

AID Reader Systems

Product and Service Overview 2017

Compliance Page 2

Comparison of the different AID Reader Systems Page 5

AID Reader Systems

AID Classic (ELR08) Page 6

AID *iSpot* (ELR08IFL) Page 7

AID *iSpot* Spectrum (ELR088IFL) Page 8

AID *iSpot* Robot (ELROB08IFL) Page 9

AID *vSpot* Spectrum (VSR078IFL) Page 10

AID *multiSpot* (MSR08) Page 11

AID *bacSpot* (BAC04) Page 12

AID *bacSpot* Robot (BACROB08) Page 13

Service Overview

Preventative Maintenance Contracts Page 14

Service Contracts Page 14

Special Features Page 15

AID Assays Page 16

Manufacturer Page 18

AID Reader Systems comply with the requirements of the “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.

CE - Declaration of conformity IVDD 98/79/EG

Since 1998 AID's QM (Quality Management) complies with the European Law on Medical Devices (Medizinproduktegesetz), particularly with the in vitro diagnostic directive (IVDD) 98/79/EC (Instruction, Technical Documentation depended on product). IVDD covers the placing on the market and putting into service of in vitro diagnostic medical devices. AID GmbH developed and manufactured products meet all of the relevant essential requirements contained within the IVDD. AID GmbH products carrying the CE sign can be sold without further validation anywhere in the European Union.

Medical devices - Quality management systems - Requirements for regulatory purposes

DIN EN ISO 13485

ISO 13485 is a quality system standard designed specifically for medical device companies. The ISO 13485 standard supplements ISO 9001 and has many of the same requirements. However, there are additional requirements for process control, design control, retention of records, accountability, traceability and more. AID GmbH is certified according to DIN EN ISO 13485.

ISO 13485 and 21 CFR Part 820 are harmonized.

Quality management systems - Requirements

DIN EN ISO 9001

ISO 9001 is a standard for quality management systems. It is designed to help organizations ensure that they meet customers' needs. AID GmbH is certified according to DIN EN ISO 9001.

Risk Assessment

DIN EN ISO 14971

Medical devices - Application of risk management to medical devices. AID GmbH is certified according to DIN EN ISO 14971 since 2003.

Medical device software - Software life cycle processes

DIN EN 62304

Software is often an integral part of medical device technology. Establishing the safety and effectiveness of a medical device containing 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.

Application of usability engineering to medical devices

IEC 62366-1

IEC 62366 is a process-based standard that aims to help manufacturers of medical devices to design for high usability replace ISO/IEC 60601-1-6: Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: 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

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

Safety requirements for portable electrical equipment, e.g. computer.

Electromagnetic Compatibility (EMC)

DIN EN 61326-2-6

Electrical equipment for measurement, control and laboratory use - EMC requirements.

Environmental Aspects

RoHS Directive 2011/65/EU - Restriction of Hazardous Substances

This Directive restricts the use of potentially hazardous substances in electro-technical and electronic equipment (limits for the permissible levels), to ensure the required level of protection for people's health and environment.

WEEE - Waste of Electrical and Electronic Equipment directive 2012/19/EU

The WEEE Directive set collection, recycling and recovery targets for all types of electrical goods.

Instruction, Technical Documentation

AID Reader Systems technical documentation are generated during the product life cycle and refers to different documents with product related data and information such as product definition and specification, design, manufacturing, quality assurance, description of features, interfaces, service and repair of a technical product as well as its safe disposal.

For a detailed manual we refer to the User Guide inter alia.

GMP/GLP

GMP is as a quality standard included in the German Law on Pharmaceutical Products (Arzneimittelgesetz). AID 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).

Comparison of the AID Reader Systems

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

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, fire wire connected digital camera
- LED ring illumination
- Automated plate input/output module
- Controlled by a high-end PC; 23" 16:9 screen
- Max. 550 mA @ 24 V DC
- CE, DIN EN ISO 9001, DIN EN ISO 13485 certified
- Manuals, videos and interactive help files included

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 megapixel, 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; 23” 16:9 screen
- Max. 550 mA @ 24 V DC
- CE, DIN EN ISO 9001, DIN EN ISO 13485 certified
- 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 megapixel, 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; 23" 16:9 screen
- Max. 750 mA @ 24 V DC
- CE, DIN EN ISO 9001, DIN EN ISO 13485 certified
- 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 megapixel, 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; 23" 16:9 screen
- 120 mA @ 240 V/ 160 mA @ 110 V
- CE, DIN EN ISO 9001, DIN EN ISO 13485 certified
- Manuals, videos and interactive help files included

AID vSpot Spectrum (VSR078IFL)

