

SphereFlash®

Instructions for Use

SphereFlash® device
Colonies Software
SphereFlash® AI Software



EN

Doc. 50007937-08

Revision date: September 2026

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Contents

Indication of the Introduced Modifications	8
Glossary	9
Part 1: SphereFlash®	10
1. Introduction	10
1.1. Intended use of the SphereFlash®, Colonies Software, SphereFlash® AI colony counting software	10
1.2. Device description.....	10
1.2.1. SphereFlash® device	10
1.2.2. Colonies software.....	11
1.2.3. SphereFlash® AI colony counting software	12
1.3. General Information.....	13
1.3.1. Scope of Delivery.....	13
1.3.2. Technical Assistance	13
1.3.3. Policy Statement.....	14
1.3.4. Requirements for SphereFlash® users	14
2. Safety Information	15
2.1. Proper use	15
2.2. Electrical Safety	16
2.3. Environment.....	17
2.4. Biological safety.....	17
2.5. Chemicals.....	17
2.6. Maintenance safety	18
2.7. Waste disposal	18
2.8. Symbols on the SphereFlash® device	18
3. General Descriptions.....	19
3.1. Device Overview	19
3.2. Accessories of the Device.....	20
3.2.1. Centering device (Ø 87-91 mm).....	20
3.2.2. PC Communication cable	20
3.2.3. Calibration disk.....	20
3.2.4. Verification disk for Colonies	20
3.2.5. Verification disk for Halos	20
3.2.6. External power supply and Power cord	21
3.3. Optional Accessories	21
3.3.1. Centering device Ø 65-70 mm	21
3.3.2. Centering device Ø 54-60 mm	21
3.3.3. COMPACT DRY Adapter	21
3.3.4. PETRIFILM™ Adapter.....	21
3.3.5. MC-MEDIA PAD Adapter	21
3.3.6. Easy Plate Adapter	21
4. Installation of the Equipment.....	22

4.1. Unpack the device	22
4.2. Site requirements.....	22
4.3. Removing the transport securing device	22
4.4. Connecting the Device to the Computer and Power Supply	24
5. Operating Procedures	25
5.1. Power-on, Power-Off, and Status LED Indicator	25
5.2. Software Installation	25
5.2.1. Colonies Software - Computer Requirements and Installation.....	25
5.2.2. SphereFlash® AI Desktop Application - Computer Requirements and Installation.....	29
6. Maintenance	33
6.1. Cleaning procedure	33
Part 2: Colonies Software	34
7. Colonies Software Desktop Application	34
7.1. User Roles.....	34
7.2. Log In	35
7.3. Main Screen Overview.....	37
7.3.1. Header Data.....	37
7.3.2. Image Viewer	37
7.3.3. Control Panel	38
7.3.4. Data Panel.....	38
7.3.5. Processing Panel	39
7.4. Colony Count Menu.....	40
7.4.1. Operation data tab.....	41
7.4.2. Results tab	42
7.5. Processing a plate	46
7.5.1. Manual result adjustments	46
7.6. Results data panel.....	51
7.7. Customizing the logo on the reports (only Colonies PRO)	54
7.8. Template methods.....	55
7.8.1. Using Upper illumination (reflected lighting) with spread distributions	55
7.8.2. Using Bottom illumination (transmitted lighting) for spread distributions.....	56
7.8.3. Using Upper or Bottom illumination for spiral distributions.....	56
7.9. Methods settings (only Colonies PRO)	57
7.9.1. Classes tab	59
7.9.1.1. Count Mode: Filter by Color	61
7.9.1.2. Classes tab: Managing colony classes.....	61
7.9.2. Image capture tab	63
7.9.3. Option settings tab	64
7.9.4. Advanced settings tab	66
7.9.5. Example cases for Advanced Settings options.....	67
7.10. Working with worksheets (only Colonies PRO)	70
7.10.1. Remote tab	70

7.10.2. Creating or editing a worksheet	71
7.10.3. Importing, exporting, and deleting worksheets.....	71
7.10.4. Working with remote file input.....	72
7.10.5. Using a worksheet to count colonies.....	72
7.11. Verify (for the SphereFlash® device).....	74
7.11.1. Verifications data panel.....	75
7.12. Calibrate (The SphereFlash® device).....	77
7.12.1. Calibrations data panel	78
7.13. View Results menu	79
7.13.1. Results and Results Summary	79
7.13.2. Methods.....	80
7.13.3. Calibration	81
7.13.4. Manage Results Group (only in Colonies PRO)	81
7.13.5. Manage custom views (only Colonies PRO).....	82
7.14. Stored Data	83
7.14.1. Audit Trail (only in Colonies PRO).....	83
7.14.2. Purge (only in Colonies PRO)	85
7.14.2.1. Location of archived database files resulting from purge operations	86
7.14.2.2. Temporary manual restoration of archived databases	86
7.15. User management.....	88
7.15.1. Change user password.....	88
7.15.2. View existing users (only Colonies PRO).....	88
7.15.3. Add new user (only Colonies PRO).....	89
7.15.4. Other user management operations (only Colonies PRO)	89
7.15.5. Failed Login Attempts and Password Recovery	89
A. User blocked	89
B. User forgets the password	90
7.16. Environment options (only Colonies PRO)	91
7.16.1. System options panel	92
7.16.2. Interfacing with a LIMS	94
7.17. External Counter (only in Colonies PRO).....	97
7.17.1. Using IUL's DOT manual colony counter	97
7.17.2. Using other means for a manual count.....	98

8. Troubleshooting Colonies Software..... 100

Part 3: SphereFlash® AI..... 102

9. General Information 102

9.1. Subscription Portal.....	102
9.2. SphereFlash® AI Desktop Application	102
9.3. User Roles.....	103

10. Subscription Portal 104

10.1. Accessing the SphereFlash® AI Subscription Portal.....	104
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10.2. Navigating the Subscription Dashboard	105
10.3. Buying a Plan.....	105
10.4. Reviewing the Active Plan and Billing Overview.....	107
10.5. Creating a New Group.....	107
10.6. Adding a New User to a Group	108
10.7. Checking if the User Has Verified Their Account.....	109
10.8. Viewing and tracking Image usage	109
11. Desktop Application	111
11.1. Log In	111
11.2. Main Screen Overview	112
11.2.1. Header Data	112
11.2.2. Image Viewer	113
11.2.3. Control Panel.....	113
11.2.4. Data Panel.....	113
11.3. Colony Counting Menu.....	114
11.3.1. Colony count data tab	115
11.3.2. Result tab	117
11.4. Processing a plate	121
11.4.1. Manual result adjustments	121
11.5. Cloud results data panel	126
11.6. Template Methods.....	128
11.7. Methods Settings.....	130
11.7.1. Classes tab.....	132
11.7.1.1. Count mode: Filter by Color.....	133
11.7.1.2. Count mode: Filter by Size	134
11.7.2. Image capture tab.....	135
11.7.3. Option settings tab	136
11.8. Verification (for the SphereFlash® device).....	138
11.8.1. Verifications data panel.....	139
11.9. Calibration (for the SphereFlash® device).....	141
11.9.1. Calibrations data panel	142
11.10. Browse Views.....	143
11.10.1. Methods.....	143
11.10.2. Results and Results Summary	144
11.10.3. Verification and Calibration	144
11.11. Stored Data	145
11.11.1. Audit trail window.....	145
11.11.2. Restore window	147
11.12. Application Parameters.....	148
11.12.1. System Options panel	149
11.12.2. Interfacing with a LIMS	151
11.13. User Settings.....	153
11.14. Account Info.....	154

11.15. About.....	155
12. Troubleshooting	156
12.1. Subscription Portal.....	156
12.2. SphereFlash® AI Colony Counting Software Desktop Application.....	157
Appendices.....	161
APPENDIX A Ordering Codes	161
APPENDIX B Technical Data.....	164
APPENDIX C Spiral Distribution	168
APPENDIX D Warranty	173
APPENDIX E Waste Electrical and Electronic Equipment (WEEE)	174
APPENDIX F EU Declaration of Conformity	175
APPENDIX G FCC Statement	176
APPENDIX H Colonies Software Regulatory compliance: FDA 21 CFR part 11 Subpart B	177
IUL Technical Support Contact.....	185

Indication of the Introduced Modifications

If this is your first time using the SphereFlash and colony counting software please read the entire document carefully.

If this is not your first time using the SphereFlash and colony counting software, you can read the indication of the introduced modifications in the table below.

Revision	Description of change
08	Update format
	Combine instructions for use for SphereFlash® device, Colonies LITE, Colonies PRO, and SphereFlash® AI

GLOSSARY

Method	Named collection of parameters that defines how plate images are processed and how colonies are detected and classified. Methods are used to adapt the AI analysis to different plate types, colony appearances, and procedural conditions.
Captured Image	Original image acquired by the SphereFlash® device or another colony counter prior to any software processing.
Processed Image	Image that has been analyzed and annotated by the software.
Subscription Portal	Web platform used to manage the SphereFlash® AI Plan account.
Desktop Application	Application used to process images using the SphereFlash® AI software.
AI Plan	Annual subscription AI plan assigned to a company (tenant). The AI Plan defines the available image limit and cloud results limit (Image Pack and Storage Pack). It is managed by the Tenant-admin(s).
Image Pack	Defines the maximum number of images that can be processed per year. This includes images from Colony Counting and Verification, but excludes Calibration.
Storage Pack	Defines the maximum number of results stored in the cloud. When the limit is reached, the oldest results are automatically deleted.
Group	Represents a group of users that share results and methods.

PART 1: SPHEREFLASH®

1. INTRODUCTION

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

Before using the instrument and the software, it is essential that you read the 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®, Colonies Software, SphereFlash® AI colony counting software

The SphereFlash® is an automatic colony counter intended for the acquisition of high-quality images of plates and for use in combination with compatible IUL software applications for microbial colony counting and related microbiological image analysis procedures.

The system is intended for use by trained laboratory personnel in microbiology laboratories, including applications in quality control, research laboratories, food and beverage industries, environmental laboratories, pharmaceutical laboratories, industrial microbiology and related microbiological testing environments.

The device can be used with the Colonies Software or with the SphereFlash® AI colony counting software.

The **Colonies software** is intended for use with the SphereFlash® instrument for the visualization, processing, analysis, enumeration, review, documentation, storage, and export of microbial colony count results obtained from plates.

The **SphereFlash® AI colony counting software** is intended for use with the SphereFlash® instrument for AI-based microbial colony counting on challenging plates.

1.2. Device description

1.2.1. SphereFlash® device

The SphereFlash® is an automatic imaging device designed to provide uniform, reflection-free illumination for microbiological plate analysis. It is compatible with 55–90 mm Petri dishes and commercially available alternative culture media formats, including Compact Dry™, Petrifilm™, MC-MEDIA PAD®, and Easy Plate™.

The system uses LED illumination directed toward the internal wall of a movable spherical chamber. This configuration creates homogeneous indirect illumination while minimizing shadows, glare, and reflections. For transparent or translucent media, transmitted illumination from below the plate is also available.

During operation, the movable spherical chamber closes around the plate, isolating the imaging area from ambient light and preventing interference from external reflections. This design improves colony visualization and reduces artifacts caused by plate walls or external lighting conditions.

The SphereFlash® device is compatible with the following IUL colony counting software applications:

- **Colonies software** for standard microbial colony counting
- **SphereFlash® AI colony counting software** for AI-based colony counting

1.2.2. Colonies software

The Colonies software is a desktop-based application designed for standard microbiology workflows, providing accurate and reliable colony counting with all the essential features needed for routine analysis.

The software operates locally on the workstation and does not require an internet connection for routine operation.

The Colonies software is available in two configurations:

- **Colonies LITE**, included as standard with the SphereFlash® device.
- **Colonies PRO**, an advanced and upgraded configuration activated once using a software license.

Colonies LITE software provides trained users with the essential features needed for routine analysis, including the ability to:

- Review, validate, save, and export colony counting results and associated image data in multiple formats, including CSV, TXT or XLSX, and PNG for image export.
- Select the appropriate illumination mode for image acquisition.
- Manually add or remove colonies and define inclusion or exclusion areas, including polygonal zones.
- Generate reports and statistical reports with embedded images, and copy result tables directly to the clipboard for immediate use in external applications.
- Perform on-site calibration procedures for the SphereFlash® instrument and verification procedures for the software

Colonies PRO software provides additional advanced functionalities, including:

- Custom colony classification and method configuration, including modification of image processing and illumination parameters to optimize colony detection performance.
- Configurable user permission levels (Administrator, Programmer, and Operator)
- LIMS integration support and remote input/output file management.
- Barcode reader support.
- Audit Trail.
- Worksheet management.
- Configuration of operational settings and application preferences, including password policies, calibration requirements, and verification intervals.
- External Counter functionality for integration of manually obtained or externally generated colony count results.

Colonies PRO includes functionality intended to support electronic records and electronic signature workflows in accordance with **21 CFR Part 11 Subpart B**.

1.2.3. SphereFlash® AI colony counting software

The SphereFlash® AI colony counting software is an AI-based application designed for challenging microbiological plates and challenging colony detection conditions.

The software processes plate images using a pre-trained Artificial Intelligence (AI) model to provide advanced colony detection and counting performance with powerful and precise results, minimizing the need for manual adjustments.

The software is especially recommended for complex or highly variable plates, including cases involving low-contrast colonies, irregular colony morphology, high colony density and complex agar backgrounds.

SphereFlash® AI is a cloud-based application and requires installation on a workstation with internet connectivity.

SphereFlash® AI is provided under a Subscription Plan model based on:

- **Image Pack:** Defines the maximum number of images that can be processed per year. This includes Colony Counting and Verification images, excluding Calibration images.
- **Storage Pack:** Defines the maximum number of results stored in the cloud. When the limit is reached, the oldest stored results are automatically deleted.

See Appendix Ordering codes to see the available packages.

The SphereFlash® AI software allows trained users to:

- Review, validate, save, and export colony counting results and associated image data in multiple formats, including CSV, TXT or XLSX, and PNG for image export.
- Select the appropriate illumination mode for image acquisition.
- Upload and process plate images stored locally on the workstation.
NOTE: Uploaded images must be captured from a direct top view, square, centered, and have a resolution of 768 × 768 pixels or higher.
- Manually add or remove colonies and define inclusion or exclusion areas, including polygonal zones.
- Generate reports and statistical reports with embedded images, and copy result tables directly to the clipboard for immediate use in external applications.
- Perform on-site calibration procedures for the SphereFlash® device and verification procedures for the software
- Custom colony classification and method configuration, including modification of image processing and illumination parameters to optimize colony detection performance.
- Configurable user permission levels (Tenant-admin, Administrator, and Operator)
- LIMS integration support and remote input/output file management.
- Barcode reader support
- Audit Trail
- Configuration of operational settings and application preferences, including password policies, calibration requirements, and verification intervals.

SphereFlash® AI software includes functionality intended to support electronic records in accordance with **21 CFR Part 11 Subpart B**.

1.3. General Information

1.3.1. Scope of Delivery

The delivery of the SphereFlash® device includes the following items:



- A. SphereFlash® device (Cat. 10007000).
- B. External power supply (Cat. 90001566).
- C. Power cord (Cat. According to destination country).
- D. PC Communication cable (Super Cable USB 3.0 Type-A) (Cat. 90001960).
- E. Calibration disk (Cat. 900010081).
- F. Verification disk for Colonies (Cat. 90004113).
- G. Centering device (Ø 87-91 mm) (Cat. 900013473)*.
- H. Verification disk for Halos (Cat. 900011876).

* Other centering devices for different plate diameters and additional adapters are available. See Section 3.3. Optional Accessories for more details.

Apart from the list of items above, the delivery also comes with the following documents:

- Design qualification (Doc. 50007945).
- SphereFlash Datamatrix Instructions for use and Software installers (Doc. 50008885).

1.3.2. Technical Assistance

At IUL 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 IUL products. If you have any questions or experience any difficulties regarding the SphereFlash® or IUL products in general, do not hesitate to contact us.

IUL 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 at IUL. We encourage you to contact us if you have any suggestions about product performance or new applications and techniques.

For technical assistance, contact the IUL Technical Service Department or local distributors.

1.3.3. Policy Statement

It is the policy of IUL to improve products as new techniques and components become available. IUL 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 IUL Technical Service with any feedback.

1.3.4. 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	IUL Service Specialists only	Trained, certified, and authorized by IUL

2. SAFETY INFORMATION

Before using the SphereFlash®, it is essential that you read these Instructions for Use carefully. Following the instructions and safety information 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.
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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.
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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.
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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.
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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 IUL 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 the technical data appendix. • 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 loosening 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 appendix and provided by IUL.
---	--

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 spilt on the instrument or over the AC adaptor, switch it off, disconnect the AC adaptor from the mains power outlet, and contact IUL Technical Services.

If the SphereFlash® becomes electrically unsafe, prevent other personnel from operating it, and contact IUL 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 appendix.
- A different AC adaptor is used other than the one provided by IUL.
- A different mains power cord is used other than the one provided by IUL.

WARNING 	Risk of electric shock In case of replacement or a loosening 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 the ordering codes appendix and provided by IUL.
---	--

2.3. Environment

Operating conditions

See technical data appendix 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.
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WARNING 	Risk of overheating Slits and openings that ensure the ventilation of the SphereFlash® must not be covered
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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 OSHA1 ACGIH2 or COSHH3 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.
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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.

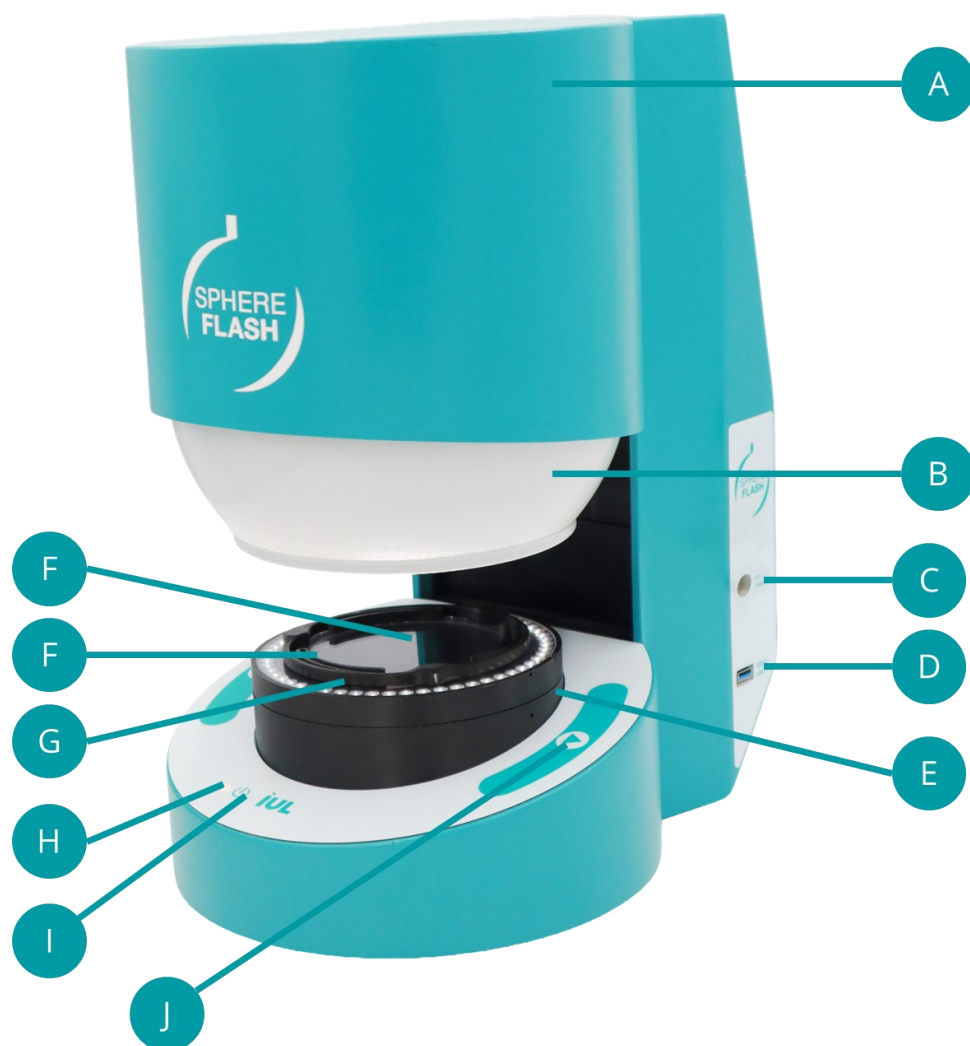
For disposal of waste electrical and electronic equipment (WEEE) see technical data appendix.

2.8. Symbols on the SphereFlash® device

Symbol	Location	Description
	Type plate on the back of the equipment	Waste Electrical and Electronic Equipment (WEEE), see the corresponding appendix.
	Type plate on the back of the equipment	CE Mark, Declaration of Conformity, see the corresponding appendix.
	On the side overlay	USB 3.0 Device compliant

3. GENERAL DESCRIPTIONS

3.1. Device Overview



- | | |
|---|---|
| A. Cover | F. Bottom illumination (transmitted lighting) |
| B. Spherical movable chamber | G. Upper illumination (reflected lighting) |
| C. External power supply Port (DC input socket) | H. Status LED indicator |
| D. PC Connection Port (USB 3.0 Type-A) | I. Power button |
| E. Platform for centering device or adapter | J. Run process button |

3.2. Accessories of the Device

3.2.1. Centering device (Ø 87-91 mm)

The centering device is designed for Petri dishes with a bottom diameter of Ø 87–91 mm. Includes 3 magnets for secure attachment to the SphereFlash platform.

3.2.2. PC Communication cable

The PC Communication cable (Super Cable USB 3.0 Type-A) (Cat. 90001960) is the blue USB cable supplied with the SphereFlash® device. It is used to connect the SphereFlash® device to the user's computer.

The PC is used to install and run the corresponding SphereFlash® Software Applications, including:

- Colonies Software
- SphereFlash® AI Software

Through this connection, the instrument device with the software application for image acquisition and analysis.

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 IUL. Please refer to the ordering codes appendix in case you need to replace this cable.
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3.2.3. Calibration disk

The calibration disk (Cat. 900010081) is used to calibrate the SphereFlash® device's imaging system (Illumination parameters, Plate centering position and Image scaling parameters) to ensure accurate and consistent measurements over time.

3.2.4. Verification disk for Colonies

The verification disk for colonies (Cat. 90004113) is used to verify the correct performance of the Colonies LITE, PRO and SphereFlash® AI software. The disk contains patterns that simulate small, medium, and large colonies, allowing the system to verify that the detected total count falls within the expected range.

3.2.5. Verification disk for Halos

The verification disk for halos (cat. 900011876) is used to verify the correct performance of the Halos PRO software. The disk contains patterns simulating six halos with a diameter of 20 mm, allowing the system to check that halo detection and diameter measurements are accurate.

Refer to the Halos PRO Instructions for Use for more information on how to perform halos measurements with the SphereFlash® and as well as optional accessories related to halo measurements.

3.2.6. External power supply and Power cord

An external power supply (Cat. 90001566) is included with the SphereFlash® device to convert the mains AC supply into the DC low-voltage supply required by the device.

The power cord is used to connect the external power supply to the mains power outlet. The power cord varies depending on the destination country.

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 IUL.
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WARNING 	Risk of electric shock In case of replacement or loss of the external power supply or the power cord, these must be replaced <u>only</u> with the external power supply or power cords listed in ordering codes appendix and these must be provided by IUL.
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3.3. Optional Accessories

3.3.1. Centering device Ø 65-70 mm

Centering device designed for Petri dishes with a bottom diameter of Ø 65–70 mm. Includes 3 magnets for secure attachment to the SphereFlash® platform. Users should verify the bottom diameter of their Petri dishes to ensure compatibility.

3.3.2. Centering device Ø 54-60 mm

Centering device designed for Petri dishes with a bottom diameter of Ø 54–60 mm. Includes 3 magnets for secure attachment to the SphereFlash® platform. Users should verify the bottom diameter of their Petri dishes to ensure compatibility.

3.3.3. COMPACT DRY Adapter

Adapter for Compact Dry™ plates, ensuring proper positioning during image capture. Includes 3 magnets for secure attachment to the SphereFlash® platform.

3.3.4. PETRIFILM™ Adapter

Adapter for Petrifilm™ plates, designed for accurate and stable positioning. Includes 3 magnets for secure attachment to the SphereFlash® platform.

3.3.5. MC-MEDIA PAD Adapter

Adapter for MC-MEDIA PAD plates, allowing correct placement and alignment. Includes 3 magnets for secure attachment to the SphereFlash® platform.

3.3.6. Easy Plate Adapter

Adapter for Easy Plate plates, ensuring correct positioning and stable positioning. Includes 3 magnets for secure attachment to the SphereFlash® platform.

4. INSTALLATION OF THE EQUIPMENT

4.1. Unpack the device

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

4.2. Site requirements

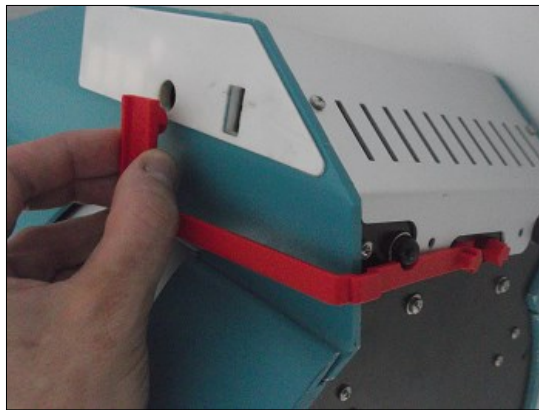
Place the SphereFlash® device on a solid, vibration-free surface. Ideally, a firmly secured benchtop, near an earthed/grounded electrical outlet.

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.

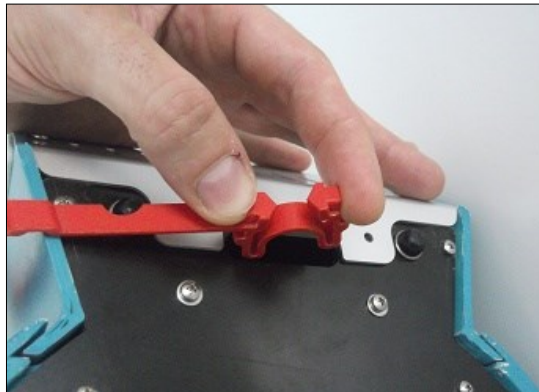
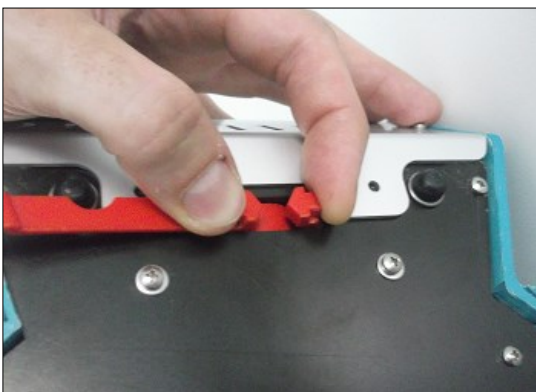
4.3. Removing the transport securing device

Lay down the device 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.

1. Pull out the cover of the power input socket:



2. Squeeze the arrows towards each other and, while squeezing, pull out the securing device:



3. Once extracted, save the securing device to re-use it in future shipments, since it is essential for the safe transport of the SphereFlash® device.

CAUTION**Damage to the instrument**

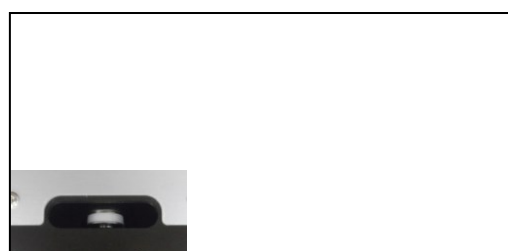
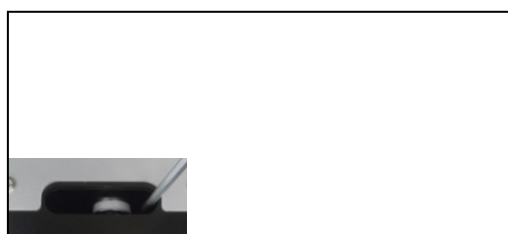
The use of the SphereFlash® without removing the transport security device may cause a failure on the spherical chamber mechanism, which will not be covered by the Warranty.

**CAUTION****Damage to the instrument**

Do not attempt to move the spherical chamber by hand at any time; it may cause a failure of the spherical chamber mechanism, which will not be covered by the Warranty.

If the SphereFlash® device must be transported, you should reuse the securing device to prevent damage caused by transport jerks.

To place the transport securing device again, 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 below but in reverse order.

4.4. Connecting the Device to the Computer and Power Supply

Before connecting the SphereFlash® device, verify that the computer meets the minimum system and connectivity requirements for the software application to be used (Colonies software or SphereFlash® AI software). See Section 5.2. Software installation.

1. Connect the PC Communication cable (Super Cable USB 3.0 Type-A) (Cat. 90001960) to the PC communication socket (USB 3.0 Type-A) of the SphereFlash® device and to a USB 3.0 port on the user's computer.

If a communication error message is displayed, verify that the computer firewall is not blocking communication between the IUL software application and the SphereFlash® device.

The SphereFlash® device implements a private IP network with address 192.168.233.1 tunnelled through the USB 3.0 connection.

2. Insert the external power supply (Cat. 90001566) output plug into the device's external power supply socket.
3. Insert the external power supply into the power cord (Cat. According to destination country).
4. Plug the power cord into the electrical outlet.

If the SphereFlash® is not used for a long period of time, disconnect the mains power cable from the electrical outlet.

CAUTION 	Risk of malfunction or harmful interference Conformity to 2014/30/EU and FCC rules could be compromised by the use of an external power supply, power cord, or PC communication cable not provided by IUL.
WARNING 	Risk of electric shock In case of replacement or loss of the external power supply or the power cord, <u>only</u> the external power supplies or power cords listed in ordering code appendix and provided by IUL shall be used.

5. OPERATING PROCEDURES

5.1. Power-on, Power-Off, and Status LED Indicator

To power on the SphereFlash® device briefly press the power button .

The status LED indicator  will light solid red for approximately 40 seconds.

The spherical chamber will then rise, and the status LED indicator will change to slow flashing red. The SphereFlash® device is now ready to communicate with the software application installed on the PC.

To power off the SphereFlash® device, briefly press the power button.

The spherical chamber will lower, and the status LED indicator will flash rapidly for several seconds until it turns off. The device is then powered off and can be safely disconnected from the external power supply and mains power outlet.

In case of an error or failure preventing normal shutdown, a forced power-off can be performed by pressing and holding the power button for more than 5 seconds.

5.2. Software Installation

For the initial setup of the application, you must be authorized by your company's management to act as Administrator of the software.

The SphereFlash® device must be connected when installing the DFM 72BUC02-MLA camera driver.

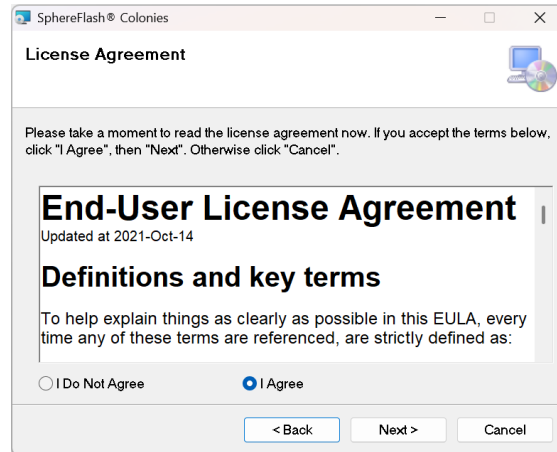
5.2.1. Colonies Software - Computer Requirements and Installation

To install and run the Colonies software, the computer must meet or exceed the following requirements:

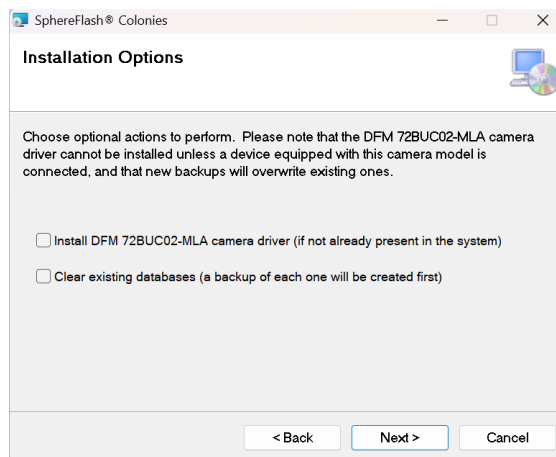
Processor	x64, 2.5 GHz
Operating System	Microsoft 64-bit Windows 7, 8.1, 10, 11 (x64 platforms)
Interface	1 free USB 3.0 port 
RAM	8 Gigabytes
Free disk space	Application: 100 Megabytes Database: 10 Gigabytes (for 5000 results stored w/images)
Screen resolution	Full HD (1920 x 1080px) (recommended)
Screen size	24" (recommended)
Optional third-party applications	• Microsoft Excel® 2007 or higher 64-bit (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)

Please follow the steps below to install the Colonies software:

1. Download the software by scanning the QR code or using the link found in the datamatrix document supplied with the device. Alternatively, the software installer can also be downloaded from the IUL Support Page.
2. Run the .exe file and follow the on-screen instructions carefully. During the installation, the screen below appears:



3. Click on 'Agree' to the End-User License Agreement to proceed.
4. After the End-User License Agreement window, the following screen will appear:

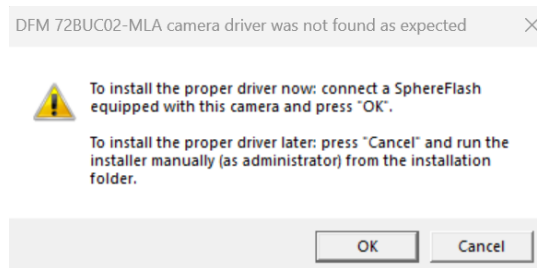


There are two check-box options:

- a. Install DFM 72BUC02-MLA camera driver (if not already present in the system).
 - Do NOT enable this option if you have a SphereFlash® device with a serial number 10007000/0576 or higher.
- NOTE:** The Serial Number can be found on the back of the device.
- ENABLE this option if you have a SphereFlash® device with a serial number 10007000/0575 or lower to install the new DFM 72BUC02-MLA camera driver.

NOTE: The SphereFlash® device must be connected to the compatible computer.

NOTE: If this option is selected while SphereFlash® device is not connected, pressing the 'Next' button will display the following error message:

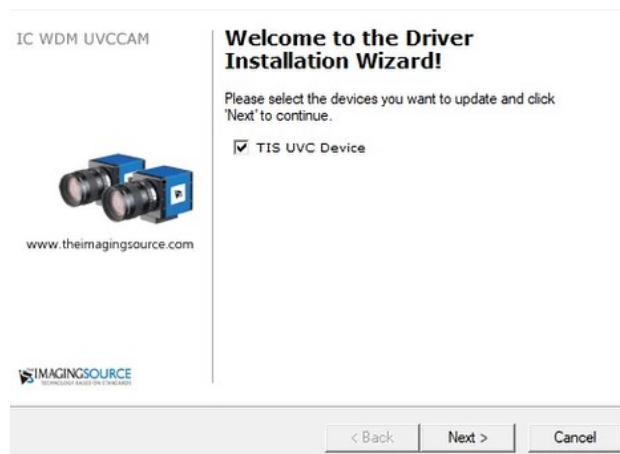


- b. Clear existing databases (a backup of each one will be created first).
- Select this option to delete existing Results and Methods databases, if present. Before deletion, a backup copy of each database is automatically created to prevent data loss.

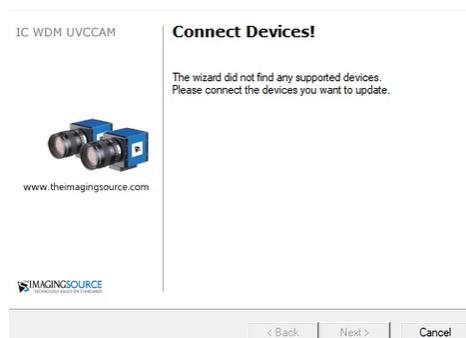
Aside from the Colonies software, the Imaging Source Processor Idle Manager and camera driver(s) will also be installed. These components are necessary to ensure correct and safe operation of the device.

NOTE: In some cases, the 'TIS UVC Device' checkbox may not appear even though the SphereFlash® device is connected. If this occurs, disconnect and reconnect the device, then wait a few seconds until the checkbox appears. The checkbox MUST be visible and enabled to ensure proper installation of the camera driver.

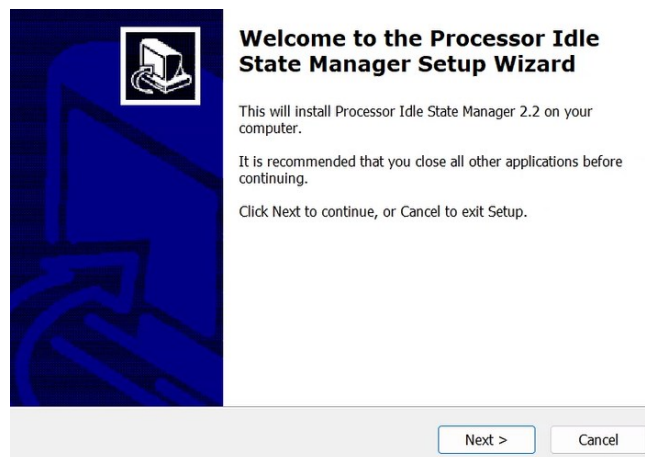
The image below is the installation window for the DFM 72BUC02-MLA camera driver when the SphereFlash® device is NOT connected (if enabled):



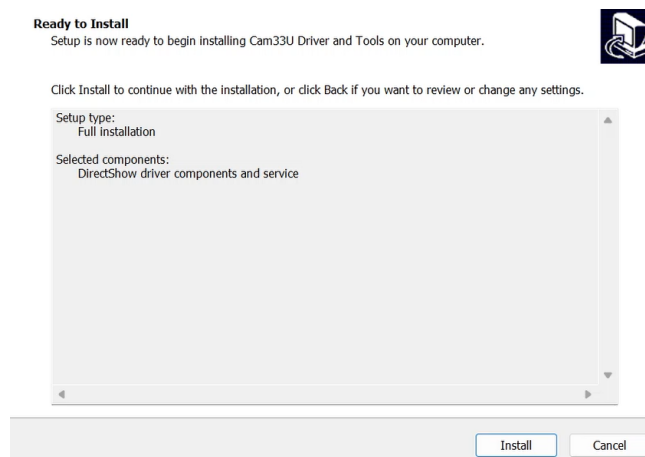
The image below is the installation window for the old camera driver when the SphereFlash® device is NOT connected (if enabled):



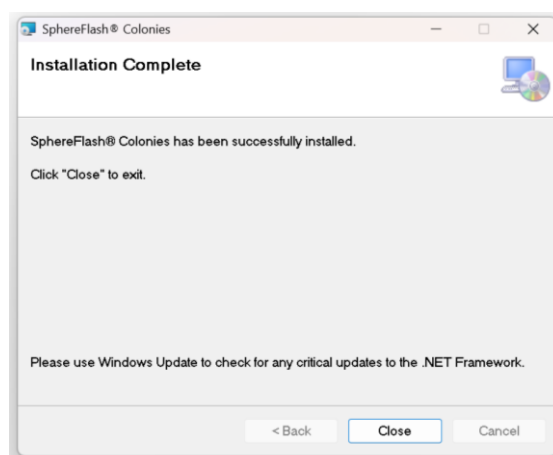
The image below is the installation window for the Imaging Source Processor Idle Manager:



The image below is the installation window for the new camera driver:



Multiple installation windows will appear during the installation process. All pre-selected options must remain enabled. Proceed with the installation as instructed. If the installation is successful, the following window appears:



Now your desktop should contain a new shortcut for the SphereFlash® Colonies software:



5.2.2. SphereFlash® AI Desktop Application - Computer Requirements and Installation

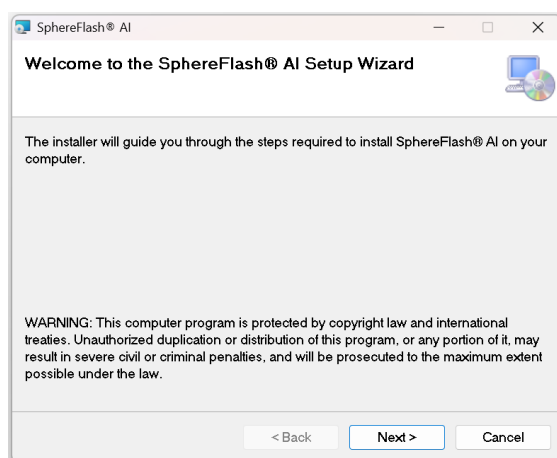
To install and run the SphereFlash® AI Desktop Application, the computer must meet or exceed the following requirements:

Processor	Multicore with a <i>CPU Mark</i> ¹ score of at least 2500 (scores over 8000 are recommended)
Operating System	Microsoft 64-bit Windows 10, Windows 11
.NET framework	Version 4.6.2 or higher
Interface	1 free USB 3.0 port 
RAM	8 Gigabytes
Free disk space	100 Megabytes
Screen resolution	Full HD 1920x1080 pixels (recommended)
Screen size	24" (recommended)
Optional third-party applications	• Microsoft Excel® 2007 or higher, 64 bits (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)
Connectivity	An internet connection is required

NOTE: The computer's internet connection should have a minimum speed of 20 Mbps for both uploads and downloads when accessing the Subscription Portal (www.aicolonycounting.com).

