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AID Reader Systems

Product and Service Overview 2021

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AID Reader Systems comply with the requirements of "international regulatory guidelines"

Our philosophy does not allow compromises. AID GmbH not only fulfills the basic requirements under consideration of the harmonized standards.

We do more!

Based on patient safety our company wants not only the highest security but also permanently satisfied customers and first-class quality. The following document provides an overview of the commitments, standards and management systems that help us to adopt the principles implemented in our company.

IVDD 98/79/EG

Since 2006 Advanced Imaging Devices GmbH Quality Management System complies with the European Law on Medical Devices, the in vitro diagnostic directive (IVDD) 98/79/EC. IVDD covers the placing on the market and putting into service of in vitro diagnostic medical devices. Advanced Imaging Devices GmbH developed and manufactured products to meet all applicable requirements contained within the IVDD.

Medical devices - Quality management systems - Requirements for regulatory purposes
DIN EN ISO 13485 and 21CFR820

ISO 13485 is the harmonized standard for a quality management system for medical device companies. It covers for medical devices all requirements regarding process control, design control, retention of records, accountability, traceability and more. Advanced Imaging Devices GmbH is certified according to DIN EN ISO 13485. Advanced Imaging Devices GmbH's quality system also fulfils the requirements of 21CFR820 (QSR).

Risk Assessment
DIN EN ISO 14971

Medical devices - Application of risk management to medical devices. Since 2006 Advanced Imaging Devices GmbH has introduced and maintained a risk management system according to DIN EN ISO 14971 (ISO 14971).

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Medical device software - Software life cycle processes
DIN EN 62304

We offer software which is an integral part of medical devices or standalone software. Establishing the safety and effectiveness of such software requires knowledge of that the software is intended to do and demonstration that the use of the software fulfils those intentions without causing any unacceptable risks. Therefore, we follow the DIN EN ISO 62304 during the design, servicing and maintenance of our software.

Application of usability engineering to medical devices
DIN EN ISO (IEC) 62366-1

We use DIN EN ISO 62366-1 to design for high usability.

FDA 21 CFR Part 11

Part 11 of the Code of Federal Regulations defines the criteria under which electronic records and electronic signatures are considered to be trustworthy, reliable and equivalent to paper records. The software of all AID devices can be adjusted to meet these requirements.

Safety
DIN EN 61010-2-101

We meet the safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for in vitro diagnostic (IVD) medical equipment to eliminate electrical hazards to operating staff.

DIN EN 62638

We meet the safety requirements for portable electrical equipment, e.g. computer.

Electromagnetic Compatibility (EMC)
DIN EN 61326-2-6

We fulfil the requirements for electromagnetic compatibility for electrical equipment for measurement, control and laboratory use - EMC requirements.

GMP/GLP

Advanced Imaging Devices GmbH products (AID Reader Systems) are designed to work in a GMP/GLP environment according to GMP conditions. They can be adapted to individual customer wishes at any time to meet the requirements of the severe internal and external guidelines (GMP/GLP).

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Comparison of the AID Reader Systems

	AID Reader Systems						
	Classic	*i*Spot	*i*Spot Spectrum	*i*Spot Robot	*v*Spot	*v*Spot Spectrum	*multi*Spot
Assay types							
EliSpot Assay	yes	yes	yes	yes	yes	yes	yes
1-, 2- and 3- color FluoroSpot Assays	no	yes	yes	yes	no	yes	yes
Neutralization Assay	96-well	96-well	96-well	96-well	6- to 96-well	6- to 96-well	96-well
Virus Plaque Assay	96-well	96-well	96-well	96-well	6- to 96-well	6- to 96-well	96-well
Cell Counting	no	no	no	no	no	no	yes
HEp-2-screening	no	no	no	no	no	no	yes
HLA-screening	no	no	no	no	no	no	yes
Colony Counting	no	no	no	no	yes	yes	no
Other experiments	on inquiry	on inquiry	on inquiry	on inquiry	on inquiry	on inquiry	on inquiry
Plate formats							
6-, 12-, 24-, 48-well plates	no	no	no	no	yes	yes	no
96-well plates	yes	yes	yes	yes	yes	yes	yes
384-well plates	yes	yes	yes	yes	no	yes	yes
Glass slides	no	no	no	no	no	no	yes (4x)
Terasaki plates	no	no	no	no	no	no	yes
Plates per run	1	1	1	≤ 30	1	1	1
Camera resolution, megapixel (MP)	5 MP	2 MP	5 MP	2 MP	5 MP	5 & 5 MP	2 & 5 MP
Objectives	-	-	-	-	-	-	4x, 10x, 20x
Max. no. of narrow-band fluorescent filters	0	3	7	3	0	7	3 & quad band filter
Narrow-band fluorescent filters on board	0	2	3	2	0	3	3 & quad band filter
Time demand (EliSpot, 96-well plate)	≈3 min	≈3 min	≈3 min	≈3 min	≈3 min	≈3 min	≈3 min
Time demand (FluoroSpot, 96-well plate)	-	≈10 min	≈10 min	≈10 min	-	≈10 min	≈10 min