High resolution EliSpot/FluoroSpot Reader for various plate formats

The **AID vSpot Spectrum** is the new high-end EliSpot/FluoroSpot device from AID. It combines AID iSpot Spectrum 96-well FluoroSpot analyzing with enzymatic multiple plate evaluation. On the enzymatic side the **AID vSpot 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 vSpot 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 vSpot 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 megapixel 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; 23" 16:9 screen
- 170 mA @ 240 V/ 260 mA @ 110 V
- CE, DIN EN ISO 9001, DIN EN ISO 13485 certified
- Manuals, videos and interactive help files included

AID *multiSpot* (MSR08)

The multifunctional imaging device from AID

The **AID *multiSpot*** 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 *multiSpot*

- EliSpot, FluoroSpot, Cell Viability Tests, HLA-screening, HEp-2 screening, other applications on request
- Digital Firewire Camera, 5 and 2 megapixel, 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; 23" 16:9 screen
- Max. 750 mA @ 24 V DC
- CE, DIN EN ISO 9001, DIN EN ISO 13485 certified
- Manuals, videos and interactive help files included

AID bacSpot (BAC04) - Technical Specifications

Hardware	
PC system	High-end PC with Intel Core i5 processor, 8 GB RAM, 500 GB hard disk 23" 16:9 screen
Illumination	Evenly spread, long life LED ring illumination, transmitted and reflected light
Camera resolution and control	5 megapixel, color, firewire-connected
Power input	40 mA @ 240 V/ 50 mA @ 110 V
Footprint	420x320x300 mm (Peripherals not included)
Barcode	On demand
Software	
Operating system	Windows 10 Professional (64 bit). W7 on request
AID Software	AID BacSpot V2.x
MS Office Version	MS Office 2010 Professional or higher
Additional software solutions included	Colony Counting Software, Zone Sizing Software
Plate formats and assays	
Applicable assays	Colony Counting, Zone Sizing (Agar diffusion test)
Plate formats	60 mm & 90 mm Petri dishes. Others after consultation
Certifications/ Validations	
DIN EN ISO 13485:2012 + AC:2012	Yes
DIN EN ISO 9001:2008-12	Yes
DIN EN ISO 14971:2013-04	Yes
DIN EN 62304 (VDE 0750-101):2013-10	Yes
EN 61010-2-101:2002	Yes
DIN EN 62638:2010 -08 (VDE 701/702)	Yes
DIN EN 61326-2-6 (VDE 0843-20-2-6): 2006-10	Yes
CE	Yes
FDA 21 CFR Part 11	After consultation
Miscellaneous	
Max. colonies per plate	up to 5,000
Colony resolution	≥ 0.07 mm
Measurement per plate	1 sec
Software licenses	2 additional software licenses included
Warranty	2 years warranty, Service and Preventative Maintenance Contracts available
Delivery schedule	4-6 weeks after ordering
Installation & on-site training	Included in quoted price

AID bacSpot Robot (BACROB08) - Technical Specifications

Hardware	
PC system	High-end PC with Intel Core i7 processor, 16 GB RAM, ≥ 1TB hard disk 23" 16:9 screen
Illumination	Evenly spread, long life LED ring illumination, transmitted and reflected light
Camera resolution and control	5 megapixel, color, firewire-connected
Power input	Max. 900 mA @ 24 V DC
Footprint	800x950x500 mm (Peripherals not included)
Barcode	Integrated, automatic
Software	
Operating system	Windows 10 Professional (64 bit). W7 on request
AID Software	AID BacSpot V2.x
MS Office Version	MS Office 2010 Professional or higher
Additional software solutions included	Colony Counting Software, Zone Sizing Software
Plate formats and assays	
Applicable assays	Colony Counting, Zone Sizing (Agar diffusion test)
Plate formats	60 mm or 90 mm Petri dish. Others after consultation
Certifications/ Validations	
DIN EN ISO 13485:2012 + AC:2012	Yes
DIN EN ISO 9001:2008-12	Yes
DIN EN ISO 14971:2013-04	Yes
DIN EN 62304 (VDE 0750-101):2013-10	Yes
EN 61010-2-101:2002	Yes
DIN EN 62638:2010 -08 (VDE 701/702)	Yes
DIN EN 61326-2-6 (VDE 0843-20-2-6): 2006-10	Yes
CE	Yes
FDA 21 CFR Part 11	After consultation
Miscellaneous	
Max. colonies per plate	up to 5,000
Max. plates per run	100-160
Plates per hour	~ 150-250
Colony resolution	≥ 0.07 mm
Measurement per plate	1-5 sec
Software licenses	2 additional software licenses included
Warranty	2 years warranty, Service and Preventative Maintenance Contracts available
Delivery schedule	4-6 weeks after ordering
Installation & on-site training	Included in quoted price

Service Overview

Preventative Maintenance Contracts

AID GmbH offers PM Contracts for AID Reader Systems to cover Preventative Maintenance Visits during manufacturer's warranty period. During the visit an AID service engineer will process a hardware and software performance check on customer site and provide a certificate about system conditions.

Please contact AID for details.

Service Contracts

AID GmbH offers different Service Contracts for AID Reader Systems that are past manufacturer's warranty.