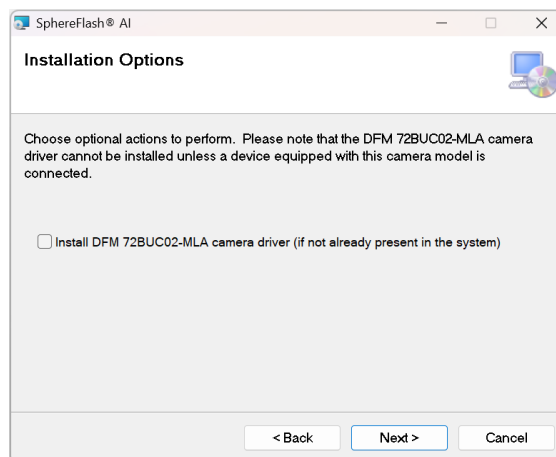
Please follow the steps below to install the SphereFlash® AI Desktop Application:

1. Download the software by scanning the QR code or using the link found in the datamatrix document supplied with the device. Alternatively, the software installer can also be downloaded from the IUL Support Page.
2. Run the .exe file and follow the on-screen instructions carefully.



¹ Check your CPU score at: https://www.cpubenchmark.net/cpu_list.php

3. Click on 'Agree' to the End-User License Agreement to proceed.
4. After the End-User License Agreement window, the following screen will appear:

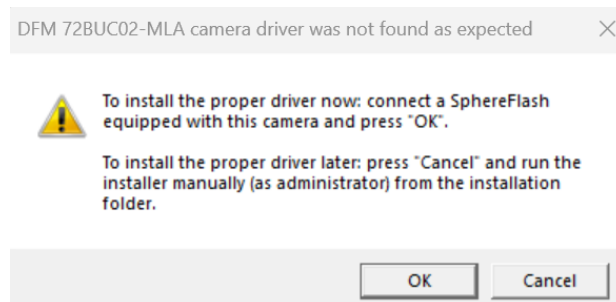


5. Install DFM 72BUC02-MLA camera driver (if not already present in the system).
 - Do NOT enable this option if you have a SphereFlash® device with a serial number 10007000/0576 or higher.
 - ENABLE this option if you have a SphereFlash® device with a serial number 10007000/0575 or lower to install the new DFM 72BUC02-MLA camera driver.

NOTE: The Serial Number can be found on the back of the device.

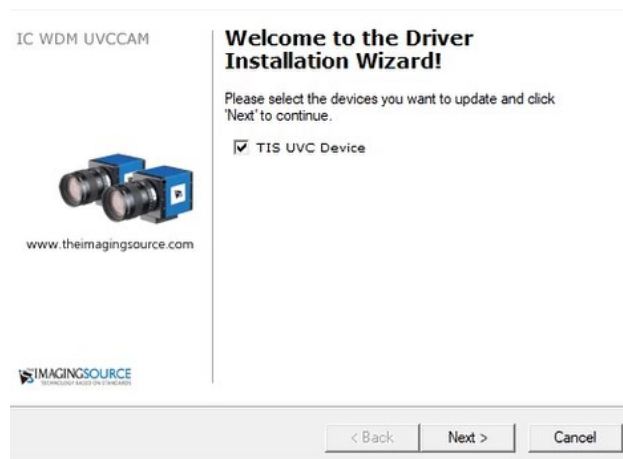
IMPORTANT: The SphereFlash® device must be connected to the computer before installing the camera driver.

NOTE: If this option is selected while SphereFlash® device is not connected, pressing the 'Next' button will display the following error message:



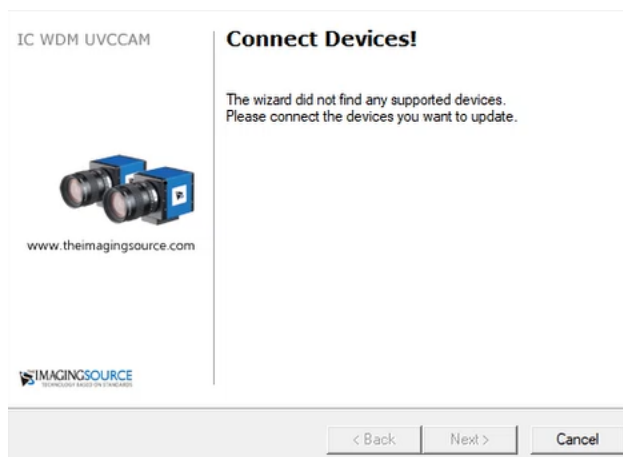
Aside from the SphereFlash® AI Desktop Application, the Imaging Source Processor Idle Manager and camera driver(s) will also be installed. These components are necessary to ensure correct and safe operation of the device.

The image below is the installation window for the DFM 72BUC02-MLA camera driver when the SphereFlash® device is connected (if enabled):

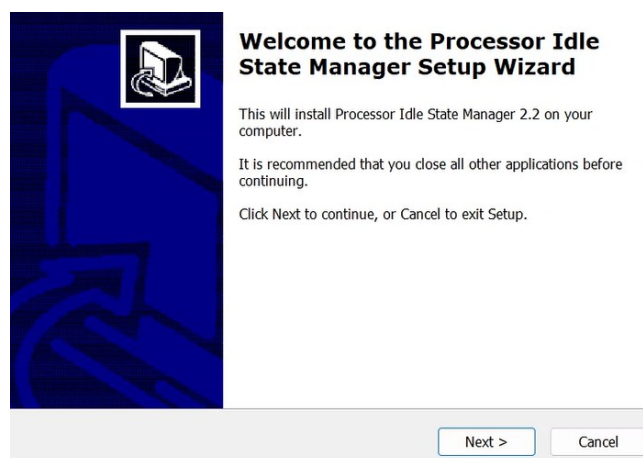


NOTE: In some cases, the 'TIS UVC Device' checkbox may not appear even though the SphereFlash® device is connected. If this occurs, disconnect and reconnect the device, then wait a few seconds until the checkbox appears. The checkbox **MUST** be visible and enabled to ensure proper installation of the camera driver.

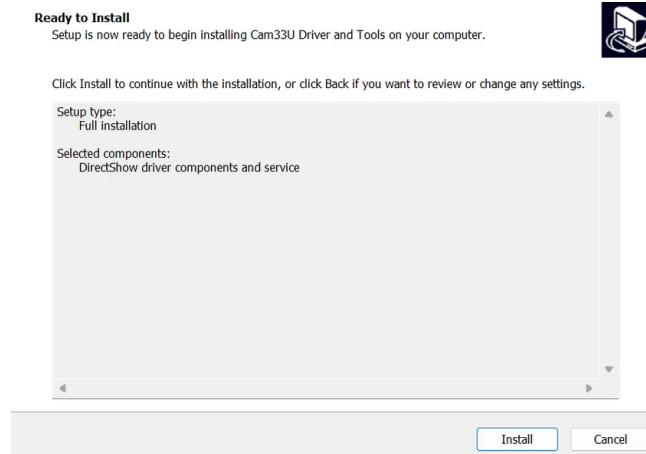
The image below is the installation window for the DFM 72BUC02-MLA camera driver when the SphereFlash® device is NOT connected (if enabled):



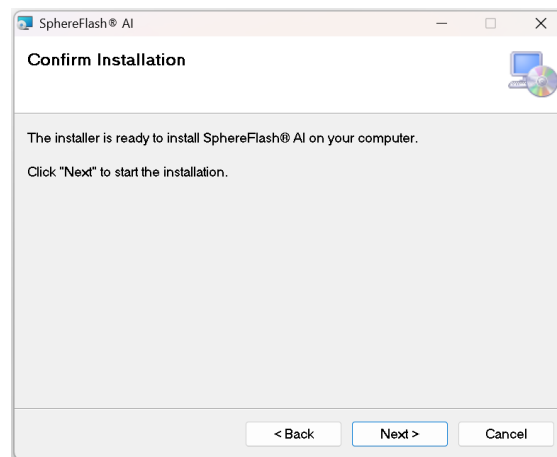
The image below is the installation window for the Imaging Source Processor Idle Manager:



The image below is the installation window for the new camera driver:



Multiple installation windows will appear during the installation process. All pre-selected options must remain enabled. Proceed with the installation as instructed. If the installation is successful, the following window appears.



Now your desktop should contain a new shortcut for the SphereFlash® AI Desktop Application:



6. MAINTENANCE

There are no serviceable parts inside the SphereFlash®. In case of any trouble, refer to the applicable troubleshooting section according to the software being used:

- **Section 8. Troubleshooting**, when using the **Colonies Software**.
- **Section 12. Troubleshooting**, when using the **SphereFlash® AI Software**.

Alternatively, contact IUL Technical Service for assistance.

6.1. Cleaning procedure

Before cleaning, disconnect the SphereFlash® device from the power supply.

Clean the centering devices and plate adaptors using a soft cloth or antistatic cloth moistened with water and mild soap.

Clean the platform using a cloth moistened or an antistatic cloth with 70% ethanol or isopropyl alcohol (IPA), preferably 90%. A 70% IPA solution may also be used for routine cleaning. If necessary, 100% IPA may be used with caution.

Clean the spherical chamber using a soft cloth moistened or an antistatic cloth with water.

Do not use abrasive products or aggressive solvents on any part of the device.

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.
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PART 2: COLONIES SOFTWARE

7. COLONIES SOFTWARE DESKTOP APPLICATION

7.1. User Roles

The Colonies LITE software defines one user role with the following access:

User role	Key Capabilities
Administrator	• Perform colony counting. • Adjust 'Run Data' and 'Run Input Values' and reload them (if method permits). • Perform verifications & calibrations. • View and export Results (CountResults), Results Summary (CountResults_lite), Methods, Verifications and Calibrations. • Change its user password.

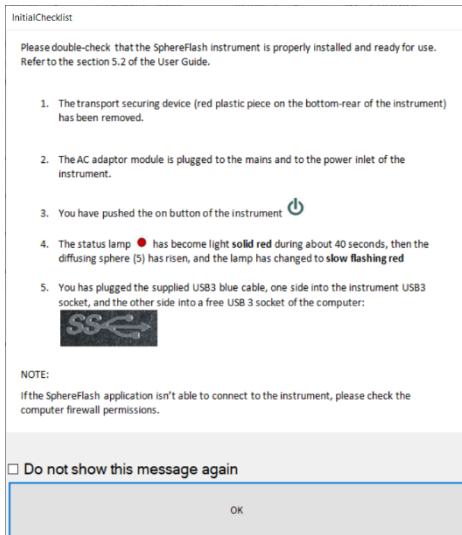
The Colonies PRO software defines three user roles with different access levels:

User role	Key Capabilities
Operator	• Perform colony counting. Perform colony counting. • Adjust 'Run Data' and 'Run Input Values' and reload them (if method permits). • Select, use, import, or export an existing worksheet or 'Remote Input' configuration. Perform verifications & calibrations. • Create Results Groups. • View and export Results (CountResults), Results Summary (CountResults_lite), Methods, Verifications and Calibrations. • Export a method. • Change its user password. • Use an External Manual Counter.
Programmer	• Operator capabilities • Re-process the image of a previously stored result of a colony count operation • Define Operator permission to adjust 'Run Data' and 'Run Input Values' parameters and perform interactive modifications to counting results. • Save into a method the 'Run Data' and 'Run Input Values' values modified during a single colony count operation. • Create, edit, and delete worksheets. • Delete Results Groups. • Create, edit, delete, import and export counting methods.
Administrator	• Access audit trail information (view, sort, filter, select, export, and print tables) • Purge outdated results from the database • Create, edit, and delete custom views • Manage users (view, create, remove, assign role and password) • Change environment settings

7.2. Log In

Make sure that the device is powered on, the Status LED indicator is flashing, and the PC communication cable (Cat. 90001960) is properly connected between the device (USB 3.0 Type-A port) and the computer (USB 3.0 port).

Click on the SphereFlash® Colonies software shortcut icon on your desktop. The application will launch, and an initial checklist dialog will appear on the screen:



InitialChecklist

Please double-check that the SphereFlash instrument is properly installed and ready for use. Refer to the section 5.2 of the User Guide.

1. The transport securing device (red plastic piece on the bottom-rear of the instrument) has been removed.
2. The AC adaptor module is plugged to the mains and to the power inlet of the instrument.
3. You have pushed the on button of the instrument 
4. The status lamp  has become light **solid red** during about 40 seconds, then the diffusing sphere (S) has risen, and the lamp has changed to **slow flashing red**
5. You have plugged the supplied USB3 blue cable, one side into the instrument USB3 socket, and the other side into a free USB 3 socket of the computer:



NOTE:
If the SphereFlash application isn't able to connect to the instrument, please check the computer firewall permissions.

☐ Do not show this message again

OK

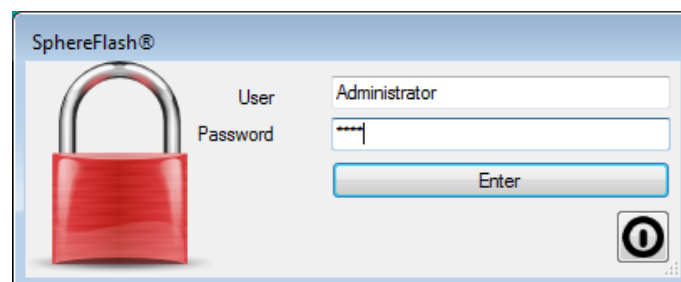
This checklist reminds you to verify the following to ensure that the device is correctly installed and ready for operation:

- The transport securing device has been removed.
- The instrument is properly connected to the power supply.
- The instrument is switched on.
- The status lamp is behaving correctly (solid red during initialization, then slow flashing red when ready).
- The USB 3.0 communication cable is correctly connected between the instrument and the computer.

If the software cannot connect to the instrument, check the computer firewall permissions.

If all conditions are met, click OK to proceed.

A login dialog will appear on your screen:



SphereFlash®



User

Password

Enter



User (input field): Enter your username. The default user on first access is *Administrator*.

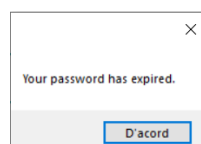
Password (input field): Enter your user password. The default password on first access is *1234*.

NOTE: In Colonies PRO, three default users are available (See Section 7.15. User Management menu for more details).

Enter (button): Click to access the desktop application.

Off (button): Click to close the desktop application.

The following message is displayed as a reminder to change the default password in Colonies PRO:

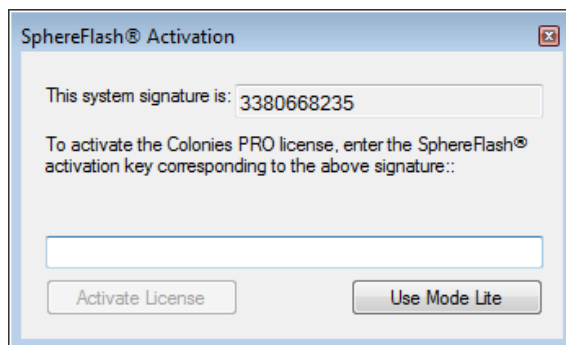


×

Your password has expired.

D'accord

A SphereFlash® Activation dialog will appear:



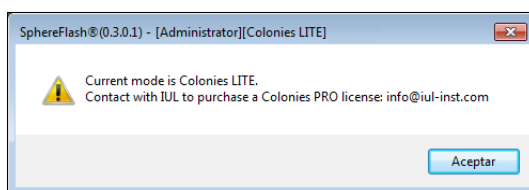
- A. **If you acquired the Colonies PRO software**, you must enter the activation key. This key is only required the first time the Colonies PRO software is launched. Enter this key in the corresponding field and click 'Activate License'.

NOTE: The activation key is provided by IUL on the invoice. If this document is no longer available, copy or write down the displayed *System Signature* (also provided by IUL in the Design Qualification document) and send it to an IUL representative together with the serial number of your SphereFlash® device. IUL will then provide the corresponding activation key.

NOTE: Each SphereFlash® device has a unique System Signature that remains the same regardless of the PC used. Consequently, the corresponding activation key is always the same for that device.

If an incorrect activation key is entered or if the device is not connected to the computer, the application will still run in Colonies LITE software.

NOTE: If a warning message about communication errors with the device appears, check whether the computer firewall is blocking the IUL application. The SphereFlash® device uses a private IP network (192.168.233.1) tunnelled through the USB 3 connection. See Section 8. Troubleshooting for more details.



- B. **If you did not acquire the Colonies PRO software**, no activation key is required. Click the 'Use Mode Lite' button to continue using the Colonies LITE software.

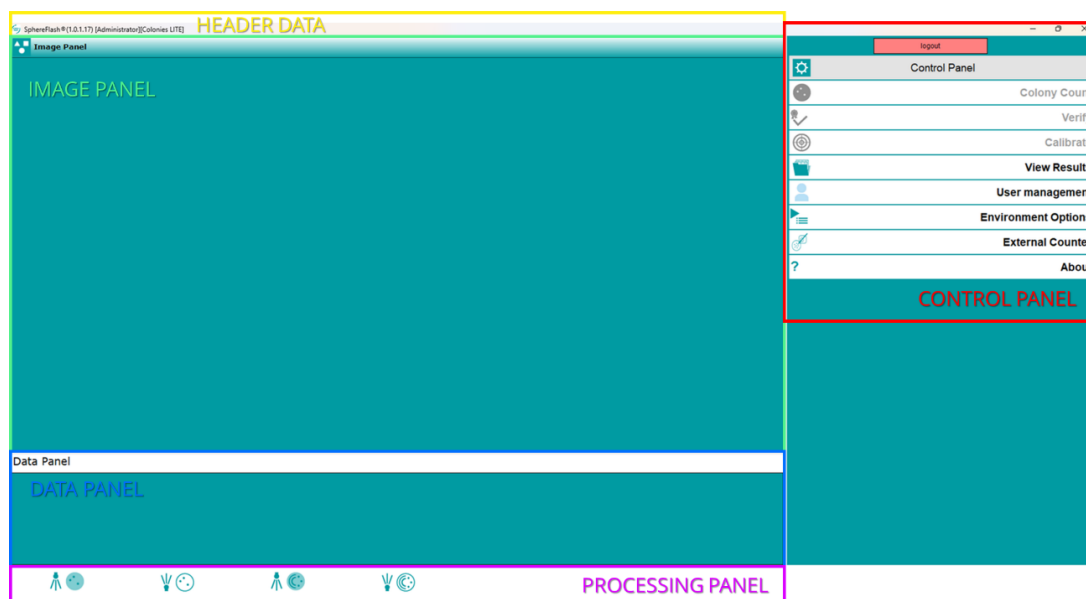
NOTE: If the device is not detected by the software, the application will automatically run in LITE version, as the activation key cannot be validated without a connected device.

IMPORTANT: After a time of inactivity, the application is blocked, and the user is required to re-enter their password in a re-login dialog.

7.3. Main Screen Overview

The main screen of the SphereFlash® Colonies Software Desktop Application is divided into 5 distinct sections, each color-coded below for easy identification:

- Header Data (yellow rectangle)
- Image Viewer (green rectangle)
- Control Panel (red rectangle)
- Data Panel (blue rectangle)
- Processing panel (purple rectangle)



These five main sections are consistently present across various screens within the application. You can resize these sections by placing the cursors over the edges of the panels and dragging them to adjust.

Additionally, interactive tooltips are provided for all buttons and controls: simply hover your cursor over any item, and a brief description of its function or purpose will be displayed.

When a particular operation panel is displayed, you can return to the selection control panel by clicking on the top-right cross icon .

7.3.1. Header Data

The header of the window displays the following information for easy reference:

- Application name (Colonies LITE or Colonies PRO) and version.
- Logged-in user.

7.3.2. Image Viewer

The Image Viewer displays plate images associated with the currently selected result. Whenever a new image is processed (from Colony Count menu) or a stored result is selected (from Views results), the corresponding image is displayed in the Image Viewer.

7.3.3. Control Panel

The Control Panel provides access to the main application functions and menus.

Operational Data

Logout: End the current user session.

Menus

Colony Count: Access the functions to process plate images. The following features are available only in Colonies PRO: Method creation and Worksheet function.

Verify: Access the verification procedure.

NOTE: Only active if SphereFlash® device is connected.

Calibrate: Access the calibration procedure for the SphereFlash® device .

NOTE: Only active if SphereFlash® device is connected.

Views Result: Access to stored data (including Results (CountResults), Results Summary (CountResults_lite), Methods and Calibrations). The following features are available only in Colonies PRO: Manage Results Group, Audit Trail, Purge, and Manage Custom Views.

User Management: Allows the user to change their password. The following features are available only in Colonies PRO: View existing users, Add new user, Remove user, Change other user password and Change Selected User role.

Environment Options (only Colonies PRO): Allow configuration of local application settings.

External Counter (only Colonies PRO): Allow manual colony count results and associated run data to be entered into the SphereFlash® database, enabling their management in the same way as automatically acquired results.

About: Display software version information and provide access to related documentation, including the Instructions for Use and the End User License Agreement.

7.3.4. Data Panel

The Data Panel will display various tables based on the current screen and selection:

- Results stored.
- Results stored summary.
- Available methods.
- Calibration results.
- Verification results.

In any of these tables, you can display the data in several ways to better view and analyze the data:

- Sorting:** Click on a column header to sort the table by that column's values. Click again to sort in reverse order.
- Filters:** Click the filter icon () in any column header to open the filter dialog for that column, which will vary depending on the data type of the column. Filters limit the display to items that meet the filter criteria. To remove filters, right-click anywhere on the table and choose 'Clear Filter'.
- Layout:** Adjust the layout by clicking and dragging a column header to a new position or by dragging the edges of any column or row to resize.

To select one of the results, click its row on the view. To select a contiguous range of results, hold the *Shift* key when clicking the first and the last results of the range. To add or remove one result from the selection, hold the *Ctrl* key and click the result as is usual in Windows programs. To select all the results in the (possibly filtered) view, click on the top of the leftmost column.

Detailed instructions and additional information are available in later sections.

7.3.5. Processing Panel

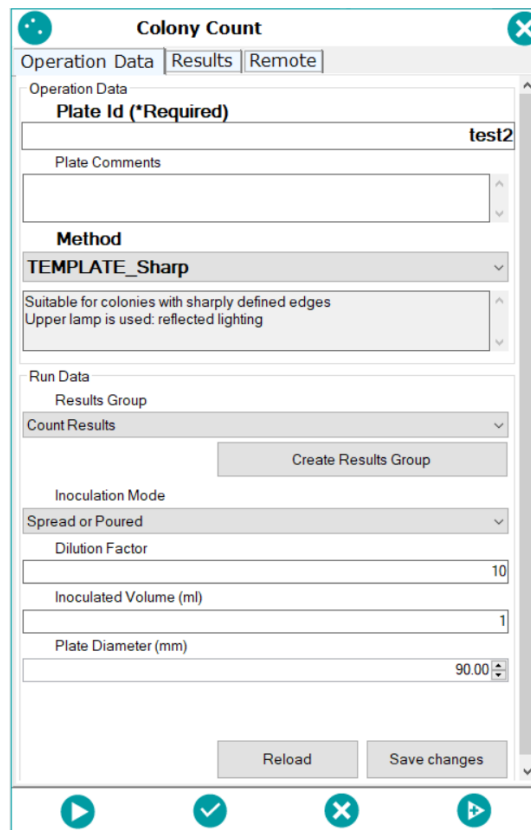
Displays different illumination options for image capture.

	Upper illumination (reflected lighting) for spread/pour distribution
	Bottom illumination (transmitted lighting) for spread/pour distribution
	Upper illumination for spiral distribution
	Bottom illumination for spiral distribution

7.4. Colony Count Menu

This menu provides access to the functions required to process plate images, review results, store or discard results, and create methods (only in Colonies PRO).

When the 'Colony Count' menu is selected, the Colony Count panel is displayed in the Control Panel area:



The screenshot shows the 'Colony Count' panel with three tabs: 'Operation Data', 'Results', and 'Remote'. The 'Operation Data' tab is active. It contains several sections: 'Operation Data' with a 'Plate Id (*Required)' field containing 'test2' and a 'Plate Comments' text area; 'Method' with a dropdown menu set to 'TEMPLATE_Sharp' and a description 'Suitable for colonies with sharply defined edges' and 'Upper lamp is used: reflected lighting'; 'Run Data' with a 'Results Group' dropdown set to 'Count Results' and a 'Create Results Group' button; 'Inoculation Mode' with a dropdown set to 'Spread or Poured'; 'Dilution Factor' with a value of 10; 'Inoculated Volume (ml)' with a value of 1; and 'Plate Diameter (mm)' with a value of 90.00. At the bottom are 'Reload' and 'Save changes' buttons. A bottom navigation bar contains four icons: a play button, a checkmark, an 'X', and a right-pointing arrow.

This panel includes the following functional buttons:

- | | | |
|---|--|---|
|  | Run | Initiates image capture and processing. |
|  | Accept | Stores the current result data. |
|  | Discard | Clears the current result data. |
|  | Method Settings
(only Colonies PRO): | Provides access to the method editing area. |

The 'Colony Count' menu includes three tabs that are displayed sequentially during the workflow:

- Tab 1: Operation data tab
- Tab 2: Results tab
- Tab 3: Remote (see Section 7.11. Working With worksheets for more details)

7.4.1. Operation data tab

The 'Operation Data' tab allows the user to define the operational and run parameters required to process a plate image:

Plate ID: Enter text to identify the sample by typing it manually or, if a barcode reader is connected, by scanning the barcode (only Colonies PRO).

NOTE: This field is mandatory. A colony count cannot be run if this field is empty.

IMPORTANT: Certain special characters are not allowed in the Plate ID content, such as: \ / : * ? " < > | .

Plate Comments: Add any relevant comments about the plate.

Method: Select a method from the drop-down list.

By default, a list of Template methods is provided (see Section 7.8. Template methods for more details).

In Colonies PRO, new methods can be created based on these templates (see Section 7.10. Methods settings for more details).

A text box below the list displays a description of the selected method.

Run Data

Results Group: Select a results group from the drop-down list.

This label allows results to be grouped or filtered later. By default, the group 'Count Results' is selected. Other groups can be chosen from the list, or a new group can be created by clicking 'Create Results Group'.

Inoculation mode: Select either spread (default) or one of the listed spiral distribution methods from the drop-down list.

NOTE: All listed spiral distribution methods are compatible with IUL's spiral platter Eddy Jet 2W.

Dilution Factor: Specify the dilution factor of the sample.

NOTE: This value is required to calculate the CFU (colony-forming units) concentration per milliliter.

Inoculate volume (ml): For spread distributions, enter the total sample volume inoculated onto the plate.

For spiral distributions, this value is automatically determined based on the selected distribution.

NOTE: This parameter is used to calculate the CFU per milliliter.

Plate Diameter (mm):

Indicate the inner diameter of the plate (inner distance between the lateral walls), within which the inoculated volume has been spread. This corresponds to the [blue circle](#) displayed in the Image Viewer.

NOTE: This field is editable when spread mode is selected. In spread distribution, the application assumes that the *Inoculated Volume* has been uniformly spread up to the limit defined by the blue circle.

Reload:

By default, the entered values are retained for subsequent plate analyses. Click this button to restore the default values.

Save changes
(only Colonies PRO):

Click this button to create a new method based on the current one, saving the modified 'Run Data' (Operation Data tab) and 'Run Input Values' (Results tab) as default.

NOTE: Default Run Data values and whether they can be edited or not by the user are options that can be defined for each method.

7.4.2. Results tab

After image processing, the 'Result tab' is displayed automatically.

The screenshot shows the 'Colony Count' application window with the 'Results' tab selected. The 'Plate Id (*Required)' field contains 'test2'. Below it is a 'Plate Comments' text area. The 'Run Input Values' section includes a slider for 'Thr. to back. (22)', a value of '0.30' for 'Absolute Min. Diameter', and a 'Class Mark Color' set to 'RGB=(255, 0, 0)'. The 'Results' section shows 'Excluded Area (%)' as '14.97%'. At the bottom, a table displays results for 'Class 1':

Colony Class	Counted Colonies	Conc. (CFU/mL)	Counted Volume
✗ Class 1	803	9.44E+003	0.850

The 'Results' tab allows the user to review results and, if required, perform manual adjustments before storing or discarding the result.

Plate ID: Inherited from the Operation Data tab.

Comments: Inherited from the Operation Data tab.

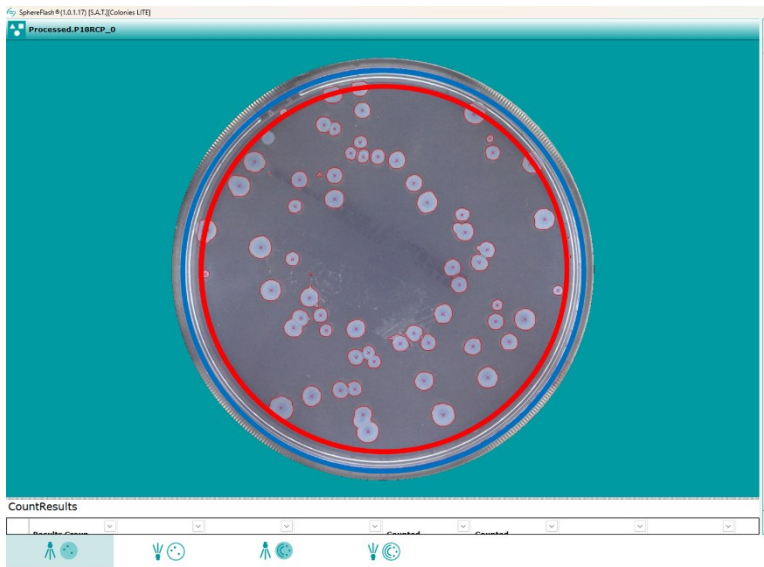
Run Input Values

Threshold to background (%):	Slider to adjust the minimum contrast required to differentiate colonies from the background. See Section 7.5.1. Manual result adjustment for more details. NOTE: When the cursor is positioned over the slider, a tooltip is displayed providing a more detailed description. Once the cursor is positioned over the slider handle, the value can be adjusted using the mouse wheel, allowing very fine and gradual adjustments while immediately observing the changes.
Absolute minimum diameter (mm):	Slider to set the minimum colony size to be counted. See Section 7.5.1. Manual result adjustment for more details. NOTE: This helps filter out small artifacts that do not correspond to colonies.
Class Mark Color:	Color of the visual markers placed at the center and borders of each counted colony. By pressing the  button, you can select another color from a palette. NOTE: When more than one colony class is defined, the marker color for each class is configured in the Method Settings (only Colonies PRO).

Results

Excluded Area (%):	Percentage of the total plate area (blue circle) that is excluded from colony counting in order to avoid artefacts. NOTE: This value is determined by the difference between the image processing area (yellow circle visible in Method settings) and the counted area (red circle), expressed as a percentage of the total plate area (blue circle), together with manual exclusions defined using the interactive feature.
Colony Class:	Name of the colony class defined in the current method. NOTE: When default template methods are used, the entire plate is counted, and a single class (Class 1) is displayed.
Counted Colonies:	Number of colonies counted for each colony class within the region of interest, including any manual inclusions or exclusions.
CFU/ml:	Calculated CFU concentration per milliliter for the class. $\text{CFU/ml} = \text{Count} \times \text{Dilution Factor} / \text{Counted Volume}$
Counted Volume (ml):	Sample volume within the analyzed plate area (inside the counting region and excluding any interactively excluded area). This volume is used to calculate CFU/mL. For spread distributions, Count Vol = Inoculated Volume x (1 – Excluded Area). For spiral distributions, only the volume corresponding to the counted spiral regions is considered. NOTE: For spiral distributions with logarithmic/exponential mode, the CFU are counted from the outer ring inward. Counting stops at the ring where the predefined threshold is exceeded, according to standard rules (e.g. 20 CFUs in a 1/8 sector corresponds to 160 CFUs over the full plate). See Appendix C Spiral distribution for more details.

The processed plate image is displayed alongside the 'Results tab' in the "Image Viewer" for visual verification before saving or discarding results.

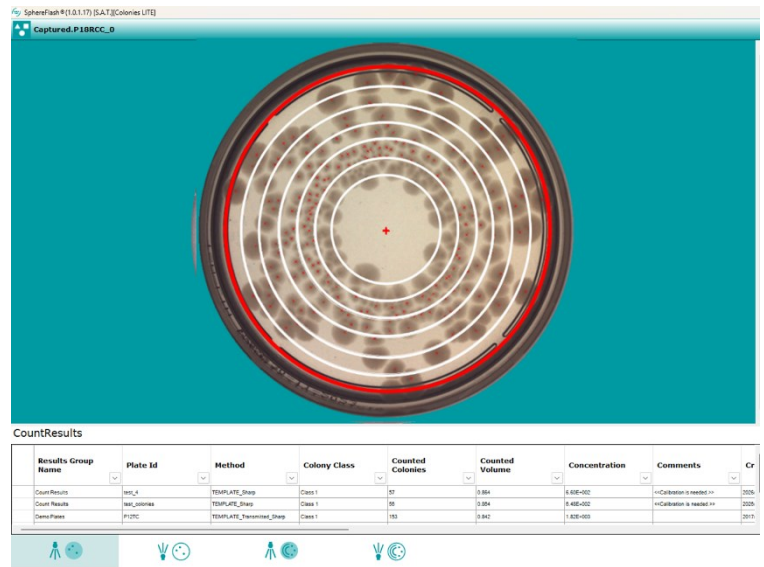


Detected colonies are marked with the corresponding class mark color at their centers and the center of the plate is also identified by a red plus (+) symbol.

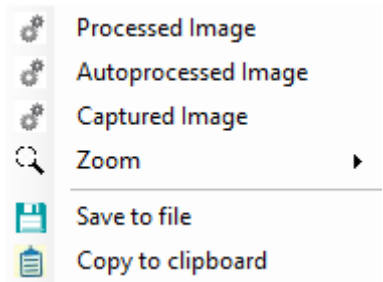
The blue circle represents the plate diameter defined in the 'Colony Count Data' tab. It corresponds to the inner diameter of the plate, within which the inoculated volume has been spread.

The red circle defines the counted area, that is the region within which colonies are included in the count. By default, this circle is positioned slightly inside the plate diameter to prevent artifacts near the plate walls from being counted as colonies.

When a spiral distribution inoculation mode is selected, the processed image also displays the 6 concentric reference circles (or spiral grids) in white, corresponding to the spiral inoculation pattern.



Additional image interaction options are available by right-clicking within the image viewer, opening a contextual menu that includes:



- Processed Image:**

View the image processed by the software, which includes visual marks. If manual adjustments have been performed, the corresponding visual overlays are also shown.
- AutoProcessed Image:**

View the image processed automatically by the software, including visual marks, without any manual adjustments.
- Captured Image:**

View the original image as captured, without any software processing or visual overlays.
- Zoom:**

Adjust the zoom level to customize the size of the displayed image. You can also use the progressive zoom with the mouse wheel: turning it forward zooms in while turning it backwards zooms out.
- Save to file:**

Save the image currently displayed in the Image Viewer (captured, processed, or auto processed, if available). Click this option to open a file browser, where you can select the destination folder and specify the file name.
- Copy to clipboard:**

Copy the image currently displayed in the Image Viewer to the clipboard, allowing it to be pasted into another application.

7.5. Processing a plate

Follow these steps to process a plate:

1. Use the correct centering device / adapter, depending on your plate size/type.
2. Position the plate into the device.
3. Click on 'Colony Count' from the Control Panel
4. Fill in the fields of the 'Operation Data' tab, as detailed in the previous section.
5. Choose the appropriate illumination mode, depending on the colony type. See Section 7.8. Template methods for more details.
6. Click the 'Run' button on the application or on the device.
7. The diffusing sphere is lowered, an image is taken, and the sphere is raised again.
8. The results appear on the screen, as detailed in the previous section.
9. Perform manual adjustments, if necessary. See Section 7.5.1. Manual result adjustment for more details.
10. After reviewing the result, the functional buttons can be used to accept, discard, or modify the method used:



Accept

Stores the current result data



Discard

Clears the processed result



**Method
Settings** (Only in
Colonies PRO)

Opens the method configuration menu, allowing adjustment of default parameters or fine-tuning for the current result

7.5.1. Manual result adjustments

The software may not detect or count all colonies visible on the plate. The following situations may occur:

- **Undetected colonies (not outlined):**
 - The colony does not have sufficient contrast against the background.
 - A color filter is applied, and the colony color is outside the accepted range defined in the method (method creation available only in Colonies PRO).
- **Detected colonies (outlined but not marked with a cross):**
 - The colony center is outside the region of interest (red circle).
 - The colony size is outside the defined diameter range (method settings or Absolute Minimum Diameter).
 - The colony center is inside a user-defined excluded area.

Five types of manual adjustments can be performed in the Image Viewer:

- Manual adjustment of the Threshold to the background
- Manual adjustment of the Absolute Minimum Diameter
- Manual adjustment of the counted area
- Manual addition or removal of individual colonies
- Manual adjustment using methods (only Colonies PRO)

Manual adjustment of the Threshold to the background

Adjust the contrast threshold used to differentiate colonies from the background. Modifying this value helps improve separation of colonies from artifacts, shadows, or uneven agar illumination:

Thr. to back. (80)



Thr. to back. (85)



NOTE: The default 'Run Input Values' and whether they can be modified by the operator, can be defined individually for each method (only Colonies PRO)

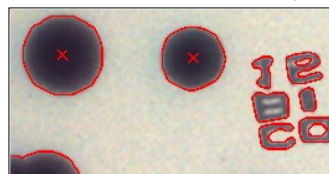
Manual adjustment of the Absolute Minimum Diameter

Adjust the minimum colony diameter required for detection. Increasing this value helps exclude small artifacts or particles that should not be counted as colonies:

Absolute Min. Diameter (0.30)



Absolute Min. Diameter (2.30)



NOTE: This control only allows increasing the minimum diameter defined in the current method. To reduce the minimum diameter value, the method settings must be edited (only Colonies PRO).

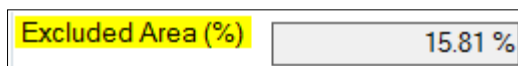
Manual adjustment of the counted area

Manual adjustment of the counted area can be performed via several options:

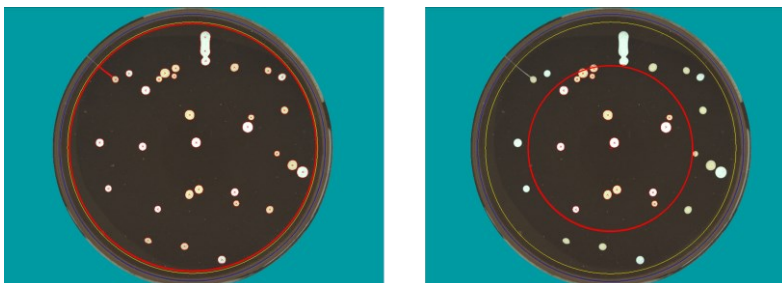
- **Option A:** Resize and reposition the counted area (red circle).
- **Option B:** Manually exclude or re-include selected regions.

Option A: Resize and reposition the counted area (red circle)

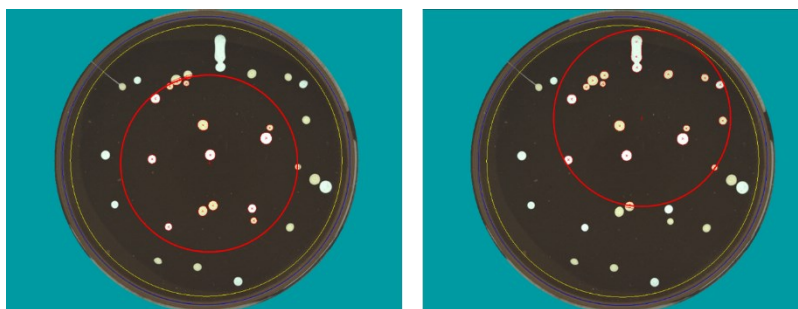
1. Click on the 'Excluded Area (%)' label. The label is highlighted in yellow:



2. Click on the red circle and resize or move it as required.

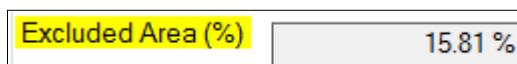


3. The plate center can be adjusted by selecting and moving the red plus (+) symbol.



Option B: Manually exclude or re-include selected regions

1. Click on the 'Excluded Area (%)' label. The label is highlighted in yellow.



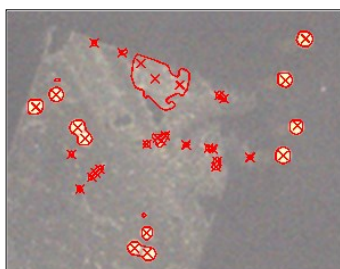
2. Two freehand drawing icons appear on the right side of the top bar of the image viewer.



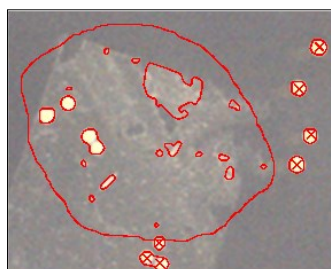
3. Use:

- **Minus** () to draw a closed curve around areas to be excluded from counting.

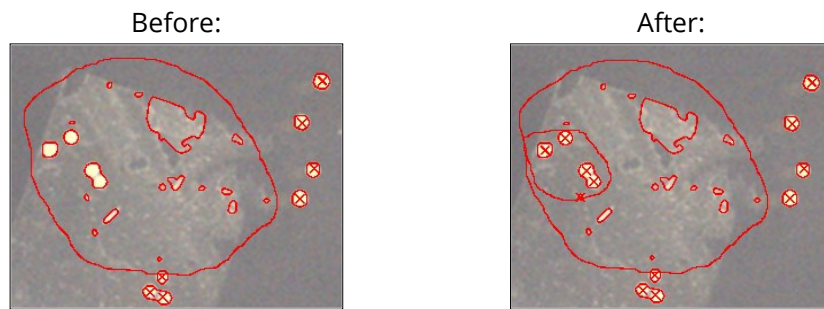
Before:



After:



- **Plus** () to define areas within an excluded region where colonies should still be counted.



