AID Autoimmun Diagnostika GmbH
Ebinger Str. 4
D-72479 Strassberg

AID Reader Systems

Product and Service Overview 2024

Homepage Version

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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.

IVDR (EU) 2017/746

Advanced Imaging Devices GmbH Quality Management System complies with the standard harmonized by European Law on Medical Devices. Since May 2022, the in vitro diagnostic regulation IVDR (EU) 2017/746 governs the requirements for in vitro diagnostic devices and related service. The products developed and manufactured by Advanced Imaging Devices GmbH complies with the relevant general requirements of the IVDR.

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).

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 **ELR09**	***i*Spot** **ELR09IFL**	***i*Spot Spectrum** **ELR098IFL**	***i*Spot Robot** **ELROB08IFL**	***v*Spot** **VSR09**	***v*Spot Spectrum** **VSR098IFL**	***multi*Spot** **MSR08**
Assay types							
EliSpot Assay, single color	yes	yes	yes	yes	yes	yes	yes
EliSpot Assay, double color	yes	yes	yes	yes	yes	yes	yes
FluoroSpot Assays (maximum number of color overlays)	no	yes (4)	yes (5)	yes (3)	no	yes (5)	yes (3)
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)	6.3 MPs	2.3 MPs	5 MPs	2 MPs	6.3 MPs	5 & 6.3 MPs	2 & 5 MPs
Light sources							
Internal white light LED light source	yes	yes	yes	yes	yes	yes	yes
Internal bottom white light LED light source	optional	optional	optional	no	optional	optional	no
External fluorescent light source	no	yes	yes	yes	no	yes	yes
Max. no. of fluorescent narrow-band filters	0	4	7	4	0	7	3 & quad band filter
Fluorescent narrow-band filters on board	0	2	3	2	0	3	3 & quad band filter
Objectives	-	-	-	-	-	-	4x, 10x, 20x
Time demand (EliSpot, 96-well plate)	≈2 min	≈2 min	≈2 min	≈2 min	≈2 min	≈2 min	≈2 min
Time demand (2- color FluoroSpot, 96-well plate)	-	<7 min	<7 min	<7 min	-	<7 min	<7 min

AID Classic (ELR09)

The basic AID Reader System for colorimetric assays in 96- and 384-well plate formats

This is the classic AID Reader type. The device is fast, efficient, user-friendly and has become one of the most successful Reader Systems on the market. The **AID Classic** enables the analysis of any type of EliSpot plate, including all brands of membrane type plates and ELISA-style plates via the Calibration module. 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, images and all other parameters can be exported to Excel, PDF or CSV-files.

Key hardware features of the AID Classic

- ≈2 minutes for complete interpretation of a colorimetric 96-well plate (incl. image capturing, counting and data export)
- High resolution images via 6.3 megapixels, USB 3.0 connected, digital color camera
- Software controlled internal white-light LED ring illumination
- Optional white light LED bottom light
- Automated plate input/output module
- Controlled by high-end PC; QHD monitor, 16:9, 27"
- CE marked

Key software features - AID EliSpot V8.1

- 4 Level User Management
- Single Well View, Plate View and open Plates container on one screen
- Improved Classification module
- Automated data export (images in jpg.; data in .csv, .xlsx, .pdf)

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AID *i*Spot (ELR09IFL)

The basic AID Reader System for colorimetric assays in 96- and 384-well plate- and fluorescent assays in 96-well plate format

The **AID *i*Spot** is one of the most successful hybrid Reader Systems on the market. The **AID *i*Spot** was the first Reader System that allowed analyzing both: Colorimetric EliSpot and multi-color fluorescent FluoroSpot assays. The **AID *i*Spot** comprises the same outstanding functionality as the AID Classic and additionally adds analysis of multi-color fluorescent assays.

The **AID *i*Spot** allows for colorimetric and 1-, 2-, 3- or even 4-color fluorescent assay analysis.

Key features of the AID *i*Spot

- Colorimetric (96- and 384-well plate format) and fluorescent analysis (96-well plate format)
- ≈2 minutes for a colorimetric EliSpot plate, <7 minutes for a 2-color FluoroSpot plate
- Digital color camera, 2.3 megapixels, USB 3.0 connected
- Software controlled internal white-light LED ring illumination, XBO fluorescence light source, 4&1 filter wheel
- Optional white-light LED bottom light
- 2 narrow-band hard coated fluorescent filters (FITC & Cy3) on board, third and fourth filter optional
- Automated plate input/output module
- Controlled by high-end PC; QHD monitor, 16:9, 27”
- CE marked

Key software features - AID EliSpot V8.1

- 4 Level User Management
- Single Well View, Plate View and open Plates container on one screen
- Up to 4-color multiplexing in FluoroSpot
- Improved Classification module
- Count Combinations module (For spot sub-class calculation in multiplex FluoroSpot assays.)
- Automated data export (images in jpg.; data in .csv, .xlsx, .pdf)

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AID *i*Spot Spectrum (ELR098IFL)

The high-end AID Reader System for colorimetric assays in 96- and 384-well plate- and fluorescent assays in 96-well plate format

The **AID *i*Spot Spectrum** is the high-end model 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 positions filter/LED changer, which allows for a customized selection of up to 7 individual narrow-band hard coated fluorescent filters, whilst still allowing to analyze colorimetric assays.

