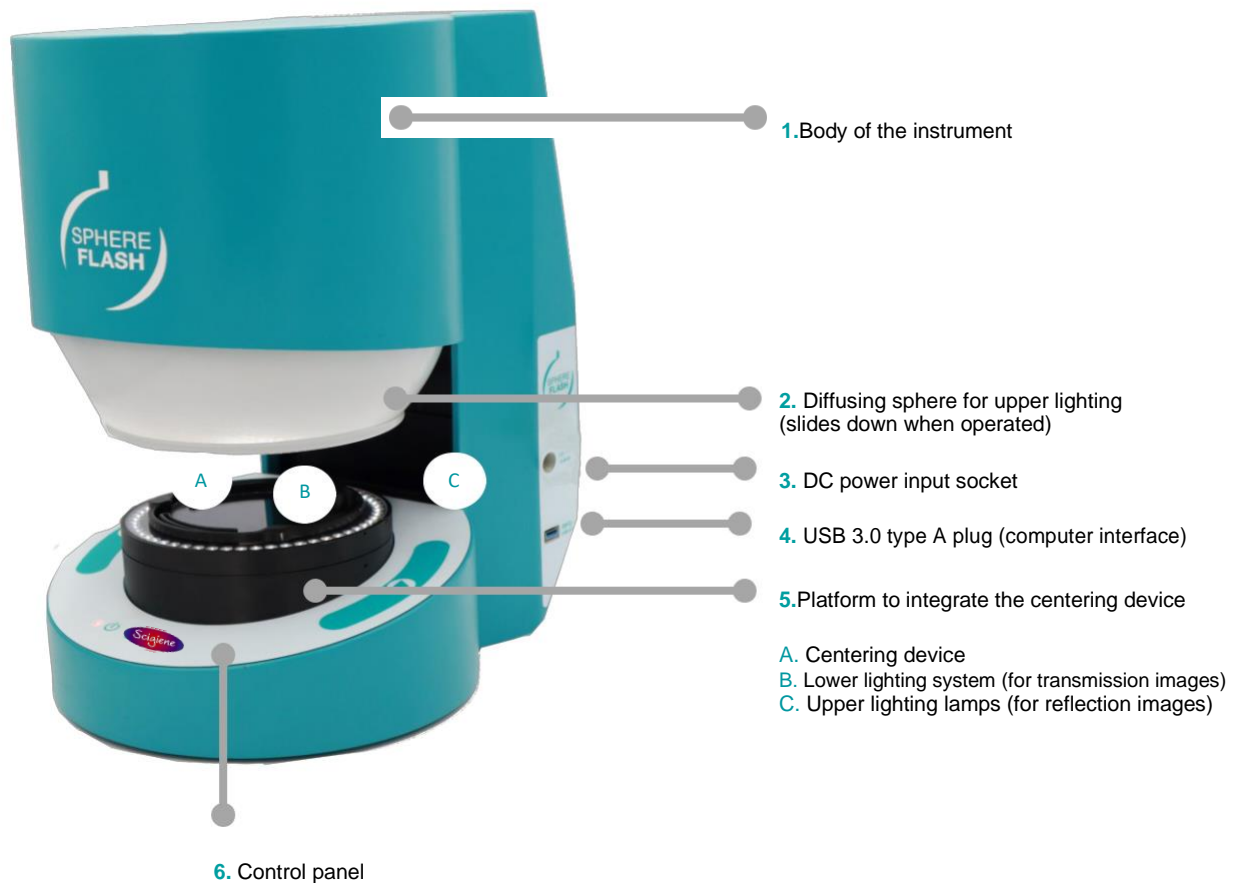
6. Control panel

4.1.1.　Control panel

🔴　Status lamp

⏻　Power on-off-reset button

▶　Run Process button

4.1.2. USB 3.0 type-A computer interface cable

The SphereFlash® is provided with a USB 3.0 type-A cable (d) to interface with the computer from which the SphereFlash® is operated by the SphereFlash® Software Applications.

CAUTION ⚠️	**Risk of malfunction or harmful interference** The use of a cable not fully compliant with USB 3.0 specifications may cause a malfunction on the SphereFlash®. Conformity to **2014/30/EU** and FCC rules could be compromised by the use of a cable not provided by Scigiene (see EC Declaration of Conformity and FCC Statement). Please refer to Ordering Codes in case you need to replace this cable.