Manual addition or removal of individual colonies

1. Click on the label of the desired colony class. The label is highlighted in yellow.

Type	Count	I
 Count Group 1	32	

2. The plus (+) and minus (-) icons appear on the right side of the top bar of the image viewer.

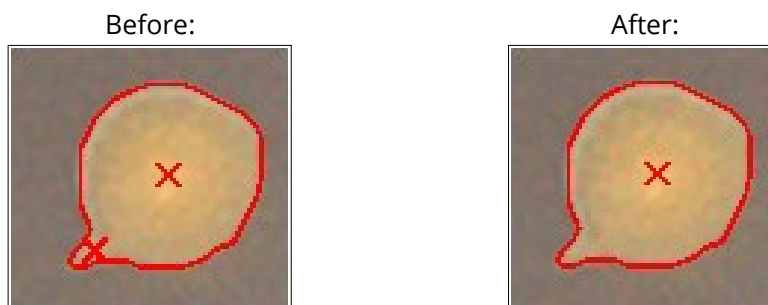


3. Use:

- **Plus** () to manually add a colony by clicking on its center.



- **Minus** () to remove a counted colony by clicking on its center.



Manual adjustment using methods

See Section 7.10. Method settings for detailed instructions on how to configure and edit methods.

After manual adjustments are performed, the results (counted colonies, concentration and counted volume) are automatically recalculated.

Colony Class	Counted Colonies	Concentration (CFU/ml)	Counted Volume (ml)
 Class 1	19	1.90E+002	1.000

Click the 'Accept' button , to save and store the processed result in the data panel. Click the 'Discard' button , to discard the processed result.

When the result is stored, the following message is displayed in the "Comments" field to indicate that manual adjustments have been applied :

<<Interactive changes have been made>>

7.6. Results data panel

The stored results are displayed in the Data Panel:

Results Group Name	Plate Id	Method	Colony Class	Counted Colonies	Counted Volume	Concentration	Comments	Timestamp	Operator	Dilution Factor	Inoculated Volume	Inoculation mode	Exc
Count Results	test1	TEMPLATE_Sharp	Class 1	442	0.842	5.25E+003		2017/03/21 16:41	User Administrator	10	1	Spread	15.81
Count Results	sdeadfs	TEMPLATE_Sharp	Class 1	430	0.842	5.18E+003		2017/03/21 10:10	User Administrator	10	1	Spread	15.81
Count Results	gdfg	FourClasses	big green	30	0.842	3.56E+002		2017/03/21 16:13	User Administrator	10	1	Spread	15.81
Count Results	gdfg	FourClasses	medium green	81	0.842	7.25E+002		2017/03/21 16:13	User Administrator	10	1	Spread	15.81
Count Results	gdfg	FourClasses	blue	149	0.842	1.77E+003		2017/03/21 16:13	User Administrator	10	1	Spread	15.81
Count Results	gdfg	FourClasses	red	149	0.842	1.77E+003		2017/03/21 16:13	User Administrator	10	1	Spread	15.81

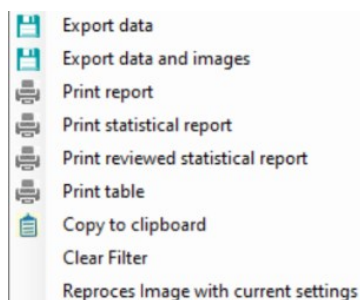
By default, the results are shown ordered by time of execution of the operation, the most recent above.

If a plate is processed using a method with multiple Colony Classes, multiple rows will be displayed for the same plate, one for each Colony Class.

Each result includes the following information:

- Results Group Name
- Created Time
- Plate ID
- Method
- Colony class
- Counted colonies: Final colony count, including any manual adjustments (if performed)
- Concentration
- Counted volume
- Comments (including status notifications (e.g., calibration or verification alerts))
- Inoculation mode
- Inoculated volume
- Dilution factor
- Excluded area
- UTC Created Time
- Count from Automatic Process: Colony count obtained from the initial automatic processing, before any manual adjustments (if performed).
- Input Values (Thr. to Back., Plate Diameter., Min. Diam.)
- Device SN

When a row is selected, the corresponding image will be displayed in the image viewer. Right-click on one or more results in the table to access the contextual menu:



Export data:

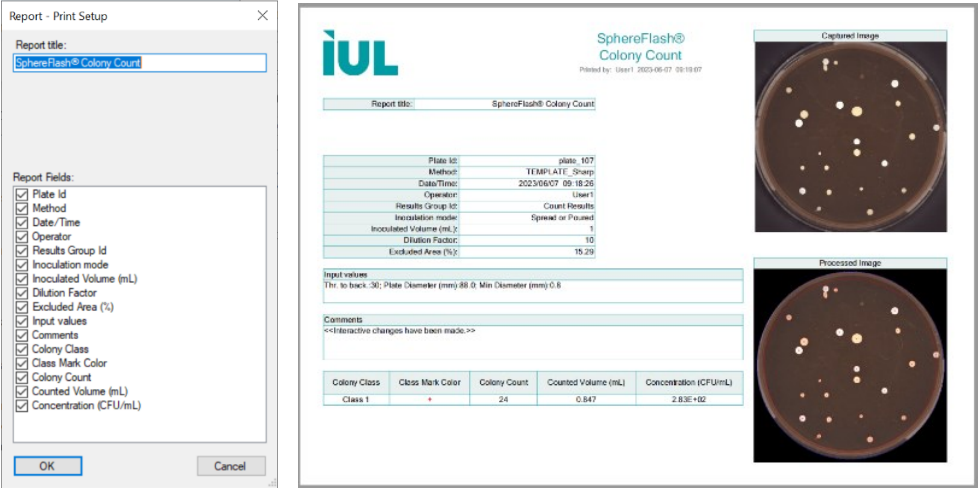
A file browser opens to export selected results with the desired format (XLSX: Excel, CSV: Comma-delimited, and TXT: Tab delimited).

Export data and images:

Same as Export data, but a sub-folder is created containing the associated images (captured, processed and autoprocessed, if available). Image file names correspond to those defined in each result.

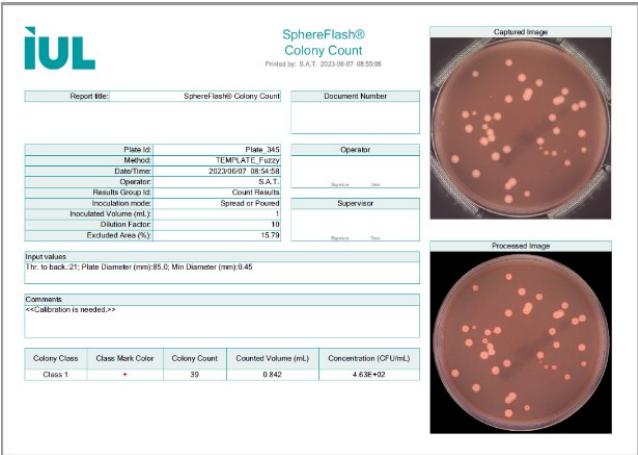
Print report:

A report is generated with one page per processed plate, including captured and processed images.



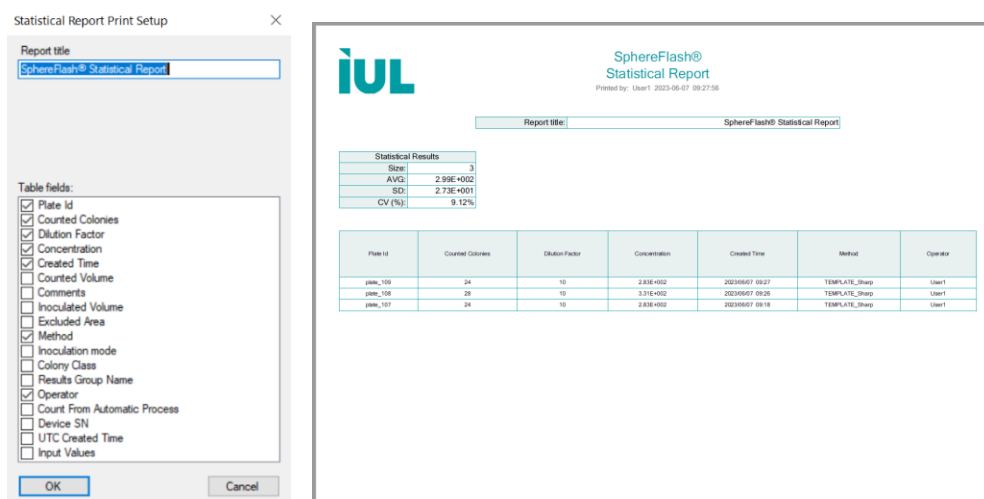
Print reviewed report:

Similar to Print report, but also includes fields for document number and signature and date boxes for the operator and supervisor.



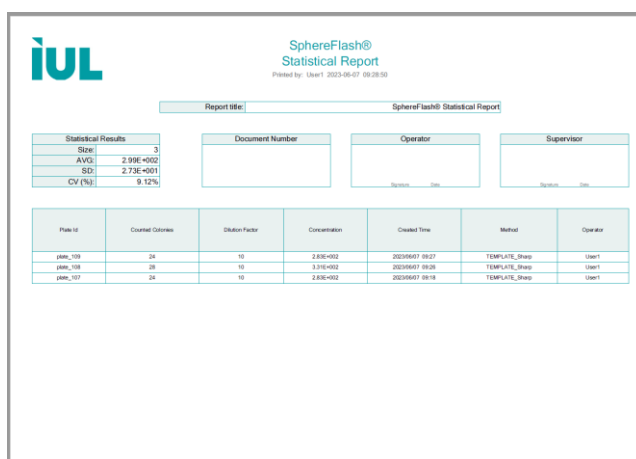
Print statistical report:

Requires multiple selections with the same class name. It will contain the following statistical values: average value, standard deviation, and coefficient of variation.



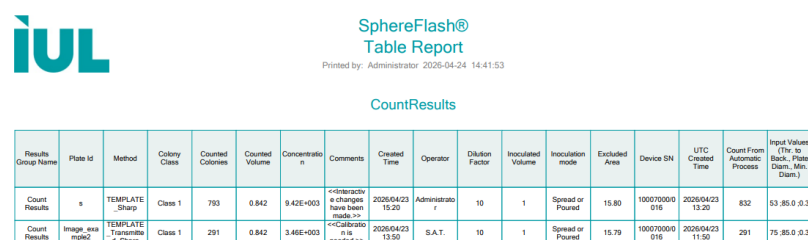
Print reviewed statistical report:

Similar to Print statistical report, but also includes fields for document number, signature and date boxes for the operator and supervisor.



Print table:

Print a table with all the parameters for the selected rows.



Copy to clipboard:

Copy all parameters of the selected results to the clipboard and then paste them into another application.

Clear filter:

Remove all active filters from the table.

Reprocess Image with current settings:

Reloads the captured image of a stored result and processes it again using the current settings, allowing the new result to be saved as if it were obtained from a new acquisition.

NOTE: For report and table generation options, a dialog opens to modify the 'Report Title' and select the result parameters (from 'Report Fields') to be included. The footer of printed reports displays the user name, date, and time of printing. If a virtual PDF printer is selected, reports can be saved as PDF files. If opened in a compatible application, digital signatures can be applied.

7.7. Customizing the logo on the reports (only Colonies PRO)

The printed reports and tables appear with the logo of IUL. If you want that your logo to appear instead, replace it with a .jpg image file with the same path and filename at:

%Program Files%\IUL\SphereFlash\logo\logo.jpg or
C:\Program Files\IUL\SphereFlashAI\Logo\logo.jpg

You can apply a digital signature to the PDF reports and tables using third-party applications properly linked to the Colonies application:

1. Install a virtual PDF printer on the computer such as *PDFCreator*
2. Configure the virtual printer to automatically open the document after the PDF file has been created.
3. Install on the computer *Adobe Acrobat Reader DC®*.
4. Associate the file type PDF to be automatically opened by *Adobe Acrobat Reader DC®*.
5. Select or filter the desired rows from the current view.
6. Left-click on them and select *Print Report* or *Print Table*.
7. On the print dialog, select the virtual PDF printer (*such as PDFCreator*).
8. When asked for, select the destination folder and give a name to the unsigned PDF file to be created.
9. When the file has been automatically opened by *Adobe Acrobat Reader DC®*, in this application, go to *Tools > Certificates > Digital Signature*.
10. You will be prompted to define an area on the document where the digital signature will be printed.
11. You will be prompted to use an existing certificate or to create a new one.
12. Select the destination folder and give a name to the digitally signed PDF file to be created.

SphereFlash® Colony Count
Printed by: User1 2023-06-07 09:19:07

Report title: SphereFlash® Colony Count

Plate Id:	plate_107
Method:	TEMBLATE (Sentry)
Date/Time:	2023/06/07 09:18:26
Operator:	User1
Results Group Id:	Count Results
Inoculation mode:	Spread or Poured
Inoculated Volume (mL):	1
Dilution Factor:	10
Excluded Area (%):	15.29

Input values
Titer: 10 back 30; Plate Diameter (mm): 88.0; Min Diameter (mm): 0.8

Comments
<<Interactive changes have been made >>

Colony Class	Class Mark Color	Colony Count	Counted Volume (mL)	Concentration (CFU/mL)
Class 1	+	24	0.047	2.83E+02

John Smith
Digitally signed by John Smith
Date: 2017.04.05 10:59:02 +02'00'

Captured Image

Processed Image

7.8. Template methods

The Colonies software includes several general-purpose methods, referred to as template methods, which cover common plate appearances and are ready to use.

By default, these methods operate in Automatic Counting Mode, where the software detects and counts either bright or dark colonies, depending on which produces the highest count. Bright and dark colonies are defined relative to the background.

NOTE: Additional counting modes are available, such as *Count All*, *Count Only Bright*, *Count Only Dark*, *Filter by Color*, and *Filter by Diameter*.

In Colonies PRO, template methods can be used as a base to create custom methods.

7.8.1. Using Upper illumination (reflected lighting) with spread distributions



Upper illumination provides diffused, homogeneous reflected light — similar to darkfield illumination — enhancing contrast and edge definition for accurate colony detection. This illumination mode is mainly used to visualize opaque colonies by highlighting their edges and contrast.

It illuminates the plate from above and allows differentiation of colonies from artifacts based on appearance (color or brightness), as well as discrimination between different colony classes.

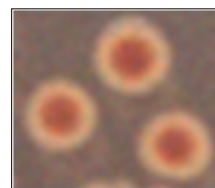
TEMPLATE_Sharp:

Suitable for colonies with sharp, clearly defined, and contrasted edges against the background.



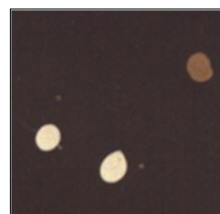
TEMPLATE_Fuzzy:

Suitable for colonies with fuzzy or blurred edges, where the boundary between the colony and the background is difficult to distinguish.



TEMPLATE_Colors and TEMPLATE_Fuzzy_Colors:

These are color-based methods with predefined color settings. To perform colony classification by color, select one of these templates and then adjust the color parameters in Method Settings (only Colonies PRO). Similar to TEMPLATE_Fuzzy, use 'TEMPLATE_Fuzzy_Colors' when the edges of the colonies are blurry.



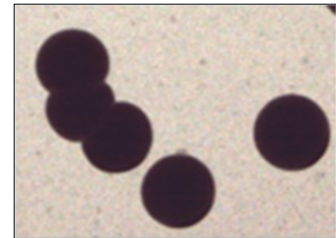
7.8.2. Using Bottom illumination (transmitted lighting) for spread distributions



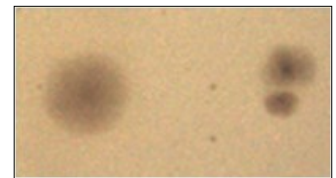
Bottom illumination provides uniform transmitted light from beneath the plate, making it ideal for visualizing low-contrast or transparent colonies.

If the colonies are opaque and the substrate is sufficiently translucent, bottom illumination can also enable accurate colony detection and counting, particularly in the absence of opaque artifacts.

TEMPLATE_Transmitted_Sharp: Suitable for opaque colonies with sharp, clearly defined edges against a transparent or translucent background.



TEMPLATE_Transmitted_Fuzzy: Suitable for opaque colonies with fuzzy, blurred edges against a transparent or translucent background



7.8.3. Using Upper or Bottom illumination for spiral distributions



There are no native default methods for spiral distributions, you can use one of the spread methods and modify it to the desired spiral.

7.9. Methods settings (only Colonies PRO)

The Method Settings panel allows you to create, edit, and manage counting methods.

The screenshot shows the 'Method Settings' panel. At the top, there is a navigation bar with four icons: a play button, a checkmark, a cross, and a play button with a right arrow (highlighted with an orange box). Below this, the panel is divided into sections. The 'Method Definition' section includes a 'Method Name' field with the value 'TEMPLATE_Sharp' and a 'Method Description' field with the text 'Suitable for colonies with sharply defined edges' and 'Upper lamp is used: reflected lighting'. There is a 'Delete Method' button. The 'Classes' section has tabs for 'Image capture', 'Option settings', 'Advanced 1', and 'Advanced 2'. Under 'Class 1', there are fields for 'Colony Class Id' (Class 1), 'Class Mark Color' (RGB=(255, 0, 0)), 'Count Mode' (Auto), 'Accept Colors' (none), 'Reject Colors' (none), 'Min Diameter (mm)' (0.30), 'Max Diameter (mm)' (20.00), 'CountedLimits' (lower, upper, Warning, alarm), and 'CFU/mL limits'. Below this is a 'Results' section showing 'Excluded Area (%)' (13.64 %) and a table for 'Colony Class'.

Colony Class	Counted Colonies	Conc. (CFU/mL)	Counted Volume
✗ Class 1	49	5.67E+002	0.864

Only users with Administrator or Programmer role can access this panel.

The Method Settings panel can be accessed in two ways:

- After processing a plate, click on the Method Settings button to edit the method applied to the current processed image.
- Under the 'Colony Count' menu, click on the Method Settings button to exclusively adjust image capture and option settings that apply independently of a specific plate.

When accessed after image processing, the processed plate image is used only to visualize and test the effect of the method settings during editing.

Once a method has been adjusted for one plate, we recommend testing additional plates using the same method and progressively fine-tuning the parameters until stable and reproducible results are achieved.

The Method Settings panel is organized into several sections:

- Common Values
- Classes tab
- Image Capture tab
- Option Settings tab
- Advanced 1 tab
- Advanced 2 tab
- Results
- Functional buttons

Common Values

Method Name (drop-down list and input box): Display the method to be edited. Enter a new name to create a modified version.
NOTE: Default template methods cannot be edited.

Method Description (input box): Provide a detailed description of the method, including its intended use or key characteristics.

Delete Method (button): Permanently delete the current method.
NOTE: Default template methods cannot be deleted.

Tabs available

Classes: Configure settings for the colony classes defined in the method. See Section 7.10.1. Classes tab for more details.

Image capture: Adjust parameters that affect the entire image capture process. See Section 7.10.2. Image capture tab for more details.

Option settings: Configure visual overlay parameters and control the availability of settings when the method is used in the 'Colonies Counting' screen. See Section 7.10.3. Option settings tab for more details.

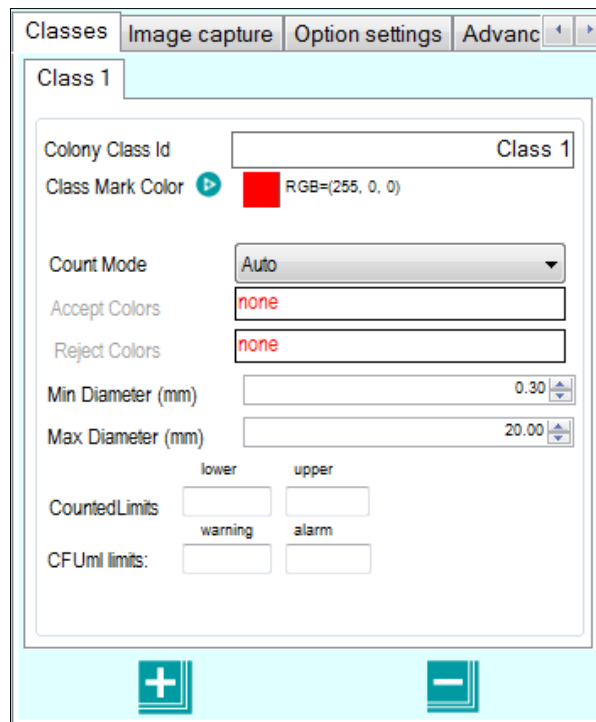
Advanced settings tabs: Configure parameters related to colony detection, including background discrimination, color differentiation, and colony separation. See section 7.10.4. Advanced settings tab for more details.

Functional buttons

- | | | |
|---|----------------|--|
|  | Run | Click to capture and process a new image to test the method. |
|  | Save | Save the current method. Once saved, the new method appears in the Methods list in the 'Colony Count Data' tab |
|  | Restore | Restore the settings of the original method, discarding the edited values |
|  | Return | Return to the 'Colony Count' panel |

7.9.1. Classes tab

The 'Classes' tab organizes settings for different colony classes associated with the method. Each class has its own tab, and there are additional controls for managing these tabs. Within each class tab, you can configure the following settings: Colony Class ID, Class Mark Color, Count Mode, Counted Limits, and CFU/ml Limits.



Classes tab fields

Colony Class ID (input box): Edit the name of the class, which will also appear on its tab label.

Class Mark Color (button): Set the visual marker color of the center and borders of each colony.

Count Mode (drop-down list): Determine the classification criteria for colonies.

Auto (default): Count either bright or dark colonies, depending on which results in a higher count. Bright and dark colonies are defined relative to the background.

All: Count all detected colonies, both dark and bright.

Dark Only: Count only dark colonies.

Light Only: Count only bright colonies.

Filter by Color: Count colonies within a defined color range.

If selected Count Mode: Filter by Color

Accept colors: Allow the selection of colony colors to be accepted for counting.

Reject colors: Allows the exclusion of specific colony colors from counting

Filtered by size

Min. CFU Size (spinner): Set the minimum size (in millimeters) for colonies to be included in the count.

Max. CFU Size (spinner): Set the maximum size (in millimeters) for colonies included in the count.

Counted Limits: Set the lower and upper count limits. Colony counts outside these limits are highlighted in red, and the text <<Overcount warning for Class 1>> or <<Undercount warning for Class 1>> will be automatically appended to the Comments field on the cloud result stored. These limits are required by certain protocols to guarantee that the count is statistically significant

Set the minimum size (in millimeters) for colonies to be included in the count.

Colony Class	Counted Colonies	Concentration (CFU/ml)
Class 1	585	5.85E+003

CFU/mL limits: Set the maximum size (in millimeters) for colonies included in the count.

Concentration below the warning limit is highlighted in white:

CFU/ml Limits:	Warning	Alarm	Colony Class	Counted Colonies	Concentration (CFU/ml)
	6.00E2	9.00E2			
			Class 1	19	1.90E+002

Concentration between the warning and alarm limits is highlighted in yellow:

CFU/ml Limits:	Warning	Alarm	Colony Class	Counted Colonies	Concentration (CFU/ml)
	6.00E2	9.00E2			
			Class 1	70	7.00E+002

Concentration exceeding the alarm limit is highlighted in red:

CFU/ml Limits:	Warning	Alarm	Colony Class	Counted Colonies	Concentration (CFU/ml)
	6.00E2	9.00E2			
			Class 1	430	4.30E+003

If an opposite behavior is required (i.e. warning or alarm triggered when the concentration is below a limit), enter an Alarm limit value lower than the Warning limit value:

CFU/ml Limits:	Warning	Alarm	Colony Class	Counted Colonies	Concentration (CFU/ml)
	9.00E2	6.00E2			
			Class 1	19	1.90E+002

Functional buttons



Plus

Add new colony class. This will create a new colony class tab.



Minus

Remove selected colony class. This will delete the currently colony class tab.

7.9.1.1. Count Mode: Filter by Color

If multiple colonies with distinct colors are present on a single plate, the 'Filtered by Color' Count Mode allows you to selectively include or exclude colonies based on their color. In addition, colonies of different colors can be categorized into distinct classes.

To use this mode, select one of these template methods in the 'Operation Data' panel as a starting point:

- TEMPLATE_Colors (if the colonies have clearly defined edges)
- TEMPLATE_Fuzzy_Colors (when the colonies have blurry edges).

The 'Count Mode' will be automatically set to 'Filtered by color'.

The following options are available by right-clicking on the 'Accept Colors' or 'Reject Colors' box:

Clear All:	Clear all accepted or rejected colors. If no colors are defined, the box displays 'none' in red.
Accept All:	Accept all colors detected by the software. The colors will appear in the 'Accept colors' box, even those previously selected in the 'Reject colors' box. The 'Reject colors' box will become empty.
Reject All:	Reject all colors detected by the software. The colors will appear in the 'Reject colors' box, even those previously selected in the 'Accept colors' box. The 'Accept colors' box will become empty.
	NOTE: The use of rejected colors is optional and intended to prevent undesired detections. By default, no rejected colors are defined.
Merge all:	Blend all selected colors together (if there is more than 1 acceptable/rejected color in the box).
Merge pair:	Blend a pair of colors together (if there is more than 1 acceptable/rejected color in the box).
Accept layer:	Accept the selected rejected color (if at least 1 color is rejected). The new accepted color will appear in the 'Accept colors' box.
Reject layer:	Reject the selected accepted color (if at least 1 color is accepted). The new rejected color will appear in the 'Reject colors' box.
Split layer:	Split a merged selection of colors (if there is more than 1 acceptable/rejected color in the box).
Split all:	Split all colors (if there is more than 1 acceptable/rejected color in the box).

7.9.1.2. Classes tab: Managing colony classes

Multiple colony classes can be created to obtain differentiated counts from the same plate, based on criteria such as color or diameter. By clicking on the  button at the end of the Class tab, a new colony class will appear.

Based on the 'Count Mode' chosen for the first class, the 'Count Mode' options for the second class will differ:

If the Class 1 'Count Mode' is Auto, All, Dark only or Light only, 'Count Mode' for additional classes is only 'Filter by Diameter'.

Class 1

Class 2

Colony Class Id

Class 1

Class Mark Color

RGB=(255, 0, 0)

Count Mode

Auto

Accept Colors

none

Reject Colors

none

Colony Class Id

Class 2

Class Mark Color

RGB=(0, 128, 0)

Count Mode

Filtered by diameter

Accept Colors

Filtered by diameter

Reject Colors

none

If the class 1 'Count Mode': Filter by Color, 'Count Mode' for additional classes can be 'Filter by Diameter' OR 'Filter by Color'.

Class 1

Class 2

Colony Class Id

Class 1

Class Mark Color

RGB=(255, 0, 0)

Count Mode

Filtered by color

Colony Class Id

Class 2

Class Mark Color

RGB=(0, 128, 0)

Count Mode

Filtered by diameter

Accept Colors

Filtered by color

Reject Colors

Filtered by diameter

Filter by Color: Define the new class based on colony color, distinct from that of the previous classes.

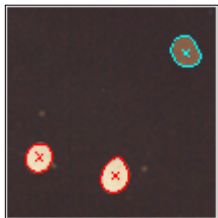
Filter by Diameter: Define the new class based on colony size, distinct from that of the previous classes, while sharing the same color criteria.

The configuration of the new classes follow the same procedure as for the default colony class.

NOTE: Colonies already selected in the previous classes will not be available for selection in the subsequent classes. Each colony is counted only once, regardless of the number of classes defined.

When a colony count is performed using a method with multiple classes:

Colonies are outlined and marked with the color corresponding to their class in the Image Viewer. Results are displayed separately for each colony class. When the result is accepted, multiple rows are generated in the Data Panel for the same Plate ID, one for each colony class.

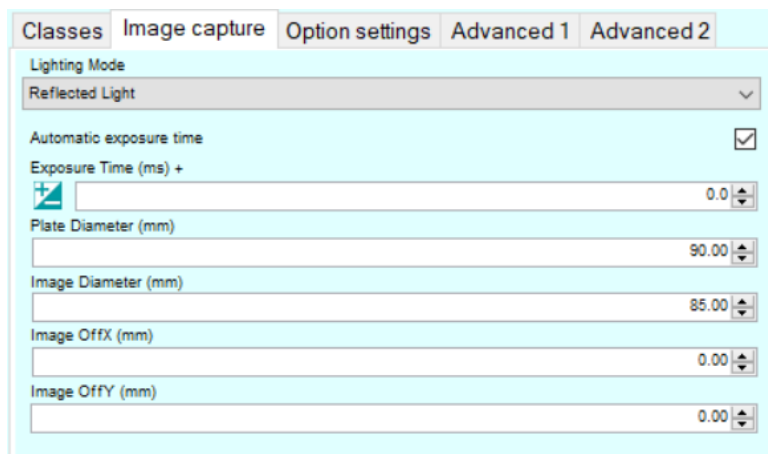


Class	Count	CFU/ml	CountVol
✖ Yellow colonies	27	3.21E+002	0.842
✖ Brown colonies	8	9.50E+001	0.842

Results Group Name	Plate Id	Method	Colony Class	Counted Colonies	Counted Volume	Concentration
Count Results	plate25	TwoColors	Yellow	29	0.842	3.44E+002
Count Results	plate25	TwoColors	Brown	2	0.842	2.38E+001

7.9.2. Image capture tab

The 'Image capture' tab allows adjusting parameters that affect the entire image capture process:



Lighting Mode (drop-down list): Select the lighting options ("Reflected light", "Transmitted light" or "Both lights") used to illuminate the plate.

Automatic exposure time (ms) (checkbox): Enable automatic adjustment of the exposure time for each image capture (in milliseconds). When enabled, the optimal exposure time is automatically determined for each plate.

Exposure Time (ms) (spinner): Set the manual exposure time for the camera of the SphereFlash® device when capturing new images. This parameter controls the overall image brightness.

Plate Diameter (mm) (spinner): Indicate the inner diameter of the plate (inner distance between the lateral walls), within which the inoculated volume has been spread.

Image Diameter (mm) (spinner): Defines the area used for image processing.

This corresponds to the **yellow circle** displayed in the Image Viewer.

It should be adjusted so that artifacts and reflections typically found close to the walls of the plate are placed outside this circle.

A **red circle** (counted area) is automatically positioned slightly inside the yellow circle. This provides a safety margin to ensure that only reliable regions are considered for counting.

NOTE: For spiral distributions, the circles of the rings pattern and their associated section volumes determine the counting area and the *Counted Volume*. The **blue** and **red circles** do not affect the spiral distributions count unless they are inside the outer ring circle of the spiral pattern.

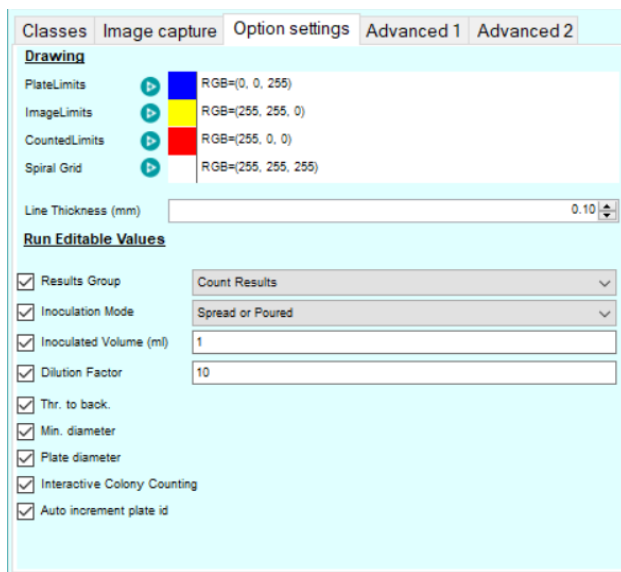
NOTE: The minimum Excluded Area value (4.41%) is obtained when both the Plate Diameter and the Image Diameter are set to the maximum value (90 mm).

Even in this configuration, the counted area (**red circle**) remains slightly smaller than the image processing area (**yellow circle**). This fixed difference creates a safety margin near the plate edge to reduce false detections caused by reflections, shadows, condensation, or other border artefacts.

- Image OffX (mm)** (spinner): Set the horizontal offset between the center of the image and the center of the plate.
- Image OffY (mm)** (spinner): Set the vertical offset between the center of the image and the center of the plate.
- NOTE:** Automatic calibration procedure and the auto-centering device of the device will ensure that the prescribed center of the circles matches the actual center of the plate, so that for normal plates there is no need to introduce any offset.

7.9.3. Option settings tab

The ‘Option settings’ tab allows users to set parameters of the overlay drawings and manage the availability of other settings when the method is used in the ‘Colony Count’ menu:



There are two groups:

- **Drawing:** includes parameters related to the markings on the captured images after image processing.
- **Run Editable Values:** defines the parameters that can be edited by the Operator during colony counting when using a specific method. For each parameter, the method defines whether it is editable (checkbox) and, where applicable, the default value (input box or drop-down list).

Drawing

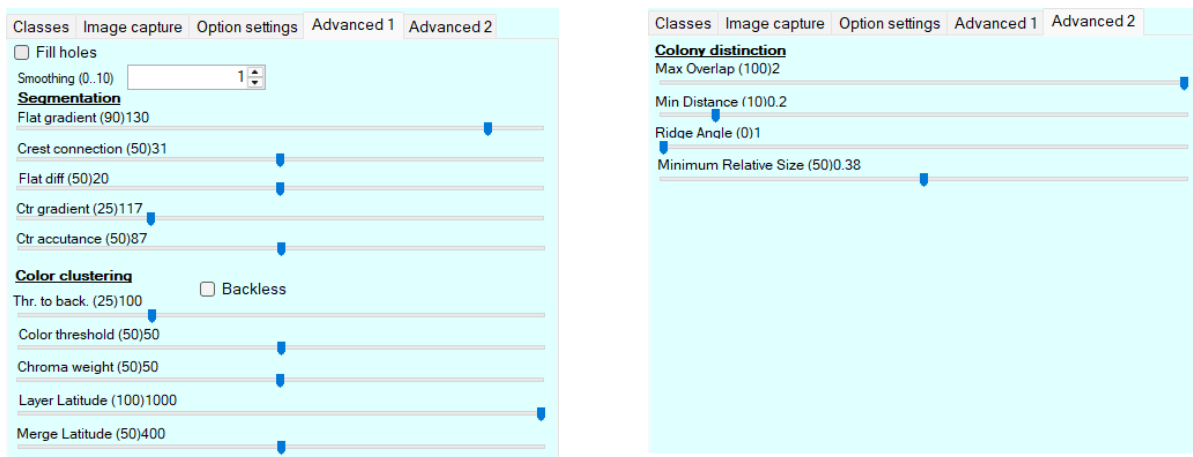
- Plate Limits** (button): Choose the color of the plate diameter circle from a predefined color palette.
- Counted Limits** (button): Choose the color of the counted area circle from a predefined color palette.
- Spiral Grid** (button): Choose the color of the spiral grid circles (for the spiral distribution) from a predefined color palette.
- Line Thickness:** Adjust the line thickness for all the overlays, including center and borders of each counted colony.
- NOTE:** The color of the center and borders of counted colonies are defined for each.

Run Editable Values

Results Group (checkbox and drop-down list):	Editable status and default results group.
Inoculation Mode (checkbox and drop-down list):	Editable status and default inoculation mode.
Inoculated Volume (checkbox and input box):	Editable status and default volume.
Dilution Factor (checkbox and input box):	Editable status and default dilution factor.
Threshold to background (checkbox):	Editable status.
Minimum diameter (checkbox):	Editable status.
Plate Diameter (checkbox):	Editable status.
Interactive Colony Counting (checkbox):	Editable status for interactive actions in the Image Viewer, including adding or removing colonies, modifying counting areas, or adjusting the counted diameter.
Auto-increment Plate ID (checkbox):	Editable status for automatic incrementation of the Plate ID. If the Plate ID does not end with a number, "1" is added. This number is then incremented for subsequent images only if the Plate ID remains unchanged.

7.9.4. Advanced settings tab

The default values of these settings in the *TEMPLATE_** built-in methods are optimized to successfully process a representative set of plate cases. If the results are not satisfactory for a specific case, these settings can be adjusted to improve counting performance by using the 'Advanced settings' tab.



These tabs contain parameters that control how colony clusters are detected, separated from the background, differentiated by color, and decomposed into individual colonies.

When the cursor is positioned over a slider, a tooltip is displayed providing a more detailed description.

The effect of each setting can be visualized directly in the Image Viewer:

- When the cursor is positioned over a slider, the image displays intermediate overlays representing an image processing stage (for example, colony separation) based on the current parameter values. Changes to the parameter value are not reflected in the overlay while the cursor remains over the slider. To update the displayed overlay, move the cursor away from the slider after adjusting the parameter value.
- When the cursor is not positioned over any slider:
 - Colonies that are not sufficiently contrasted or do not match the selected color criteria of the current *Colony Class* are not outlined.
 - Colonies that are outlined but outside the defined diameter range of the current *Colony Class* or identified as part of a cluster (e.g. protrusions) are not marked with a cross.

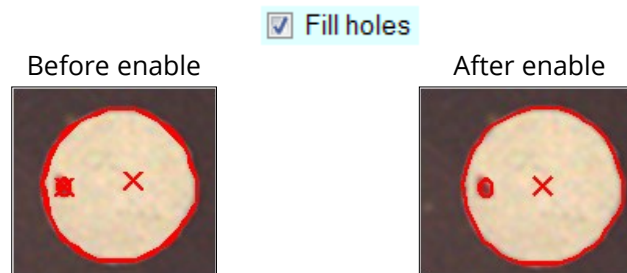
Slider adjustments should always be performed progressively while observing how the processed image evolves.

The specific actions of the available options are described in Section 7.9.5. Example cases for Advanced Settings.

7.9.5. Example cases for Advanced Settings options

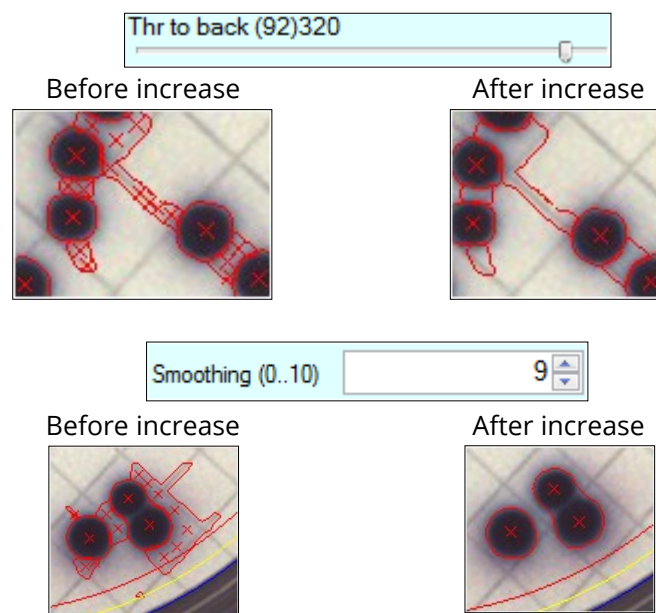
Case 1: Holes and stains inside big colonies

To avoid counting holes and small stains inside a big colony as smaller colonies, you can enable the box 'Fill holes'. If the stain or hole has a color similar to that of the background, you can also enable the box 'Backless':

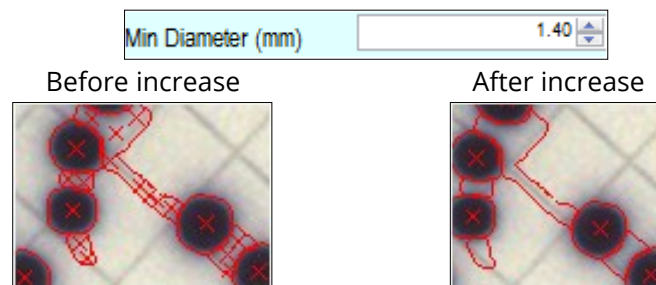


Case 2: Dim or narrow artifacts

If there are dim or narrow artifacts in the background, such as grid lines of a filter, you can avoid them from being counted incorrectly as colonies by increasing the 'Threshold to background' setting, or increasing the degree of 'Smoothing':

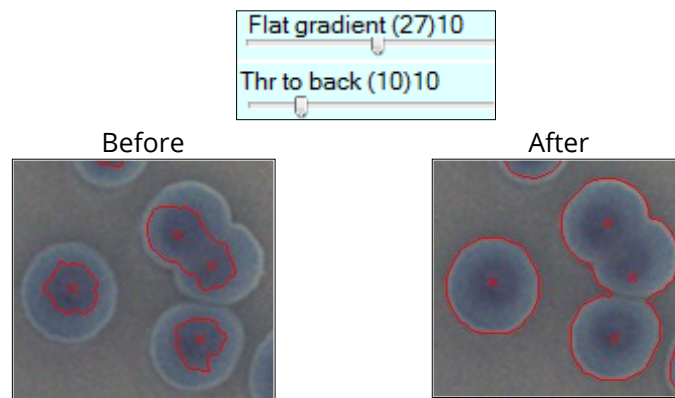


Alternatively, if the actual colonies are big enough, the 'Min Diameter' setting in the 'Classes' tab can be increased:



Case 3: Colonies with smooth or fuzzy edges

To detect colonies with smooth or fuzzy edges, it is recommended to use the built-in methods 'TEMPLATE_fuzzy' or 'TEMPLATE_transmitted_fuzzy'; but if the result using these methods is not good enough, you can improve it by trying some of the settings of the group 'Segmentation' in the tab 'Advanced 1' (particularly 'Flat gradient' and 'Ctr. Gradient'), and possibly lowering 'Threshold' to background:



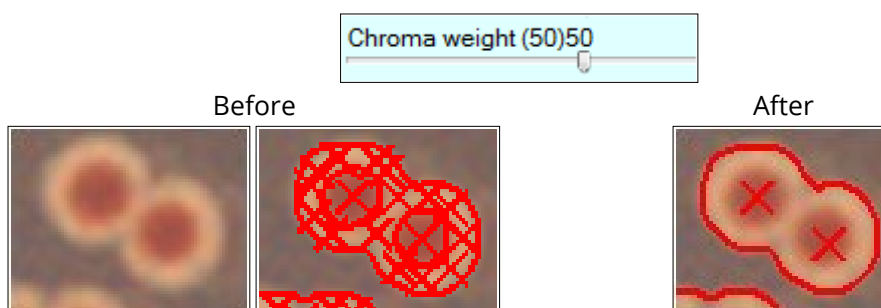
Case 4: Detecting low-contrasted colonies

When the colonies are faint and have low contrast against the background, lowering the setting 'Thr to back' can help to properly detect and count them. In some cases, checking the box 'Backless' can also help, and as well as changing the 'Count Mode' to 'All' instead of 'Auto'.