The insertion of a high resolution 5 megapixels digital camera provides well images of unprecedented quality.

Key features of the AID *i*Spot Spectrum

- Colorimetric (96- and 384-well plate format) and fluorescent analysis (96-well plate format)
- ≈2 minutes for a colorimetric EliSpot plate, <7 minutes for a 2-color FluoroSpot plate
- Digital color camera, 5 megapixels, USB 3.0 connected
- Software controlled internal white-light LED ring illumination, XBO fluorescence light source, 7&1 positions filter wheel
- Optional white-light LED bottom light
- 3 narrow-band hard coated fluorescent filters (FITC & Cy3 & Cy5) on board; fourth, fifth, sixth and seventh filter optional
- Automated plate input/output module
- Controlled by high-end PC; QHD monitor, 16:9, 27”
- CE marked

Key software features - AID EliSpot V8.1

- 4 Level User Management
- Single Well View, Plate View and open Plates container on one screen
- Up to 5 color multiplexing in FluoroSpot
- Improved Classification module
- Count Combinations module (For spot sub-class calculation in multiplex FluoroSpot assays.)
- Automated data export (images in jpg.; data in .csv, .xlsx, .pdf)

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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 colorimetric 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.

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 and fourth filter on request
- Optimized for 1-, 2- and 3-color fluorescent analysis
- Controlled by a high-end PC; QHD monitor, 16:9, 27"
- 120 mA @ 240 V/ 160 mA @ 110 V
- CE marked

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AID *v*Spot (VSR09)

The versatile AID Reader System for colorimetric assays in various plate formats

The **AID *v*Spot** provides analysis of colorimetric assays in multiple plate formats. 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 assays in 96-well plate formats, additionally it reads 6-, 12-, 24- and 48-well plates.

Key hardware features of the AID *v*Spot

- Analysis of EliSpot, Viral Plaque Assays, Neutralization Assays, Colony Counting …
- ≈2 minutes for complete interpretation of a colorimetric 96-well plate (incl. image capturing, counting and data export)
- High resolution images via 6.3 megapixels, USB 3.0 connected, digital color camera
- Software controlled internal white-light LED ring illumination
- Optional white light LED bottom light
- Automated plate input/output module
- Controlled by high-end PC; QHD monitor, 16:9, 27”
- CE marked

Key software features - AID EliSpot V8.1

- 4 Level User Management
- Single Well View, Plate View and open Plates container on one screen
- Improved Classification module
- Automated data export (images in jpg.; data in .csv, .xlsx, .pdf)

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AID *v*Spot Spectrum (VSR098IFL)

The versatile, high-end AID Reader System for colorimetric assays in various plate formats and fluorescent assays in 96-well plate format

The **AID *v*Spot Spectrum** is the high-end Reader System from AID. It combines AID *i*Spot Spectrum 96-well FluoroSpot analyzing with colorimetric multiple plate evaluation. Due to a genuine optical zoom, versatile stage settings and unique software features this Reader is not restricted to the analysis of assays in 96-well plate format. It will also read 6-, 12-, 24-, 48- and 384-well plates. The **AID *v*Spot Spectrum** is equipped with a 7&1 positions filter/LED changer, which allows for a customized selection of up to 7 individual narrow-band fluorescent filters.

The insertion of high-resolution digital cameras provide well images of unprecedented quality.

Key features of the AID *v*Spot Spectrum

- Colorimetric (6-, 12-, 24-, 48-, 96- and 384-well plate format) and fluorescent analysis (96-well plate format)
- ≈2 minutes for a colorimetric EliSpot plate, <7 minutes for a 2-color FluoroSpot plate
- 2 digital color camera, 5 & 6.3 megapixels, USB 3.0 connected
- Software controlled internal white-light LED ring illumination, XBO fluorescence light source, 7&1 positions filter wheel
- Optional white-light LED bottom light
- 3 narrow-band hard coated fluorescent filters (FITC & Cy3 & Cy5) on board; fourth, fifth, sixth and seventh filter optional
- Automated plate input/output module
- Controlled by high-end PC; QHD monitor, 16:9, 27”
- CE marked

Key software features - AID EliSpot V8.1

- 4 Level User Management
- Single Well View, Plate View and open Plates container on one screen
- Up to 5-color multiplexing in FluoroSpot
- Improved Classification module
- Count Combinations module (For spot sub-class calculation in multiplex FluoroSpot assays.)
- Automated data export (images in jpg.; data in .csv, .xlsx, .pdf)

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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 colorimetric 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

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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.

Special Features

- **LED light source** for all AID Reader Systems with **fluorescence** applications.
  Advantage: Longer lifetime (about 40x longer lifetime than Xenon light source)

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

- **Barcode Scanner** - available on request

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-well 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, AID QC plate, 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.

Manufacturer details

Manufacturer AID Reader Systems

Advanced Imaging Devices GmbH
Ebinger Str. 4
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GERMANY

VAT Number

DE246217077

Legal

Registergericht Stuttgart, HRB 401435

Due to different requirements in the regulation of medical devices in countries worldwide, the IVD label is not applicable for US market and countries related to FDA regulations. For US, China and other countries which do not apply to European IVD Regulation the AID Reader Systems are intended to be used as RUO.