4.1.3. AC Adapter

An AC Adaptor is included (b) in order to convert the mains AC supply into the DC low voltage supply required by the SphereFlash®.

4.1.4. Power cord

The SphereFlash® AC Adaptor (b) is equipped with a power cable with a plug suitable for the destination country. See Ordering Codes for details.

CAUTION ⚠️	**Risk of malfunction or harmful interference** Conformity to **2014/30/EU** and FCC rules could be compromised by the use of an AC adaptor or power cord not provided by Scigiene (see EC Declaration of Conformity and FCC Statement).

WARNING ⚠️	**Risk of electric shock** In case of replacement or a loosing of the AC adaptor or the mains power cord, these must be replaced <u>only</u> with the AC adaptors or power cords listed in Ordering Codes and these must be provided by Scigiene.

5. INSTALLATION

5.1.   Unpack the instrument
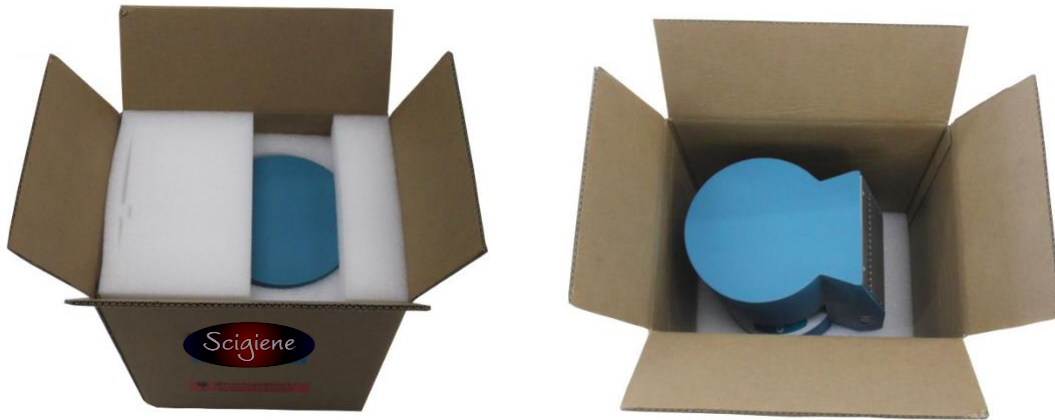
The packaging of the SphereFlash® can be stored for reuse.

5.2.   Removing the transport securing device

Lay down the instrument on a soft surface to avoid damaging its surfaces. You will see the red securing device that blocks the movement of the sphere during transport.

Pull out the cover of the power input socket:
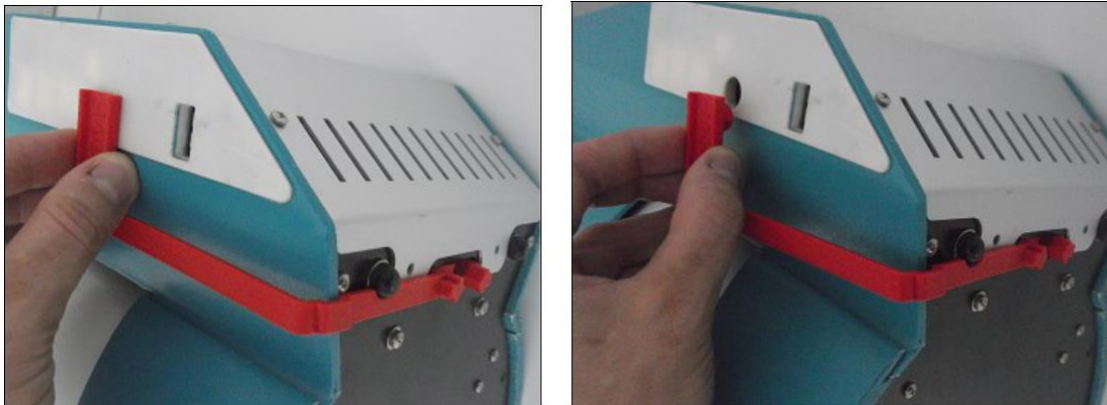
Squeeze the arrows towards each other and while squeezing, pull out the securing device:
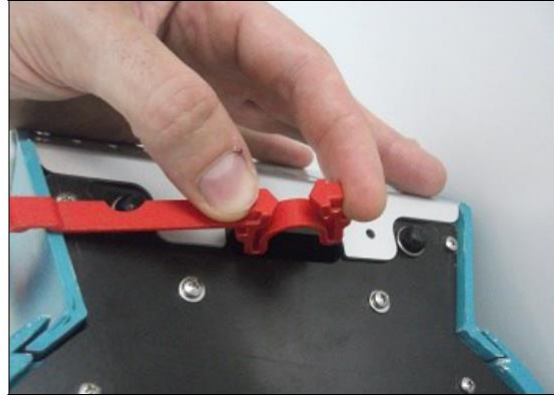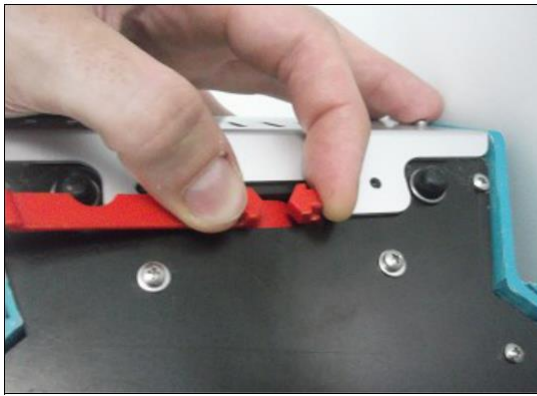
Once extracted, save the securing device to re-use it in future shipments, since it is essential for the safe transport of the SphereFlash®.