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AID Classic (ELR08)

The basic 96- and 384-well plate EliSpot Reader

This is the classic AID EliSpot Reader type. The device is fast, efficient, user-friendly and has become one of the most successful EliSpot Reader Systems on the market. The **AID Classic** interprets any type of EliSpot plate, including all brands of membrane type plates, ELISA-style plates and low volume plates. The Reader simultaneously takes high resolution images, auto centers the well and counts according to the user's settings.

Data acquisition is fully automated. Counting results and all other parameters can be exported to Word, Excel, PowerPoint, PDF or csv-files. A compact footprint of only 50 cm x 40 cm saves laboratory space.

Key features of the AID Classic

- <3 minutes for complete interpretation of an enzymatic 96-well plate (incl. image capturing, counting, analyzing and data export)
- High resolution images with a 5 megapixel, firewire connected digital camera
- LED ring illumination
- Automated plate input/output module
- Controlled by a high-end PC; QHD, 27", 16:9 monitor
- Max. 550 mA @ 24 V DC
- CE marked
- Manuals, videos and interactive help files included

EliSpot

Experience counts!

AID *i*Spot (ELR08IFL)

The basic 96- and 384-well plate EliSpot & FluoroSpot Reader

The **AID *i*Spot** is one of the most successful EliSpot/FluoroSpot Reader developments in recent years. The **AID *i*Spot** for the first time allows analyzing both: Enzymatic and fluorescent (FluoroSpot) based EliSpot assays. The **AID *i*Spot** comprises the same outstanding functionality, such as layout-generator, rule-compiler, various export possibilities etc., as the AID Classic.

Beside all of the popular functions of the AID Classic, the **AID *i*Spot** simultaneously allows for 1-, 2- or even 3-color FluoroSpot analysis. A simple "one-click switch" between enzymatic and fluorescent mode, without the need of hardware changes, is enough to switch from one mode to the other.

Key features of the AID *i*Spot

- Enzymatic and fluorescent analysis
- <3 minutes for an enzymatic EliSpot plate, ≈10 minutes for a 2-color FluoroSpot plate
- Digital firewire camera, 2 megapixels, color, optimized for fluorescence imaging
- LED ring illumination, XBO light source, 3&1 filter wheel
- 2 narrow-band hard coated fluorescent filters (FITC and Cy3) on board, third filter on request
- Optimized for 1-, 2- and 3-color fluorescent analysis
- Automated plate input/output module
- Controlled by a high-end PC; QHD, 27", 16:9 monitor
- Max. 550 mA @ 24 V DC
- CE marked
- Manuals, videos and interactive help files included

AID *i*Spot Spectrum (ELR088IFL)

The ultimate high resolution 96- and 384-well plate EliSpot/FluoroSpot Reader

The **AID *i*Spot Spectrum** is the newest generation of the successful AID *i*Spot, the first commercially available combined EliSpot/FluoroSpot Reader. The **AID *i*Spot Spectrum** is equipped with a 7&1 filter wheel, which allows for a customized selection of up to 7 individual narrow-band hard coated fluorescent filters, whilst still allowing for our "one-click switch" to analyze enzymatic EliSpot assays via LED illumination.

The insertion of a high resolution 5 megapixel digital camera provides well images of unprecedented quality. Like in AID's *i*Spot Reader System the patented FluoroAID image overlay technology permits exact detection of cells secreting multiple cytokines.