Please contact AID for details.

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

AID Assays

AID offers CE-marked ready to use 96-well plate EliSpot/FluoroSpot assays, pre-coated with primary antibody, in a complete kit containing secondary antibody, conjugate and substrate.

In addition, AID also provides a selection of CE-marked ready to use kits for routine diagnostics, specific antigens are already included.

EliSpot Kits - all CE-marked

Customized kits available

Art.-No.	Product	Format
Human	EliSpot Kits	
ELSP 5000	Interferon- γ	1 x 96-well plate
ELSP 5050	Interleukin-2	1 x 96-well plate
ELSP 5060	Interleukin-4	1 x 96-well plate
ELSP 5010	Interleukin-5	1 x 96-well plate
ELSP 5040	Interleukin-10	1 x 96-well plate
ELSP 5082	Interleukin-17	1 x 96-well plate
ELSP 5500	Interferon- γ	1 x 96-well strip plate
ELSP 5650	Interleukin-2	1 x 96-well strip plate
ELSP 5660	Interleukin-4	1 x 96-well strip plate
ELSP 5610	Interleukin-5	1 x 96-well strip plate
ELSP 5400	Interleukin-10	1 x 96-well strip plate
ELSP 5682	Interleukin-17	1 x 96-well strip plate

Art.-No.	Product	Format
Human	iSpot (FluoroSpot) Kits	
ELSP 5710	Interferon- γ + Interleukin-2	1 x 96-well plate
ELSP 5720	Interferon- γ + Interleukin-5	1 x 96-well plate
ELSP 5730	Interferon- γ + Interleukin-17	1 x 96-well plate
ELSP 6000	IFN- γ + Interleukin-2 + Interleukin-17	1 x 96-well plate
ELSP 5810	Interferon- γ + Interleukin-2	1 x 96-well strip plate
ELSP 5820	Interferon- γ + Interleukin-5	1 x 96-well strip plate
ELSP 5830	Interferon- γ + Interleukin-17	1 x 96-well strip plate
ELSP 6100	IFN- γ + Interleukin-2 + Interleukin-17	1 x 96-well strip plate

Art.-No.	Product	Format
Human	B-cell EliSpot Kits	
ELSP 5210	B-cell EliSpot Assay - IgG	1 x 96-well plate
ELSP 5220	B-cell EliSpot Assay - IgA	1 x 96-well plate
ELSP 5230	B-cell EliSpot Assay - IgM	1 x 96-well plate
ELSP 5310	B-cell EliSpot Assay - IgG	1 x 96-well strip plate
ELSP 5320	B-cell EliSpot Assay - IgA	1 x 96-well strip plate
ELSP 5330	B-cell EliSpot Assay - IgM	1 x 96-well strip plate
Human	EliSpot Quality Control Kits	
ELSP 5150	EliSpot performance Kit PBMC	
ELSP 5160	EliSpot performance Kit blood	

EliSpot Kits for routine diagnostics – all CE-marked

Art.-No.	Product
ELSP 5510	LymeSpot Interferon- γ assay for the detection of Borrelia specific T-cells.
ELSP 5520	EBVSpot Interferon- γ assay for detection of Epstein-Barr-Virus (EBV) specific T-cells.

EliSpot Antigens

Art.-No.	Product
	Bacterial Antigens
ELSP 5905	Borrelia B31 Lysate
ELSP 5946	Borrelia OSP-Mix
ELSP 5919	Borrelia OSP C
ELSP 5958	Borrelia miyamotoi
ELSP 5903	PPD (Tuberculin)
ELSP 5922	Chlamydia trachomatis Lysate
ELSP 5923	Chlamydia pneumoniae Lysate
ELSP 5981	Ehrlichia Proteins
ELSP 5949	Yersinia YOP's
ELSP 5912	Helicobacter Lysate
ELSP 5962	Mycoplasma pneumoniae
ELSP 5963	Babesia microti
ELSP 5964	Bartonella henselae

Art.-No.	Product
	Fungi
ELSP 5950	Aspergillus Peptide-Mix 1
ELSP 5951	Aspergillus Peptide-Mix 2
ELSP 5915	Candida Lysate
	Mitogens
ELSP 5901	PHA-P (Phytohaemagglutinin)
ELSP 5904	Pokeweed mitogen
	Viral Antigens
ELSP 5909	EBV Lysate
ELSP 5938	EBV Lytic-Mix
ELSP 5939	EBV Latent-Mix
ELSP 5924	EBV Peptide-Mix
ELSP 5916	HSV 1 Lysate
ELSP 5917	HSV 2 Lysate
ELSP 5956	BKV Peptide-Mix VP1
ELSP 5957	BKV Peptide-Mix LT
ELSP 5965	Varicella zoster Virus (gE)
ELSP 5935	CEF Pool
	Miscellaneous
ELSP 5941	LFA-1 Peptide-Mix

Manufacturer

AID Reader Systems

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AID Assays

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