CAUTION ⚠	**Damage to the instrument** The use of the SphereFlash® without removing the transport security device may cause a failure on the sphere mechanism, that failure will not be covered by the Warranty.

CAUTION ⚠	**Damage to the instrument** Do not attempt to move the sphere by hand at any time; it may cause a failure on the sphere mechanism, and that failure will not be covered by the Warranty.

5.3.   Placing again the securing device for a shipment

If the SphereFlash$^{®}$ must be transported, you should re-use the securing device to prevent damages caused by transport jerks.

To place again the transport securing device, first, check through the bottom slit whether the crank white wheel is centered in the slit. If not, gently press the wheel with a tool until the wheel is centered:
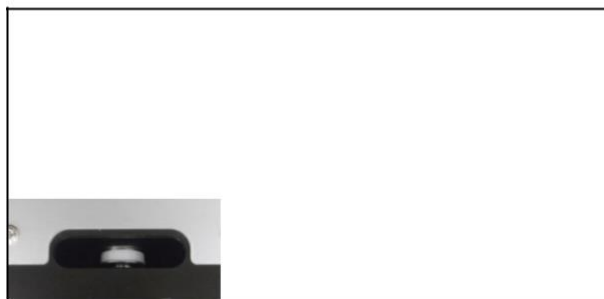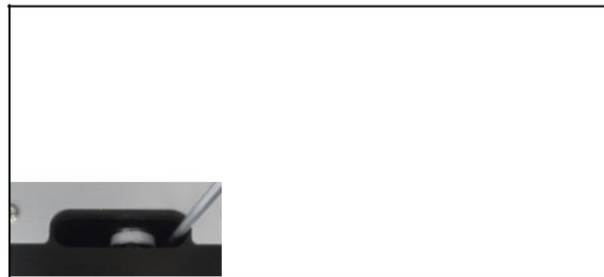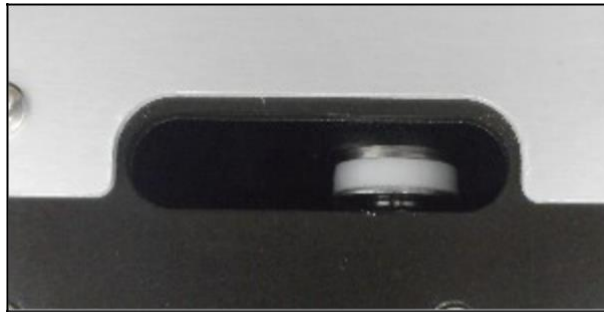
After centering the wheel, place the securing device following the steps of section 5.2 but in reverse order.

5.4. Site requirements

Place the SphereFlash® instrument on a level, stable surface, ideally a firmly secured benchtop, near an earthed/grounded electrical outlet. Allow at least 10 cm (4 in) of clearance on all sides of the unit for proper ventilation. While operating, make sure that the instrument does not touch other objects. See Technical Data to see operational conditions.