Key features of the AID *i*Spot Spectrum

- Enzymatic and fluorescent analysis
- Digital firewire camera, 5 megapixels, color, optimized for fluorescence imaging
- LED ring illumination, XBO light source, 7&1 filter wheel
- 3 narrow-band hard coated fluorescent filters on board; FITC, Cy3 and Cy5. Others on request. Up to 7 separate fluorescent filters possible
- Optimized for 1-, 2- and 3-color fluorescent analysis
- Automated plate input/output module
- Controlled by a high-end PC; QHD, 27", 16:9 monitor
- Max. 750 mA @ 24 V DC
- CE marked
- Manuals, videos and interactive help files included

AID *i*Spot Robot (ELROB08IFL)

High throughput 96- and 384-well plate EliSpot/FluoroSpot analysis

Designed for high throughput and traceable results, this is the ultimate tool for large groups of samples. The **AID *i*Spot Robot** can take up to 30 plates in one automated, walk-away process and will analyze them in less than 90 minutes. The system is designed to interpret enzymatic EliSpot assays as well as 1-, 2- and 3-color fluorescence EliSpot assays. The **AID *i*Spot Robot** simultaneously takes high resolution images, auto centers the well and counts according to user's settings.

Data acquisition is fully automated. In addition, the count results can automatically be analyzed with the integrated rule compiler.

Customized robotic AID Reader Systems able to handle other plate formats or upscale for more plates per run on request. Please contact AID for details.

Key features of the AID *i*Spot Robot

- Hands-off, walk-away system
- Automatic barcode recognition
- Integrated system, not a reader/stacker solution
- Up to 30 96-well plates in one run
- Digital firewire camera, 2 megapixels, color, optimized for fluorescence imaging
- LED ring illumination, XBO light source, 3&1 filter wheel
- 2 narrow-band hard coated fluorescent filters (FITC and Cy3) on board, third filter on request
- Optimized for 1-, 2- and 3-color fluorescent analysis
- Controlled by a high-end PC; QHD, 27", 16:9 monitor
- 120 mA @ 240 V/ 160 mA @ 110 V
- CE marked
- Manuals, videos and interactive help files included

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AID *v*Spot (VSR07)

The versatile Reader System for various plate formats

The **AID *v*Spot** is the new high-end device from AID that provides colorimetric/enzymatic multiple plate evaluation. The **AID *v*Spot** handles a variety of different assay types including EliSpot, Viral Plaque Assays and Neutralization Assays. Colony Counting is possible when performed in 6-well plate format. Due to a genuine optical zoom, versatile stage settings and unique software features this Reader System is not restricted to the analysis of 96-well plate formats. It additionally reads 6-, 12-, 24- and 48-well plates. The insertion of a high resolution digital camera provides well images of unprecedented quality.

Key features of the AID *v*Spot

- EliSpot, Viral Plaque Assays, Neutralization Assays, Colony Counting …
- <3 minutes to analyze a complete 96-well plate
- Handles 6-, 12-, 24-, 48-, and 96-well plates
- High resolution images via 5 megapixels, firewire connected digital camera
- LED ring illumination
- Controlled by a high-end PC; QHD, 27", 16:9 monitor
- 170 mA @ 240 V/ 260 mA @ 110 V
- CE marked
- Manuals, videos and interactive help files included

AID *v*Spot Spectrum (VSR078IFL)

High resolution EliSpot/FluoroSpot Reader for various plate formats

The **AID *v*Spot Spectrum** is the new high-end EliSpot/FluoroSpot device from AID. It combines AID *i*Spot Spectrum 96-well FluoroSpot analyzing with enzymatic multiple plate evaluation. On the enzymatic side the **AID *v*Spot Spectrum** can handle a variety of different assay types including Viral Plaque Assays and Neutralization Assays. Colony Counting is possible when performed in a 6-well plate format. Other formats on inquiry. Due to a genuine optical zoom, versatile stage settings and unique software features this Reader is not restricted to the analysis of 96-well plate formats. It will also read 6-, 12-, 24-, 48- and 384-well plates. The insertion of high resolution digital cameras provides well images of unprecedented quality.

