GenASIs

Pre-Installation Guide

DOC000295 Rev.J

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1 Conventions in this Guide

Certain symbols, fonts and language are used throughout this guide. Below is a list of these conventions.

Document Conventions	
	**Note**: Highlights helpful information immediately above or below an instruction.
	**Caution:** Indicates potential damage to hardware or software, or loss of data.
	**Warning:** This symbol warns of situations that could result in loss of life or severe injury. Be sure to read and follow all information presented.
	**Attention:** This symbol points out information that can affect the outcome of the procedure and is therefore worth special attention.
	**Tip**: This symbol supplies useful advice intended to simplify the procedure at hand.

2 General Guidelines

Read the following warnings carefully before operating any part of GenASIs Platform.

ATTENTION

Federal law restricts the sale of this device to sale by or on the order of a Physician. For in vitro diagnostic use:

- Only trained personnel are authorized to use ASI software or to operate the required hardware during the use of these product.
- Results acquired using this product must always be reviewed by a qualified Pathologist.
- Limitations:
  - This device has not been tested, or its safety and effectiveness validated using remote access, when used with a personal computer (PC) from home or with a mobile/handheld device.
  - According to the 1988 Clinical Laboratory Improvement Amendments (CLIA '88), each laboratory that introduces an FDA cleared system must demonstrate that it can obtain performance specifications comparable to those established by the manufacturer. Please see "Performance Characteristics" below to review those specifications.
  - As with any change in diagnostic methodology, and especially one that relies on visual interpretation of complex images, a transition from conventional microscopy to digital microscopy presents the possibility of unintended, but systematic changes in diagnostic performance. Users should be aware that their IHC categorizations may be biased when switching from conventional to digital microscopy and as such; training beyond self-study should be undertaken as needed to assure concordance before clinical adoption of the device. The laboratory is responsible for ensuring that concordance goals are reached and maintained.

- The system must be installed and serviced only by qualified personnel authorized by ASI Ltd. The operator of the system is not authorized to remove or open system covers, panels, or plugs without instructions from ASI. Any unauthorized installation and service renders the product warranty null and void.
- The system may not be modified in any way without written approval from ASI Ltd. Any unauthorized modification renders the product warranty null and void.
- User-provided programs or scripts are not validated or warranted by ASI Ltd. Use of data obtained using such programs or scripts is the sole responsibility of the user. Problems arising from use of non-ASI programs or scripts are not covered by the warranty. Users exchanging files should be aware of the risk of software viruses.
- Operators of the system must be fully qualified and professionally trained to do so and must read and fully understand the user guide before operating the system. The user guide should be kept at hand and reviewed periodically. However, reading the guide does not qualify the reader to operate, test or calibrate the system.

CAUTION

- Avoid positioning the system in direct sunlight or near any other heat source, near moisture or excessive humidity, or near magnetic objects.
- To provide sufficient electrical grounding for prevention of electric shock, plug the three-conductor AC power cables provided with the system into a UL-approved, three-contact electrical outlet. Do not use an adapter to plug the system into an ungrounded outlet. Verify that the main plug and socket are easily accessible when positioning the equipment.
- The owner should ensure continuous power supply to the system, with voltage and current according to the product specifications. If power failures occur regularly, UPS (Uninterrupted Power Supply) should be installed to prevent loss of data.
- Do not operate the system if worn wire or open leads are detected.
- Do not move the computer while it is running, or within one minute of turning it off.
- Do not operate the system in the presence of flammable or explosive liquids, vapours, or gases such as flammable anaesthetic, oxygen, or nitrous oxide. Do not plug in or turn on the system if hazardous substances are detected in the environment. If flammable substances are detected after the system is turned on, first evacuate and ventilate the area and then turn off and unplug the system.

- Verify that the on-site fire extinguisher is approved for use on electrical caused fires.
- In the event of hardware failure that could cause smoke or fire, turn off the power and unplug the power cords of all subsystems.
- Do not block the ventilation ports of electronic equipment. Always maintain at least 6 inch/15 cm clearance around the ventilation ports to prevent overheating and damage to the electronic hardware. Do not place any object on top of the system monitor.
- Do not place any objects on top of the system.
- Do not place fluids or food on any part of the system.
- Be aware that high-frequency electrical signals may interfere with pacemaker function.

CAUTION

- In the event of hardware failure that could cause smoke or fire, turn off the power and unplug the power cords of all subsystems.
- Do not block the ventilation ports of electronic equipment. Always maintain at least 6 inch/15 cm clearance around the ventilation ports to prevent overheating and damage to the electronic hardware. Do not place any object on top of the system monitor.
- Do not place any objects on top of the system.
- Do not place fluids or food on any part of the system.
- Be aware that high-frequency electrical signals may interfere with pacemaker function.
- To ensure proper operation of the system, archiving procedures from the hard drive must be performed on a regular basis.