5.5. Connecting to the computer

Connect the socket end of the supplied USB 3.0 type-A cable (d) to the USB plug of the instrument (4). Connect the other end of the cable to a free USB 3.0 socket: of the computer where the SphereFlash® Application Software will be run:

5.6. Power supply connection

1. Insert the AC Adaptor output plug into the DC power input socket (3).

2. Insert the mains power cord (c) into the AC Adaptor.

3. Plug the mains power cord (c) into the electrical outlet.

When the SphereFlash® is not in use for a long period of time, we recommend disconnecting the mains power cable.

CAUTION	**Risk of malfunction or harmful interference** Conformity to **2014/30/EU** and FCC rules could be compromised by the use of an AC adaptor, power cord, or USB cable not provided by Scigiene see EC Declaration of Conformity and FCC Statement.

WARNING	**Risk of electric shock** In case of replacement or a loosing of the AC adaptor or the mains power cord, these must be replaced only with the AC adaptors or power cords listed in Ordering Codes and provided by Scigiene.

6. OPERATING PROCEDURES

6.1.　　Power-on, Power-Off, and Status Lamp

Push shortly the power button ⏻. The status lamp ● will light **solid red** for about 40 seconds, then the diffusing sphere (2) will rise, and the lamp will change to **slow flashing red**. Now the SphereFlash® is ready to communicate with the Software Application on the computer.

To power off the SphereFlash®, push shortly the power button ⏻. The diffusing sphere (2) will lower, and the status lamp will change **to fast blinking** for some seconds until it will turn off. Now the instrument is powered off, then you can safely unplug the DC plug and the mains power cord.

In case of some error or failure that would prevent powering off by the above-mentioned

procedure, you can force a hard power-off by keeping the power button ⏻ pressed for more than 5 seconds.

6.2.　　Software installation

Please check that the computer you are going to use with the SphereFlash® meets the requirements stated in section 3, particularly that the operating system is a 64 bits version, and the USB sockets are USB 3 – compliant.

Check that the instrument is connected to the computer and to the power supply as described in section 5.

Insert the supplied DVD into your computer's DVD reader, and let it automatically execute the installation procedure. When asked for, select the installation of the desired software application (Colonies or Halos PRO software)

Alternatively, obtain the installer executable file:

SphereFlash_Installer_vn.n.n.n.exe (for colonies)
or
SphereFlash_Halos_PRO_Installer_vn.n.n.n.exe (for halos)

copy it into a local folder of your computer, and double-click on this file.

Follow the instructions given on the installer dialog appearing on the screen.

In a first installation, it is recommended that you leave the checkboxes with the default values. If your computer is equipped with an Intel Core i3 processor or similar, we recommend that you keep checked the *'Processor Idle State Manager'* checkbox.
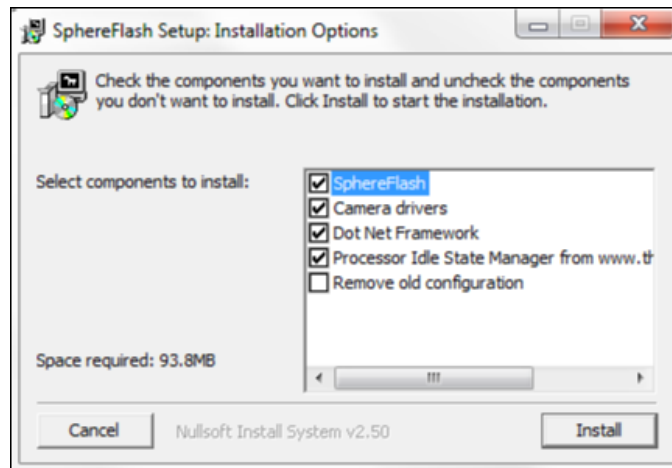
NOTE: Do not check the box *Remove old configuration* unless you are aware that all the processing results and recipes previously stored in the database will be erased.