Case 5: Changing color detection behavior

When the colonies show an internal structure with different colors, the colonies may not be detected properly. You can improve the results by changing the setting 'Chroma Weight'.

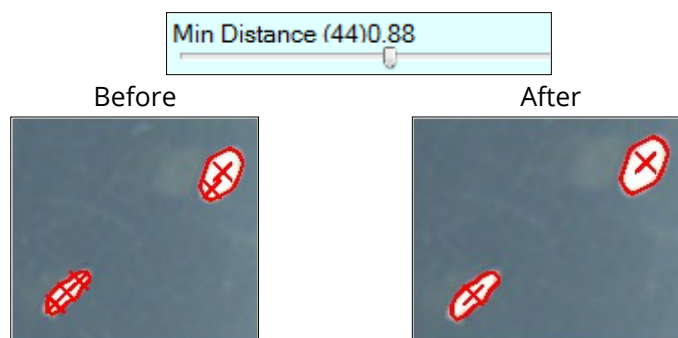


You can also try to modify the settings 'Color Threshold' and 'Backless'.

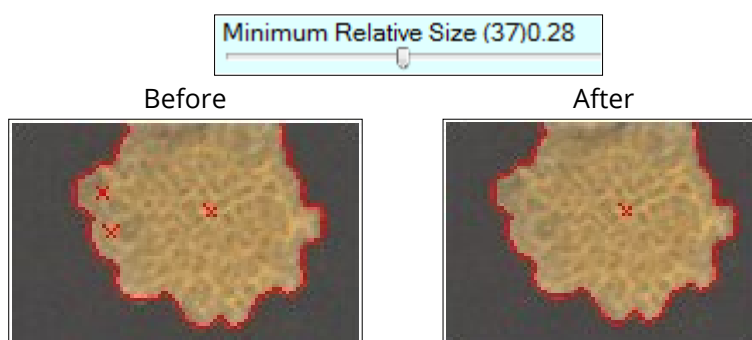
Case 6: Controlling how overlapped colonies are segregated

The settings in the tab 'Advanced 2' control how the clusters of overlapped colonies are decomposed into individual colonies

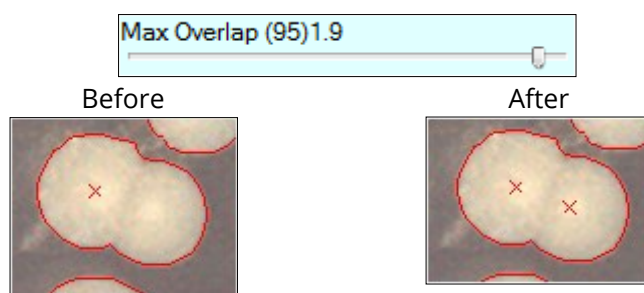
When there are elongated colonies, they could be misinterpreted as a cluster of overlapped colonies, resulting in a count of several colonies where there is only one. By raising the setting 'Min Distance', you can avoid counting spurious colonies that are too close to other colonies:



In the case of colonies with irregular or bulged edges, sometimes their lobes could be incorrectly counted as colonies. By adjusting the setting 'Minimum Relative Size', you can avoid the small bulges being recognized as independent colonies.



Sometimes, two round colonies that overlap may be counted as a single elongated colony; in this case, 'Max Overlap' setting can be useful to achieve counting both colonies instead of only one.



7.10. Working with worksheets (only Colonies PRO)

Worksheets allow predefined association of Plate IDs with specific methods and optional 'Run Data' and 'Run Input Values', minimizing the Operator errors during colony counting operations.

Users with Administrator or Programmer roles can create and manage worksheets, defining, for each Plate ID:

- The method to be used.
- Optional 'Run Data' and 'Run Input Values'.

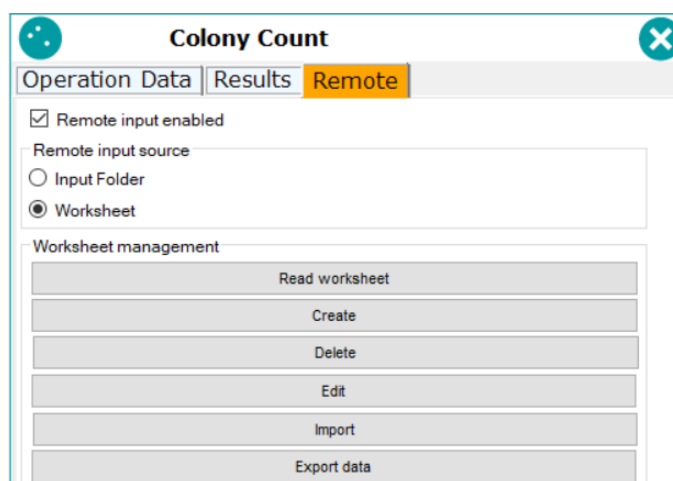
Later, users with Operator role can process plates simply by entering or scanning the Plate ID with a barcode. If the Plate ID exists in the active worksheet, all associated parameters are automatically loaded before processing the plate.

7.10.1. Remote tab

This section is accessible only to users with Administrator or Programmer roles.

In the 'Colony Count' menu select the 'Remote' tab, enable 'Remote Input Enabled' and select the 'Worksheet' radio button.

The 'Remote' tab will be highlighted in orange to indicate that the 'Remote' mode is active:



Several options are available:

- | | |
|------------------------|---|
| Read Worksheet: | Open an existing worksheet. |
| Create: | Create a new worksheet. Click on this option, then enter a new worksheet name |
| Delete: | Delete a worksheet. Click on this option, then select a worksheet to remove. |
| Edit: | Edit an existing worksheet, after using the 'Read Worksheet' option. |
| Import: | Load an external worksheet (i.e. a worksheet created using an external application not the Colonies Software). |
| Export data: | Export worksheet for use as a template to create external worksheet with the expected structure and field names |

7.10.2. Creating or editing a worksheet

To create a new worksheet, click 'Create' and enter a worksheet name.

To edit an existing worksheet, click 'Read Worksheet', select the desired worksheet, and click 'Edit'. The worksheet editor dialog is displayed:

Plate_Id	Method_Name	Inoculation_Mode	Inoculated_Volume	Dilution_Factor
PD192643	TEMPLATE_Sharp	Spread	1	10
PD192644	TEMPLATE_Sharp	Spread	1	100
PD192645	TEMPLATE_Sharp	Spread	1	100
PD192646	TEMPLATE_Fuzzy	E Mode 50ul	1	10
PD192647	TEMPLATE_Fuzzy	C Mode 100ul	1	10
PD192648	TEMPLATE_Tra...	Spread	1	10

For each plate you want to include in the worksheet:

- Enter or scan the 'Plate ID'.
- Select the desired Method.
- Optionally, enable 'Add input values' to define specific 'Run Data' and 'Run Input Values' different from the method defaults.

NOTE: Modified Input Values remain active for subsequent plates until the method is reloaded or changed.

Click 'Add' to include the edited plate in the worksheet list.

Existing entries can be:

- Modified using 'Overwrite'
- Removed using 'Remove'

Click 'Save' to store the worksheet in the database.

7.10.3. Importing, exporting, and deleting worksheets

A worksheet can be created in an external application and then imported into the Colonies PRO software application for its use in the following formats: Excel, CSV, and XML. Use the 'Import' button to load an external worksheet.

To create compatible external worksheets, it is recommended to:

1. Create a sample worksheet within the Colonies PRO.
2. Export it using 'Export Data'.

3. Use the exported file as a template to create your external worksheet with the expected structure and field names.

To delete an existing worksheet, click 'Delete' then select the worksheet to remove.

7.10.4. Working with remote file input

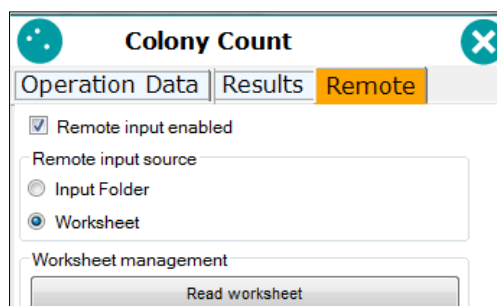
Instead of using a worksheet, the 'Input Folder' option can be selected in the 'Remote' tab.

In this mode, the method, 'Run Data', and 'Run Input Values' associated with each Plate ID are automatically retrieved from XML files stored in a remote folder.

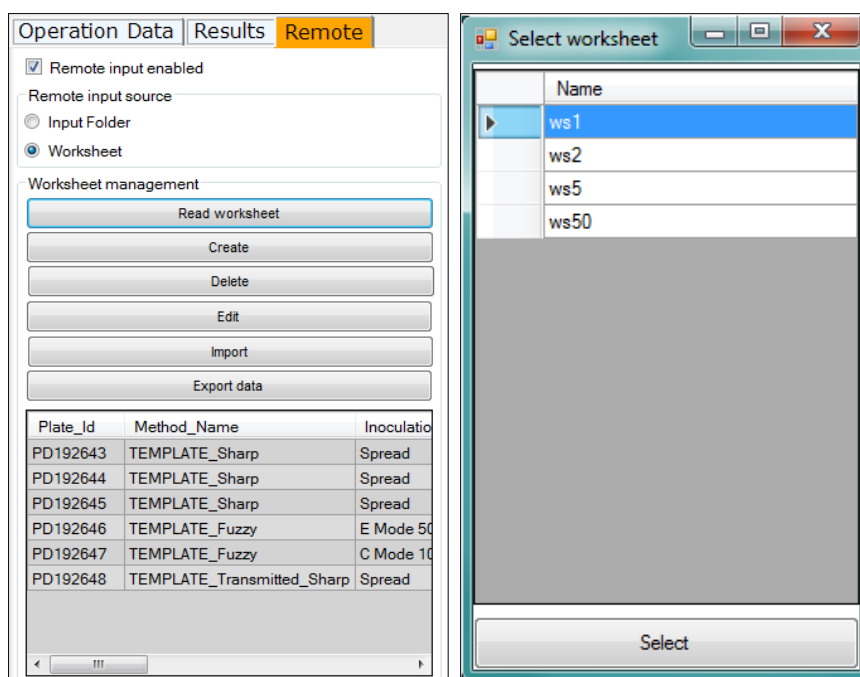
7.10.5. Using a worksheet to count colonies

Follow these steps to use a worksheet to count colonies:

1. In the 'Colony Count' menu, select the 'Remote' tab, and then check the box 'Remote Input Enabled' and the 'Worksheet' radio button.



2. Click 'Read worksheet', select the worksheet to use. The list of associated Plate IDs is displayed:



3. Select the 'Operation Data' tab. The 'Plate Id' field will automatically be filled with the first one from the worksheet list. Alternatively, you can enter (or use the barcode reader) a 'Plate Id ':

The screenshot shows a dialog box titled "Colony Count". It has three tabs: "Operation Data", "Results", and "Remote". The "Operation Data" tab is active. Below the tabs, there is a section labeled "Operation Data" containing a text input field for "Plate Id (*Required)". To the right of the input field, there are navigation arrows and the text "1 of 5". Further right is a disabled "OK" button. At the bottom right, there is a button labeled "Example 1".

4. When a Plate ID included in the worksheet is entered or scanned, the predefined method and parameters are automatically loaded. The 'OK' button becomes available.
5. Click 'OK' and the colony count operation can be performed normally.
6. If the Plate ID does NOT exist in the worksheet, the 'OK' button remains disabled and colony counting cannot be started. Navigation arrows allow browsing through the Plate IDs included in the worksheet.

7.11. Verify (for the SphereFlash® device)

Verification ensures accurate colony counting by the SphereFlash® Colonies software, and it may be required when the device is detected for the first time or as part of a routine schedule defined by the user.

Verification is carried out using the verification disk (Cat. No. 90004113), which simulates colonies of 3 different sizes (1, 2 and 3mm). The disk has two sides:

- Black colonies on a white background
- White colonies on a black background



Follow these steps to perform the verification process:

1. Select Verification from the Control Panel.
2. Place the centering device (Ø 87–91 mm) on the device platform, followed by the verification disk with the desired disk side facing up.
3. When the Verification panel is displayed, select the corresponding option:
 - Black Colonies on White Background, or
 - White Colonies on Black Background.
4. Click the Run button ().

The device captures an image of the verification disk and displays the results, with colony counts grouped into predefined size classes:

Verify

Imaging Device

Last Calibration Date

2026/08/31 13:40

Due Calibration Date

2026/09/30 13:40

Last Verification Date

2026/06/10 15:07

Due Verification Date

2026/08/09 15:07

Verification Data

☒ Black Colonies on White Background

☐ White Colonies on Black Background

Admissible Results (Test Plate)

1 mm: 169 - 189

2 mm: 153 - 163

3 mm: 120 - 126

Colony Class	Counted Colonies
✖ 1 mm Count	179
✔ 2 mm Count	158
✖ 3 mm Count	123

If all counts are within the expected ranges, select Accept to save the result to the cloud and finalize the verification. Select Reject to discard the results.

If the count for any size class falls outside the expected range, the corresponding result box is highlighted in red as a warning.

NOTE: Users with Administrator roles have the capability to set the verification frequency and decide if reminders for verification should be shown after the set period has expired.

7.11.1. Verifications data panel

All verifications stored are displayed in the Data Panel in the “Colony Count” menu. They are also available in the “View Results” menu when selecting the “CountResults” or “CountResults_lite” results groups.

Verifications									
Creation Date (UTC)	Created By	Method Name	Method Version Date (UTC)	Colony Class	Counted Colonies	Class Mark Color	Comments	Min. Size (mm)	
2026/04/30 09:04	example@email.com	Custom_Method_1	2023/11/21 10:19	1 mm Count	179	✖	<<Admissible Results (Test Plate): 1 mm: 169 - 189, 2 mm: 153 - 163...	0.80	
2026/04/30 09:04	example@email.com	Custom_Method_1	2023/11/21 10:19	2 mm Count	158	✔	<<Admissible Results (Test Plate): 1 mm: 169 - 189, 2 mm: 153 - 1...	0.80	
2026/04/30 09:04	example@email.com	Custom_Method_1	2023/11/21 10:19	3 mm Count	124	✖	<<Admissible Results (Test Plate): 1 mm: 169 - 189, 2 mm: 153 - 163...	0.80	

Each verification generates 3 entries, one for each colony size class (e.g. 1 mm, 2 mm, 3 mm). Although these entries correspond to the same processed image, they differ in:

- Colony Class (e.g. 1 mm, 2 mm, 3 mm)

- Number of counted colonies (169 - 189, 153 - 163, or 120 - 126)
- Class mark color (e.g. Blue, Lime, Red) assigned to that specific size class.

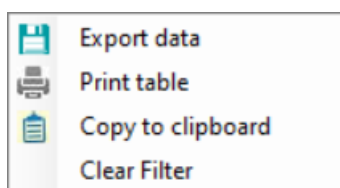
This means that a single verification run will appear as several rows in the Data Panel, one per colony size class.

Each verification result includes the following information:

- Results Group Name
- Created Time
- Operator
- Device SN
- Plate ID
- Method Name either *VERIFICATION_BlackOnWhite* or *VERIFICATION_WhiteOnBlack* (depending on which side of the verification disk was used)
- Colony Class (e.g. 1 mm, 2 mm, 3 mm)
- Counted Colonies
- Comments
- UTC Created Time.

The Comments section shows the admissible results for the plate test "*<<Admissible Results (Test Plate): 1 mm: 169 - 189, 2 mm: 153 - 163, 3 mm: 120 - 126>>*".

Right-click on one or more verification results in the table to access the contextual menu:



- | | |
|---------------------------|--|
| Export data: | A file browser opens to export selected calibration results with the desired format (XLSX: Excel, CSV: Comma-delimited, and TXT: Tab delimited). |
| Print table: | Print a table with all the parameters. |
| Copy to clipboard: | Copy all parameters of the selected results to the clipboard and then paste them into a document. |
| Clear filter: | Remove all active filters from the table. |

7.12. Calibrate (The SphereFlash® device)

Calibration ensures that the SphereFlash® device operates with accurate positioning, scaling, and illumination. It may be required when a SphereFlash® device is detected for the first time or as part of a routine schedule defined by the user.

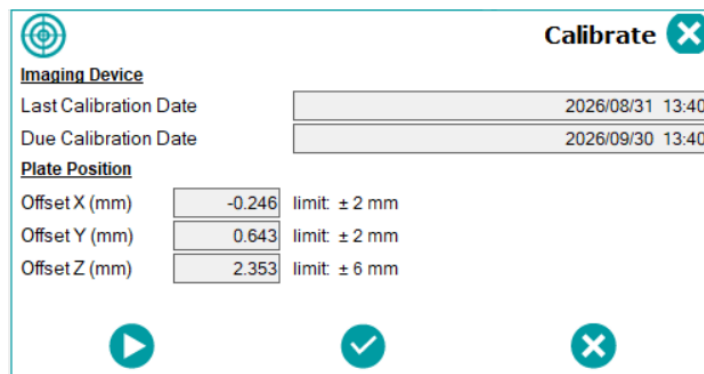
Calibration is performed using the calibration disk (Cat. No. 900010081).



Follow these steps to perform the calibration process:

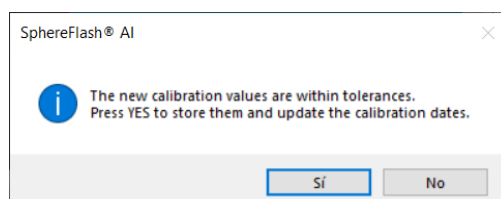
1. Select Calibration from the Control Panel.
2. Place the centering device (Ø 87–91 mm) on the device platform, followed by the calibration disk.
3. Click the Run button (▶).

The SphereFlash® device performs multiple image captures to automatically adjust image centering, dimensional scaling, and illumination settings, the final processed result is displayed in the application:



Once completed, an image of the calibration disk is displayed in the Image Viewer. This image may be used only for a visual verification of the calibration disk geometry, including the correct alignment and concentricity of the reference circles.

If calibration is successful, a prompt is displayed requesting confirmation to accept the calibration results:



If the calibration results fall outside the acceptable range, contact Technical support for assistance.

NOTE: Users with Tenant-admin and Administrator roles have the ability to set how frequently calibration should be performed. They can also activate reminders that will notify users when it's time to recalibrate the device after a certain period has elapsed.

7.12.1. Calibrations data panel

All calibrations stored for the equipment are displayed in the 'Browse Views' > 'View' > Calibrations:

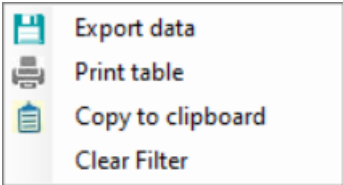
Calibrations						
Creation Date (UTC)	Created By	Device S/N	Offset X (mm)	Offset Y (mm)	Offset Z (mm)	Comments
2026/01/14 10:34	example@email.com	10007000/0016	-0.281	0.620	2.319	<<Limits (OffsetX OffsetY OffsetZ)mm: (2.00 2.00 6.00)>>
2026/01/14 10:30	example@email.com	10007000/0016	-0.281	0.620	2.319	<<Limits (OffsetX OffsetY OffsetZ)mm: (2.00 2.00 6.00)>>
2026/01/14 10:29	example@email.com	10007000/0016	-0.304	0.596	2.305	<<Limits (OffsetX OffsetY OffsetZ)mm: (2.00 2.00 6.00)>>
2024/10/29 15:15	example@email.com	10007000/0016	-1.552	-1.085	2.762	<<Limits (OffsetX OffsetY OffsetZ)mm: (2.00 2.00 6.00)>>

Each calibration result includes the following information:

- Creation date
- Created By
- Device S/N
- Offset X
- Offset Y
- Offset Z
- Comments

The Comments section shows the admissible limits "<<Limits (OffsetX|OffsetY|OffsetZ)mm: (2.00|2.00|6.00)>>".

Right-click on one or more calibration results in the table to access the contextual menu:



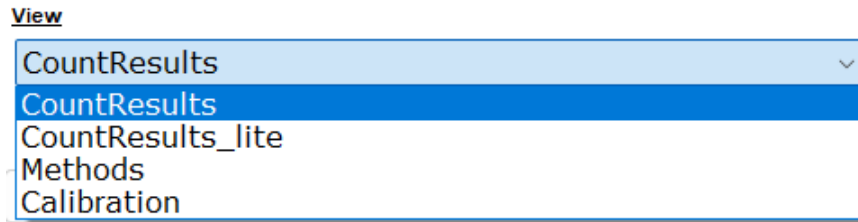
- Export data:** A file browser opens to export selected calibration results with the desired format (XLSX: Excel, CSV: Comma-delimited, and TXT: Tab-delimited).
- Print table:** Print a table with all the parameters.
- Copy to clipboard:** Copy all parameters of the selected results to the clipboard and then paste them into a document.
- Clear filter:** Remove all active filters from the table.

7.13.

7.13. View Results menu

The View Results menu provides access to stored data, allowing the user to browse, review, export, and manage results, verifications and calibrations.

When clicking on 'Browse Views' in the main menu, the Control panel area displays the following panel:



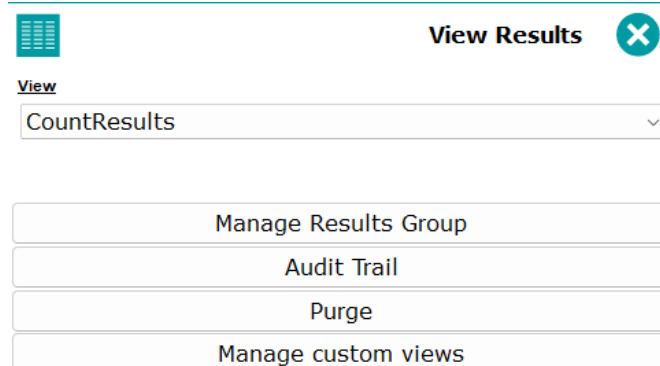
At the top, the 'View' drop-down list allows you to select which table to display in the Data panel:

- Results (CountResults)
- Results Summary (CountResults_lite)
- Methods and Calibrations

Verification results are also included in the Results and Results Summary tables.

The following features are available only in Colonies PRO:

- Manage Results Group
- Audit Trail
- Purge
- Manage Custom Views



7.13.1. Results and Results Summary

The "CountResults" table displays the complete set of parameters associated with each stored result, including verifications:

- | | |
|--------------------|---------------------|
| • Results Group | • Operator |
| • Name | • Dilution factor |
| • Plate ID | • Inoculated volume |
| • Method | • Inoculation mode |
| • Colony class | • Excluded area |
| • Counted colonies | • Device SN |
| • Counted volume | • UTC Created Time |
| • Concentration | • Count from |
| • Comments | • Automatic process |
| • Created Time | • Input values |

The “CountResults_lite” table provides a simplified view of the results, displaying a reduced set of columns for quick review:

- Results
- Group Name
- Plate ID
- Method
- Colony class
- Counted colonies
- Concentration
- Comments
- Created Time
- UTC Created Time

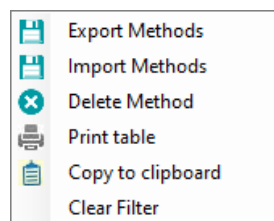
In the “CountResults” and “CountResults_lite” tables, the same contextual menu options described in previous sections are available when right-clicking on the table.

7.13.2. Methods

The ‘Methods’ table displays the complete set of parameters associated with each stored method:

- Method
- Description
- Operator
- Created Time
- UTC Created time

In the “Methods” table, the following actions are available when the table is right-clicked:



Export Methods:	A file browser opens to export selected methods in XML format. The exported method file will be named after the method name.
Import Methods:	A file browser opens to import previously exported methods in XML format. NOTE: Only available with Administrator and Programmer roles.
Delete Method:	Delete the selected methods. NOTE: Only available with Administrator and Programmer role.
Print table:	Print a table with all the parameters for the selected rows.
Copy to clipboard:	Copy all parameters of the selected row to the clipboard and then paste them into a document.
Clear filter:	Remove all active filters from the table.

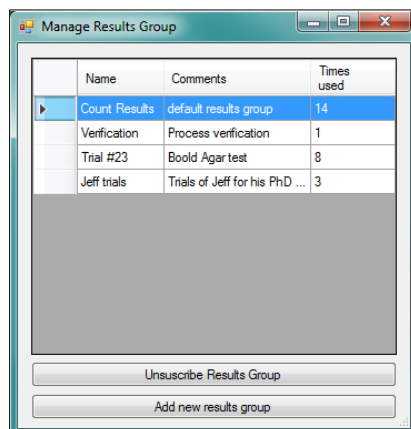
7.13.3. Calibration

In the “Calibrations” tables, the same contextual menu options described in the previous sections.

7.13.4. Manage Results Group (only in Colonies PRO)

This section is accessible only to users with Administrator or Programmer roles.

A Results Group is a label assigned to results, allowing subsequent grouping and filtering in the different views. To manage results groups, click the ‘Manage Results Groups’ button in the ‘View Results’ panel. A dialog will display the existing groups, with options to create a new group or remove an existing one:



The native built-in groups are:

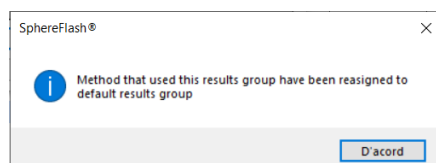
Count Results: Default group assigned to colony count operations.

Verification: Automatically assigned to verification results.

When creating or editing a method, it is possible to define the default ‘Results Group’ assigned to results generated with that method, as well as whether the operator is allowed to modify this group.

NOTE: A ‘Result Group’ cannot be deleted while results assigned to that group remain stored in the database. Before deletion, the corresponding results must be purged or reassigned to another group.

NOTE: Methods associated with a deleted ‘Result Group’ are automatically reassigned to the default ‘Count Results’ group:

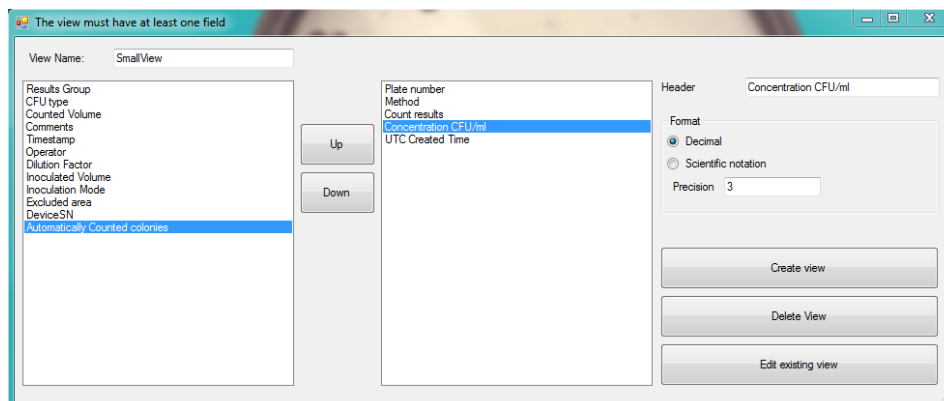


7.13.5. Manage custom views (only Colonies PRO)

This section is accessible only to users with Administrator or Programmer roles.

This function allows the creation of customized result views that will appear in the 'View' drop-down list. Custom views can be configured by selecting which columns are displayed, defining their order, modifying column header names, and setting the numeric display format for non-integer numeric fields.

When 'Manage custom views' is selected, a view configuration dialog is displayed:



1. Enter a name for the new view in the 'View Name' field. The left panel contains the list of available columns.
2. To include a column in the custom view, double-click on it. The selected column will move to the right panel. The right panel contains the columns included in the custom view. The following actions are available:

Up / Down buttons: Change the display order of the selected column.

Header Name field: Modify the displayed column name.

Numeric Format options: Define the display format for compatible numeric fields (decimal or scientific notation, including the number of decimal places).

Double-click on a selected column: Remove the column from the custom view and return it to the available columns list.

3. When configuration is complete, click 'Create View' to save the custom view. The new view will then be available in the 'View' drop-down list.
4. To modify an existing custom view, click 'Edit Existing View' and select the view to edit. Existing custom views can also be deleted using the 'Delete View' button.

7.14. Stored Data

It is the responsibility of the client's computer Systems Administrator to perform a reliable, regular backup copy of the active database files where the settings and results created by the application are stored.

The path where these active database files are stored is:

%ProgramData%\IUL\SphereFlash

All the files inside this folder are to be backed up regularly, as prescribed by the client's policies and by the regulatory frameworks that must be fulfilled.

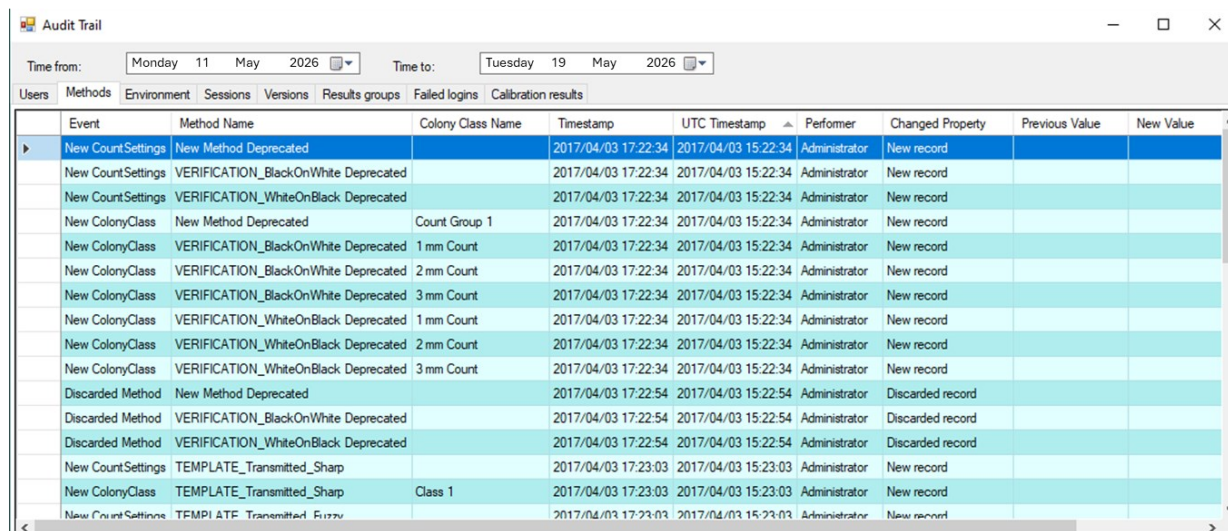
The database cannot be modified or overwritten by the user.

7.14.1. Audit Trail (only in Colonies PRO)

This section is accessible only to users with Administrator role.

The Audit Trail is a historical record of all actions and modifications performed by users within the application. Audit Trail functionality may be required under certain regulatory frameworks, such as FDA 21 CFR Part 11 Subpart B.

To access the 'Audit Trail', open the 'View Results' menu and click on the button 'Audit Trail'. A window containing multiple tabs is displayed:



The screenshot shows the 'Audit Trail' window with a tabbed interface. The 'Users' tab is selected, displaying a table of audit events. The table has columns for Event, Method Name, Colony Class Name, Timestamp, UTC Timestamp, Performer, Changed Property, Previous Value, and New Value. The data shows various actions like 'New CountSettings', 'New ColonyClass', and 'Discarded Method' performed by the 'Administrator' on 2017/04/03.

Event	Method Name	Colony Class Name	Timestamp	UTC Timestamp	Performer	Changed Property	Previous Value	New Value
New CountSettings	New Method Deprecated		2017/04/03 17:22:34	2017/04/03 15:22:34	Administrator	New record		
New CountSettings	VERIFICATION_BlackOnWhite Deprecated		2017/04/03 17:22:34	2017/04/03 15:22:34	Administrator	New record		
New CountSettings	VERIFICATION_WhiteOnBlack Deprecated		2017/04/03 17:22:34	2017/04/03 15:22:34	Administrator	New record		
New ColonyClass	New Method Deprecated	Count Group 1	2017/04/03 17:22:34	2017/04/03 15:22:34	Administrator	New record		
New ColonyClass	VERIFICATION_BlackOnWhite Deprecated	1 mm Count	2017/04/03 17:22:34	2017/04/03 15:22:34	Administrator	New record		
New ColonyClass	VERIFICATION_BlackOnWhite Deprecated	2 mm Count	2017/04/03 17:22:34	2017/04/03 15:22:34	Administrator	New record		
New ColonyClass	VERIFICATION_BlackOnWhite Deprecated	3 mm Count	2017/04/03 17:22:34	2017/04/03 15:22:34	Administrator	New record		
New ColonyClass	VERIFICATION_WhiteOnBlack Deprecated	1 mm Count	2017/04/03 17:22:34	2017/04/03 15:22:34	Administrator	New record		
New ColonyClass	VERIFICATION_WhiteOnBlack Deprecated	2 mm Count	2017/04/03 17:22:34	2017/04/03 15:22:34	Administrator	New record		
New ColonyClass	VERIFICATION_WhiteOnBlack Deprecated	3 mm Count	2017/04/03 17:22:34	2017/04/03 15:22:34	Administrator	New record		
Discarded Method	New Method Deprecated		2017/04/03 17:22:54	2017/04/03 15:22:54	Administrator	Discarded record		
Discarded Method	VERIFICATION_BlackOnWhite Deprecated		2017/04/03 17:22:54	2017/04/03 15:22:54	Administrator	Discarded record		
Discarded Method	VERIFICATION_WhiteOnBlack Deprecated		2017/04/03 17:22:54	2017/04/03 15:22:54	Administrator	Discarded record		
New CountSettings	TEMPLATE_Transmitted_Sharp		2017/04/03 17:23:03	2017/04/03 15:23:03	Administrator	New record		
New ColonyClass	TEMPLATE_Transmitted_Sharp	Class 1	2017/04/03 17:23:03	2017/04/03 15:23:03	Administrator	New record		
New CountSettings	TEMPLATE_Transmitted_Fuzzy		2017/04/03 17:23:03	2017/04/03 15:23:03	Administrator	New record		

NOTE: If the application was previously used with the Colonies LITE configuration and later upgraded to Colonies PRO, previously records generated while using Colonies LITE remain available and accessible in the database.

Records can be:

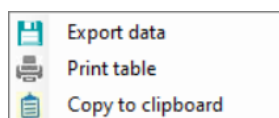
- **Sorted** by clicking on a column header
- **Filtered by date and time** using the **Time From** and **Time To** fields.

The following tabs are available:

Users:	Record user management actions, such as creation, deletion, role assignment, password changes, etc. Includes the following information: Event (new user, changed property, discarded user), User name (user affected by the event), Timestamp, UTC Timestamp, Performer (user who performed the event), User Role (role assigned to the user name), Changed Property (new record, password date creation, discarded record, role name, etc.), Previous Value and New Value.
Methods:	Record events related to the method creation, editing, modification, and deletion. Includes the following information: Event (new count settings, discarded method, new colony class, method edited, colony class edited), Method name, Colony Class Name, Timestamp, UTC Timestamp, Performer, Changed Property (new record, discarded record, threshold to background, etc.), Previous Value, New Value and Reason for Change (improving result, null).
Environment:	Record the changes made in the settings under the 'Environment' and 'System options' menus. Includes the following information: Event (new environment, changed property, etc.), Timestamp, UTC Timestamp, Performer, Changed Property (new record, Imaging device S/N, include images, language, force new calibration, etc.), Previous Value, New Value and Reason for change (new license key, improving results).
Sessions:	Record user login and logout sessions. Includes the following information: User name, Start Timestamp, End Timestamp, Start UTC Timestamp and End UTC Timestamp.
Versions:	Record user login and logout sessions. Includes the following information: Item, Version, Update Timestamp and Update UTC Timestamp.
Results Groups:	Record the creation and deletion of 'Results Groups'. Includes the following information: Results Group Name, Comment, Creation Timestamp, Creation UTC Timestamp, Deletion Timestamp, Deletion UTC Timestamp and Udeleted by (user).
Failed Logins:	Record unsuccessful login attempts caused by incorrect user names or passwords. Includes the following information: User name, Timestamp and UTC Timestamp.
Calibration Results:	Display the results of calibration operations. Includes the following information: Performer, Offset X, Offset Y, Offset Z, Timestamp and UTC Timestamp.

NOTE: Entries dated in the year 2017 correspond to the creation of the default database, default user roles, and report templates. These timestamps were generated by IUL S.A. during the design of the Colonies software. They are embedded within the master database.

Right-click on one or more audit trail records in the table to access the contextual menu:



Export data:	A file browser opens to export selected records with the desired format (XLSX: Excel, CSV: Comma-delimited, and TXT: Tab-delimited).
Print table:	Print a table with all the records.
Copy to clipboard:	Copy all records of the selected results to the clipboard and then paste them into a document.

7.14.2. Purge (only in Colonies PRO)

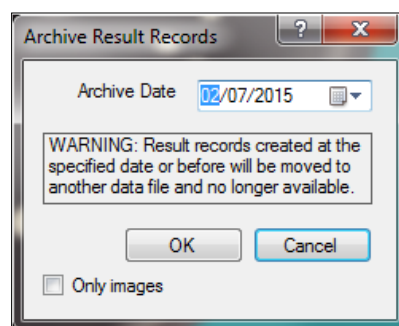
This section is accessible only to users with Administrator role.

The Purge function allows the removal of old results and associated images, or only associated images, from the database by transferring them to a historical archive file. This helps prevent excessive database growth and maintains application performance over time.

NOTE: Backups remain accessible when software updates are performed, so the old backups and purged data can still be consulted in the new software version.

Before performing a purge operation, ensure that all required information has been previously exported or printed to external media (e.g. Excel files, printed reports, or PDF reports).

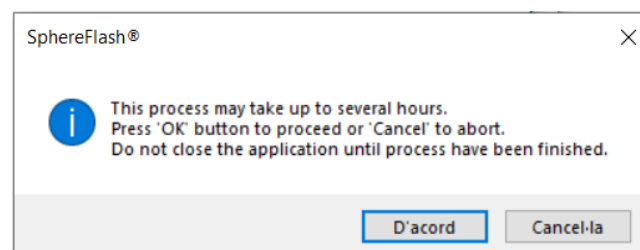
To access the 'Purge', open the 'View Results' menu and click on the 'Purge' button. The following panel is displayed:



Archive date: Define the cutoff date. Results older than this date will be removed from the active database.

Only images: Check-box option that allows purging only the stored images while keeping the associated result data. This can significantly reduce disk space usage, since images occupy most of the storage space.

A warning message will indicate that the purge process may require a long execution time:

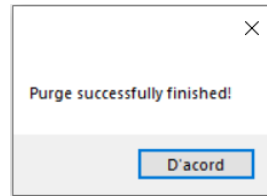


In extreme cases, the operation may take up to one hour. It is recommended to perform the purge operation at the end of the workday and allow it to run without interruption.

During the purge process:

- Do NOT close the application.
- Do NOT terminate the process using the Windows Task Manager.
- Do NOT restart or shut down the computer.

The following message will be displayed, indicating that the purge process has completed successfully:



NOTE: Certain regulatory frameworks require retention of records for a minimum period of time. It is the responsibility of the Administrator to ensure compliance with applicable regulations before purging database contents.

7.14.2.1. Location of archived database files resulting from purge operations

Each time a purge operation is performed, the system creates a dedicated archive folder under:

`%ProgramData%\IUL\SphereFlash`

The folder name begins with @YYYYMMDD, including date and time corresponding to the purge cutoff date:

 @2016-10-14_636269827042756418

The folder creation date reflects the timestamp of the purge operation, allowing previous purge events to be identified and reviewed.

Each archive folder contains copies of the database files generated during the purge operation, including the following key database files:

FGrow20.Images.crypted.sqlite

FGrow20.Settings.crypted.sqlite

FGrow20.Views.crypted.sqlite

7.14.2.2. Temporary manual restoration of archived databases

This procedure allows temporary restoration of previously archived database files for historical review, disaster recovery verification, or data validation purposes.

Only the System Administrator can temporarily restore an archived database by following these steps:

1. Close the application
2. Locate the active database folder:

`%ProgramData%\IUL\SphereFlash`

3. Rename or move the current active database files to a secure location.

4. Locate the desired archive folder:

 @2016-10-14_636269827042756418

5. Copy the archived database files (FGrow20...) into the active database folder:

%ProgramData%\IUL\SphereFlash

6. Open the application. The application will load the restored database, allowing access to the historical results and associated records to perform the required review, export, printing or verification operations.
7. Close the application and restore the original active database files.

7.15. User management

7.15.1. Change user password

A. Colonies LITE

Only one user is available: Administrator

The default user on first access is "Administrator" and the default password is "1234".

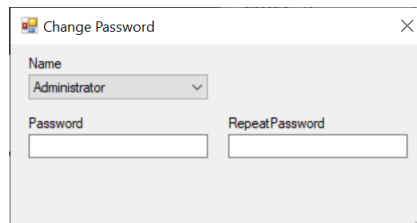
B. Colonies PRO

Three default users are available: *Administrator*, *Programmer*, and *Operator*.

Each default username corresponds to a different permission level (user role).

At first access, users must enter one of these predefined usernames in the login dialog. The default password for all users is 1234.

It is recommended to change the usernames and passwords during system setup.



When entering a password, the application displays its strength classification.