The **AID *v*Spot Spectrum** is equipped with an 8 position filter wheel, which allows for a customized selection of up to 7 individual narrow-band fluorescent filters, whilst still allowing for our "one-click switch" to perform enzymatic analysis via LED illumination on different plate formats.

Key features of the AID *v*Spot Spectrum

- EliSpot, FluoroSpot, Virus Plaque Assays, Colony Counting
- <3 minutes for an enzymatic EliSpot plate, ≈10 minutes for a 2-color FluoroSpot plate
- Handles 6-, 12-, 24-, 48-, 96- and 384-well plates
- 2 digital firewire cameras,5 megapixels each, color, optimized for fluorescence imaging
- LED ring illumination, XBO light source, 7&1 filter wheel
- 3 narrow-band hard coated fluorescent filters on board; FITC, Cy3 and Cy5. Others on request. Up to 7 separate filters
- Optimized for 1-, 2- and 3-color fluorescent analysis
- Controlled by a high-end PC; QHD, 27", 16:9 monitor
- 170 mA @ 240 V/ 260 mA @ 110 V
- CE marked
- Manuals, videos and interactive help files included

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AID *multi*Spot (MSR08)

The multifunctional imaging device from AID

The **AID** *multi***Spot** fulfills probably all needs in a modern immunology lab. Equipped with a combined EliSpot/FluoroSpot module for counting and interpreting enzymatic as well as fluorescent EliSpot assays this device also comes with an automated microscope. This unit is provided with 4x, 10x and 20x software controlled objectives, allowing for a simple switch between different magnifications.

The stage handles 96- and 384-well plates, up to 4 conventional slides or classical Terasaki plates. The software is adapted to FluoroSpot/EliSpot assays, HEp-2 screening, Cell Counting, HLA-screening and many more applications.

Key features of the AID *multi*Spot

- EliSpot, FluoroSpot, Cell Viability Tests, HLA-screening, HEp-2 screening, other applications on request
- Digital firewire camera, 5 and 2 megapixels, color, optimized for fluorescence imaging
- LED ring illumination, two XBO light sources, 3&1 filter wheel, 4x, 10x and 20x objectives on a software controlled objective changer (other objectives on request)
- 3 narrow-band hard coated fluorescent filters on board; FITC, Cy3 and Cy5. Others on request
- Optimized for 1-, 2- and 3-color fluorescent analysis
- Controlled by a high-end PC; QHD, 27", 16:9 monitor
- Max. 750 mA @ 24 V DC
- CE marked
- Manuals, videos and interactive help files included

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AID *bac*Spot ML (BAC05)

System for automatic colony counting and manual load of Petri dishes

The **AID *bac*Spot ML** originally served as technology carrier and testing platform to construct illumination technologies realized in the AID *bac*Spot Robot. Due to selective inquiries the **AID *bac*Spot ML** has been adopted to the assortment and functions as automatic colony counter for smaller amounts of plates.

Based on an equivalent illumination construction and identical software compared to the AID *bac*Spot Robot, the **AID *bac*Spot ML** ensures comfortable counting and proper documentation of results. Due to the versatile software capabilities this smaller device does not stand behind the robotic system in terms of analysis or data integration.

Key features of the AID *bac*Spot ML

- **AID *bac*Spot ML** (BAC05) e.g. for 90 mm and 60 mm plates
- Automatic and manual differentiation of colonies according to size, color shape and other parameters
- Automated counting of pour plates, surface inoculated plates, spiral and membrane filtration plates, settle plates etc.
- Easy loading of single plates
- User defined counting rule generator and prefixed rules (e.g. APC-counting)
- Zone sizing module for antibiotic resistance testing
- Compatibility to all LIMS systems using .csv format and flexible integration into customer workflows (data export to Excel, data merging etc.)
- Sophisticated illumination techniques using bright field (reflected and transmitted light) and dark field illumination
- Audit trail and integrated quality control module

AID *bac*Spot Robot (BACROB096 & BACROB099)

Robotic Systems for automatic colony counting, processing and sorting of Petri dishes

The **AID *bac*Spot Robot** enables automatic processing of large numbers of Petri dishes in a single run. Two different versions are available to cover the use of 60 mm Petri dishes (BACROB096) and 90 mm Petri dishes (BACROB099) respectively.