In the same installation DVD, you will find the *Software Use Guides: Colonies (Basic),* Colonies (*Advanced),* and *Halos.*

6.3.   Log in to the SphereFlash® Software Application

When starting the application, a log-in dialog will be shown; the first time type in the user '*Administrator'* and the password *'1234'*. Later you must change the username and the password and create new users.
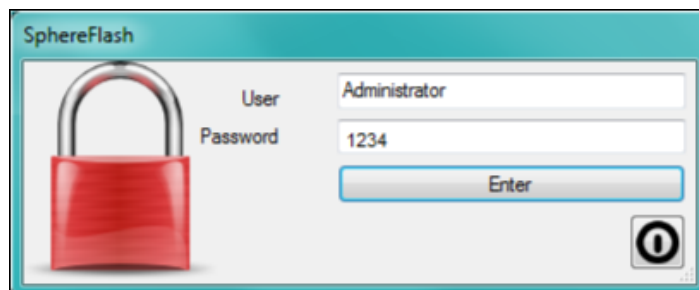
6.4.   Introducing the Activation Key

The first time you are using a particular SphereFlash® instrument, the Software Application will prompt you to introduce your *Colonies PRO / Halos PRO* license activation key for that instrument:
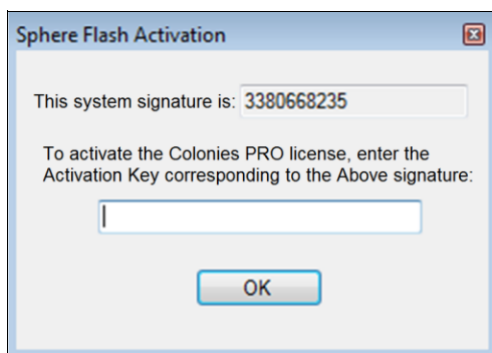
To activate the *Colonies PRO / Halos PRO* license, copy or write down the displayed '*system signature'* and send it to an SCIGIENE representative along with the serial number of your SphereFlash® instrument. In return, SCIGIENE will provide your personalized key, which must be introduced in the *'Activation Key'* field, and then press *OK*.

For the *Colonies Software*, if you cancel this dialog, or fill in a wrong Activation Key, or the instrument is not connected to the computer, the application will run the default *Colonies LITE* license version, where only a basic subset of features is available:
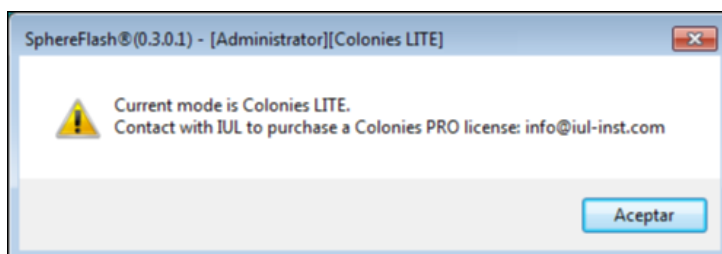
6.5.   Communication issues

If you get a message warning about communication errors with the instrument, it is advisable that you check whether the computer firewall is blocking the access of the SCIGIENE application to the instrument (the SphereFlash® instrument implements a private IP network, with address 192.168.233.1, which is tunneled through the USB 3 connection). Please refer to Chapter 8 Troubleshooting.

6.6.   Calibrating the SphereFlash®

The first time you are using a particular SphereFlash® instrument, and after the use of the instrument for a scheduled number of days, the Software Application will prompt you to perform a calibration procedure. Insert the calibration disk (e) into the platform (5) and proceed as described in the calibration section of the corresponding Software Manual.

6.7. Running a Colony Count / Halos Process operation

Please refer to the *Colony Count / Halos Process* section of the corresponding Software Manual for the details referring to this operation.

The Colony Count / Halos Process panel must be selected in the Application window.

Insert the Petri dish with the colonies or halos to be processed into the platform (5), select a processing method or recipe, fill in the plate ID field, and push the Run process button

▶ to proceed. Alternatively, you can click on the Run process button ▶ of the panel in the application window.

After pushing the button, the diffusing sphere (2) will descend to cover the Petri dish, the lighting and image acquisition procedures will be performed, and finally, the diffusing sphere will return to its upper resting position. Then the process results will be displayed on the screen.

6.8. Running a Verification procedure

According to your laboratory standard procedures, you might be required to perform a periodic verification procedure.

Insert the verification disk (f for Colonies, g for Halos) into the platform (5) and proceed as described in the Verification section of the corresponding Software Manual.

7. MAINTENANCE

There are no serviceable parts inside the SphereFlash® or the AC Adaptor. In case of any trouble refer to Chapter 8 Troubleshooting or contact the SCIGIENE SA Technical Service (see Technical Assistance).