A password is considered valid when it meets minimum security requirements. Password strength is classified as follows:

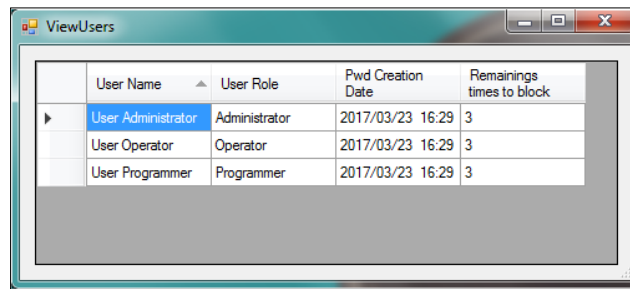
- **Weak:** The password contains at least 5 characters and includes uppercase letters, lowercase letters, and numbers.
- **Moderate:** The password contains at least 5 characters and includes letters, numbers, and symbols.
- **Strong:** The password contains at least 7 characters and includes letters and numbers.
- **Very strong:** The password contains at least 7 characters and includes uppercase letters, lowercase letters, and symbols.

7.15.2. View existing users (only Colonies PRO)

This section is accessible only to users with Administrator role.

A table displays:

- Username
- User role
- Date of last password change
- Remaining failed login attempts before user blocking: A user is automatically blocked after 3 consecutive failed login attempts (incorrect password).



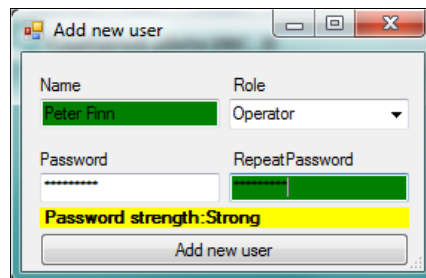
	User Name	User Role	Pwd Creation Date	Remainings times to block
▶	User Administrator	Administrator	2017/03/23 16:29	3
	User Operator	Operator	2017/03/23 16:29	3
	User Programmer	Programmer	2017/03/23 16:29	3

7.15.3. Add new user (only Colonies PRO)

This section is accessible only to users with Administrator role.

The Administrator can create a new user by assigning:

- Username
- User role
- Password



Dialog box titled "Add new user" with the following fields:

- Name: Peter Finn
- Role: Operator (dropdown menu)
- Password: [masked with asterisks]
- Repeat Password: [masked with asterisks]
- Password strength: Strong (highlighted in yellow)
- Add new user button

NOTE: The first time a new user accesses the application, the password assigned by the Administrator should be changed.

7.15.4. Other user management operations (only Colonies PRO)

The Administrator can also:

- Remove existing users
- Change the password of other users
- Change the role of an existing user

7.15.5. Failed Login Attempts and Password Recovery

A. User blocked

Each user (Administrator, Programmer, and Operator) has three (3) consecutive attempts to log in. After the third incorrect password entry, the user is automatically blocked for 24 hours.

To unblock a user, wait until the temporary blocking period expires (24h) and log in again.

NOTE: After the blocking period expires (24 hours), the user is automatically unblocked and can attempt to log in again.

NOTE: During login, after each incorrect password entry, the application indicates the number of remaining attempts before the user is blocked.

NOTE: All failed login attempts are recorded in the Audit Trail.

B. User forgets the password

If a **Programmer** or **Operator** user forgets the password, ask a user with Administrator role to:

- change the user password or
- recreate the user

If the **Administrator** user forgets the password, contact IUL Technical Service to arrange a Remote Recovery Session.

In this case,

1. Access the following folder in your PC:

`%ProgramData%\IUL\SphereFlash`

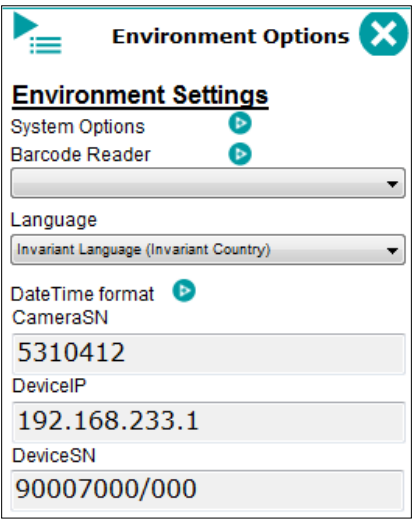
2. Send the following file to IUL Technical Service for password recovery:

`FGrow20.Settings.crypted.sqlite`

NOTE: It is strongly recommended to configure at least two users with Administrator role to avoid loss of administrative access.

7.16. Environment options (only Colonies PRO)

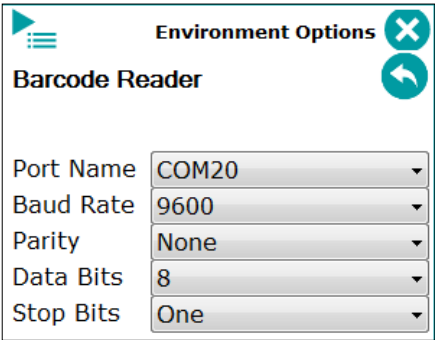
This menu enables users with the Administrator role to customize and modify the settings of the Colonies PRO Desktop Application:



It contains the following items:

System Options
(button): Access the 'System Options' panel.

Barcode Reader
(button): Access the configuration of the barcode reader serial interface. Fill in or select the proper values according to the barcode reader manufacturer's indications.



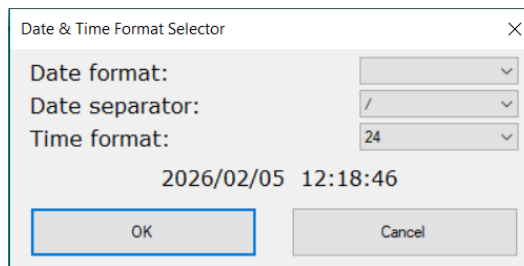
You can find the port name where the reader is connected to the computer using the PC Windows *Device Manager* dialog.

Language (drop-down list): Select the application language among those available.

NOTE: To apply language changes, you must restart the Colonies Software desktop application.

Date/Time Format
(button): Displays the 'Date & Time Format Selector' dialog:

- Date format: DMY, MDY, or YMD
- Date separator: /, ., ,, or space
- Time format: 12-hour or 24-hour



A dialog box titled "Date & Time Format Selector" with a close button (X) in the top right corner. It contains three dropdown menus: "Date format:" (empty), "Date separator:" (set to "/"), and "Time format:" (set to "24"). Below these is a preview of the date and time: "2026/02/05 12:18:46". At the bottom are "OK" and "Cancel" buttons.

Camera S/N (text box): Displays the serial number of the camera in the detected SphereFlash® device.

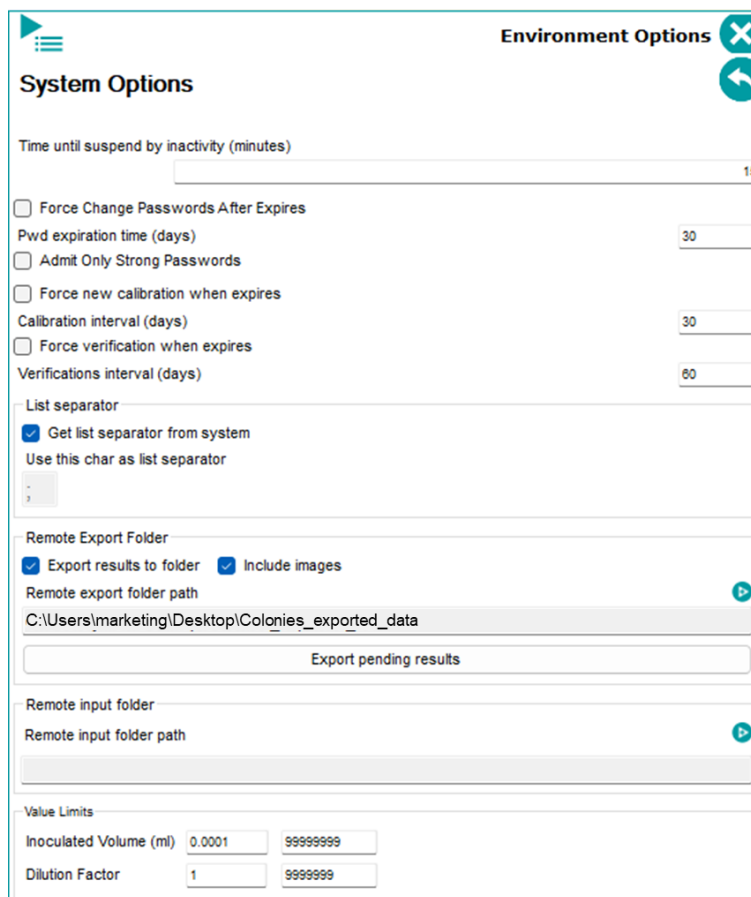
Device IP (text box): Displays the Internet Protocol address assigned to the detected SphereFlash® device.

Device S/N (text box): Displays the serial number of the detected SphereFlash® device.

NOTE: If the Desktop Application is started without a SphereFlash® device connected, this field will indicate 'No Device'

7.16.1. System options panel

The 'System options' panel enables configuration of operational settings and application preferences.



The "System Options" panel is part of the "Environment Options" section. It contains several configuration sections:

- Time until suspend by inactivity (minutes):** A slider set to 15.
- Force Change Passwords After Expires:** A checkbox.
- Pwd expiration time (days):** A text box set to 30.
- Admit Only Strong Passwords:** A checkbox.
- Force new calibration when expires:** A checkbox.
- Calibration interval (days):** A text box set to 30.
- Force verification when expires:** A checkbox.
- Verifications interval (days):** A text box set to 60.
- List separator:** A section with a checked checkbox "Get list separator from system" and a text box "Use this char as list separator" containing a comma character.
- Remote Export Folder:** A section with checked checkboxes "Export results to folder" and "Include images", a text box for "Remote export folder path" containing "C:\Users\marketing\Desktop\Colonies_exported_data", and a button "Export pending results".
- Remote input folder:** A section with a text box for "Remote input folder path".
- Value Limits:** A section with two rows of text boxes: "Inoculated Volume (ml)" with values "0.0001" and "9999999", and "Dilution Factor" with values "1" and "999999".

It contains the following items:

Time until suspend by inactivity (input box): Enter the delay time in minutes before the application logs out due to inactivity.

Force Change Password After Expires (checkbox): Enable mandatory password change once the password expiration warning is displayed.

Password expiration time (input box): Enter the number of days the password remains valid before the user is prompted to change it.

Admit only strong passwords (checkbox): Enabled, only passwords that meet strong password requirements

Force new calibration when expires (checkbox): Block the 'Colony Count' and 'Verify' menus when the calibration is out of date.

Calibration interval (input box): Enter the number of days that the calibration remains valid. If 'Force new calibration when expires' is enabled and the current calibration has expired, a pop-up warning will be displayed at every attempt to access 'Colony Count' and 'Verify'. Additionally, the comment *<<Calibration is needed>>* is always added to 'Comments' when a result is saved with an expired calibration.

Force new verification when expires (checkbox): Block the 'Colony Count' menu when the verification is out of date.

Verification interval (input box): Enter the number of days that the verification remains valid. If 'Force new verification when expires' is enabled and the current verification has expired, a pop-up warning will be displayed at every attempt to access 'Colony Count'.

List separator

Get list separator from system (checkbox): Enable the application to get the list separator character from the operating system, and later use it in the exported CSV files.

Use this char as a list separator (input box): Enter the desired character to use as a list separator in the CSV files.

Remote Export Folder

Export results to folder (checkbox): Enable the automatic output of results in XML format, including associated images.

NOTE: If the configured destination folder is unavailable or inaccessible, the export operation cannot be completed, and the results will remain pending until the folder becomes accessible or a new destination folder is configured.

Include images (checkbox): Include images in the exported XML result files.

Remote export folder path (button and text box): Enter the destination folder where the results files will be automatically saved. The chosen path will appear in the box.

Export pending results (button): Export all results previously marked as pending due to unavailable or inaccessible export folders. This function is available only when 'Export Results to Folder' is enabled.

Remote input folder

Remote input path (button and text box): Enter and display the destination folder of the input path containing the remote input files used as external worksheets. The chosen path will appear in the box. The selected remote input folder can later be activated from the 'Remote' tab in the 'Colony Count' menu.

Value Limits

Inoculated Volume (two input boxes): Enter the minimum and maximum values to use as the sample inoculated volume within the scope of the application.

NOTE: This limitation helps minimize the risk of entering illogical values that could lead to incorrect results. This safety measure may be required by certain regulatory frameworks.

Dilution Factor (two input boxes): Enter the minimum and maximum values to use as dilution factors within the scope of the application.

NOTE: The maximum limit for the Dilution Factor is 999,999,999 (9 digits).

NOTE: This limitation helps minimize the risk of entering illogical values that could lead to incorrect results. This safety measure may be required by certain regulatory frameworks.

7.16.2. Interfacing with a LIMS

The Colonies PRO desktop application can automatically provide results data to a corporate network with a LIMS:

- Send to the LIMS the Colony Count results after processing each plate ('Remote Out' to a folder).
- Retrieve from the LIMS which method and which Run / Input values must be applied to process each plate, in a similar way to working from worksheets ('Remote In' from a folder).

To implement these features, the following subjects must be addressed:

- a. Two folders have to be designated as the 'Remote In' and the 'Remote Out' folders; they may be located either in the computer containing the application or in some server reachable through the network.
- b. The PC systems administrator must grant the proper access permissions to both folders by the Colonies PRO desktop application as well as the LIMS system.
- c. The PC systems administrator must ensure the rules of privacy and restricted access to the data in these folders, as mandated by the company policies and any regulatory framework that would be applicable.

- d. In the 'System Options' panel define the paths to the respective remote folders.
- e. In the 'System Options' panel check the 'Export results to folder' checkbox. Optionally, check the 'Include images'. The images will be saved in XML format.
- f. In the 'Remote' tab of the 'Colony Count' menu, check the 'Remote input enabled' checkbox, and select the button 'Input folder'.
- g. Each plate must have a unique identifier (Plate ID), it's advisable to use a barcode to avoid operator errors.
- h. The LIMS must create in advance, for each 'Plate ID', an XML file containing the settings (method and 'Run / Input Values') required to process the plate and place this file into the 'Remote In' folder.
- i. The LIMS must collect from the 'Remote Out' folder each XML file that will appear after each 'Colony Count' operation, parse it and transfer the count results to its database.

The LIMS should delete from both 'Remote In' and 'Remote Out' folders the files corresponding to the plates already processed.

Remote output file example

File name:

37254674.xml

(where 37254674 is an incremental unique number, not the Plate ID)

File contents:

```
<?xml version="1.0" standalone="yes"?>
<DocumentElement>
  <ColonyClass>
    <InputValues>80 ;85.0 ;0.3</InputValues>
    <Id>5</Id>
    <CountFromAutomaticProcess>27</CountFromAutomaticProcess>
    <UTCCreatedTime>2017-03-29T14:01:14.225+02:00</UTCCreatedTime>
    <DeviceSN>90007000/000</DeviceSN>
    <ExcludedFraction>0</ExcludedFraction>
    <InoculationMode>D Mode 50ul</InoculationMode>
    <InoculatedVolume>0.05</InoculatedVolume>
    <DilutionFactor>10</DilutionFactor>
    <Operator>User Administrator</Operator>
    <CreatedTime>2017-03-29T16:01:14.225+02:00</CreatedTime>
    <Comments />
    <CFUml>5400</CFUml>
    <CountedVolume>0.0500000007450581</CountedVolume>
    <Count>27</Count>
    <ColonyName>Class 1</ColonyName>
    <MethodName>TEMPLATE_Sharp</MethodName>
    <PlateId>plate28</PlateId>
    <ResultsGroupName>Count Results</ResultsGroupName>
  </ColonyClass>
</DocumentElement>
```

Remote input file example

File name:

RI05.xml

(where *RI05* is the plate ID to be processed with the settings in the file)

File contents:

```
<?xml version="1.0" standalone="yes"?>
<plate>
  <plate_id>RI05</plate_id>
  <method_name>TEMPLATE_Sharp</method_name>
  <inoculation_mode>Spread</inoculation_mode>
  <inoculated_volume>1</inoculated_volume>
  <dilution_factor>10</dilution_factor>
  <result_group>Count Results</result_group>
  <th_to_background>79</th_to_background>
  <abs_min_diameter>0.30</abs_min_diameter>
  <plate_diameter>80.0</plate_diameter>
</plate>
```

NOTE: Only nodes <plate_id> and <method_name> are compulsory.

7.17. External Counter (only in Colonies PRO)

Automatic colony counting using the SphereFlash® device may not be feasible for certain plate or colony sizes, shapes, or characteristics. In such cases, manual colony count results and associated run data can be entered into the SphereFlash® database. Once entered, these results are managed identically to results automatically generated by the SphereFlash® device.

This functionality also supports laboratories migrating from manual counting procedures or legacy colony counting systems (including DOT) by enabling the integration of historical or externally generated colony count data into the SphereFlash® database workflow.

7.17.1. Using IUL's DOT manual colony counter

The DOT manual colony counter by IUL (Cat. 90008700/8701) can be connected to the Colonies PRO software through a USB Type A-B cable, allowing automatic transfer of the final colony count result.

Select the 'External Counter' menu. The following panel is displayed:

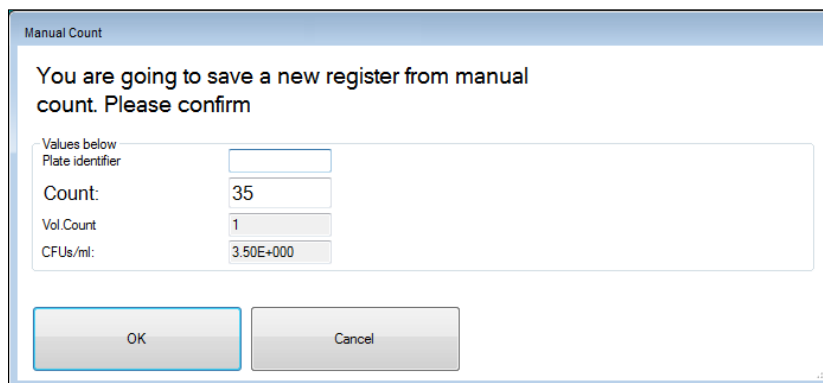
The application automatically checks whether a DOT device is connected to the computer. If detected, a confirmation message indicates that the DOT counter is connected to the v.

Similar to "Colony Count" menu, this panel allows the user to define the operational and run parameters required to calculate the CFU concentration:

- Operation Data
 - Plate ID
 - Method
 - Comments
- Run Data
 - Results Group
 - Inoculation mode
 - Dilution Factor
 - Inoculate volume (ml)

A. Spread distributions

After completing the manual count and pressing the '00' button on the DOT, this dialog is displayed:



The dialog box is titled "Manual Count" and contains the text "You are going to save a new register from manual count. Please confirm". It has four input fields: "Plate identifier" (empty), "Count:" (35), "Vol.Count" (1), and "CFUs/ml:" (3.50E+000). At the bottom are "OK" and "Cancel" buttons.

The transmitted colony count is automatically received and the CFU concentration is calculated, assuming that all colonies present on the plate have been counted.

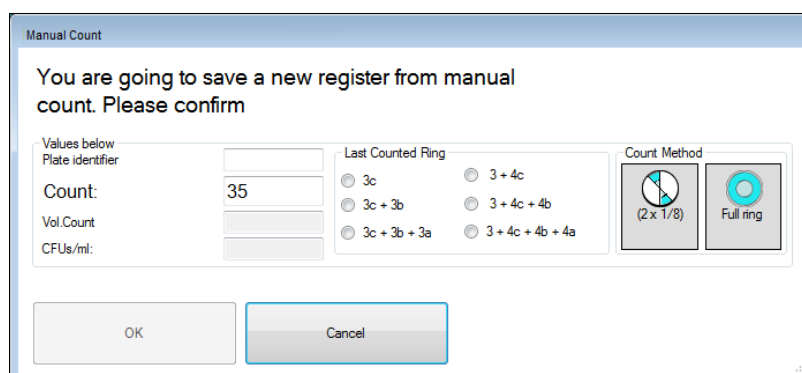
Enter or scan the 'Plate ID', then click 'OK' to save the result in the SphereFlash® database.

B. Spiral distributions

For spiral distributions, proceed similarly to what is described above.

In this case, the displayed dialog additionally requires specification of how the spiral plate was counted, including:

- Whether complete rings or two opposite 1/8 sectors were counted
- The ring up to which counting was performed (the zone 3c being the outermost ring)



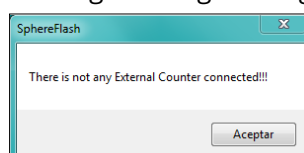
The dialog box is titled "Manual Count" and contains the text "You are going to save a new register from manual count. Please confirm". It has four input fields: "Plate identifier" (empty), "Count:" (35), "Vol.Count" (empty), and "CFUs/ml:" (empty). To the right of these fields is a "Last Counted Ring" section with six radio button options: "3c", "3c + 3b", "3c + 3b + 3a", "3 + 4c", "3 + 4c + 4b", and "3 + 4c + 4b + 4a". To the right of that is a "Count Method" section with two icons: a pie chart labeled "(2 x 1/8)" and a full ring labeled "Full ring". At the bottom are "OK" and "Cancel" buttons.

The software then automatically calculates the CFU concentration and stores the result in the database.

7.17.2. Using other means for a manual count

If the DOT manual colony counter is not used, manual colony counts can still be entered directly into the application while maintaining the automatic calculation features provided by SphereFlash® device.

If no external counter is detected, the following warning message is displayed:



The user can manually enter the colony count value in the 'Count' field of the panel:

Manual Colony Counter

There are any external counter connected!!! :-(

Operation Data

Plate Id (* Required)

Method

Comments

Run Data

Results Group

Inoculation Mode

Dilution Factor

Inoculate Volume (ml)

Results

Count:

Concentration

After clicking the 'Save' button, the application saves the result in the same way as using the DOT colony counter, automatically calculating the concentration based on the selected method and run data values.

8. TROUBLESHOOTING COLONIES SOFTWARE

Error	Probable cause	Recommended actions
The Status LED indicator 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 activation license for this device S/N	Copy the System Signature number from the message box and contact an IUL representative to get the Activation Key corresponding to the PRO license. In the case of Colonies Software, by cancelling the dialog you can still work with the default Colonies LITE license (with a limited set of features).
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 Colonies desktop application was installed while the SpherFlash® device was powered off or disconnected.	Uninstall the desktop application and connect the SpherFlash device with the PC and power on the insdevice.
	SpherFlash® device is powered off.	Close the application, push the power-on button of the device, and wait until its Status LED indicator is slow-flashing. Now you can start the application again.
	USB cable not connected between the device and the computer.	Connect the USB 3.0 cable (Cat. 90001960) to the USB 3.0 port from the PC.
	The USB cable is not USB 3.0 compliant	Unplug the USB cable, wait for a few seconds, and plug it in again.
	There is a loose connection between the USB cable and the USB socket of the computer.	Use a computer with a USB 3.0 compliant socket:  Check the tightness of the USB cable-socket contact, and possibly use a different socket on the PC.
	The PC firewall is blocking the IP communication between the Colonies software and the device .	Disable the firewall.
	The PC has entered some idle or sleep status and lost communication with the device.	Unplug the USB cable, wait for a few seconds, and plug it in again. Configure the computer not to enter an idle or sleep status.

Error	Probable cause	Recommended actions
	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 <i>'The Imaging Source Europe...'</i> , and a network adapter and controller named <i>'Realtek USB GbE...'</i> , or <i>'USB GbE family controller'</i> (this name depends on the Windows version). Unplug the USB cable, wait a few seconds, and plug it 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 PC.
The application shows the following error: 'User Not Recognized'	The credentials entered are incorrect.	Enter the correct user credentials. See Section 7.15. User Management menu for more details.
The application shows an: 'Operation Run Error'	The transport securing device has not been removed.	Remove the transport securing device as described in the Removing the transport securing device section.
	Mechanical blocking of the sphere.	Remove any blocking object.
	Electronic failure.	Contact IUL 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.
The application shows some of the following errors: 'Bad Calibration Image' 'Bad calibration image: 70mm circle line not found, out of range or duplicated' error message appears when executing a calibration procedure	Dirt or obstruction on the calibration disk.	Clean the platform and the calibration disk (Cat. 900010081).
	Incorrect centering device placement.	Correctly position the centering device Ø 87-91 mm (Cat. 900013473).
When printing a report, not all table columns are printed	The report or table is being printed using a paper size smaller than A4 or with incorrect page orientation settings.	Configure the printer to use A4 paper size and landscape orientation as default settings in the printer properties before printing.

PART 3: SPHEREFLASH® AI

9. GENERAL INFORMATION

This section provides general contextual information to help users understand the structure of the SphereFlash® AI colony counting software, the roles involved, and how access to the system is organized before installation and use.

The SphereFlash® AI colony counting software has two main components – the Subscription Portal and the Desktop Application.

9.1. Subscription Portal

The SphereFlash® AI Subscription Portal is the central web platform used to select and manage the AI Subscription Plan, including image and storage packs, and manage access to the SphereFlash® AI Desktop Application.

The Subscription Portal is accessible at: <https://aicolonycounting.com/> or <https://aicolonycounter.com/>.

Access to the Subscription Portal is restricted to users with the Tenant-admin role.

Configuration in the Subscription Portal is a mandatory prerequisite before using the Desktop Application.

9.2. SphereFlash® AI Desktop Application

SphereFlash® AI colony counting software is an Artificial Intelligence–powered desktop application used to analyze images of microbiological culture plates for automated colony counting and classification.

The software operates as a cloud-connected solution: image processing and cloud result storage are performed through secure cloud services, while users interact with the system locally via the Desktop Application.

The software can be used:

- In combination with the SphereFlash® automatic colony counter, or
- Independently, by importing previously acquired plate images from a computer.

When the device is not connected, calibration and verification menus in the Desktop Application are disabled.

9.3. User Roles

The SphereFlash® AI system defines three user roles with different access levels:

User role	Access	Key Capabilities
Operator	Desktop Application	• Perform colony counting • Adjust 'Run Data' and 'Run Adjustment' parameters (if method permits) • Perform verifications & calibrations (if the SphereFlash® device is connected) • View and export cloud results, verifications, calibrations, and methods.
Administrator	Desktop Application	• Operator capabilities • Create, edit, delete, import and export counting methods • Define operator permission to adjust Run Adjustment parameters and perform interactive modifications counting results • Configure application parameters • Access audit trail information
Tenant-admin	Desktop Application & Subscription Portal	• Full access to the Desktop Application • Full access to the Subscription Portal Through the Subscription Portal: • Create and manage the organization account (tenant) • Purchase and renew AI plans • Create and manage groups and their users • Set image and cloud results limits per group • Monitor usage and subscription status • Receive all notifications related to the active AI Plan requests from users within the Desktop Application.

NOTE: It is mandatory to have at least one Tenant-admin user. Without a Tenant-admin, it is not possible to access the Subscription Portal.

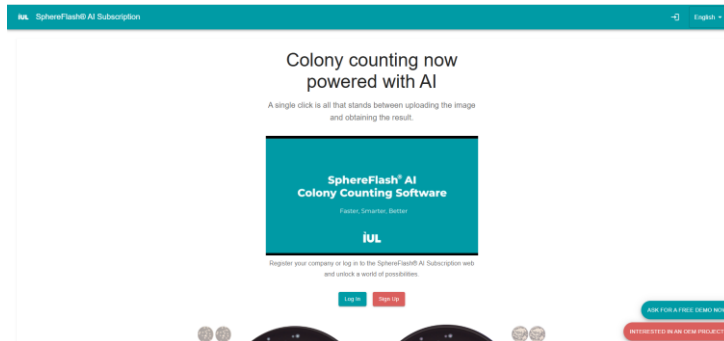
NOTE: Each user account permits only one active session at a time. Simultaneous access is NOT supported.

Once the system has been configured in the Subscription Portal and the Desktop Application has been installed on a compatible computer, users can access all operational functions through the Desktop Application.

10. SUBSCRIPTION PORTAL

10.1. Accessing the SphereFlash® AI Subscription Portal

1. Go to aicolonycounting.com / aicolonycounter.com
2. Click on the 'Sign Up' button to create your company account



3. Enter your company details.

NOTE: Use your company email address (e.g., sales@iul-inst.com).

IMPORTANT: Only one registration is allowed per company domain. If you don't know who registered for your company, please contact IUL (sales@iul-inst.com).

The following pop-up message will be displayed:

Signup application success ✕
An activation email has been sent to the address provided. Please check your inbox to complete the registration process

4. Activate your account by completing the following steps:
 - a. **Activate account:** Check your inbox and click the link to verify the account.
NOTE: The link expires in 72 hours.
 - b. **Password setting:** Create the login password for the Subscription Portal and SphereFlash® AI Desktop Application. An email will be received confirming that the password has been updated.
 - c. **Read and accept terms:** End-User License Agreement (EULA) and Service License Agreement (SLA).

5. Log in to the Subscription Portal using your credentials.

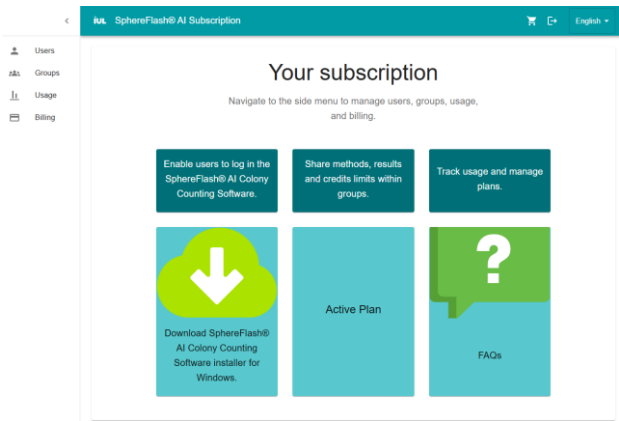
The screenshot shows the login interface for the SphereFlash® AI Subscription portal. It features a teal header with the logo and a language dropdown set to 'English'. Below the header are two input fields for 'Email' and 'Password', followed by a teal 'LOGIN' button. A link to 'reset your password' is provided for users who have forgotten their password. A 'signup' link is also present for new users. At the bottom, there is a 'Personalization Cookies Notice' and a statement that using the portal constitutes acceptance of the cookies and privacy policy.

NOTE: If you have forgotten your password, you can reset it using the password recovery option available in the Subscription Portal.

10.2. Navigating the Subscription Dashboard

The Subscription Dashboard provides access to the main subscription management functions, allowing the Tenant-admin to:

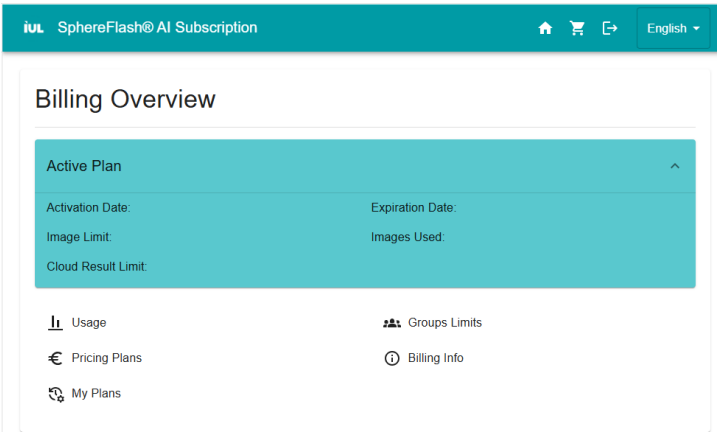
- Navigate the side menu to manage users, groups, and billing.
- Buy Plans (Image Pack & Storage Pack).
- View the Active AI Plan.
- Download the SphereFlash® AI Desktop Application installer (Windows).
- Access FAQs for additional information and support.
- Select a preferred language for the Subscription Portal.



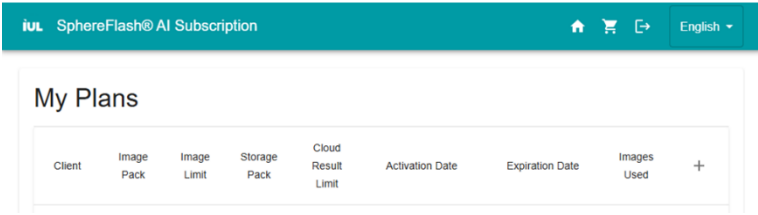
10.3. Buying a Plan

To acquire or renew an AI Plan:

1. Open the side menu and select “Billing”.

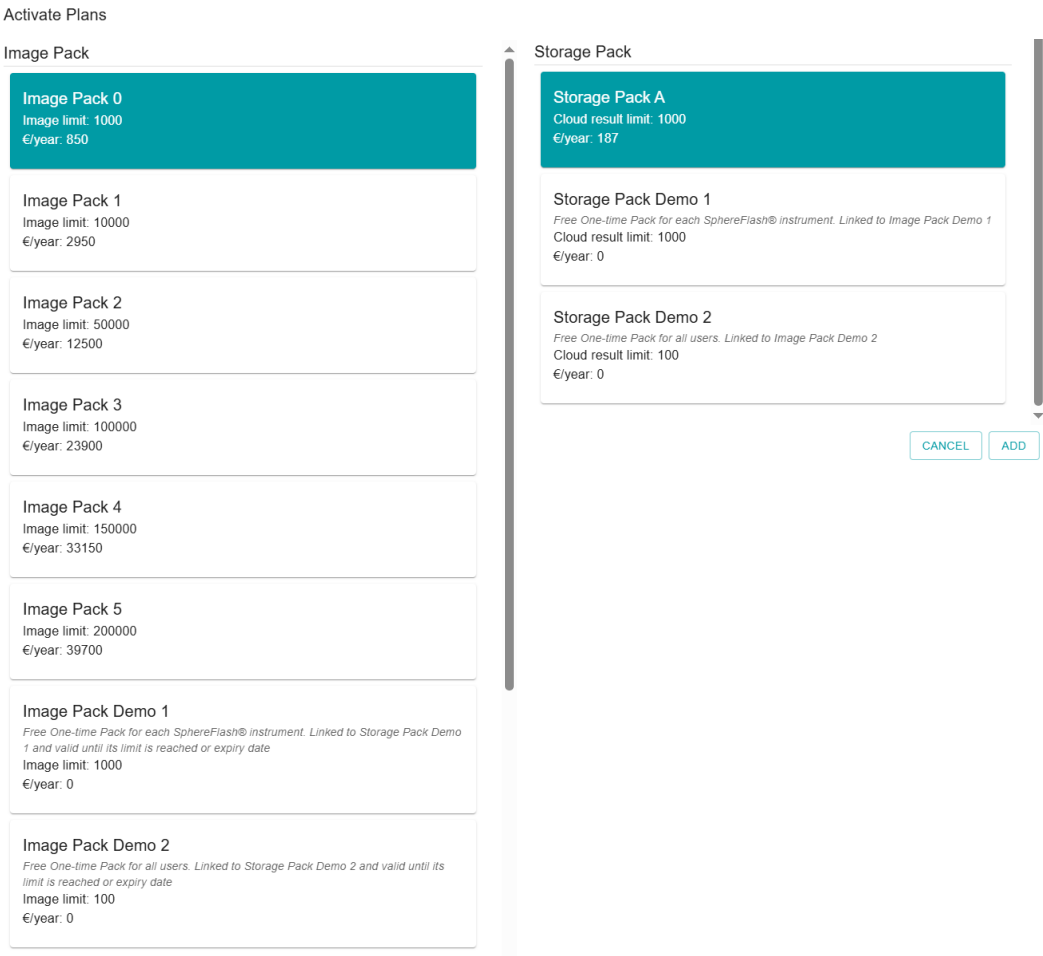


2. Click “My Plans”. My Plans Overview will be displayed.



3. Click the plus (+) icon to add a new plan.
4. Select the desired Image Pack and Storage Pack.

NOTE: Payment is processed through invoice and purchase order, in accordance with the IUL’s procurement procedures.



5. Click “Add” to confirm the purchase.

My Plans Overview will display the selected AI Plan with a Pending status until activation by IUL.

My Plans								
Client	Image Pack	Image Limit	Storage Pack	Cloud Result Limit	Activation Date	Expiration Date	Images Used	+
Customer	0€/year	100	0€/year	100			0	Pending

Once IUL activates the AI Plan, its status will change to Active, and the plan will be ready for use.

My Plans								
Client	Image Pack	Image Limit	Storage Pack	Cloud Result Limit	Activation Date	Expiration Date	Images Used	+
Customer	0€/year	100	0€/year	100	2026-12-19T08:07:42.601Z	2027-01-19T15:10:34.918Z	0	Active

10.4. Reviewing the Active Plan and Billing Overview

1. Open the side menu and select “Billing”.
2. View your current “Active Plan” and billing information.

IUL SphereFlash® AI Subscription

Home

Shopping

Language

English

Billing Overview

Active Plan

Activation Date: 01/01/2026

Expiration Date: 01/01/2027

Image Limit: 100

Images Used: 0

Cloud Result Limit: 100

Usage

Groups Limits

Pricing Plans

Billing Info

My Plans

10.5. Creating a New Group

Creating at least one group is **mandatory** to use the SphereFlash® AI Desktop Application.

In the Subscription Portal, each group represents a different department, laboratory, or organizational unit. It is the responsibility of the Tenant-admin to decide whether each department or laboratory has its own group.

All users who belong to the same group share cloud results and audit trail (only available in Tenant-admin and Administrator role).

1. Go to the side menu and select “Groups”.

IUL SphereFlash® AI Subscription

Home

Shopping

Language

English

Groups Overview

Name	Description	Members	Images used	Image limit	Cloud results limit	+
------	-------------	---------	-------------	-------------	---------------------	---

2. Click the plus (+) icon to add a new group.

3. Enter the group information (Name, Description, assign Group Image and Cloud Results Limit, and assigned Members). Use the Members search field to search for and select the users to be added to the group.

Add Group

Name

Description

Group Credit Limit
0

Group Results Limit
0

Members

CANCEL

ADD

4. Click “Add” to create the group.

SphereFlash® AI Subscription						
Groups Overview						
Name ↑	Description	Members	Images used	Image limit	Cloud results limit	+
Group A	Department 2	Name of user 1, Name of user 2, etc.	14	14	10	 

NOTE: Once users are assigned to a group, they will appear in the “Members” column.

5. After the group is created:
 - Modify the group information using the Pencil icon (), then confirm.
 - Delete the group using the Trash icon (), then confirm.

WARNING: Deleting a group permanently removes access to all associated cloud results. This action cannot be undone.

6. Click the column headers to sort the groups by Name, Images Used, Image Limit, or Cloud Results Limit.

10.6. Adding a New User to a Group

Assigning a user to a group is **mandatory** to use the SphereFlash® AI Desktop Application.

1. Go to the side menu and select “Users”.
2. Click the plus (+) icon to add a new user.
3. Enter the user information (Name, Email, assigned Group and Role). Use the Groups search field to search for and select the group to which the user will be assigned.
4. Click “Add” to create the user.
5. After the user is created:
 - Modify the user info using the Pencil icon (), then confirm.
 - Delete the user using the Trash icon (), then confirm.

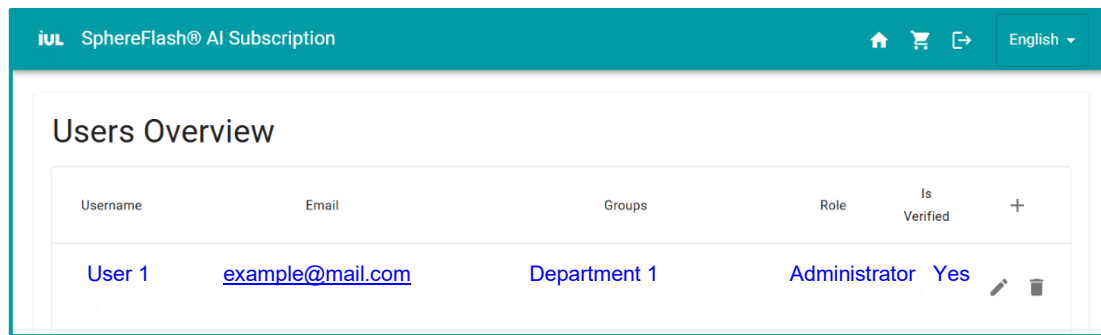
Once the user is added, the user should activate their account.

- If the user has the Tenant-admin role, follow the activation process described in the earlier section.
- If the user has the Administrator or Operator role, complete the following steps:
 - a. **Activation email:** Check the inbox and click the link to verify the account and download the desktop application.
 - b. **Password setting:** Create the login password for the SphereFlash® AI Desktop Application. An email will be received informing that the password has been updated.
 - c. **Read and accept terms:** End-User License Agreement (EULA) and Service License Agreement (SLA).
- 6. Click the column headers to sort the users by Username, Email, Role or Verification Status.

10.7. Checking if the User Has Verified Their Account

After adding a new user, it is important to check that they have completed the email verification process.

1. Go to the “Users” section in the side menu.



2. Check the “Is Verified” column next to the user’s name.
 - **If the status is “Yes”:** The user can access the Desktop Application and, if applicable, the Subscription Portal (only Tenant-admin).
 - **If the status is “No”:** The user has not yet completed the email verification. Wait up to **72 hours**, as the user may still complete the verification process.
3. If the user has not verified the account after 72 hours:
 - a. Delete the user account.
 - b. Create the user account again.
 - c. Contact the user and request completion of the new email verification link.

10.8. Viewing and tracking Image usage

1. Go to the side menu and select “Usage”.
2. Select the desired usage view:
 - **By Group:** View the total number of images used for each group. Click the arrow next to a group to expand it and view the total by each user within that group.
 - **By User:** View usage history for individual users, including Date, Group, and Images Used.