3 Regulatory Compliance

The equipment complies with the requirements of the following EMC and safety standards:

- IEC EN 61326-1
- IEC/EN 61326-2-1
- IEC/EN 61010-1
- IEC 61010-2-101

3.1 Electromagnetic Compatibility - Emission

The system complies with the emission limits of Group 1 Class A Devices as stated in

- IEC EN 61326-1 and

- FCC Part 15 Subpart B.

Note:

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

If the equipment is found to cause interference, qualified service personnel should attempt to correct the problem by one or more of the following measures:

- Re-orientation or relocation of the affected device(s)
- Increased separation between the equipment and the affected device
- Communication with the point-of-purchase or service representative for further suggestions.

3.2 Electromagnetic Compatibility - Immunity

To comply with the regulations on electromagnetic interference for a Group 1 Class A Medical Device, all cables to peripheral devices must be shielded and properly grounded. Use of cables that are improperly shielded and grounded may result in the equipment causing radio frequency interference in violation of the local regulations. The manufacturer is not responsible for any interference caused by use of cables that are not recommended, or by unauthorized changes or modifications to this equipment.

This equipment may be exposed to electromagnetic and electrostatic interference. To ensure a high level of reliability when exposed to such interference, this equipment complies with immunity requirements. Do not use devices that intentionally transmit RF signals, such as cellular phones, transceivers, or radio-controlled products, in the vicinity of this equipment as it may cause performance outside the published specifications. Keep the power of these devices turned off, when they are located near the system.

CAUTION

External disturbance might cause freeze on the display monitor.
GenASIs application restart is required to restore normal operation.

3.3 EU Conformance

This product conforms with the requirements of the applicable requirements of IVDR (EU) 2017/746 concerning in-vitro diagnostic medical devices and legacy medical devices, and is registered with EUDAMED.

This product complies with last amended requirements of:

- Annex VII of EC-Directive 2015/863 (of 31 March 2015), the Council Directive 2011/65/EC (of 08 June 2011), concerning RoHS
- Annexes of EC-Directive, the Council Directive 2012/19/EC of 04 July 2012, concerning, WEEE

Therefore bears the CE mark of conformity.

3.4 Australian ATG Conformance

This product conforms with the applicable requirements of Essential Principles on the safety and performance of medical devices and Clause 1.8 of Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002 relating to ASs Interactive software IVD medical device, ARTG ID – 293777.

3.5 Canada Health Conformance

This product conforms with the applicable Safety and Effectiveness Requirements of the latest version of Canadian Medical Devices Regulations SOR/98-282, relating to ASI IVD Medical Device.
- License No. – 76013.

3.6 USA FDA Conformance

This product conforms with the applicable requirements of USA FDA 21 CFR Part 801, Part 803, Part 806, Part 807, and Part 809, relating to ASI IVD Medical Devices. ASI IVD device is listed with FDA in its website.

- Market authorization No. - K012103, K050236, K071398, K101291, K110345, K122554, K140957

3.7 UK Conformance

The product conforms with the applicable requirements of the UK MDR (2002) as amended by MDR (2020) and is registered with the UK MHRA.

3.8 HIPAA and GSPR Compliance

ASI manages and assures the privacy, security and integrity of patient data embedded in ASI products and is committed to conformance to all the related HIPAA regulations and GDPR (EU) 2016/679. ASI's products are designed to facilitate HIPAA and GDPR compliance by providing customizable solutions to protect patients' privacy and confidentiality.

4 General Maintenance

ASI comprehensively tests the software configuration of its products. After proper installation by qualified personnel, no further maintenance or calibration is required. For optimal functioning of the system, make sure that the microscope is properly maintained according to the manufacturer's instructions.

CAUTION

It is not allowed to install any third-party software, drivers, etc. on an ASI system. In specific cases, written approval may be requested from ASI to install specific additional software. Without such approval, the system warranty is void.

Disk image restoration overwrites the Windows operating system. Therefore, restoration must be performed by advanced users only with the guidance of ASI personnel, and only after the backup of all necessary files.

4.1 Cleaning the System

Use only a soft, wet cloth to clean the surfaces of the system. Strong detergents, alcohol and organic cleaners may damage the finish. Do not wet surfaces that are not closed or sealed, such as that of the keyboard.

4.2 Environmental Protection Policy

- ASI is committed to the protection of the environment and natural resources and to the prevention of pollution
- ASI minimizes harmful effects on the environment that may be caused by its activities
- ASI environmental control encompasses the entire product life cycle (design, production, storage and delivery, installation, and service)
- ASI encourages its customers to protect the environment by controlled disposal of products at the end of their useful life.

NOTE

Several components of system hardware may not be treated as common disposable waste, but must be brought to a special collection point for environmentally sensitive waste after their life span is completed. These components include:

- Lithium (button) batteries
- PC boards greater than 10 square centimetres
- Plastics containing brominated flame retardants.