7.1.   Cleaning procedure

Disconnect the SphereFlash® from the power supply for cleaning. Use a lightly moistened cloth or an antistatic cloth. Do not use cleaning agents or abrasive solvent products.

CAUTION ⚠	**Damage to the instrument** Do not use spray bottles containing alcohol or disinfectant to clean the surfaces of the SphereFlash® instrument or its parts. Spray bottles should be used only to clean items that have been removed from the instrument.

8. TROUBLESHOOTING

Symptom	Possible Cause	Actions
The status lamp does not light when pressing the power button	The instrument is not powered	Check that the mains cable is plugged into a mains socket and that the output cable of the power supply module is plugged into the instrument
The status lamp stays solid red indefinitely and/or the sphere does not move up to the uppermost position	The transport securing device has not been removed	Remove the transport securing device as described in section 5.2
	Mechanical blocking of the sphere	Remove any blocking object
	Electronic failure	Contact SCIGIENE technical service
The status lamp is slow flashing, but the application shows a message: *'To activate the Colonies PRO / Halos PRO license, enter the Activation Key corresponding to the above signature'*	You do not have a *Colonies PRO / Halos PRO* license for this instrument S/N	Copy the *System Signature* number from the message box and contact an SCIGIENE representative to get the Activation Key corresponding to the *PRO* license In the case of Colonies Software, by canceling the dialog you can still work with the default *Colonies LITE* license (with a limited set of features)
The application shows an *'Operation Run Error'*	The transport securing device has not been removed	Remove the transport securing device as described in section 5.2
	Mechanical blocking of the sphere	Remove any blocking object
	Electronic failure	Contact SCIGIENE technical service
The image of the plate shows faulty or wrong horizontal lines	Your computer is equipped with an Intel Core i3 processor or similar, which may enter into an *'Idle state'*, causing some image data to be lost during USB transmission	Run again the installation file, and when asked to select components to install, uncheck all the checkboxes, but keep the *'Processor Idle State Manager'* checkbox checked

Symptom	Possible Cause	Actions
The application shows some of the following errors: *'Device Camera not found'* *'Device not discovered'* *'Connection Failed'* *'Connection refused'* '*USB device not recognized'* (Windows message)	The instrument was not powered on or its lamp was not slow-blinking when the application was started	Close the application, push the power-on button of the instrument, and wait until its lamp is slow-flashing. Now you can start again the application
	USB cable not connected between the instrument and the computer	Connect the USB cable
	The USB cable is not USB 3.0 compliant	Use the USB cable supplied with the instrument
	The USB socket of the computer is not USB 3.0 compliant	Use a computer with a USB 3.0 compliant socket: **SS⮂**
	There is a loose contact between the USB cable and the USB socket of the computer	Check the tightness of the USB cable-socket contact, and possibly use a different socket of the computer
	The computer firewall is blocking the IP communication between the SCIGIENE application and the instrument	Disable the firewall; if then the problem is solved, ask your IT service to create a custom rule to allow FULL communication between the SCIGIENE application and the instrument's private network address (192.168.233.1)
	The computer has entered some idle or sleep status and lost communication with the device	Unplug the USB cable, wait some seconds, and plug it in again. Configure the computer not to enter into an idle or sleep status
The application shows some of the following errors: *'Device Camera not found'* *'Device not discovered'* *'Connection Failed'* *'Connection refused'*	Some drivers have not been loaded by the Operating System. Check on the Windows Device Manager list that there is an imaging device controller named *'The Imaging Source Europe...',* and a network adapter and controller named *'Realtek USB GbE...',* or '*USB GbE family controller'* (this name depends on the Windows version)	Unplug the USB cable, wait some seconds, and plug it in again; check that the mentioned device controllers appear on the Device Manager list some seconds after having plugged the USB 3 cable Alternatively, reboot the computer

Symptom	Possible Cause	Actions
'*USB device not recognized'* (Windows message)		
The application terminates unexpectedly when opening a save file or open file dialog	Your computer has an active old version of 'Dell Backup & Recovery' program	Update the 'Dell Backup & Recovery' program to the most recent version, or uninstall it if you are not using it
A *'Bad Calibration Image'* error message appears when executing a calibration procedure	There are some dirt or stains on the calibration disk or on the transparent platform	Clean the platform or remove the dirt on the calibration disk if possible. If there are stains on the calibration disk that cannot be removed, order a new one

APPENDIX A: TECHNICAL DATA

Scigiene reserves the right to change specifications at any time.