By Group:

iuL SphereFlash® AI Subscription

Usage Overview

Groups

Users

	Group	Total Images Used
▼	Customer 1	10
▼	Department 1	100
▼	Group A	14
▼	Group B	21
▼	Group C	1

iuL SphereFlash® AI Subscription

Usage Overview

Groups

Users

	Group	Total Images Used
^	Customer 1	10
Usage by User		
	Email	Total Images Used
	user1@company.com	10
^	Department 1	100
Usage by User		
	Email	Total Images Used
	user1@company.com	12
	user2@company.com	170
^	Group A	14

By user:

iuL SphereFlash® AI Subscription

Usage Overview

Groups

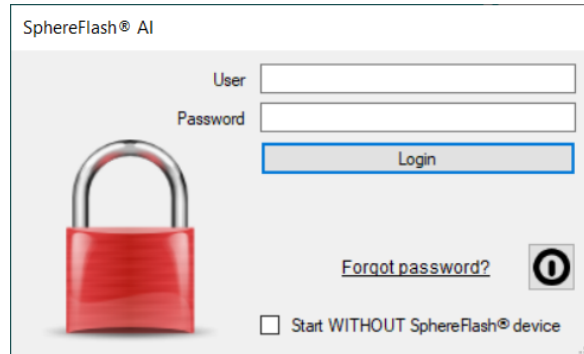
Users

	Email	Total Images Used
▼	user1@company.com	44
▼	user2@company.com	192

11. DESKTOP APPLICATION

11.1. Log In

Click the SphereFlash® Desktop Application shortcut icon on your desktop. The application will launch, and a login dialog will appear on your screen:

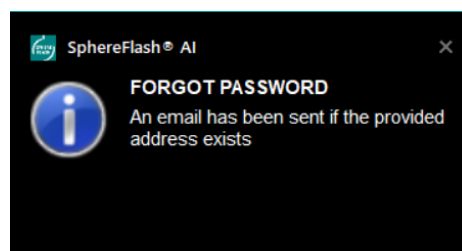
The image shows the SphereFlash® AI login dialog. It has a title bar with the text "SphereFlash® AI". Below the title bar, there is a red padlock icon on the left. To the right of the padlock, there are two input fields: "User" and "Password". Below the "Password" field is a "Login" button. To the right of the "Login" button is a link that says "Forgot password?". Below the "Forgot password?" link is a checkbox labeled "Start WITHOUT SphereFlash® device".

User (input field): Enter your username. Login credentials should be obtained by contacting the Tenant-Admin to request the creation of a new user account.

Password (input field): Enter your user password.

Login (button): Click to access the desktop application.

Forgot password (link): If you have forgotten your password, click here to receive an email with a link to reset your password. Ensure that the email entered in the "User" input box belongs to an active user.



Start WITHOUT SphereFlash® device (radio button): Select this checkbox to use the application without the SphereFlash® device connected. This will disable calibration and verification menus, and images will be uploaded via the file browser for processing.

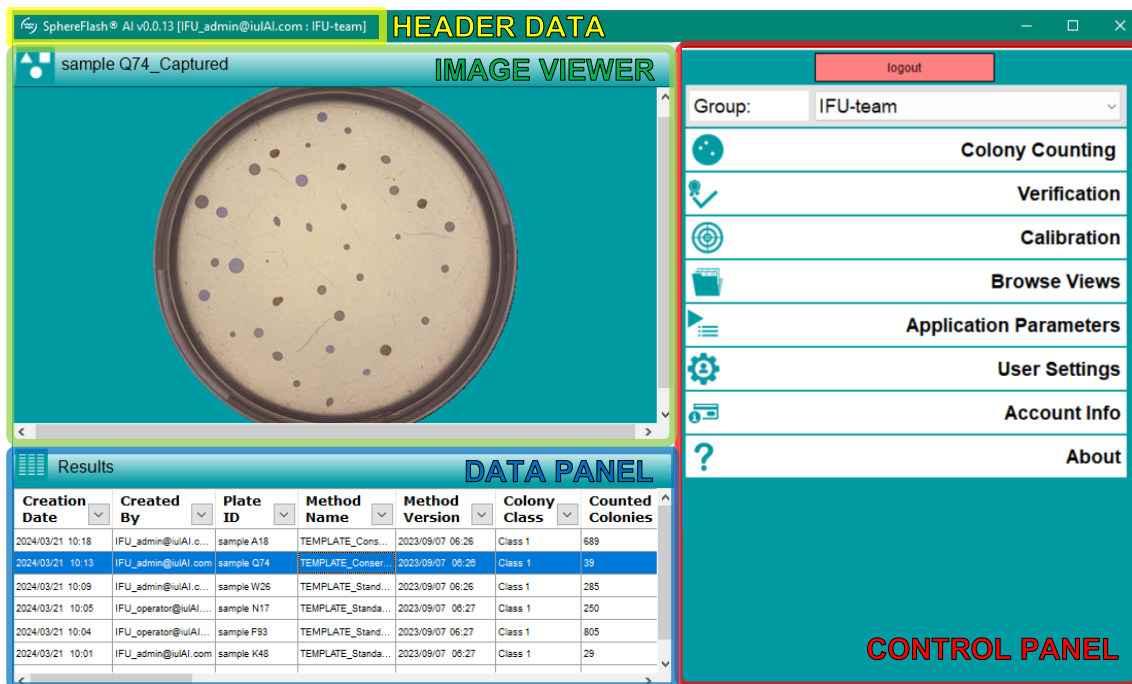
Off (button): Click to close the desktop application.

IMPORTANT: After a time of inactivity, the application is blocked, and the user is required to re-enter their password into a re-login dialog.

11.2. Main Screen Overview

The main screen of the SphereFlash® Desktop Application is divided into four distinct sections, each color-coded below for easy identification:

- Header Data (yellow rectangle)
- Image Viewer (green rectangle)
- Control Panel (red rectangle)
- Data Panel (blue rectangle)



These four main sections are consistently present across various screens within the application. You can resize these sections by placing the cursors over the edges of the panels and dragging them to adjust.

Additionally, interactive tooltips are provided for all buttons and controls: simply hover your cursor over any item, and a brief description of its function or purpose will be displayed.

When a particular operation panel is displayed, you can return to the selection control panel by clicking on the top-right  cross icon.

11.2.1. Header Data

The header of the window displays the following information for easy reference:

- Application name and version.
- Logged-in user.
- Current group (a single user can be assigned to multiple groups by the Tenant-Admin within the Subscription Portal).

11.2.2. Image Viewer

The Image Viewer displays plate images associated with the currently selected result. Whenever a new image is processed (from Colony Counting menu) or a stored cloud result is selected (from Browse Views), the corresponding image is displayed in the Image Viewer.

11.2.3. Control Panel

The Control Panel provides access to the main application functions and menus.

Operational Data:

- Logout:** End the current user session.
- Group:** Display the current active group. If the user is assigned to multiple groups, a different group can be selected by clicking on this field.
- NOTE:** Only data associated with the currently selected group is displayed. Plate results and audit trail information (available to Tenant-admin and Administrator roles only) are shown exclusively for the active group.

Menus:

- Colony Counting:** Access the functions to process plate images and create counting methods.
- Verification:** Access the verification procedure.
- NOTE:** Only active if SphereFlash® device is connected.
- Calibration:** Access the calibration procedure for the SphereFlash® device.
- NOTE:** Only active if SphereFlash® device is connected.
- Browse Views:** Provide access to stored data, including Results, Results Summary, Methods, Calibrations, and Verifications. In addition, access to Audit Trail.
- Application Parameters:** Allow configuration of local application settings. Accessible only to users with a Tenant-Admin or Administrator role.
- User Settings:** Allows the current user to change their password.
- Account Info:** Display current AI Plan account information and allows requesting additional images for processing.
- About:** Display software version information and provide access to related documentation, including the Instructions for Use and the End User License Agreement.

11.2.4. Data Panel

The Data Panel will display various tables based on the current screen and selection. Possible data tables include:

- Cloud results stored
- Cloud results stored summary
- Available methods

- Calibration results
- Verification results

In any of these tables, you can display the data in several ways to better view and analyze the data:

- Sorting:** Click on a column header to sort the table by that column's values. Click again to sort in reverse order.
- Filters:** Click the filter icon (▼) in any column header to open the filter dialog for that column, which will vary depending on the data type of the column. Filters limit the display to items that meet the filter criteria. To remove filters, right-click anywhere on the table and choose 'Clear Filter'.
- Layout:** Adjust the layout by clicking and dragging a column header to a new position or by dragging the edges of any column or row to resize.

To select one of the results, click its row on the view. To select a contiguous range of results, hold the *Shift* key when clicking the first and the last results of the range. To add or remove one result from the selection, hold the *Ctrl* key and click the result as is usual in Windows programs. To select all the results in the (possibly filtered) view, click on the top of the leftmost column.

11.3. Colony Counting Menu

This menu provides access to the functions required to process plate images, review AI results, store or discard cloud results and create methods.

When the 'Colony Counting' menu is selected, the Colony Counting panel is displayed in the Control Panel area:

This panel includes the following functional buttons:



Run

Initiates image capture and processing when the SphereFlash® device is connected. Right-clicking the button allows selection of an image file for processing.

NOTE: If the 'Start WITHOUT SphereFlash® device' option is active, this will open a file browser to select an image for processing.

IMPORTANT: Uploaded plate images shall be square, centered, and have a minimum resolution of 768*768 pixels (PNG format).



Accept

Stores the current cloud result data.



Discard

Clears the current cloud result data.



Method Settings

Provides access to the method editing area.

NOTE: This button is only active for users with the Tenant-admin or Administrator role.

The Colony Counting panel includes two tabs that are displayed sequentially during the workflow:

- Colony count data tab
- Result tab

11.3.1. Colony count data tab

The 'Colony Count Data' allows the user to define the operational and run parameters required to process a plate image:

Operational Data

Plate ID: Enter text to identify the sample by typing it manually or, if a barcode reader is connected, by scanning the barcode.

NOTE: This field is mandatory. A colony count cannot be run if this field is empty.

IMPORTANT: Certain special characters are not allowed in the Plate ID content, such as: \ / : * ? " < > |.

Comments: Add any relevant comments about the plate.

Method: Select a method within your current group from the drop-down list.

By default, a list of Template methods is provided (see Section 11.6. Template methods for more details). The list may feature various AI models (e.g. Conservative or Standard) and lighting modes (top, bottom, or both).

A text box below the list displays a description of the selected method (if applicable).

Run Data

Inoculation Mode: Select either spread (default) or one of the listed spiral distribution methods from the drop-down list.

NOTE: All listed spiral distribution methods are compatible with IUL's spiral platter Eddy Jet 2W.

Dilution Factor: Specify the dilution factor of the sample.

NOTE: This value is required to calculate the CFU (colony-forming units) concentration per milliliter.

Inoculated Volume (ml): For spread distributions, enter the total sample volume inoculated onto the plate.
For spiral distributions, this value is automatically determined based on the selected distribution.

NOTE: This parameter is used to calculate the CFU per milliliter

Plate Diameter (mm): Indicate the inner diameter of the plate (inner distance between the lateral walls), within which the inoculated volume has been spread.

NOTE: This field is editable when spread mode is selected.

Once all data is entered, place the corresponding centering device with the plate to be counted on the SphereFlash® device platform. The image is then processed by clicking the Run button ().

The diffusing sphere is lowered, an image is taken, and the sphere is raised again.

11.3.2. Result tab

After image processing, the 'Result tab' is displayed automatically.

The screenshot shows the 'Colony Counting' application window with the 'Result' tab selected. The interface includes a 'Plate ID (*Required)' field with the value 'sample A45', a 'Comments' text area, and 'Run Adjustment' sliders for 'CFU Size (0.10 - 15.00 mm)' and 'AI Score (75.00 %)'. The 'Class Mark Color' is set to 'RGB = (255, 0, 0)'. A 'Classification' section shows 'Excluded Area (%)' at 0.01%. Below this is a table with columns: 'Colony Class', 'Counted Colonies', 'Concentration (CFU/ml)', and 'Counted Volume (ml)'. The table contains one row for 'Class 1' with values 133, 1.33E+003, and 1.000. At the bottom are four navigation icons: a play button, a checkmark, an 'X', and a right arrow.

Colony Class	Counted Colonies	Concentration (CFU/ml)	Counted Volume (ml)
Class 1	133	1.33E+003	1.000

The 'Result' tab allows the user to review results and, if required, perform manual adjustments before storing or discarding the cloud result:

Result

Plate ID: Inherited from the Colony Count Data tab.

Comments: Inherited from the Colony Count Data tab.

Run Adjustment parameters

CFU Size: Slider that features two handles to set the minimum and maximum colony sizes to be counted.

NOTE: This helps filter out small artifacts that do not correspond to colonies.

NOTE: When the cursor is positioned over the slider, a tooltip is displayed providing a more detailed description. Once the cursor is positioned over the slider handle, the value can be adjusted using the mouse wheel, allowing very fine and gradual adjustments while immediately observing the changes.

AI Score (%): Slider to adjust the balance between sensitivity (detect more colonies) and specificity (reduce false positives) according to your specific colony detection needs. The AI score is the ratio of specificity to sensitivity.

- Decreasing the AI Score increases sensitivity (less stringent criteria for colonies to be detected) but reduces specificity (higher risk of false positives).
- Increasing the AI Score has the opposite effect, applying more stringent detection criteria, improving specificity to reduce false positives.

Class Mark Color: Color of the visual markers placed at the center of each counted colony. The color can be changed by selecting the  button and choosing a color from a palette

NOTE: When more than one colony class is defined, the marker color for each class is configured in the Method Settings.

Classification

Excluded Area (%): Percentage of the inoculated area excluded from counting in order to avoid artifacts.

NOTE: This value is determined by the difference between the defined plate diameter (**blue circle**) and the counted area (**red circle**), or by manual exclusion using the interactive feature.

Colony Class: Names of the classes defined in the current method.

NOTE: When default template methods are used, the entire plate is counted, and a single class (Class 1) is displayed.

Counted Colonies: Number of colonies counted for each colony class within the region of interest, including any manual inclusions or exclusions..

Concentration (CFU/ml): Calculated CFU concentration per milliliter for the class.
$$\text{CFU/ml} = \text{Count} \times \text{Dilution Factor} / \text{Counted Volume}$$

Counted Volume (ml): Sample volume within the analyzed plate area (inside the counting region and excluding any interactively excluded area). This volume is used to calculate the CFU per milliliter.
For spread distributions, $\text{Count Vol} = \text{Inoculated Volume} \times (1 - \text{Excluded Area})$.
For spiral distributions, only the volume corresponding to the counted spiral regions is considered.

NOTE: For spiral distributions with the logarithmic/exponential method, colonies are counted from the outer ring inward. Counting stops at the ring where the predefined threshold is exceeded, according to standard rules (e.g. 20 CFUs in a 1/8 sector corresponds to 160 CFUs over the full plate).

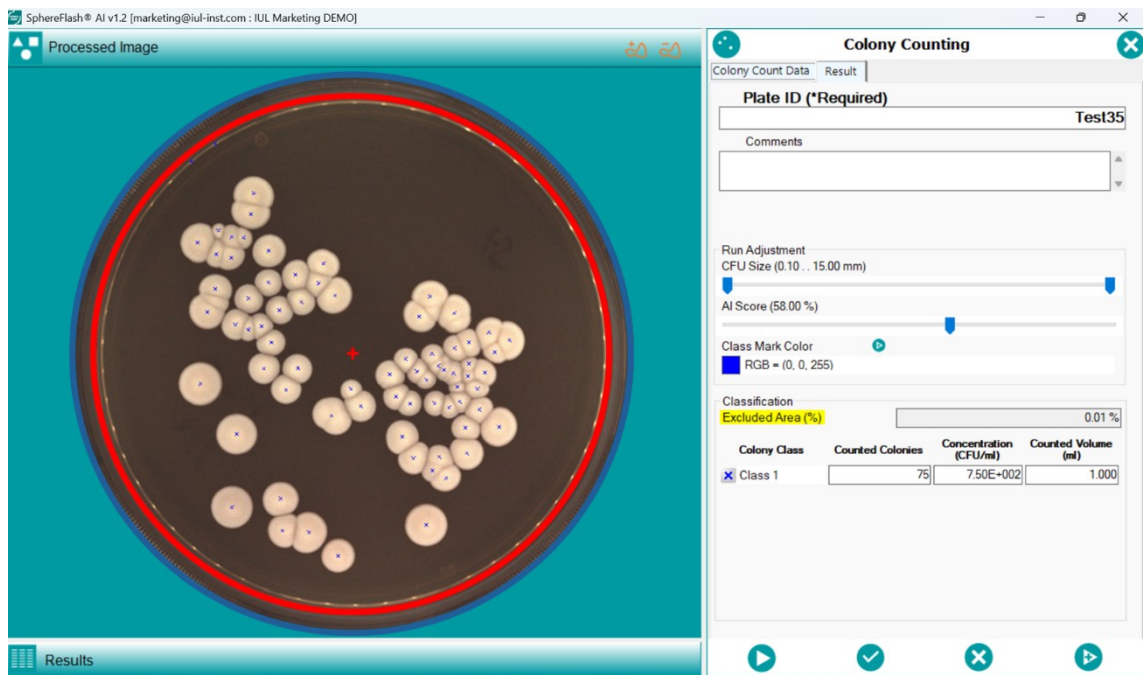
Functional buttons

- | | | |
|---|------------------------|---|
|  | Accept | Stores the current cloud result data |
|  | Discard | Clears the processed result |
|  | Method Settings | Opens the method configuration menu, allowing adjustment of default parameters, and fine-tunes the method used for the current cloud result |

If required, see Section 11.4.1. Manual result adjustments for detailed instructions on how to perform manual adjustments.

After reviewing the result, the functional buttons can be used to accept, discard, or modify the method used.

The processed plate image is displayed alongside the Results tab in the Image Viewer for visual verification before saving or discarding results.

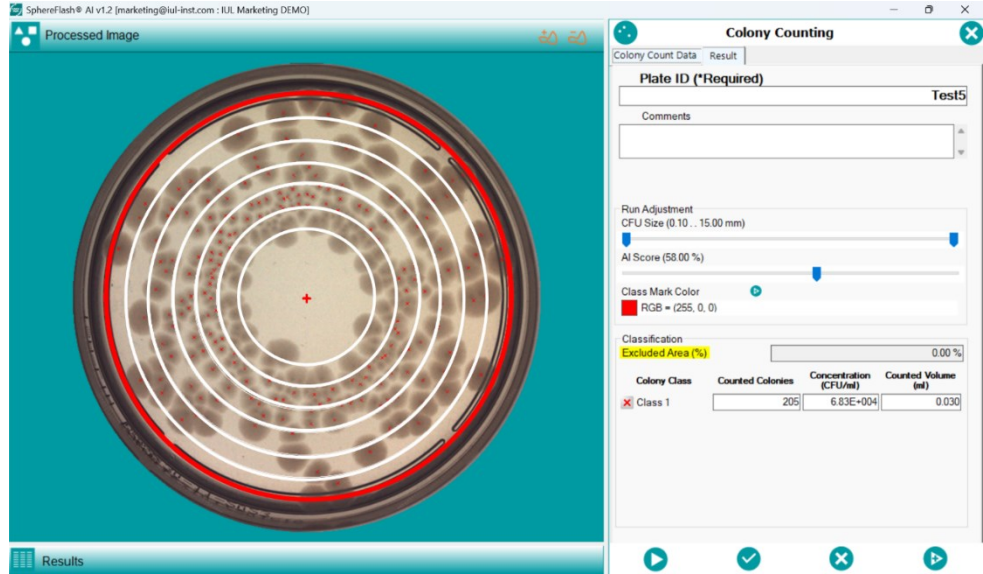


Detected colonies are marked with the corresponding class mark color at their centers and the center of the plate is also identified by a red plus (+) symbol.

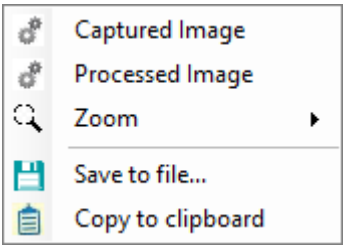
The blue circle represents the plate diameter defined in the 'Colony Count Data' tab. It corresponds to the inner diameter of the plate, within which the inoculated volume has been spread.

The red circle defines the counted area, that is the region within which colonies are included in the count. By default, this circle is positioned slightly inside the plate diameter to prevent artifacts near the plate walls from being counted as colonies.

When a spiral distribution inoculation mode is selected, the processed image also displays the 6 concentric reference circles (or spiral grids) in white, corresponding to the spiral inoculation pattern.



Additional image interaction options are available by right-clicking within the image viewer, opening a contextual menu that includes:



- Captured Image:** View the original captured image, without software processing.
- Processed Image:** View the image processed by the software, which includes visual marks. If manual adjustments have been performed, the corresponding visual overlays are also shown.
- Zoom:** Adjust the zoom level to customize the size of the displayed image. The image can be displayed using predefined zoom options (*Fit Width*, *Fit Height*, *1:1*, *2:1*, *4:1*, *8:1*, *16:1*, and *32:1*). Alternatively, progressive zoom can be performed using the mouse wheel: scrolling forward zooms in, while scrolling backward zooms out.
- Save to file...:** Save the image currently displayed in the Image Viewer (captured or processed). A file browser will open, allowing you to select the destination folder and specify the file name.
- Copy to clipboard:** Copy the image currently displayed in the Image Viewer to the clipboard, allowing it to be pasted into another application.

11.4. Processing a plate

A detailed guide on how to process a plate using the SphereFlash® AI. For a summarized workflow, refer to document 50009060, "Quick Guide: How to Use SphereFlash® AI".

Detailed instructions for processing a plate are provided below:

1. Use the correct centering device / adapter, depending on your plate size/type.
2. Position the plate into the device.
3. Click on 'Colony Counting' from the Control Panel
4. Fill in the fields of the 'Operation Data' tab, as detailed in the previous section.
5. Choose the appropriate illumination mode, depending on the colony type. See Section 11.6. Template methods for more details.
6. Click the 'Run' button on the application or on the device.
7. The diffusing sphere is lowered, an image is taken, and the sphere is raised again.
8. The results appear on the screen, as detailed in the previous section.
9. Perform manual adjustments, if necessary. See Section 11.4.1. Manual result adjustment for more details.
10. After reviewing the result, the functional buttons can be used to accept, discard, or modify the method used:



Accept

Stores the current result data



Discard

Clears the processed result



**Method
Settings**

Opens the method configuration menu, allowing adjustment of default parameters or fine-tuning for the current result

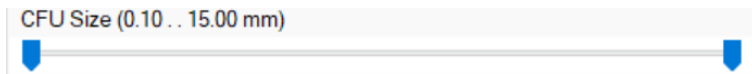
11.4.1. Manual result adjustments

Types of manual adjustments can be performed in the Image Viewer:

- Manual adjustment of the CFU size filter
- Manual adjustment of the AI score
- Manual adjustment of the counted area
- Manual addition or removal of individual colonies
- Manual adjustment using methods

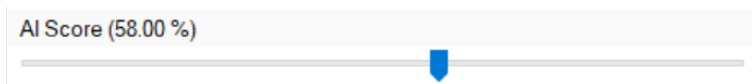
Manual adjustment of the CFU size filter

Use the CFU size slider to adjust the CFU size range for counting.



Manual adjustment of the AI score

Use the slider to increase or decrease the AI score.



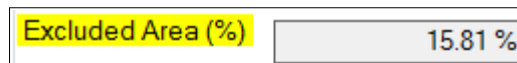
Manual adjustment of the counted area

Manual adjustment of the counted area can be performed via several options:

- **Option A:** Resize and reposition the counted area (red circle)
- **Option B:** Manually exclude or re-include selected regions

Option A: Resize and reposition the counted area (red circle)

1. Click on the 'Excluded Area (%)' label. The label is highlighted in yellow:



2. Click on the red circle and resize or move it as required.

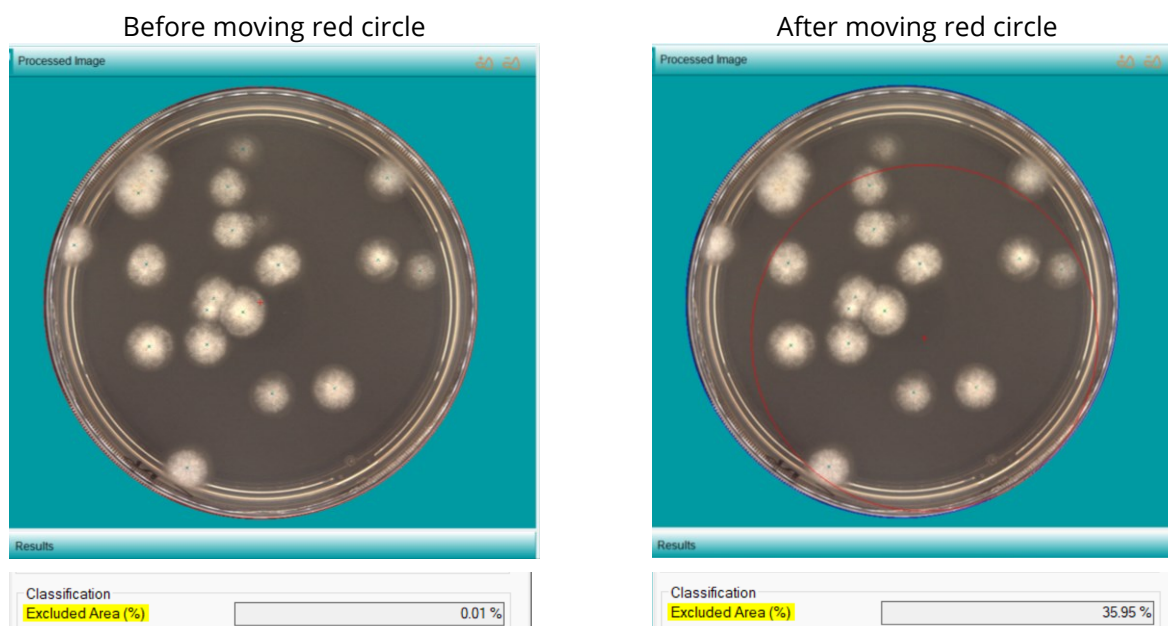
Before resizing of red circle



After resizing of red circle

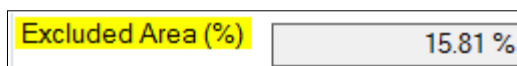


3. The plate center can be adjusted by selecting and moving the red plus (+) symbol.



Option B: Manually exclude or re-include selected regions

1. Click on the 'Excluded Area (%)' label. The label is highlighted in yellow.

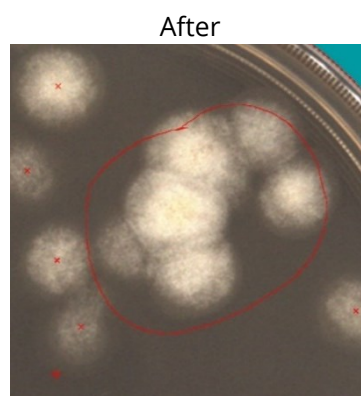
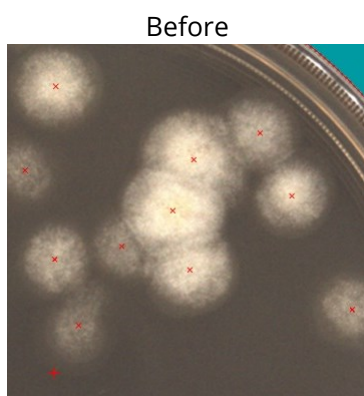


2. Two freehand drawing icons appear on the right side of the top bar of the image viewer.

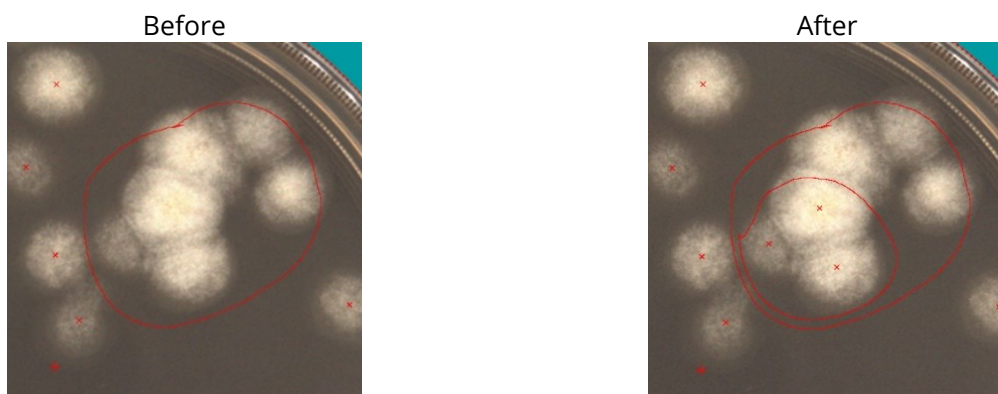


3. Use:

- **Minus** () to draw a closed curve around areas to be excluded from counting.

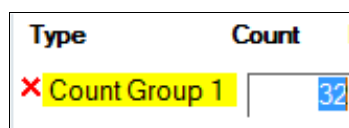


- **Plus** () to define areas within an excluded region where colonies should still be counted.



Manual addition or removal of individual colonies

1. Click on the label of the desired colony class. The label is highlighted in yellow.

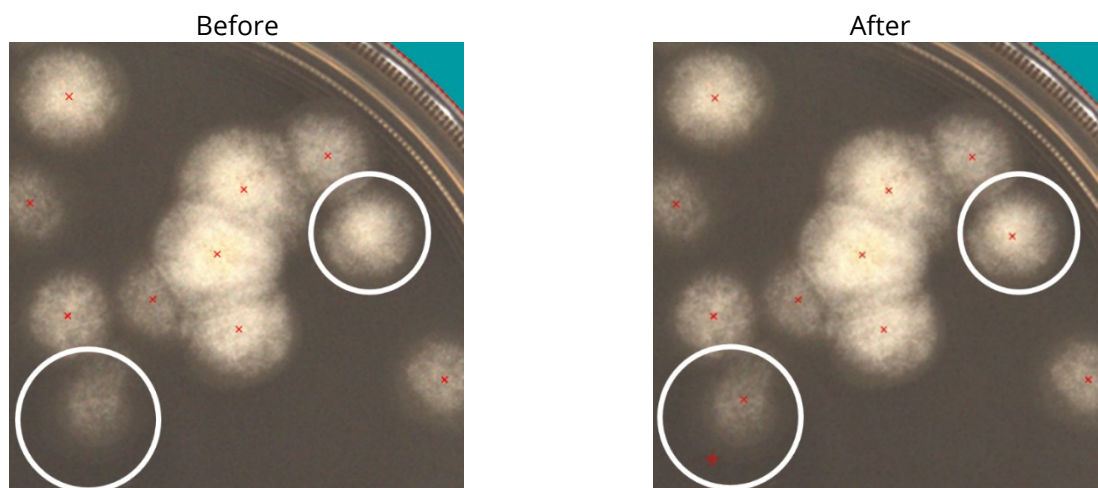


2. The plus (+) and minus (-) icons appear on the right side of the top bar of the image viewer.

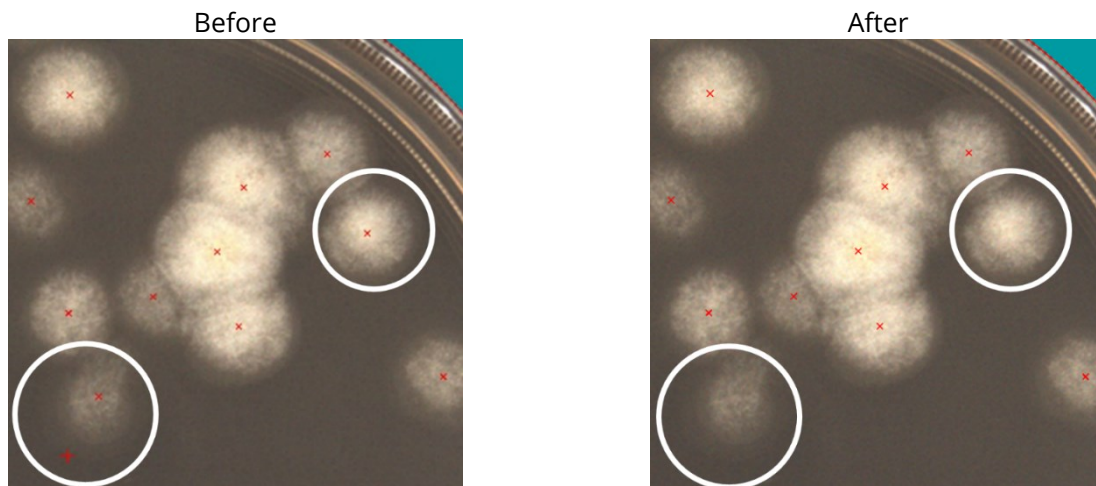


3. Use:

- Plus () to manually add a colony by clicking on its center.



- Minus () to remove a counted colony by clicking on its center.



Manual adjustment using methods

See Section 11.7. Methods settings for detailed instructions on how to create and edit methods.

After manual adjustments are performed, the results (counted colonies, concentration and counted volume) are automatically recalculated.

Colony Class	Counted Colonies	Concentration (CFU/ml)	Counted Volume (ml)
 Class 1	19	1.90E+002	1.000

Click the 'Accept' button,  , to store the processed result in the data panel. By doing so, one cloud result will be used. Click the 'Discard' button,  , to discard the processed image.

When the cloud result is stored, the following message is displayed in the "Comments" field to indicate that manual adjustments have been applied :

<<Interactive changes have been made>>

For a more detailed guide on how to perform manual adjustments, refer to Doc. 50009060.

11.5. Cloud results data panel

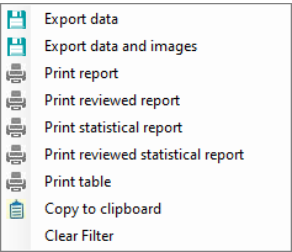
The latest cloud results stored for the current group are displayed in the Data Panel:

Results							
Creation Date (UTC)	Created By	Plate ID	Method Name	Method Version Date (UTC)	Colony Class	Counted Colonies	Concentration (CFU/mL)
2024/03/21 10:18	IFU_admin@iulAI.c...	sample A18	TEMPLATE_Cons...	2023/09/07 06:26	Class 1	689	6.89E+003
2024/03/21 10:13	IFU_admin@iulAI.com	sample Q74	TEMPLATE_Conser...	2023/09/07 06:26	Class 1	39	3.90E+002
2024/03/21 10:09	IFU_admin@iulAI.c...	sample W26	TEMPLATE_Stand...	2023/09/07 06:26	Class 1	285	2.85E+003
2024/03/21 10:05	IFU_operator@iulAI...	sample N17	TEMPLATE_Stand...	2023/09/07 06:27	Class 1	250	2.50E+003
2024/03/21 10:04	IFU_operator@iulAI...	sample F93	TEMPLATE_Stand...	2023/09/07 06:27	Class 1	805	8.05E+003
2024/03/21 10:01	IFU_admin@iulAI.com	sample K48	TEMPLATE_Stand...	2023/09/07 06:27	Class 1	29	2.90E+002

Each cloud result includes the following information:

- Creation date
- Plate ID
- Method name
- Method version date
- Colony class
- Counted colonies
- Concentration
- Counted volume
- Class mark color
- Comments
- Inoculation mode
- Inoculation volume
- Dilution factor
- Plate diameter
- Excluded area
- Minimum and maximum size (for the CFU)
- AI Score and Device S/N

When a row is selected, the corresponding image will be displayed in the image viewer. Right-click on one or more cloud results in the table to access the contextual menu:



- Export data:** A file browser opens to export selected results with the desired format (XLSX: Excel, CSV: Comma-delimited, and TXT: Tab-delimited).
- Export data and images:** Same as Export data, but a sub-folder is created containing the associated images (captured and processed). Image file names correspond to those defined in each result.
- Print report:** A dialog opens to select the result parameters to be included in the report. The report is generated with one page per processed plate and includes captured and processed images.
- Print reviewed report:** Same as Print report, but also includes a box for document number and signature boxes for the operator and supervisor.
- Print statistical report:** Requires multiple selections with the same class name.

A dialog opens to select the result parameters that will be included in the report to be printed. It will contain average value, standard deviation, and coefficient of variation.

Print reviewed statistical report: Similar to Print statistical report, but also includes fields boxes for document number, signature and date for the operator and supervisor.

Print table: Print a table with all the parameters for the selected rows.

Copy to clipboard: Copy all parameters of the selected results to the clipboard and then paste them into a document.

Clear filter: Remove all active filters from the table.

NOTE: For report and table generation options, a dialog opens to modify the 'Report Title' and select the result parameters (from 'Report Fields') to be included. The footer of printed reports displays the user name, date, and time of printing. If a virtual PDF printer is selected, reports can be saved as PDF files. If opened in a compatible application, digital signatures can be applied.

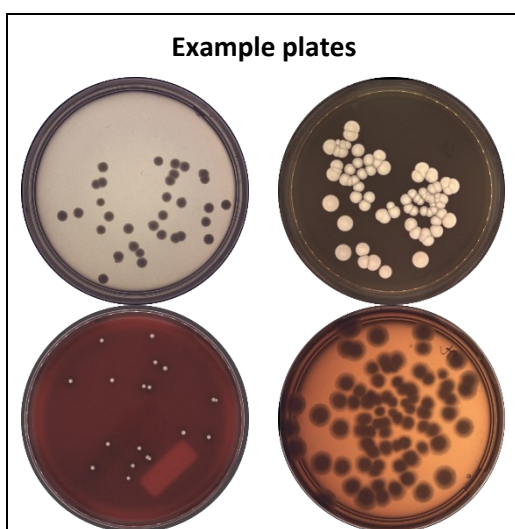
11.6. Template Methods

The SphereFlash® AI Colony Counting Software includes general-purpose methods, referred to as template methods, which cover common plate appearances and are ready to use.

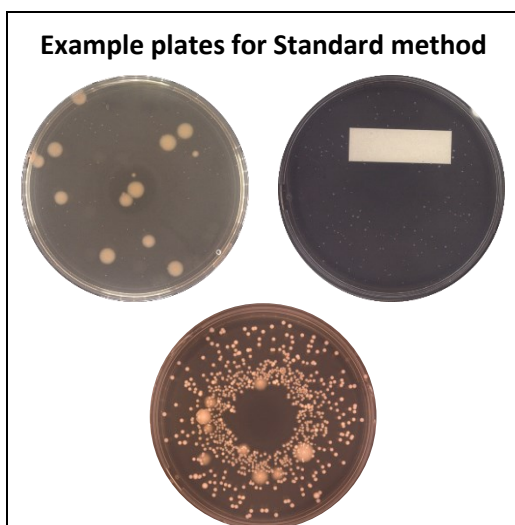
The template methods can be used as a base to create custom methods (See Section 11.7. Methods settings for more details).

The following templates are natively included within the software:

- Conservative:** Recommended for most plate types and routine colony counting applications. Generally provides the most robust performance for plates containing:
- Low to moderate overlapping colonies
 - Medium or large colonies
 - Colonies with irregular or fuzzy edges



- Standard:** Recommended only for specific plate conditions where colony detection is more challenging. Typical applications include:
- High overlapping colonies
 - Very small colonies
 - Colonies with well-defined and rounded edges



Each AI template method is available with different illumination configurations. The appropriate illumination mode depends on the appearance of the colonies and the culture medium.

Reflected lighting (Upper illumination):

Provides diffused, homogeneous reflected light — similar to darkfield illumination — enhancing contrast and edge definition for accurate colony detection. This illumination mode is mainly used to visualize opaque colonies by highlighting their edges and contrast.

It illuminates the plate from above and allows differentiation of colonies from artifacts based on appearance (color or brightness), as well as discrimination between different colony classes.

Transmitted lighting (Bottom illumination)

Provides uniform transmitted light from beneath the plate, making it ideal for visualizing low-contrast or transparent colonies.

If the colonies are opaque and the substrate is sufficiently translucent, bottom illumination can also enable accurate colony detection and counting, particularly in the absence of opaque artifacts.

Both (Combined illumination)

Combines reflected and transmitted illumination and may provide improved performance for difficult plates where neither illumination mode alone gives optimal results.

11.7. Methods Settings

The Method Settings panel allows you to create, edit, and manage counting methods used by the SphereFlash® AI Colony Counting Software.

The screenshot shows the 'Method Settings' panel with the following sections:

- Method Definition:** Includes 'Common values' with a 'Method Name' dropdown set to 'Standard' and a text field 'AI Reflected'. Below is a 'Method Description' section with a 'Template' text area and a 'Delete Method' button.
- Classes:** Includes tabs for 'Image capture' and 'Option settings'. Under 'Option settings', there is a 'Class 1' section with fields for 'Colony Class ID' (set to 'Class 1'), 'Class Mark Color' (set to 'RGB = (255, 0, 0)'), 'Count Mode' (set to 'Filtered by size'), 'Accept colors' (set to 'none'), 'Reject colors' (set to 'none'), 'Min. CFU Size (mm)' (set to '0.10'), and 'Max. CFU Size (mm)' (set to '15.00'). There are also 'Counted Limits' and 'CFU/ml Limits' sections with 'Lower' and 'Upper' input fields.
- Result:** Includes a 'Result' section with 'Excluded Area (%)' (set to '0.01 %'). Below is a table showing results for 'Class 1':

Colony Class	Counted Colonies	Concentration (CFU/ml)	Counted Volume (ml)
Class 1	178	1.78E+003	1.000

Only users with Tenant-admin or Administrator role can access this panel.

The software is provided with a set of predefined AI methods, designed to cover the most common use cases. These methods are ready for use and can also serve as templates for creating new methods.

The Method Settings panel can be accessed in two ways:

- After processing a plate, click on the Method Settings button to edit the method applied to the current processed image
- Under the 'Colony Counting' menu, click on the Method Settings button to exclusively adjust image capture and option settings that apply independently of a specific plate.

When accessed after image processing, the processed plate image is used only to visualize and test the effect of the method settings during editing.