Each **AID *bac*Spot Robot** can easily be loaded batch wise and is able to sort plates into negative and positive ones depending on selectable threshold numbers of colonies. The device is equipped with two rotating carrousels for uptake and deposition of Petri dishes.

To allow convenient loading or even incubation in your incubation chamber both carrousels can be removed/returned with one single grip. As a customizable product the **AID *bac*Spot Robot** and its software algorithms can be flexible adapted to customer specific requirements to ensure optimal counting results.

Key features of the AID *bac*Spot Robot

- **AID *bac*Spot Robot** (BACROB096) for 60mm plates processes up to 200 plates/h and 150 plates/run (depending on plate height)
- **AID *bac*Spot Robot** (BACROB099) for 90mm plates processes up to 250 plates/h and 100 plates/run (depending on plate height)
- Automatic and manual differentiation of colonies according to size, color, shape and many other parameters
- Customizable system, i.e. algorithm adaptations to customer specific colony morphologies
- Automated counting of pour plates, surface inoculated plates, spiral and membrane filtration plates, settle plates etc.
- Separation of negative and positive plates depending on user defined counting thresholds
- Easy loading of batches and removable carrousels
- User defined counting rule generator and prefixed rules (e.g. APC counting)
- Zone sizing module for antibiotic resistance testing
- Compatibility to all LIMS systems using .csv format and flexible integration into customer workflows (data export to Excel, data merging etc.)
- Sophisticated illumination techniques using bright field (reflected and transmitted light) or dark field illumination
- Audit trail and integrated quality control module

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Service Overview

AID Reader System Protection Packages

AID GmbH offers AID Reader System Protection Packages for AID Reader Systems to cover Preventative Maintenance visits, software updates, user training, system checks and repair. During the visit an AID service engineer will processes a hardware and software performance check on costumer site and provide a certificate about system conditions.

Please contact AID for details.

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Special Features

- **LED light source** for all AID Reader Systems with **fluorescence** applications. Advantages: Longer life time and less plate handling time - available on request

- **Apple iMAC Versions** for all AID Reader Systems - available on request

- **Uninterruptible Power Supply**, UPS - available on request

- **Barcode Scanner** - available on request

- **Punched Membrane Frame**. For customers who like to reanalyze assays where membranes were punched out of their plastic frame - available on request

- **Customized AID Reader Systems**. Please discuss tailor-made options with us

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System Description

The AID Reader Systems are computer-based systems for the (semi)automatic interpretation of colorimetric assays in 6-, 12-, 24-, 48-, 96- and 384-well plates, as well as of fluorescent assays with up to three colors per well in 96-wel plates (Plate formats are dependent on the AID Reader System model used. For an overview of the available AID Reader Systems please refer to our homepage www.aid-diagnostika.com or our AID Product Overview brochure.).

AID Reader Systems are designed for routine usability, to give reproducible results in very little time. They work with all standard flat bottom 6-, 12-, 24-, 48-, 96- and 384-well plates (others on request).

AID Reader Systems are equipped to read, interpret and digitally store EliSpot-, FluoroSpot- and other data.

Since different types of assays give characteristic spot/plaque/foci/colony/… patterns, individual Count Settings for each assay type will be created, modified and selectively applied by the user.

AID Reader Systems consist of a Reader Unit that acquires the images of each well of the plate, and a Control Unit connected to the Reader.

The Reader Unit contains a high-end digital camera and a scanning stage which positions the wells in the camera view.

The Control Unit consists of PC and Software equipped to run the Reader Unit.

Each AID Reader System is delivered as a complete functioning system which also includes monitor, keyboard, mouse, QC plate, USB stick, AID Software Card and User Guide.

Do not replace any of these items without first contacting AID GmbH, as this may impair system performance. The PC must not be used to run software or equipment not supplied by AID GmbH. AID GmbH will assume no responsibility for this and warranty will be impaired.

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Legal

Registergericht Stuttgart, HRB 401435

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IVD

Attention:
Due to the more restrictive regulations by the U.S. Food and Drug Administration (FDA), the IVD label is not applicable for the U.S. American market and markets that apply respective FDA regulations.

For the US, China and the countries that do not apply the European IVD directive AID Reader Systems are to be applied as RUO.