Specifications

Device

Computer interface	USB 3.0 Type-A socket
Mains AC Adaptor Output	12V DC 3.43A
Illuminating system	automatic lifting sphere
Reflection lighting	LED, diffused by the sphere
Transmitted lighting	LED, homogenous surface
Protection against the external sphere **light interference**	Opaque
Kind of samples	90mm dishes; 60mm dishes; filter discs; films
Sensor	CMOS 5 Mpixel
Operation time	2 seconds (minimum)

CAUTION ⚠️	**Risk of malfunction or harmful interference** Conformity to **2014/30/EU** and FCC rules could be compromised by the use of an AC adaptor, power cord, or USB cable not provided by Scigiene see EC Declaration of Conformity and FCC Statement.

WARNING ⚡	**Risk of electric shock** In case of replacement or a loosing of the AC adaptor or the mains power cord, these must be replaced only with the AC adaptors or power cords listed in Ordering Codes and provided by Scigiene.

Colonies PRO Software

Regulatory compliance   CFR 21 part 11

Minimum spot (colony) size   0,046mm

Filtering   by colors and sizes

Classification   by colors and sizes

Overlapping segregation   amount of overlap, distance between centres

Alarm limits   total amount of colonies or concentration (CFU/ml)

Halos PRO Software

Regulatory compliance   CFR 21 part 11

Number of halos per plate   up to 8

Results in diameter   referred to halo area

Diameter resolution   0,01mm

Limits selection   minimum and maximum diameter

Operating conditions

Power range   100 ~ 240VAC

Frequency range   50 ~ 60Hz

Maximum power   40W

Overvoltage category   II

Air temperature   15-30ºC (59-86ºF)

Relative humidity   10-75% (non-condensing)

Altitude   Up to 2000m (6500ft.)

Place of operation   For indoor use only

Pollution level   2

Transportation conditions

Air temperature	5ºC to 40ºC (41ºF to 104ºF) In manufacturer's packaging
Relative humidity	Maximum of 75% (non-condensing)

Storage conditions

Air temperature	5ºC to 40ºC (41ºF to 104ºF) In manufacturer's packaging
Relative humidity	Maximum of 75% (non-condensing)

Dimensions and Weight

Dimensions (LxWxH)	288x220x371 mm (11.34x8.66x14.6 in)
Weight	5500 g (12.13 lb)

APPENDIX B: WARRANTY

The SphereFlash® instrument has a 12-month warranty period which starts when the instrument is purchased from Scigiene.

The warranty is void when misuse of the equipment can be proved. Damage or manufacturing faults caused by impacts, chemical or corrosive products, liquids, damp, or other external factors, such as radiation, fire, or inadequate transport are not included.

In addition, the warranty will not apply if the equipment has been handled, repaired, or modified by not qualified or specifically designated personnel.

As part of this warranty, all shipping costs to the selected technical service are the responsibility of the Buyer.

APPENDIX C: WASTE ELECTRICAL AND ELECTRONIC EQUIPMENT (WEEE)

This section provides information about the disposal of waste electrical and electronic equipment by users.

The crossed-out wheeled bin symbol (see below) indicates that this product must not be disposed of with other waste; it must be taken to an approved treatment facility or to a designated collection point for recycling, according to local laws and regulations.

The separate collection and recycling of waste electronic equipment at the time of disposal helps to conserve natural resources and ensures that the product is recycled in a manner that protects human health and the environment.

APPENDIX D: ORDERING CODES

Product	Contents	Part Number
SphereFlash® with Software Colonies LITE	1 unit	MC-90007000
Software Upgrade Colonies PRO	1 unit	MC-90007001
Software Upgrade Halos PRO	1 unit	MC-90007002

OTHER ORDERING CODES

The following accessories can be purchased separately. State the order number (Cat. #) when ordering the accessory.