IMPORTANT: Images used during method editing are not stored as cloud results and will be lost when the session is closed.

When the Method Settings button is selected, the Method Settings panel is displayed in the Control Panel area.

The Method Settings panel is organized into several sections:

- Common Values
- Classes tab
- Image Capture tab
- Option Settings tab
- Results
- Functional buttons

Common Values

Method Name
(drop-down list and input box): Select the AI template method to be edited. Enter a new name to create a modified version.

Method Description
(input box): Provide a detailed description of the method, including its intended use or key characteristics.

Delete Method
(button): Permanently delete the current method.
NOTE: Default template methods cannot be deleted.

Tabs available:

Classes: Configure settings for the colony classes defined in the method. See Section 11.7.1. Classes tab section for more details.

Image capture: Adjust parameters that affect the entire image capture process. See Section 11.7.2. Image capture tab for more details.

Option settings: Configure visual overlay parameters and control the availability of settings when the method is used in the 'Colony Counting' menu. See Section 11.7.3. Option setting tab for details.

Functional buttons



Run

Click to capture and process a new image to test the method when the SphereFlash® device is connected. Right clicking the button allows selection of an image file (PNG format) for processing.

NOTE: If the 'Start WITHOUT SphereFlash® device' option is active, this will open a file browser to select an image for processing.

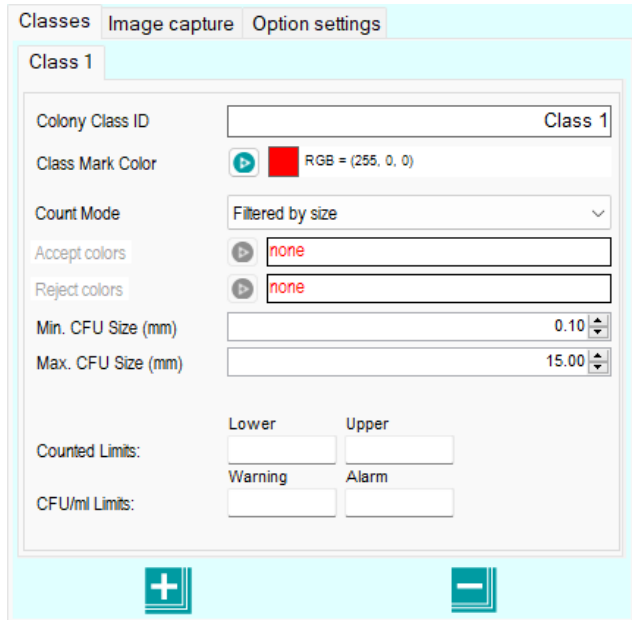


Save

Save the current method. Once saved, the new method appears in the Methods list in the 'Colony Count Data' tab.

11.7.1. Classes tab

The 'Classes' tab organizes settings for different colony classes associated with the method. Each class has its own tab, and there are additional controls for managing these tabs. Within each class tab, you can configure the following settings: Colony Class ID, Class Mark Color, Count Mode, Counted Limits, and CFU/ml Limits.



Classes tab fields

Colony Class ID (input box): Edit the name of the class, which will also appear on its tab label.

Class Mark Color (button): Set the visual marker color of the center of each colony.

Count Mode (drop-down list): Determine the classification criteria for colonies: either “Filtered by color” or “Filtered by size”. Each class in a method shares the same count mode setting.

If selected Count Mode: Filter by Color

Accept colors: Allows the selection of colony colors to be accepted for counting.

Reject colors: Allows the exclusion of specific colony colors from counting

If selected Count Mode: Filtered by size

Min. CFU Size: Sets the minimum size (in millimeters) for colonies to be included in the count.

Max. CFU Size: Sets the maximum size (in millimeters) for colonies included in the count.

Counted Limits (input fields): Set the lower and upper count limits. Colony counts outside these limits are highlighted in red, and the text <<Overcount warning for Class 1>> or <<Undercount warning for Class 1>> will be automatically appended to the *Comments* field on the cloud result stored. These limits are required by certain protocols to guarantee that the count is statistically significant.

	Lower	Upper	Colony Class	Counted Colonies	Concentration (CFU/ml)
Counted Limits:	30	300	Class 1	585	5.85E+003

CFU/ml Limits (input fields):

Define warning and alarm CFU/ml threshold values.

- Concentration below the warning limit is highlighted in white:

CFU/ml Limits:	Warning	Alarm	Colony Class	Counted Colonies	Concentration (CFU/ml)
	6.00E2	9.00E2	Class 1	19	1.90E+002

- Concentration between the warning and alarm limits is highlighted in yellow:

CFU/ml Limits:	Warning	Alarm	Colony Class	Counted Colonies	Concentration (CFU/ml)
	6.00E2	9.00E2	Class 1	70	7.00E+002

- Concentration exceeding the alarm limit is highlighted in red:

CFU/ml Limits:	Warning	Alarm	Colony Class	Counted Colonies	Concentration (CFU/ml)
	6.00E2	9.00E2	Class 1	430	4.30E+003

- If an opposite behavior is required (i.e. warning or alarm triggered when the concentration is below a limit), enter an Alarm limit value **lower** than the Warning limit value:

CFU/ml Limits:	Warning	Alarm	Colony Class	Counted Colonies	Concentration (CFU/ml)
	9.00E2	6.00E2	Class 1	19	1.90E+002

Functional buttons



Plus

Add a new colony class. A new colony class tab is created using the same Count Mode (*Filtered by color* or *Filtered by size*) as the currently selected colony class.



Minus

Remove selected colony class. This will delete the currently active colony class tab.

When a colony count is performed using a method with multiple classes:

Colonies are outlined and marked with the color corresponding to their class in the Image Viewer. Results are displayed separately for each colony class. When the result is accepted, multiple rows are generated in the Data Panel for the same Plate ID, one for each colony class.

11.7.1.1. Count mode: Filter by Color

If multiple colonies with distinct colors are present on a single plate, the 'Filtered by Color' Count Mode allows you to selectively include or exclude colonies based on their color. In addition, colonies of different colors can be categorized into distinct classes.

With a plate image loaded, click "Accept Colors" and then select the colony colors you want to include. To exclude colors, click "Reject Colors" and select the colony colors to be excluded.

NOTE: Select only one or a few representative colonies for both Accept Colors and Reject Colors. There is no need to click on every colony on the plate.

NOTE: The Reject Colors field is optional and is intended to prevent undesired counts. By default, no rejected colors are defined

Accepted and/or rejected colours will appear in the box next to the 'Accept colours' or 'Reject colours' button, respectively. In case there are no accepted and/or rejected colours, the box next to it will show the word '**none**' in red.

To access additional options, right-click on the 'Accept colors' or 'Reject colors' box. This will open a menu with several actions you can perform (depending on the selected box):

Clear All:	Clear all accepted or rejected colors.
Accept All:	Accept all colors. The colours will appear in the 'Accept colors' box, even those previously selected in the 'Reject colors' box. The 'Reject colors' box will become empty.
Reject All:	Reject all colors. The colours will appear in the 'Reject colors' box, even those previously selected in the 'Accept colors' box. The 'Accept colors' box will become empty.
Merge all:	Blend all selected colors together to create one unified color (if there is more than 1 acceptable/rejected color in the box).
Accept layer:	Accept the selected rejected color (if at least 1 color is rejected). The new accepted color will appear the 'Accept colors' box.
Reject layer:	Reject the selected accepted color (if at least 1 color is rejected). The new rejected color will appear the 'Reject colors' box.

If necessary, more colony classes can be added. If a new class is added, the 'Filtered by Color' count method will be set automatically and cannot be changed.

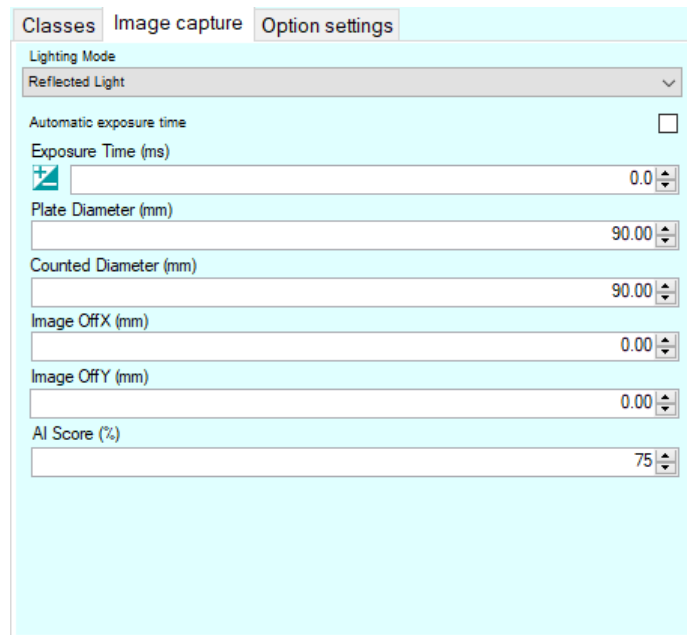
11.7.1.2. Count mode: Filter by Size

If multiple colonies with distinct sizes are present on a single plate, the 'Filtered by Size' Count Mode allows you to selectively include or exclude colonies based on their size. In addition, colonies of different size can be categorized into distinct classes.

The size range for each colony can be set by defining the minimum and maximum CFU size.

11.7.2. Image capture tab

The 'Image capture' tab allows adjusting parameters that affect the entire image capture process. The parameters in this tab apply only if plate images are taken using the SphereFlash® device.



The screenshot shows the 'Image capture' tab with the following settings:

- Lighting Mode: Reflected Light (dropdown)
- Automatic exposure time: ☐ (checkbox)
- Exposure Time (ms): 0.0 (spin box)
- Plate Diameter (mm): 90.00 (spin box)
- Counted Diameter (mm): 90.00 (spin box)
- Image OffX (mm): 0.00 (spin box)
- Image OffY (mm): 0.00 (spin box)
- AI Score (%): 75 (spin box)

- Lighting Mode** (drop-down list): Select the lighting options ("Reflected light", "Transmitted light" or "Both lights") used to illuminate the plate.
- Automatic exposure time** (checkbox): Enable automatic adjustment of exposure time for each image capture (in milliseconds). When enabled, the optimal exposure time is automatically determined for each plate.
- Exposure Time (ms):** Set the manual exposure time for the camera of the SphereFlash® device when capturing new images (in milliseconds). This parameter controls the overall image brightness.
- Plate Diameter (mm):** Indicate the inner diameter of the plate (inner distance between the lateral walls), within which the inoculated volume has been spread.
- Counted Diameter (mm):** Define the default diameter of the area within which the colonies will be counted.
- Image OffX (mm):** Set the horizontal offset between the center of the image and the center of the plate.
- Image OffY (mm):** Set the vertical offset between the center of the image and the center of the plate.
- NOTE:** Automatic calibration procedure and the auto-centering device of the device will ensure that the prescribed center of the circles matches the actual center of the plate so that for normal plates there is no need to introduce any offset.
- AI Score (%):** Set the default AI score that controls the balance between sensitivity and specificity for colony detection.

11.7.3. Option settings tab

The 'Option settings' tab allows users to set parameters of the overlay drawings and manage the availability of other settings when the method is used in the 'Colony Counting' menu:

The screenshot shows the 'Option settings' tab with the following settings:

- Drawing**
 - Plate Limits: RGB = (0, 0, 255)
 - Counted Limits: RGB = (255, 0, 0)
 - Spiral Grid: RGB = (255, 255, 255)
 - Line Thickness (mm): 0.10
- Run Editable Values**
 - ☒ Inoculation Mode: Spread or Poured
 - ☒ Inoculated Volume (mL): 1
 - ☒ Dilution Factor: 10
 - ☒ AI Score
 - ☒ CFU Size
 - ☒ Plate diameter
 - ☒ Interactive Colony Counting
 - ☒ Auto increment plate ID

There are two groups: 'Drawing' and 'Run Editable Values'. The 'Drawing' section includes parameters related to the markings on the captured images after image processing. The 'Run Editable Values' section defines the parameters that can be edited by the Operator during colony counting when using a specific method. For each parameter, the method defines whether it is editable (using the checkbox) and, where applicable, the default value (input box or drop-down list).

Drawing

Plate Limits (button): Choose the color of the plate diameter circle from the predefined color palette.

Counted Limits (button): Choose the color of the counted area circle from the predefined color palette.

Spiral Grid (button): Choose the color of the spiral grid circles (for the spiral distribution) from the predefined color palette.

Line Thickness: Adjust the line thickness for all the overlays, including center of each counted colony.
NOTE: The color of the center and borders of counted colonies are defined for each.

Run Editable Values

Inoculation Mode (checkbox and drop-down list): Editable status and default inoculation mode.

Inoculated Volume (checkbox and input box):	Editable status and default volume.
Dilution Factor (checkbox and input box):	Editable status and default dilution factor.
AI Score (checkbox):	Editable status.
CFU Size (checkbox):	Editable status.
Plate Diameter (checkbox):	Editable status.
Interactive Colony Counting (checkbox):	Editable status for interactive actions in the Image Viewer, including adding or removing colonies, modifying counting areas, or adjusting the counted diameter.
Auto-increment Plate ID (checkbox):	Editable status for automatic incrementation of the Plate ID (for images taken using the SphereFlash® device). If the Plate ID does not end with a number, "1" is added. This number is then incremented for subsequent images only if the Plate ID remains unchanged.

11.8. Verification (for the SphereFlash® device)

This section covers the verification process if the SphereFlash® device is used for capturing images.

Verification ensures accurate colony counting by the SphereFlash® device, and it may be required when the device is detected for the first time or as part of a routine schedule defined by the user.

Verification is carried out using the verification disk (Cat. No. 90004113), which simulates colonies of 3 different sizes (1, 2 and 3mm). The disk has two sides:

- Black colonies on a white background
- White colonies on a black background



Follow these steps to perform the verification process:

1. Select Verification from the Control Panel.
2. Place the centering device (Ø 87–91 mm) on the device platform, followed by the verification disk with the desired disk side facing up.
3. When the Verification panel is displayed, select the corresponding option:
 - Black Colonies on White Background, or
 - White Colonies on Black Background.
4. Click the Run button ().

The device captures an image of the verification disk and displays the results, with colony counts grouped into predefined size classes:

Verification

Imaging Device

Last Calibration Date

Due Calibration Date

Last Verification Date

Due Verification Date

Verification Data

☒ Black Colonies on White Background
☐ White Colonies on Black Background

Admissible Results (Test Plate)

1 mm: 169 - 189
2 mm: 153 - 163
3 mm: 120 - 126

Colony Class	Counted Colonies
1 mm Count	179
2 mm Count	158
3 mm Count	122

If all counts are within the expected ranges, select Accept to save the result to the cloud and finalize the verification. Select Reject to discard the results.

If the count for any size class falls outside the expected range, the corresponding result box is highlighted in red as a warning.

NOTE: Users with Tenant-admin and Administrator roles have the capability to set the verification frequency and decide if reminders for verification should be shown after the set period has expired.

11.8.1. Verifications data panel

All verifications stored for the current group are displayed in the :

Verifications								
Creation Date (UTC)	Created By	Method Name	Method Version Date (UTC)	Colony Class	Counted Colonies	Class Mark Color	Comments	Min. Size (mm)
2026/04/30 09:04	example@email.com	TEMPLATE_Conservative_AI_BlackOnWhite	2023/11/21 10:19	1 mm Count	179		<<Admissible Results (Test Plate): 1 mm: 169 - 189, 2 mm: 153 - 163...	0.80
2026/04/30 09:04	example@email.com	TEMPLATE_Conservative_AI_BlackOnWhite	2023/11/21 10:19	2 mm Count	158		<<Admissible Results (Test Plate): 1 mm: 169 - 189, 2 mm: 153 - 1...	0.80
2026/04/30 09:04	example@email.com	TEMPLATE_Conservative_AI_BlackOnWhite	2023/11/21 10:19	3 mm Count	124		<<Admissible Results (Test Plate): 1 mm: 169 - 189, 2 mm: 153 - 163...	0.80

Each verification generates 3 entries, one for each colony size class (e.g. 1 mm, 2 mm, 3 mm).

Although these entries correspond to the same processed image, they differ in:

- Colony Class (e.g. 1 mm, 2 mm, 3 mm)
- Number of counted colonies (169 - 189, 153 - 163, or 120 - 126)
- Class mark color (e.g. Blue, Lime, Red) assigned to that specific size class.

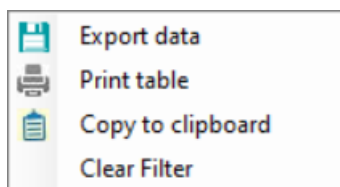
This means that a single verification run will appear as several rows in the Data Panel, one per colony size class.

Each verification result includes the following information:

- Creation date
- Created By
- Device S/N
- Method Name either *TEMPLATE_Conservative_AI_BlackOnWhite* or *TEMPLATE_Conservative_AI_WhiteOnBlack*, depending on which side of the verification disk was used)
- Method Version Date
- Colony Class (e.g. 1 mm, 2 mm, 3 mm)
- Counted Colonies
- Class Mark Color
- Comments
- Minimum and maximum size (for CFU classification)
- AI Score

The Comments section shows the admissible results for the plate test "<<Admissible Results (Test Plate): 1 mm: 169 - 189, 2 mm: 153 - 163, 3 mm: 120 - 126>>".

Right-click on one or more verification results in the table to access the contextual menu:



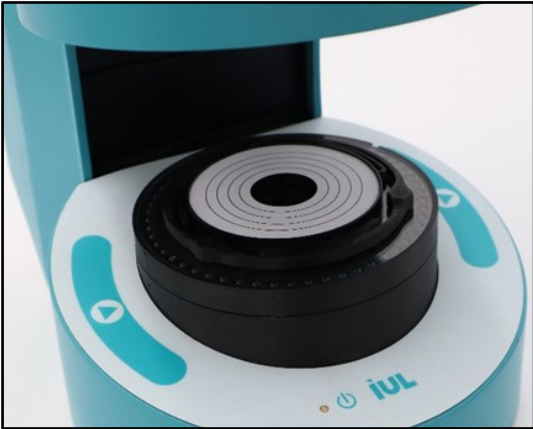
- | | |
|---------------------------|--|
| Export data: | A file browser opens to export selected calibration results with the desired format (XLSX: Excel, CSV: Comma-delimited, and TXT: Tab delimited). |
| Print table: | Print a table with all the parameters. |
| Copy to clipboard: | Copy all parameters of the selected results to the clipboard and then paste them into a document. |
| Clear filter: | Remove all active filters from the table. |

11.9. Calibration (for the SphereFlash® device)

This section covers the calibration process if the SphereFlash® device is used for capturing images.

Calibration ensures that the SphereFlash® device operates with accurate positioning, scaling, and illumination. It may be required when a SphereFlash® device is detected for the first time or as part of a routine schedule defined by the user.

Calibration is performed using the calibration disk (Cat. No. 900010081).



Follow these steps to perform the calibration process:

1. Select Calibration from the Control Panel.
2. Place the centering device (Ø 87–91 mm) on the device platform, followed by the calibration disk.
3. Click the Run button ().

The SphereFlash® device performs multiple image captures to automatically adjust image centering, dimensional scaling, and illumination settings, the final processed result is displayed in the application:

Calibration

Imaging Device

Last Calibration Date

2024/03/25 08:33

Due Calibration Date

2024/06/23 08:33

Plate Position

Offset X (mm)

0.502

limit: ± 2 mm

Offset Y (mm)

-0.860

limit: ± 2 mm

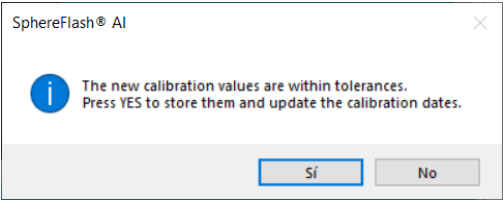
Offset Z (mm)

-2.026

limit: ± 6 mm

Once completed, an image of the calibration disk is displayed in the Image Viewer. This image may be used only for a visual verification of the calibration disk geometry, including the correct alignment and concentricity of the reference circles.

If calibration is successful, a prompt is displayed requesting confirmation to accept the calibration results:



If the calibration results fall outside the acceptable range, contact Technical support for assistance.

NOTE: Users with Tenant-admin and Administrator roles have the ability to set how frequently calibration should be performed. They can also activate reminders that will notify users when it's time to recalibrate the device after a certain period has elapsed.

11.9.1. Calibrations data panel

All calibrations stored for the equipment are displayed in the 'Browse Views' > 'View' > Calibrations:

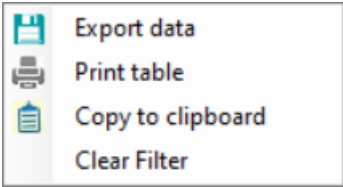
Calibrations							
Creation Date (UTC)	Created By	Device S/N	Offset X (mm)	Offset Y (mm)	Offset Z (mm)	Comments	
2026/01/14 10:34	example@email.com	10007000/0016	-0.281	0.620	2.319	<<Limits (OffsetX OffsetY OffsetZ)mm: (2.00 2.00 6.00)>>	
2026/01/14 10:30	example@email.com	10007000/0016	-0.281	0.620	2.319	<<Limits (OffsetX OffsetY OffsetZ)mm: (2.00 2.00 6.00)>>	
2026/01/14 10:29	example@email.com	10007000/0016	-0.304	0.596	2.305	<<Limits (OffsetX OffsetY OffsetZ)mm: (2.00 2.00 6.00)>>	
2024/10/29 15:15	example@email.com	10007000/0016	-1.552	-1.085	2.762	<<Limits (OffsetX OffsetY OffsetZ)mm: (2.00 2.00 6.00)>>	

Each calibration result includes the following information:

- Creation date
- Created By
- Device S/N
- Offset X
- Offset Y
- Offset Z
- Comments

The Comments section shows the admissible limits "<<Limits (OffsetX|OffsetY|OffsetZ)mm: (2.00|2.00|6.00)>>".

Right-click on one or more calibration results in the table to access the contextual menu:



- Export data:

A file browser opens to export selected calibration results with the desired format (XLSX: Excel, CSV: Comma-delimited, and TXT: Tab delimited).
- Print table:

Print a table with all the parameters.
- Copy to clipboard:

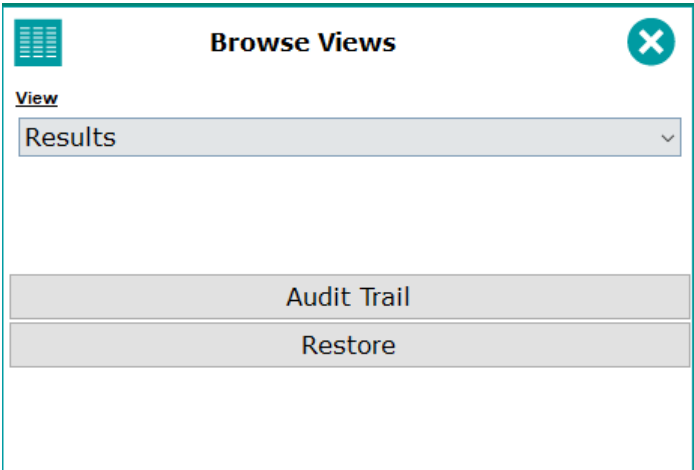
Copy all parameters of the selected results to the clipboard and then paste them into a document.
- Clear filter:

Remove all active filters from the table.

11.10. Browse Views

The Browse Views menu provides access to stored cloud data, allowing the user to browse, review, export, and manage results, methods, calibrations, and verifications.

When clicking on 'Browse Views' in the main menu, it displays the following panel in the Control panel area:



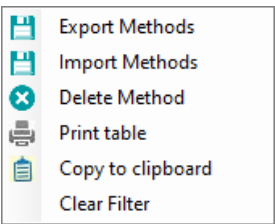
At the top, the 'View' drop-down list allows you to select which table to display in the Data panel. The available options are Results, Results Summary, Methods, Calibrations, and Verifications.

11.10.1. Methods

The 'Methods' table displays the complete set of parameters associated with each stored method:

- Method
- Description
- Operator
- Created Time
- UTC Created time

In the "Methods" table, the following actions are available when the table is right-clicked:



- Export Methods:**

A file browser opens to export selected methods in XML format. The exported method file will be named after the method name.
- Import Methods:**

Delete the selected methods.
NOTE: Only available with Tenant-admin and Administrator role.
- Delete Method:**

Delete the selected methods.
NOTE: Only available with Tenant-admin and Administrator role.

Print table:	Print a table with all the parameters for the selected rows.
Copy to clipboard:	Copy all parameters of the selected row to the clipboard and then paste them into a document.
Clear filter:	Remove all active filters from the table.

11.10.2. Results and Results Summary

The “Results” table displays the complete set of parameters associated with each stored cloud result. See Section 11.5. Cloud result data panel for more details.

The “Results Summary” table provides a simplified view of the cloud results, displaying a reduced set of columns for quick review:

- Creation date
- Plate ID
- Method name
- Method version date
- Colony class
- Counted colonies
- Concentration
- Comments

In the “Results” and “Results Summary” tables, the same contextual menu options described in previous sections are available when right-clicking on the table.

11.10.3. Verification and Calibration

In the “Verifications” and “Calibrations” tables, the same contextual menu options described in the previous sections.

11.11. Stored Data

For users with Tenant-admin and Administrator roles, the following options are available in the Browse Views panel:

- **Audit Trail:** Review results and methods currently stored in the cloud or from retention files, from the current group.
- **Restore:** Upload retained data (Retention files) and make it available in the Audit Trail.

The software automatically creates retention data locally when:

- Results are stored
- Methods are created or modified

These files preserve historical data for traceability and audit purposes. Retention folders are stored locally in the configured path, by default is:

C:\ProgramData\IUL\SphereFlashAI\Retention

Every sub-folder includes:

- *results.rst*
- *methods.rst*

IMPORTANT: Do not rename retention files (results.rst or methods.rst). Renaming will prevent a successful upload.

WARNING: If the retention file cannot be accessed or updated, the application will be blocked until access is restored or a valid alternative folder is configured.

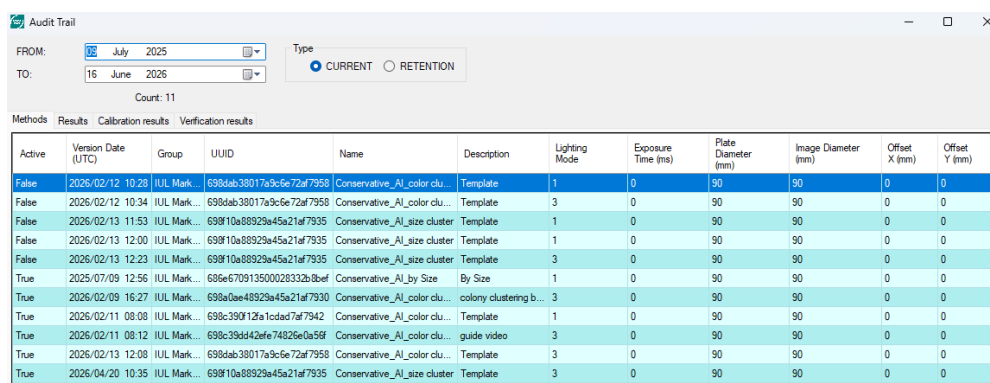
NOTE: When a retention file reaches 512 MB, a new sub-folder is automatically created. Sub-folders are named based on timestamps.

11.11.1. Audit trail window

This section is accessible only to users with Tenant-admin and Administrator role.

The Audit Trail is a historical record of all actions and modifications performed by users within the application. Audit Trail functionality may be required under certain regulatory frameworks, such as FDA 21 CFR Part 11 Subpart B.

The Audit Trail is available under 'Browse Views' > 'Audit Trail' and contains multiple tabs:



The screenshot shows the 'Audit Trail' window with a search filter set to 'FROM: 02 July 2025' and 'TO: 16 June 2026'. The 'Type' is set to 'CURRENT'. The table displays 11 records with columns: Active, Version Date (UTC), Group, UUID, Name, Description, Lighting Mode, Exposure Time (ms), Plate Diameter (mm), Image Diameter (mm), Offset X (mm), and Offset Y (mm). The records are filtered by 'Active' status, showing only 'True' entries.

Active	Version Date (UTC)	Group	UUID	Name	Description	Lighting Mode	Exposure Time (ms)	Plate Diameter (mm)	Image Diameter (mm)	Offset X (mm)	Offset Y (mm)
False	2026/02/12 10:28	IUL Mark...	698dab38017a9c5e72af7958	Conservative_AI_color clu...	Template	1	0	90	90	0	0
False	2026/02/12 10:34	IUL Mark...	698dab38017a9c5e72af7958	Conservative_AI_color clu...	Template	3	0	90	90	0	0
False	2026/02/13 11:53	IUL Mark...	698f10a88929a45a21af7935	Conservative_AI_size cluster	Template	1	0	90	90	0	0
False	2026/02/13 12:00	IUL Mark...	698f10a88929a45a21af7935	Conservative_AI_size cluster	Template	1	0	90	90	0	0
False	2026/02/13 12:23	IUL Mark...	698f10a88929a45a21af7935	Conservative_AI_size cluster	Template	3	0	90	90	0	0
True	2025/07/09 12:56	IUL Mark...	698e670913500028332b8bef	Conservative_AI by Size	By Size	1	0	90	90	0	0
True	2026/02/09 16:27	IUL Mark...	698a0ae48929a45a21af7930	Conservative_AI_color clu...	colony clustering b...	3	0	90	90	0	0
True	2026/02/11 08:08	IUL Mark...	698c390f12a1c0da7af7942	Conservative_AI_color clu...	Template	1	0	90	90	0	0
True	2026/02/11 08:12	IUL Mark...	698c39dd42efe74826e0a56f	Conservative_AI_color clu...	guide video	3	0	90	90	0	0
True	2026/02/13 12:08	IUL Mark...	698dab38017a9c5e72af7958	Conservative_AI_color clu...	Template	3	0	90	90	0	0
True	2026/04/20 10:35	IUL Mark...	698f10a88929a45a21af7935	Conservative_AI_size cluster	Template	3	0	90	90	0	0

Records can be:

- **Sorted** by clicking on a column header
- **Filtered by date and time** using the **Time From** and **Time To** fields.

The following tabs are available:

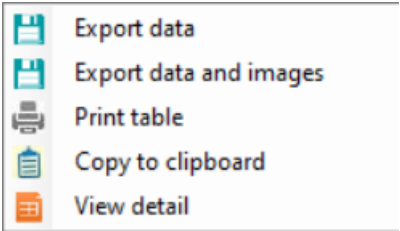
Methods:	Record events related to the method creation, editing, modification, and deletion. Includes the following information: Active (whether the method is currently enabled for use), Version Date (UTC), Group, UUID (unique identifier assigned to the method version), Method Name, Description, Lighting Mode (1=Reflected_Light ; 2=Transmitted_Light ; 3=Both_Lights) Exposure Time (ms), Plate Diameter (mm), Image Diameter (mm), Offset values (mm), enabled configuration parameters, inoculation settings, dilution settings, AI score threshold, and other method configuration parameters (true or false).
Results	Record stored result information and associated operation parameters. Includes the following information: Group, Device S/N, Created By (User Name), Creation Date (UTC), Plate ID, Comments, Method Name, Method Version Date (UTC), Plate Diameter (mm), Dilution Factor, Inoculation Mode, Inoculated Volume (mL), AI Score Threshold (%), Minimum and Maximum colony size (mm), excluded area auto (%) and excluded area (%).
Calibration Results:	Displays the results of calibration operations performed on the SphereFlash® device. Includes the following information: Creation Date (UTC), Creation Date, Created By (user name), Device S/N, Offset X, Offset Y, Offset Z, transmitted illumination calibration values (T. Red level, T- intensity, T- Blue level), and reflected illumination calibration values (R. Red level, R. intensity, R. Blue level).
Verification Results:	Display the results of verification operations. Includes the following information: Group, Device S/N, Created By, Creation Date (UTC), Plate ID, Comments, Method Name, Method Version Date (UTC), and AI Score Threshold (%).

The tables 'Methods', 'Results' and 'Verification results' also have two different 'Types' of displayed data:

- CURRENT:** Displays all the available data of the current group that is stored in the cloud, from all users. With this option, the maximum number of displayed results (including items from 'Results' and 'Verification results' tables), is the results limit of the current group (dictated by the number of Cloud results made available to the group by the tenant-admin). When the limit is surpassed, the oldest result will be removed from this view.
- RETENTION:** Displays data contained in retention files that have been previously uploaded using the Restore function.

This allows separation between active cloud data and historical retained data, as required for audit and regulatory review.

Right-clicking on an Audit Trail table displays a contextual menu with the following options (depending on the table):

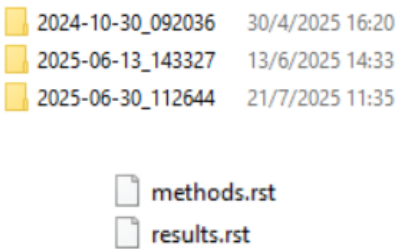


- Export data:** A file browser opens to export all displayed parameters of the selected rows with the desired format (XLSX: Excel, CSV: Comma-delimited, and TXT: Tab delimited).
- Export data and images:** Similar to the above, but also includes related images (both captured and processed). Only available for 'Results' table.
- Print table:** Print a table with all the parameters for the selected rows.
- Copy to clipboard:** Copy all parameters of the selected row to the clipboard and then paste them into a document.
- View detail:** An Audit Trail Details window opens with all available data related to the selected item. Only available for 'Methods', 'Results' and 'Verification results' tables.

11.11.2. Restore window

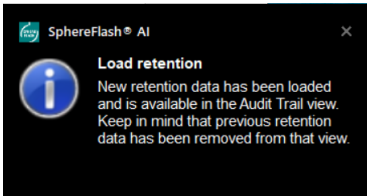
To review retained data for audit purposes, the user must use the Restore function.

1. Selecting Restore opens a file browser opens to select and upload a retention file from the current directory (default is *C:\ProgramData\IUL\SphereFlashAI\Retention*) to the cloud:



NOTE: The file name of the retention files (results.rst or methods.rst) should not be edited, as this will cause the upload to fail.

2. Once uploaded, the data contained in the selected retention files becomes available in the Audit Trail window, under the Retention view. After the restore process is completed, a confirmation pop-up is displayed.



11.12. Application Parameters

This menu enables the Tenant-admin or Administrator role to customize and modify the settings of the SphereFlash® AI Desktop Application.

The screenshot shows a window titled "Application Parameters" with a close button (X) in the top right corner. Below the title bar, there is a section titled "Environment Parameters". Under this section, there are two buttons: "System Options" and "Barcode Reader", each with a right-pointing arrow icon. Below these buttons, there is a dropdown menu for "Language" currently showing "Invariant Language (Invariant Country)". Below the language dropdown, there is a button for "Date/Time Format" with a right-pointing arrow icon. Below this, there are four text input fields: "Camera S/N" with the value "46220609", "Device IP" with the value "192.168.233.1", and "Device S/N" with the value "10007000/999".

It contains the following items:

System Options (button): Access the 'System Options' panel.

Barcode Reader (button): Access the configuration of the barcode reader serial interface. Fill in or select the proper values according to the barcode reader manufacturer's indications.

The screenshot shows a window titled "Barcode Reader" with a close button (X) in the top right corner. Below the title bar, there are five text input fields, each with a right-pointing arrow icon: "Port Name:", "Baud Rate:", "Parity:", "Data Bits:", and "Stop Bits:".

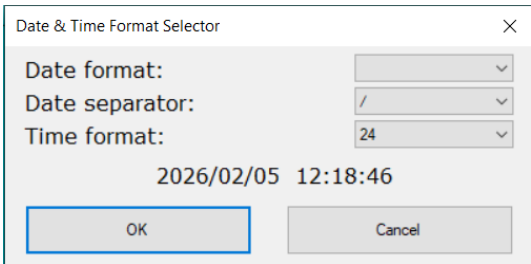
You can find the port name where the reader is connected to the computer using the PC Windows *Device Manager* dialog.

Language (drop-down list): Select the application language among those available.

NOTE: To apply language changes, you must restart the SphereFlash® AI Colony Counting Software desktop application.

Date/Time Format
(button):

- Displays the 'Date & Time Format Selector' dialog:
- Date format: DMY, MDY, or YMD
 - Date separator: /, ., ,, or space
 - Time format: 12-hour or 24-hour



Camera S/N (text box): Displays the serial number of the camera in the detected SphereFlash® device.

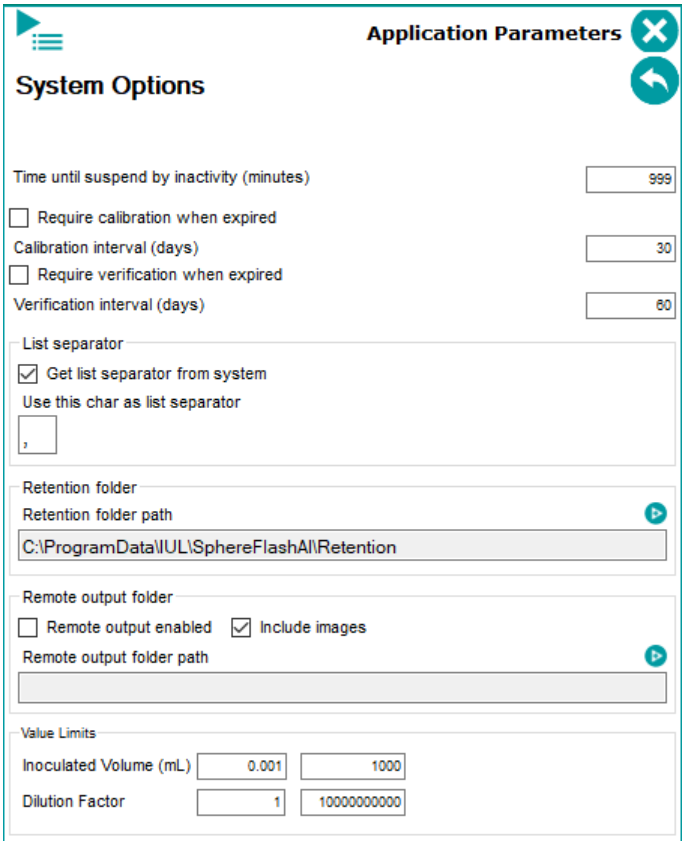
Device IP (text box): Displays the Internet Protocol address assigned to the detected SphereFlash® device.

Device S/N (text box): Displays the serial number of the detected SphereFlash® device.

NOTE: If the Desktop Application is started without a SphereFlash® device connected, this field will indicate 'NoDevice'

11.12.1. System Options panel

The 'System options' panel enables configuration of operational settings and application preferences.



It contains the following items:

Time until suspend by inactivity (input box): Enter the delay time in minutes before the application logs out due to inactivity.

Require calibration when expired (checkbox): Block the 'Colony Counting' and 'Verification' screens when the calibration is out of date.

Calibration interval (input box): Enter the number of days that the calibration remains valid. If 'Require calibration when expired' is enabled and the current calibration has expired, a pop-up warning will be displayed at every attempt to access 'Colony Counting' and 'Verification'. Additionally, the comment *<<Calibration is needed>>* is always added to 'Comments' when a result is saved with an expired calibration.

Require verification when expired (checkbox): Block the 'Colony Counting' screen when the verification is out of date.

Verification interval (input box): Enter the number of days that the verification remains valid. If 'Require verification when expired' is enabled and the current verification has expired, a pop-up warning will be displayed at every attempt to access 'Colony Counting'.

List separator

Get list separator from system (checkbox): Enable the application to get the list separator character from the operating system, and later use it in the exported CSV files.

Use this char as a list separator (input box): Enter the desired character to use as a list separator in the CSV files.

Retention folder

Retention Folder Path (button and text box): Enter and display the folder path where retention files are automatically saved. This field is mandatory.

Remote output folder:

Remote output enabled (checkbox): Enable the automatic output of the stored cloud results in XML format.

NOTE: When it is not possible to save the XML result file in the remote output folder (due to access or permission issues), the application will be blocked until the folder is accessible or an alternative folder is supplied.

Include images (checkbox): Include images in the exported XML result files.

Remote output folder path (button and text box): Enter and display the folder path where the results files will be automatically saved. The chosen path will appear in the box.

Value Limits

Inoculated Volume (two input boxes): Enter the minimum and maximum values to use as sample inoculated volume within the scope of the application.

Dilution Factor (two input boxes): Enter the minimum and maximum values to use as dilution factors within the scope of the application.

NOTE: This limitation helps minimize the risk of entering illogical values that could lead to incorrect results. This safety measure may be required by certain regulatory frameworks.

11.12.2. Interfacing with a LIMS

The SphereFlash® can automatically provide results data to a corporate network with a LIMS.

To implement this feature, the following subjects must be addressed:

- a. A folder has to be designated to share the results data with the LIMS; it may be located either on the computer containing the application or on a server reachable through the network.
- b. The PC systems administrator must grant the proper access permissions to the folder for the SphereFlash® AI Colony Counting Software as well as the LIMS system.
- c. The PC systems administrator must ensure the rules of privacy and restricted access to the data in this folder, as mandated by the company policies and any regulatory framework that may be applicable.
- d. In the System Options panel, activate the 'Remote output enabled' option, and optionally the 'Include images' option.
- e. In the System Options panel, define the 'Remote output folder path' as the designated folder.
- f. The LIMS must collect from the designated folder each XML file that appears after saving a result, interpret it, and transfer the data to its database.
- g. The LIMS should delete the files corresponding to the results it has already processed from the designated folder.

The file names of the exported results will be composed of:

- The 'Plate ID' of the result.
- The underscore character "_".
- A timestamp of the exportation time coded as YYYYMMDDhhmmssfff, where
YYYY→year; MM→month; DD→day; hh→hour; mm→minute; ss→second; fff→millisecond
- The extension of the file ".xml".

Example of a remote output file example:

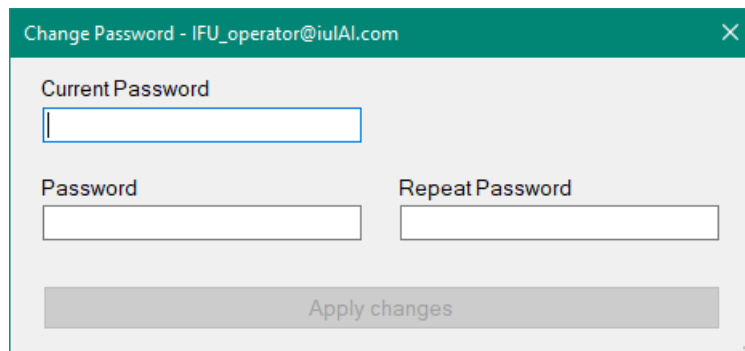
File name: "sample R57_20240429102433723.xml".

Content (without image):

```
<?xml version="1.0" standalone="yes"?>
<Result>
  <ClassResult>
    <Id>662f7561ffff8d5c3f169b35</Id>
    <CreatedUTC>2024-04-29T10:24:33.723Z</CreatedUTC>
    <CreatedBy>IFU_operator@iulAI.com</CreatedBy>
    <PlateID>sample R57</PlateID>
    <MethodID>64f987a8d19b3d8dcc9e82c3</MethodID>
    <MethodName>TEMPLATE_Standard_AI_Reflected</MethodName>
    <MethodUpdatedUTC>2023-09-07T06:26:08.991Z</MethodUpdatedUTC>
    <Class>Class 1</Class>
    <Count>36</Count>
    <CFUmL>360.064062549276</CFUmL>
    <CountedVolume>0.999822080135346</CountedVolume>
    <MarkColor>Red</MarkColor>
    <Comments />
    <InoculationMode>Spread or Poured</InoculationMode>
    <InoculatedVolume>1</InoculatedVolume>
    <DilutionFactor>10</DilutionFactor>
    <PlateDiameter>90</PlateDiameter>
    <ExcludedFraction>0.01779199</ExcludedFraction>
    <MinSize>0.1</MinSize>
    <MaxSize>15</MaxSize>
    <Score>0.75</Score>
    <SerialNumber>10007000/999</SerialNumber>
  </ClassResult>
</Result>
```

11.13. User Settings

When clicking on the 'User Settings' in the main menu, the 'Change Password' dialog will appear, allowing the user to update their application password:

A screenshot of a 'Change Password' dialog box. The title bar is green and contains the text 'Change Password - IFU_operator@iulAI.com' and a close button (X). The dialog has a light gray background. It contains three input fields: 'Current Password' at the top, 'Password' on the left, and 'Repeat Password' on the right. Below these fields is a wide, light gray button labeled 'Apply changes'. The 'Current Password' field is currently empty and has a blue border. The 'Password' and 'Repeat Password' fields are also empty.

The current password must be entered in the 'Current Password' input box.

The new password must then be entered in both the 'Password' and 'Repeat Password' input boxes.

The password is only updated after clicking the 'Apply Changes' button. Once the password has been successfully changed, a confirmation email is automatically sent to the user.

When entering a password, the application displays its strength classification. A password is considered valid when it meets minimum security requirements.

Password strength is classified as follows:

- **Weak:** The password contains at least 5 characters and includes uppercase letters, lowercase letters, and numbers.
- **Moderate:** The password contains at least 5 characters and includes letters, numbers, and symbols.
- **Strong:** The password contains at least 7 characters and includes letters and numbers.
- **Very strong:** The password contains at least 7 characters and includes uppercase letters, lowercase letters, and symbols.

11.14. Account Info

When clicking on the 'Account info' in the main menu, the 'Subscription Account Info' dialog appears with details about the current subscription:

Subscription Account Info

Active Plan

Activation date:

2025/12/19

Expiration date:

2026/12/19

Credit Limits

Tenant

100

Group:

100

Consumed Credits

Tenant

22

Group:

12

REQUEST RESOURCES

Active Plan

Activation date: Date of activation of the current subscription AI plan.

Expiration date: Date of expiration of the current subscription AI plan

Credit Limits

Tenant: Maximum number of images that can be processed with the current AI plan.

Group: Maximum number of images that can be processed by the current group.

Consumed Credits

Tenant: Total number of images used within the current AI plan.

Group: Total number of images used by the current group, within the current subscription plan.

Request Resources: Request more images to the Tenant-admin. Clicking this button will send an email to the Tenant-admin.

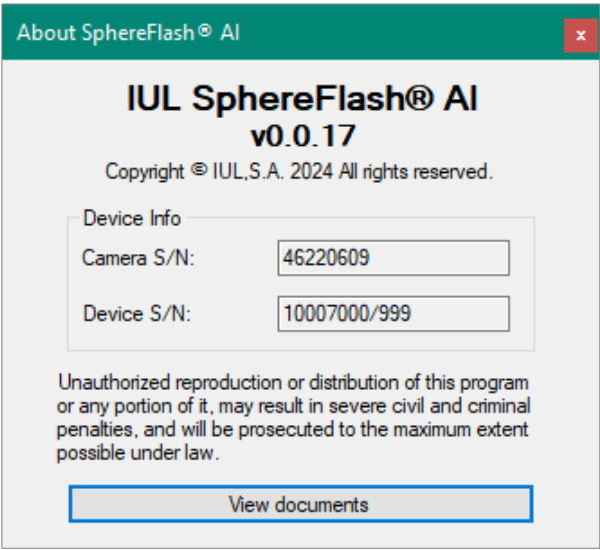
NOTE: If the Active AI Plan has expired or there is an internet connection problem, all the displayed values will be shown as dashes.

Doc. 50007937-08 (EN)

Page 154 of 182

11.15. About

When clicking 'About' in the main menu, the 'About SphereFlash® AI' dialog opens:



It includes the current application version, information on the SphereFlash® device, and a button to open the folder where some application documents are stored.

View Documents: includes the latest version of the Instructions for Use and the end-user license agreement.

12. TROUBLESHOOTING

12.1. Subscription Portal

Error	Probable cause	Recommended actions
<i>"401 Provided credentials does not belong to web user"</i>	The user has an Administrator or Operator role, so they do not have access to the Subscription Portal.	Administrators and operators can use their credentials to access ONLY the SphereFlash® AI Desktop Application
<i>"409 You are already registered, please use login"</i>	The user has already completed the registration process and clicked the Sign Up button again. An activation email has been sent.	Check the email inbox (and spam folder) for the activation email
		Complete the account activation by following the link provided in the email
		Once the account is activated, access the application using the Login option instead of Sign Up
<i>"409 Company data already registered. Please contact support."</i>	The company information has already been registered in the system by another user from the same organization. NOTE: Only one user per company domain can register.	Verify that the company data entered during registration is correct.
		Check internally whether another user from your organization has already completed the registration using the same company details
		If the registration was performed by another colleague, use different user credentials or request access through them
		If the issue persists, contact the IUL Technical Service team for support.
User did not receive the activation email	Activation email filtered or blocked by the email provider (especially Microsoft 365 / Outlook)	Check the spam/junk folder
		Confirm whether you're using Microsoft 365 (Outlook), as activation emails are often blocked by its filters
		If the email is still not received, please contact IUL Technical Service for assistance
		If you are creating users as a tenant-admin, you can also try deleting and re-creating the user to trigger a new verification email.
<i>"409 Email already registered"</i>	The email address is already registered in the AI Plan	Check with your tenant-admin, whether the user already appears in user list in the Subscription Portal

Error	Probable cause	Recommended actions
		In the Subscription Portal under 'Users', "Is Verified = No", delete the user and create the account again If the user does not appear in your list, they may have already attempted to Sign up via the Subscription Portal — in this case, please contact IUL Technical Service
<i>"409 Group credits limits exceed the remaining tenant credits. Please, update other groups credits limits and try again. Alternatively, contact sales for more credits."</i>	The total number of image limits and cloud results limits assigned to groups exceeds the limits included in the AI Plan of the Tenant Admin (company account).	Review the image and cloud results limits assigned to all user groups.
		Reduce the limits of one or more groups so that the total assigned limits do not exceed the limits of the AI Subscription Plan.
		If higher limits are required, once you have used all image limit, renew your AI Plan

12.2. SphereFlash® AI Colony Counting Software Desktop Application

Symptom	Probable cause	Recommended actions
The application shows the following error: <i>'HTTP response not OK Invalid email or password'</i>	The credentials entered are incorrect.	Enter the correct user credentials. Contact the Tenant-Admin to request the creation of a new user account.
<i>"Unhandled exception has occurred in your application. If you click Continue, the application will ignore this error and attempt to continue. If you click Quit, the application will close immediately.</i> <i>InvalidArgumentValue of '1' is not valid for 'SelectedIndex'. Parameter name: SelectedIndex"</i>	The user account is not assigned to any group in the Subscription Portal.	Tenant-admin must create a group and include the required users in this group in the Subscription Portal.
<i>"Device cannot be found. Make sure the video connection is correctly connected."</i> <i>"ApplicationException in 'None' operation step: Device cannot be found.</i>	The SphereFlash® camera is internally disconnected, or the SphereFlash® camera drivers are not installed or not detected (the software was installed without	Make sure the blue USB cable is connected directly to a USB 3.0 or port on the computer. Note: Do not use any USB HUB or adapter.
		Connect the SphereFlash® device to the computer and powered ON before the software installation

Symptom	Probable cause	Recommended actions
<i>Make sure the video connection is correctly connected."</i> <i>"No devices are discovered. Check power, network, and USB connections. Some operations with SphereFlash will be disabled."</i>	the SphereFlash® connected and powered ON).	IT member must check if there are other cameras connected to the computer (webcam, external camera), and if so, disable the camera: 1. Go to Device Manager 2. Right-click the mouse on your camera. 3. Disable the camera.
		If the problem persists, please provide: - Computer brand and model - Operating system and version - Whether it is a laptop or desktop PC - Any other cameras connected to the computer To our IUL Technical Support team
<i>"Connection Failed Please make sure all cables are properly connected."</i>	There's no connectivity with Subscription Portal	IT member must disable the firewall
<i>"IOException in 'None' operation step: timeout elapsed"</i>	Computer and SphereFlash device not well connected	Connect the device with the computer using the USB 3.0 port and the blue supercable USB 3.0
<i>"HTTP response not OK Service Unavailable"</i>	Network connectivity issue preventing access to the AI Colony Counting cloud services.	IT member must verify connectivity to the following endpoints: https://aicolonycounter.com and https://inference.aicolonycounter.com. Ensure that Port 443 (HTTPS) is open and accessible.
<i>"An unhandled exception has occurred in the application. If you click Continue, the application will ignore this error and attempt to continue. If you click Exit, the application will close immediately. The column named Name could not be found. Parameter name: column"</i>	The desktop application is not updated	Install the new desktop application (v1.2.4)

Symptom	Probable cause	Recommended actions
<i>"Please Enter a New Folder Name It looks like a root folder already exists for this project. Please choose a different name, or specify a different directory. A root folder is being created at this path."</i>	In Application Parameters, the option "Remote output enabled" is activated, but the field "Remote output folder path" has been left empty.	Tenant-admin must disable the option "Remote output enabled", or Enter a valid folder path in the field "Remote output folder path"
<i>"No active plan found for given tenant"</i>	The user does not have an active AI plan assigned	Tenant-admin must include more Image Limit or renew the AI Plan in the Subscription Portal
<i>"Group has reached the maximum credits for inference"</i>	The Image Limit included in the AI Plan or the group has been exhausted	Tenant-admin must renew the AI Plan or upgrade it to include additional images
Clicking RUN opens the file browser instead of capturing an image from SphereFlash	The option "Start WITHOUT SphereFlash® device" was selected at log in dialog	- Log out of the application - At the Log In screen, make sure the "Start WITHOUT SphereFlash® device" checkbox is deselected - Ensure the SphereFlash® device is properly connected to the PC - Log in again — the system will then allow image capture directly from the device instead of only uploading an image
<i>"Verification failed. Verification is out of limits."</i>	The centering device and/or the verification disk are not correctly positioned on the platform. The verification disk is placed with the wrong side facing up.	- Ensure the centering device (~87-91 mm Ø, Cat. 900013473) is properly placed on the platform, fully enclosing the reference area. - Ensure the correct side of the plate is facing up: • Black colonies on a white background • White colonies on a black background
<i>"Calibration too old."</i>	The calibration date of the device has expired	Perform a new calibration of the device following the calibration procedure.

Symptom	Probable cause	Recommended actions
<i>"Calibration failed: Please verify that the calibration disk is in optimal condition and correctly positioned. If issues persist, kindly contact your technical support for assistance.</i> <i>Device camera not found. Make sure the video connection is correctly connected."</i>	The SphereFlash® camera drivers are not installed (the software was installed without the SphereFlash® connected and powered ON). As a result, the camera cannot be recognized and calibration cannot be completed.	Connect the SphereFlash® device to the computer using the USB 3.0 cable. Make sure the device is switched ON. Reinstall the SphereFlash® software with the device connected, running the installer as Administrator. After installation, repeat the calibration procedure, ensuring the calibration disk is correctly positioned and in good condition.

APPENDICES

APPENDIX A ORDERING CODES

Product	Contents	Cat.
SphereFlash® Colonies LITE software	1 unit	90007000

Software Upgrades

Product	Cat.
Colonies PRO software (permanent license)	90007001
Halos PRO software (permanent license)	90007002
SphereFlash® AI colony counting software (annual license: Image Pack + Storage Pack)	
SphereFlash® AI software. Storage Pack A. 1000 cloud results limit	90007009
SphereFlash® AI software. Image Pack 0. 1000 image limit	90007016
SphereFlash® AI software. Image Pack 1. 10000 image limit	90007010
SphereFlash® AI software. Image Pack 2. 50000 image limit	90007011
SphereFlash® AI software. Image Pack 3. 100000 image limit	90007012
SphereFlash® AI software. Image Pack 4. 150000 image limit	90007013
SphereFlash® AI software. Image Pack 5. 200000 image limit	90007014
SphereFlash® AI software. Image Pack 6. >200000 image limit	90007015

Spare parts

Product	Contents	Cat.
PC Communication cable (Super Cable USB 3.0 Type A)	1 unit	90001960
Centering device Ø 87-91 mm	1 unit	900013473
Calibration disk	1 unit	900010081
Verification disk for Halos	1 unit	900011876
Verification disk for Colonies	1 unit	90004113
External power supply	1 unit	90004013
EU Power Cord (Schuko CEE 7/4) 1.5m	1 unit	90004017
UK Power Cord (BS 1363) 2.5m	1 unit	90004019
US Power Cord US / Japan (NEMA 5-15P) 1.8m	1 unit	90004018
CN Power Cord China / Australia (GB 1002, GB 2099.1) 1.8m	1 unit	90004027
AR Power Cord Argentina (IRAM 2073) 2.5m	1 unit	90004026

Optional accessories (for Colonies LITE, PRO & SphereFlash® AI)

Product	Contents	Cat.
Centering device Ø 54-60 mm	1 unit	900013512
Centering device Ø 65-70 mm	1 unit	900013513
COMPACT DRY™ Adapter	1 unit	900013524
PETRIFILM™ Adapter	1 unit	900013525

Product	Contents	Cat.
MC-MEDIA PAD® Adapter	1 unit	900013537
Easy Plate™ Adapter	1 unit	900014759

APPENDIX B TECHNICAL DATA

IUL reserves the right to change specifications at any time.

Device specifications

Illumination System	Dual LED lighting and a patented spherical lighting system. • Upper lighting provided by LEDs on the crown, oriented towards the internal wall of the sphere, offering a diffused and homogenous reflected lightning (darkfield-like). • Lower lighting is done through LEDS positioned just beneath the plate, offering transmitted lighting through a homogeneous surface.
Sensor	CMOS 5 MP Color Camera
Zoom	Captured and processed image supports up to x32 zoom
Plate and media compatibility	Petri dishes diameter: 55 to 90 mm in diameter. Inoculation method: spread, pour, surface, drop/circle and spiral plating. Accessories available for Petrifilm™, Compact Dry™, MC-Media Pad®, Easy Plate™ and filter membranes. Compatible with selective and chromogenic agar.
Outer casing material	ABS plastic cover, aluminium back plate, and zinc-coated steel frame
Communication	USB 3.0 Type-A to PC
IUL Switching Adapter (90001566)	12V DC 3.43A
Dimensins (LxWxH)	28.8 x 37.1 x 22.0 cm / 11.3 x 14.6 x 8.7 in
Weight	5.5 kg / 12.1 lb

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 IUL see the corresponding appendices.
WARNING 	Risk of electric shock In case of replacement or a loss 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 Appendix and provided by IUL

Colonies LITE Software

Minimum colony diameter	0.3mm*
Alarm limits	total amount of colonies or concentration (CFU/ml)
Manual interaction	Threshold to background and Absolute Minimum Diameter, Add or remove colonies, and define custom inclusion/exclusion areas by drawing polygonal or circular zones.
Operation time	2 seconds (minimum)
Calibration and Verification	Automatic
Data results	Results Group Name, Created Time, Plate ID, Method, Colony class, Counted colonies, Concentration, Counted volume, Comments (including status notifications (e.g., calibration or verification alerts)), Inoculation mode, Inoculated volume, Dilution factor, Excluded area, UTC Created Time, Count from Automatic Process, Input Values (Thr. to Back., Plate Diameter., Min. Diam.) and Device SN
Data Export formats	XLSX: Excel, CSV: Comma-delimited, TXT: Tab-delimited, print the table (PDF) and clipboard

Colonies PRO Software

Regulatory compliance	CFR 21 part 11 subpart B
Audit Trail & User Management	Available; 3 user roles
LIMS connectivity	Available; XML format
Minimum colony diameter	0.046mm*
Filtering and Classification	by colors and sizes
Alarm limits	Equivalent to Colonies LITE
Manual interaction	
Operation time	
Calibration and Verification	
Data results	
Data Export formats	Equivalent to Colonies LITE Logo customization and digital signature on the reports included

SphereFlash® AI Software

Regulatory compliance	CFR 21 part 11 subpart B
Audit Trail & User Management	Available; 3 user roles
LIMS connectivity	Available; XML format
Minimum colony diameter	0.046mm*
Filtering and Classification	by colors and sizes
Alarm limits	total amount of colonies or concentration (CFU/ml)
Manual interaction	AI score, CFU Size, Add or remove colonies, and define custom inclusion/exclusion areas by drawing polygonal or circular zones.
Operation time	2 seconds (minimum)** Supports uploading images
Calibration and Verification	Automatic
Data results	Creation date, Plate ID, Method name, Method version date, Colony class, Counted colonies, Concentration, Counted volume, Class mark color, Comments (including status notifications (e.g., calibration or verification alerts)), Inoculation mode, Inoculation volume, Dilution factor, Plate diameter, Excluded area, Minimum and maximum size (for the CFU), AI Score and Device S/N
Data Export formats	XLSX: Excel, CSV: Comma-delimited, and TXT: Tab-delimited, print the table (PDF) and clipboard

*Contrast-dependent

**Depending on internet connectivity

Operating conditions

Power range	100 ~ 240VAC
Frequency range	50 ~ 60Hz
Maximum power	40W
Overvoltage category	II
Air temperature	15-30°C (59-86°F)
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	5°C to 40°C (41°F to 104°F) In manufacturer's packaging
Relative humidity	Maximum of 75% (non-condensing)

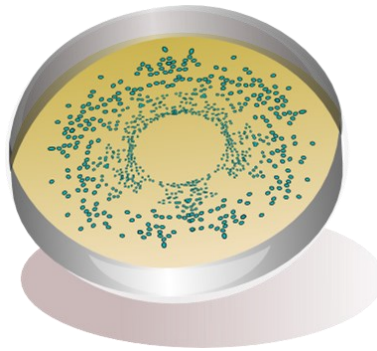
Storage conditions

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

APPENDIX C SPIRAL DISTRIBUTION

Introduction to Spiral Plating

Spiral plating is a widely accepted microbiological surface plating technique that was created in the 1970s to reduce the number of agar plates used in surface spreads. Initially, this technique was implemented to test dairy samples¹, however, over the years it has gained a very broad application range and has become one of the most extended techniques when performing viable bacterial/fungal counts. Spiral plating has been awarded full approval by organizations like the AOAC², the ISO³, and the FDA⁴.



Spiral platers rotate an agar plate while pouring decreasing amounts of liquid sample onto its surface describing an Archimedean spiral. After incubating the plates, colonies appear distributed along the spiral's track with a radial decrease in concentration. In this fashion, a single 90 mm Petri plate contains across its surface the equivalent to a threefold decimal dilution concentration range.



Spiral plating can be done with IUL's Eddy Jet 2W. The core feature of the Eddy Jet 2W is the use of high-precision disposable micro-syringes. Microsyringes have a capacity of 110 µl and deliver extremely precise volumes of sample to agar surfaces. The angle at which a micro-syringe's tip contacts the agar's surface ensures constant liquid deposition.

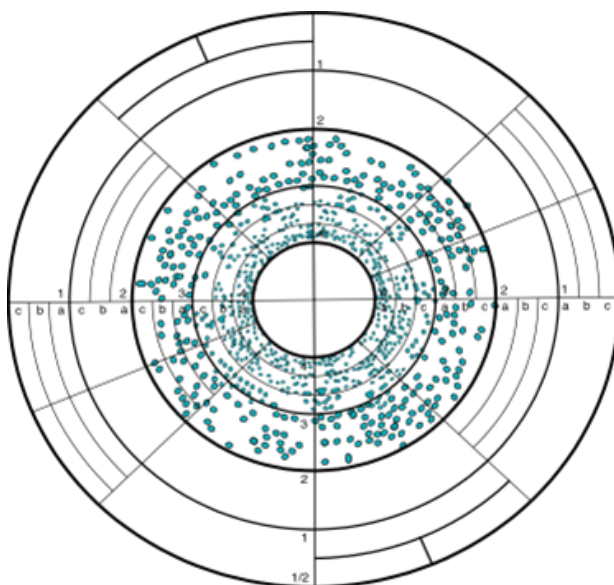


Main Applications of Spiral Plating

Spiral plating's main application, as previously described, is that of performing surface spreads for viable microorganism enumeration where a single spread can have a detection range between 2×10^2 and 4×10^5 CFU/ml. This application is mainly used to assess bacterial concentrations during and after the manufacturing or processing of food, drinks, pharmaceuticals, and cosmetics. It is also widely implemented during challenge testing (also known as preservative efficacy testing). This method has also been applied to test environmental water samples⁵. Agricultural and environmental industries implement spiral platers in bio-pesticide challenges, frost prevention, and leaf studies.

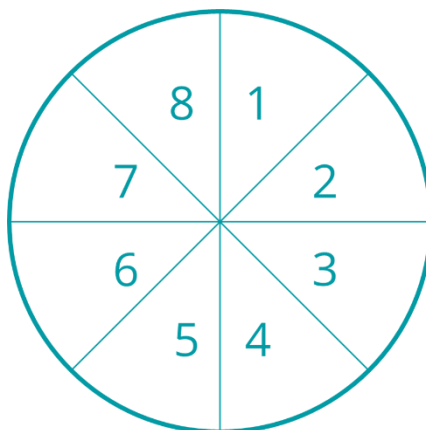
Colony Counting

Counting colonies in a spiral distribution can be done manually using of a specific counting grid together with a manual colony counter or using the SphereFlash® device.

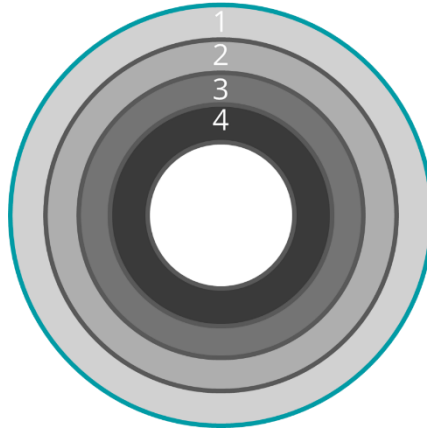


Manual colony counting

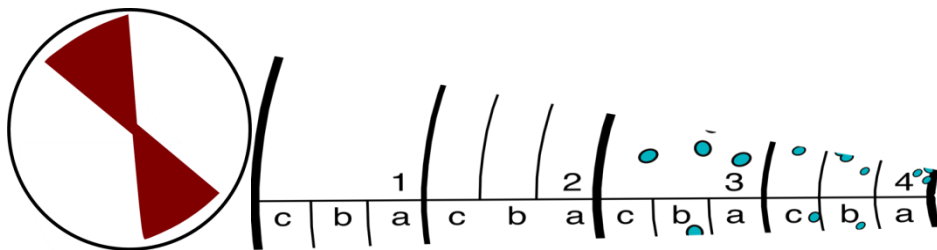
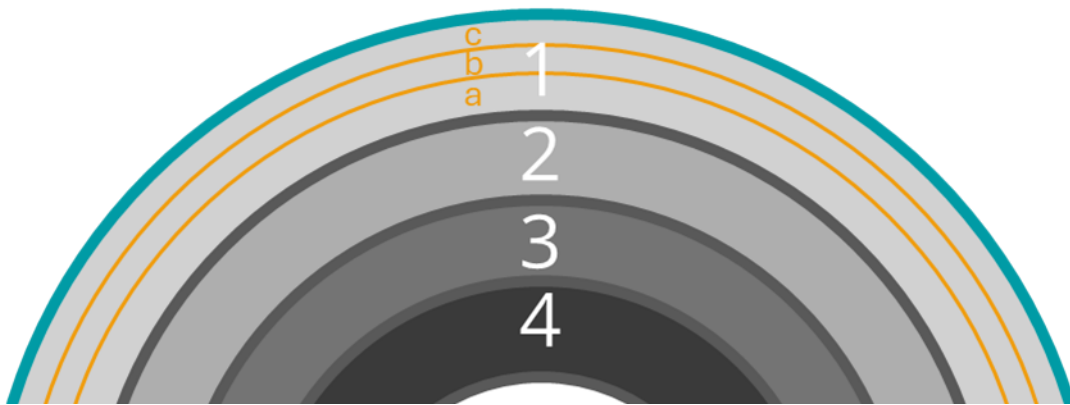
When counting manually, the counting grid divides the plate into 8 equal sectors:



It is also divided into 4 concentric sections:



With each section, further divided into 3 rings:



For 100 mm plates, only sections 3 and 4 are considered and counting starts from section 3. For 150 mm plates, sections 1-4 are considered and counting starts from section 1.

The following formula must be used to calculate CFU concentrations:

$$C = D * (N' + N'') / (V / 4)$$

C = CFU concentration = CFU ml⁻¹

N' = CFU count in the first 1/8 ring sector = CFU

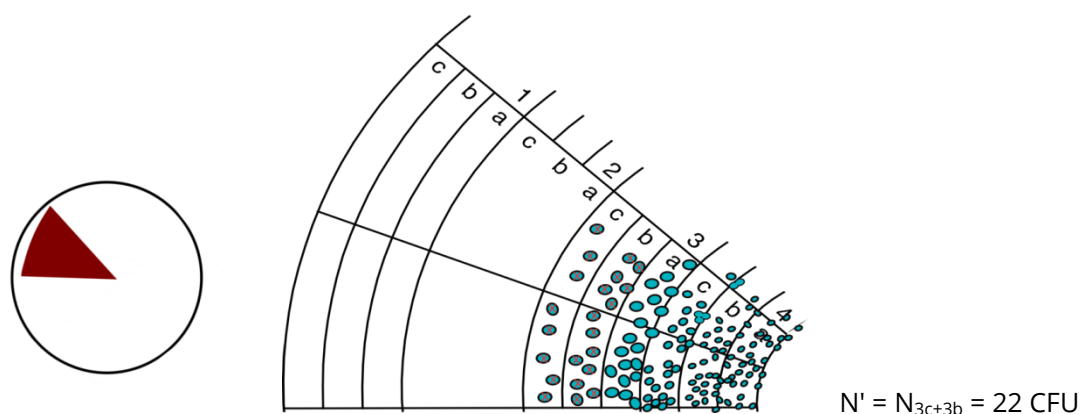
N'' = CFU count in the opposite 1/8 ring sector = CFU

D = Dilution factor

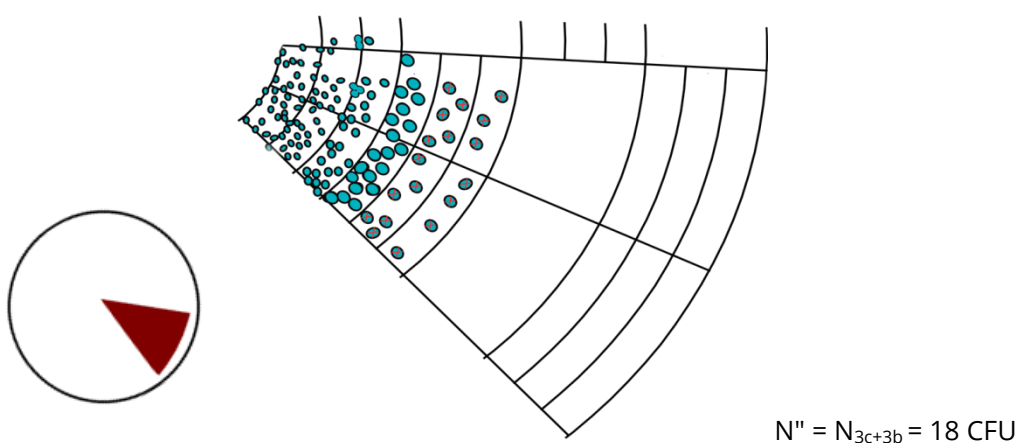
V = volume of sample inoculated in the counted rings (can be obtained from a table and is based on the distribution mode and plate size)

To perform the manual counting, 1 of the 8 sectors is chosen and colonies are counted starting from the outermost towards the innermost ring of a section (i.e. for 100 mm plates - counting starts from 3c, while for 150 mm plates - counting starts from 1c). The counting threshold is 20. If all the colonies of a ring has been counted and the threshold value of 20 has not been reached, continue counting to the next ring of the same section, and if needed to the outermost ring of the next section. When the threshold value is reached, continue counting until all the colonies in the same ring has been counted. Perform the same to the opposite sector. See the example below:

Note: An E-Mode 50 μ l distribution was supposedly used to inoculate the 100 mm plate being counted in the following example.



The count starts at 3c with 8 colonies. As the number of colonies does not reach the threshold of 20, the count is continued to the next ring, 3b. In this example, 3b contains 14 colonies resulting to a total of 22 colonies, exceeding the threshold. Therefore, counting stops at 3b. The same is done for the opposite sector, also stopping at 3b.



Automatic colony counting

When the SphereFlash® is used to colony counting of spiral distribution, the following formula is applied:

$$\text{CFU concentration} = D \times N / V$$

D = Dilution Factor

N = Number of colonies counted in the selected rings

V = Inoculated volume contained within the selected rings

In case of the SphereFlash® the whole sector is counted, not just an eight of sector, hence the threshold value is 160 instead of 20.

Bibliography

1. C.B. Donnelly, G.E. Gilchrist, J.T. Peeler and J.E. Campbell, Spiral plate method for examination of raw and Pasteurized Milk, Ap. And Env. Micr. 1 (1976) 21-27.
2. AOAC Method 977.27
3. ISO 7218: 2007, Microbiology of food and animal feeding stuffs. General Requirements and Guidance for Microbiological Examinations.
4. L. Maturin and J.T. Peeler, Bacteriological Analytical Manual Chapter 3. Aerobic Plate Count. FDA (2001).
5. Wada M., Statistical study of the optimal conditions of the spiral method for counting bacterial numbers in river water. Nihon Eiseigaku Zasshi.:4 (1992) 798-810.

APPENDIX D WARRANTY

The SphereFlash® instrument has a 12-month warranty period, which starts when the instrument is purchased to IUL.

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.

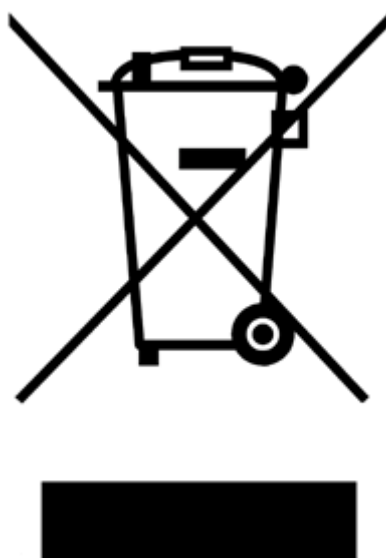
As part of this warranty, all shipping costs to the selected technical service are the responsibility of the Buyer.

APPENDIX E 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 F EU DECLARATION OF CONFORMITY

Manufacturer Name:

IUL SA

Manufacturer Address:

C/ Ciutat d'Asunción, 4 08030 Barcelona (SPAIN)

Declares that the product Name:

SphereFlash®

Catalog Numbers:

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



Daniel Blanch
(Director of Electronical Engineering)

David Guerrero
(Quality Manager)

APPENDIX G FCC STATEMENT

FCC Declaration of Conformity

Responsible party:

IUL SA

C/ Ciutat d'Asunción 4

08030 Barcelona

Spain



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 modifications 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.

APPENDIX H COLONIES SOFTWARE REGULATORY COMPLIANCE: FDA 21 CFR PART 11 SUBPART B

NOTE: The availability of the features described in this section requires the Colonies PRO software.

The Colonies PRO software is designed to enable the customer to comply with FDA regulations related to 21 CFR part 11 Subpart B, allowing the use of electronic records instead of paper records.

Summary of the key elements of compliance:

- The original electronic records are encrypted and protected to ensure authenticity, integrity, confidentiality, and ready retrieval throughout the retention period (§11.10 a, c).
- The software has the ability to generate accurate and complete copies of records both in human-readable and electronic form (§11.10 b).
- The access to the software, its use, and its operation, is limited to authorized individuals (§11.10 d, g).
- The software automatically generates an Audit Trail that records all the user actions that create, modify or delete electronic records. This Audit Trail is time-stamped and encrypted, and cannot be altered by the users (§11.10 e).
- The correct and appropriate sequence of operations, steps, and events is enforced by the software and cannot be altered by the user (§11.10 f)
- Data input from the user is checked or limited to valid and appropriate values (§11.10 h)

Features of Colonies PRO software related to FDA 21CFR part 11 Subpart B compliance:

#	section of FDA 21CFR part 11	Topic	Requirement	SphereFlash® software implementation	Customer action is required to comply	Comments
1	11.10 (a)	Validation	The system must be validated for the intended use		X	The customer is responsible for the validation of the system in which the SphereFlash® is integrated, according to the particular use intended by the customer.
				X		The SphereFlash® software provides standard template methods to be used for customer validation.
2	11.10 (a)	Changes on records	It must be possible to discern invalid or altered records	X		The results of all the operations and the settings of methods are recorded in an encrypted database, which prevents any modification of its contents neither from the application nor from outside it. If an operator re-processes the same plate or the image of a previously processed plate, both the old and new results records are kept, being distinguishable by their respective timestamps. All the operator actions, changes, and entries to the operation results, system settings, and operation methods, that are relevant to the validity of the results of the operations, are automatically recorded in an Audit Trail which includes the date, local, and UTC time, user, and change that has been performed. It is the responsibility of the customer to ensure that the date/time has not been manipulated.
					X	The customer must ensure that, on the computer where the SphereFlash® software is installed, the date and hour cannot be modified by unauthorized individuals.

#	section of FDA 21CFR part 11	Topic	Requirement	SphereFlash® software implementation	Customer action is required to comply	Comments
3	11.10 (b)	Report, printout, electronic record, FDA review	The system must be able to produce accurate and complete copies of the records on paper as well as in electronic form, allowing for their review by FDA.	X		Records data can be exported to Excel, CSV, and text files. The results data of each operation can be automatically exported in real-time to an XML file when <i>Remote Out</i> mode is active. Records data can be printed to paper or PDF files in table and report formats. Generated PDF reports and tables can be automatically linked to a third-party application, to be digitally signed to ensure its authenticity, integrity, and authorship. When exporting or printing reports, the exact data contents of the records in the database are automatically transferred to the file or printout; there is no possibility to modify the data.
					X	After exporting to a file outside the application, it is the responsibility of the customer to ensure the integrity of its contents.
4	11.10 (c)	Protection of records, retention period	The records must be readily available throughout their retention period	X		The results of all the operations and the settings of methods are kept in an encrypted database, which prevents any modification of its contents neither from the application nor from outside of it. All the records of the active database are directly available for review, export, and print until the authorized user performs a purge of the outdated records into an archive file. Even in the archive file, the outdated records are still safeguarded under encryption, and they can be retrieved for their consultation if needed.
					X	It is the responsibility of the customer to perform periodic back-ups of the database files

#	section of FDA 21CFR part 11	Topic	Requirement	SphereFlash® software implementation	Customer action is required to comply	Comments
5	11.10 (d)	Login, access authorization	The system must limit access to the system to only authorized individuals	X		The SphereFlash® software is provided with a login feature that limits access only to authorized individuals using a username and a password. Each user is assigned a role that defines the subset of features for which they have permission. The users with administrator roles have the responsibility to create or delete users, and to assign them the proper role. The system can be configured by the administrator to request the users a periodical change of their password. After several failed login attempts, a user becomes blocked and the intervention of the administrator is required to unblock them. All the changes to the users and their roles, as well as the login events, successful or not, are recorded in the Audit Trail. If the operator leaves the computer unattended for more than a scheduled time, the application will be blocked, requiring a new login.
					X	The customer has the responsibility to designate and empower a staff member to act as administrator of the SphereFlash® software application
6	11.10 (e)	Audit trail, timestamps	The system must automatically generate a secure, time-stamped audit trail, that logs the date and time of user entries and actions which create, modify or delete electronic records	X		All the operator actions, changes, and entries to the operation results, system settings, and operation methods, that are relevant to the validity of the results of the operations, are automatically recorded in an Audit Trail which includes the date, local and UTC time, user, and change that has been performed.

#	section of FDA 21CFR part 11	Topic	Requirement	SphereFlash® software implementation	Customer action is required to comply	Comments
					X	The customer must ensure that, on the computer where the SphereFlash® software is installed, the date and hour cannot be modified by unauthorized individuals.
7	11.10 (e)	Overwriting data	When modifying electronic records, the previously recorded information must still be available in the system, not being overwritten by the modification	X		All the operation results data, after being recorded, are kept in the database with no possibility of further modification. If an operator re-processes the same plate, or the image of a previously processed plate, both the old and new results records are kept, being distinguishable by their respective timestamps. All the modifications of the settings of methods or the general system settings are recorded in the Audit trail, where the user, date and time, and changed values can be seen.
8	11.10 (e)	Audit Trail, retention period	The Audit Trail of an electronic recording must be retrievable throughout the retention period of the record	X		The Audit Trail entries are kept in the same encrypted database as the results records, which prevents any modification of its contents neither from the application nor from outside of it. All the Audit Trail entries of the active database are directly available for review until the authorized user performs a purge of the outdated records into an archive file. Even in the archive file, the outdated records are still safeguarded under encryption, and they can be retrieved for their consultation if needed.
					X	It is the responsibility of the customer to perform periodic back-ups of the database files

#	section of FDA 21CFR part 11	Topic	Requirement	SphereFlash® software implementation	Customer action is required to comply	Comments
9	11.10 (e)	Audit Trail, FDA review	The Audit Trail must be available for review and copying by the FDA	X		Audit Trail PDF reports can be generated and automatically linked to a third-party application, to be digitally signed to ensure their authenticity, integrity, and authorship. When exporting or printing those reports, the exact Audit Trail contents in the database are automatically transferred to the file or printout; there is no possibility to modify the data.
					X	After exporting the Audit Trail to a file outside the application, it is the responsibility of the customer to ensure the integrity of its contents.
10	11.10 (f)	Sequence of steps	The system must use operational checks to enforce the permitted sequence of steps and events as appropriate	X		The sequence and setting values required for each operation type are enforced by the method definition, which doesn't allow the operator to modify any of the steps or settings except those data that purposely have been decided that will be entered by the operator. Additionally, the <i>Remote In</i> and <i>Worksheet</i> features will enforce the application of the method and setting values required for each particular plate ID. Only users having assigned <i>Programmer</i> or Administrator roles are able to define method settings and associate in a worksheet each plate ID with the method and settings required for its processing.
					X	The customer has the responsibility to designate and empower suitable staff members to act as <i>Programmers</i> .

#	section of FDA 21CFR part 11	Topic	Requirement	SphereFlash® software implementation	Customer action is required to comply	Comments
11	11.10 (g)	User permissions	The system must ensure that only authorized individuals can use the system, access the functions, modify a record, or perform other operations	X		The SphereFlash® software is provided with a login feature that limits access only to authorized individuals using a username and a password. Each user is assigned a role that defines the subset of features for which they have permission. The users with administrator roles have the responsibility to create or delete users, and to assign them the proper role. The system can be configured by the administrator to request the users a periodical change of their password. After several failed login attempts, a user becomes blocked and the intervention of the administrator is required to unblock them. All the changes to the users and their roles, as well as the login events, successful or not, are recorded in the Audit Trail. If the operator leaves the computer unattended for more than a scheduled time, the application will be blocked, requiring a new login.
					X	The customer has the responsibility to designate and empower a staff member to act as administrator of the SphereFlash® software application.

#	section of FDA 21CFR part 11	Topic	Requirement	SphereFlash® software implementation	Customer action is required to comply	Comments
12	11.10 (h)	Validity check of input data	The system must determine, as appropriate, the validity of the source of data input or operational instruction	X		The <i>Activation Key</i> for the <i>Colonies PRO</i> license is linked to the serial number of the SphereFlash® instrument of the client. No plate images acquired with devices other than this particular instrument will be admitted to be processed. The values that the operator is allowed to introduce manually, are either limited to a selection list that contains only the possible meaningful values or are numerical values that can be restricted to lie within minimum and maximum values, defined in the general settings of the application. Additionally, the <i>Remote In</i> and <i>Worksheet</i> features will enforce the application of the method and setting values required for each particular plate ID.

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