Product	Contents	Part Number
AC Adapter 12VDC 40W Universal Range	1 unit	MC-90004013
EU Power Cord (Schuko CEE 7/4) 1.5m	1 unit	MC-90004017
UK Power Cord (BS 1363) 2.5m	1 unit	MC-90004019
US Power Cord US / Japan (NEMA 5-15P) 1.8m	1 unit	MC-90004018
CN Power Cord China / Australia (GB 1002, GB 2099.1) 1.8m	1 unit	MC-90004027
AR Power Cord Argentina (IRAM 2073) 2.5m	1 unit	MC-90004026
Verification disk for Halos	1 unit	MC-900011876

Product	Contents	Part Number
Verification disk for Colonies	1 unit	MC-90004113
Calibration disk	1 unit	MC-900010081
Cable USB 3.0 (A Male/A Female) 2 m	1 unit	MC-90001960
Centering device ~87-91 mm ø	1 unit	MC-900013473
Centering device 65-70 mm ø (Rodac plates)	1 unit	MC-900013513
Centering device 54-60 mm ø	1 unit	MC-900013512
Compact Dry adapter	1 unit	MC-900013347
Petrifilm adapter	1 unit	MC-900013525
MC-MEDIA adapter	1 unit	MC-900013536
Instructions for Use	1 unit	MC-50007938

APPENDIX E: EC DECLARATION OF CONFORMITY

Distributor Name:

Scigiene Corporation

Manufacturer Address:

1295 Morningside Ave., Units 16-18, Scarborough, ON, M1B 4Z4

Declares that the product Name:

SphereFlash®

Catalog Numbers:

MC-90007000

Conforms the Council Directives:

- Directive **2014/30/EU** of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (recast).

- Directive **2014/35/EU** of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits (recast).

- Directive **2011/65/EU** of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment and its amendments.

Standards which Conformity is Declared:

- **EN 61326-1:2013** Electrical equipment for measurement, control and laboratory use - EMC requirements -- Part 1: General requirements (IEC 61326-1:2012)

- **EN 61010-1:2010** Safety requirements for electrical equipment for measurement, control, and laboratory use -- Part 1: General requirements**.**

Barcelona, June 1st 2021

CE

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Daniel Blanch
(Director of Electonical Engineering)

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David Guerrero
(Quality Manager)

APPENDIX F: CHINA ROHS STATEMENT

The following information has been made available to comply with SJ/T11364-2006 Marking for Control of Pollution Caused by Electronic Information Products as required by China's Management Methods for the Control of Pollution from Electronic Products.

Part Name - 部件名称	Toxic or hazardous Substances and Element - 有毒或有害的物质成分					
	Lead (Pb) 铅	Mercury (Hg) 汞	Cadmium (Cd) 镉	Hexavalent Chromium (Cr6+) 六价铬	Polybrominated biphenyls (PBB) 多溴联苯	Polybrominated diphenyl ethers (PBDE) 多溴联苯醚
Plastics - 塑料						
Enclosure / Plastics parts - 外壳/塑料部件	O	O	O	O	O	O
Mechanical units - 机械部分						
Chassis / Moving parts - 底盘/可动部分	O	O	O	O	O	O
Electrical Units - 电器部分						
PCB's a. components / Sensors - 印刷电路板部分/传感器	O	O	O	O	O	O
AC Adapter – 交流适配器	X	O	X	O	O	O
Cables - 电缆						
Connecting cables – 连接电缆	O	O	O	O	O	O
Motors - 电机						
Motors / Pumps / Fans - 电机/泵/风扇	O	O	O	O	O	O

O: Indicates that this toxic or hazardous substance contained in all of the homogeneous materials for this part is below the limit requirement in SJ/T11364-2006.

O：代表用于此部件的所有同类型的包含该种有毒或者有害物质的材料均在 SJ/T11364-2006 的规定界限以下

X: Indicates that this toxic or hazardous substance contained in at least one of the homogeneous materials used for this part may be above the limit requirement in SJ/T11364-2006. (EU RoHS2 Exemption).

X：代表用于此部件的至少一种此类型的包含该种有毒或者有害物质的材料可能在 SJ/T11364-2006 的规定界限以上

(属于欧盟 RoHS2 豁免项)

The Environment Friendly Using Period for the SphereFlash® is:

APPENDIX G: FCC STATEMENT

FCC Declaration of Conformity

Responsible party:

Scigiene Corporation

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and

(2) This device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.

- Increase the separation between the equipment and receiver.

- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

- Consult the dealer or an experienced radio/TV technician for help.

Any changes or modification not expressly approved by the party responsible for compliance could void the user's authority to operate the device. Where shielded interface cables have been provided with the product or specified additional components or accessories elsewhere defined to be used with the installation of the product, they must be used in order to ensure compliance with FCC regulations.

Notes