4.3 Environmental Requirements

Temperature: 5ºC to 40ºC (41ºF to 104ºF)

Humidity: 80% for up to 31ºC (88ºF)

Appropriate lighting and/or isolation from light: N/A

4.4 Storage

While storing the system or when it is not in operation, disconnect the device from the main power supply.

4.5 Data Integrity

- The responsibility for backing up all data on any hard drives or storage devices is the sole responsibility of the customer.

5 User Authentication

5.1 Login/ Logoff Mechanism

- Logging into the system depends on user identification, which is accomplished by a secret password and username.
- To prevent misuse by unauthorized users, the user should manually activate the login and logoff mechanism.
- Case Data Manager supports two authentication modes:

  (a) SQL Authentication- Requires login to Case Data Manager with username and password.

  (b) Active Directory Authentication- Login to CDM is based protected by Operation System login credential, per local IT policy and security

5.2 Power Plan

For optimal performance of the system, each system is configured with predefined PC power plan settings. It is highly recommended to preserve the power plan settings.

5.3 User Authorization

- Authorization is a security function that protects sensitive information from individuals who have no job-related need to access it.
- Allow Case Changes protected with “Lab index” mechanism; to use Allow Case Changes, the user must enter username and password.
- Activate "Lab index" to prevent certain users from deleting cases and to prevent changes of completed cases. This mechanism is set by the user based on the role a person fulfils, e.g., Administrator, Field Engineer, Researcher and Pathologist.

5.4 Secured Communication

- To secure the cross-connection between the applications, it is recommended to use HTPPS secure connection protocol (port 443).
- To secure the import/archive mechanism, the user must activate the logoff mechanism while he is away from the computer, otherwise and as part of HIPPA compliance we have an auto logoff mechanism after 15 minutes.
- Prevention of Hostile Penetration to Networks.
- An anti-virus software is installed where applicable.
  ESET NOD32 Antivirus software is recommended to be installed and configured with the GenASIs software.

  The ESET NOD32 Antivirus software has been configured, tested, and validated to perform optimally on ASI systems. Systems provided by ASI are installed with ESET NOD32.

  In case different antivirus software in use, it will be at the customer responsibility and ASI will not be liable to any failure relating to the use of such anti-virus, whether used in accordance with ASI’s guidelines or not.

  In case different antivirus software in use, follow ASI's exclusion guidelines.

6 General Information

6.1 ASI Products

The ASI Product Portfolio consists of the following products:

6.1.1 HiBand

Provides a full solution set for cytogenetic chromosome analysis and karyotyping for multiple sample types, pre-natal, post-natal and cancer genetic sample types.
It also supports most in demand staining types such as Giemsa, R-banding (BF and FL), Q-banding and FL whole chromosome stains such as DAPI and FISH.

6.1.1.1 Product Platform

Scan & Analysis platform:

- PC: Dell Precision T3660
- Camera: Basler 5 MP Monochrome
- Scanning Stage: Marzhauser 9-slide motorized stage
- Optional: High Throughput Tray Loader 99 slides. Certified to use with automatic microscope (Olympus BX61/ BX63, Zeiss AXIO Imager Z2).

Related hardware components:

- ASI Controller
- Barcode Reader
- Barcode Printer
- Oil Dispenser

Capture & Analysis Platform:

- PC: Dell 3660/ Other- which comply with the defined PC minimal specifications
- Camera: Basler 5 MP Monochrome

Review & Analysis Platform:

- PC: Dell 3660/ Other- which comply with the defined PC minimal specifications

AnyWhere Review Platform

- Server/ Virtual Server for VDI environment (VMWare), Citrix Virtual Apps and Desktops, or Microsoft Remote Desktop Services (RDS)
- Thin client application for remote connection.

ScanLink Cyto Conversion Platform:

- PC: Dell 3660/ Other- which comply with the defined PC minimal specifications

6.1.2 HiFISH

Provides image acquisition and automated analysis for interphase cell fluorescent in-situ hybridization (FISH). HiFISH consists of the well branded SpotScan application for cell suspension and tissue imaging and analysis.

6.1.2.1 Product Platform

Scan & Analysis platform:

- PC: Dell Precision T3660
- Camera: Basler 5 MP Monochrome
- Scanning Stage: Marzhauser 9-slide motorized stage
- Optional: High Throughput Tray Loader 99 slides. Certified to use with automatic microscope (Olympus BX61/BX63, Zeiss AXIO Imager Z2).

Related hardware components:

- ASI Controller
- Barcode Reader
- Barcode Printer
- Oil Dispense

Capture & Analysis platform:

- PC: Dell 3660/ Other- which comply with the defined PC minimal specifications
- Camera: Basler 5 MP Monochrome

Review & Analysis platform:

- PC: Dell 3660/ Other- which comply with the defined PC minimal specifications

AnyWhere review platform

- Server/ Virtual Server for VDI environment (VMWare), Citrix Virtual Apps and Desktops, or Microsoft Remote Desktop Services (RDS)
- Thin client application for remote connection

6.1.3 CytoPower

Combines HiBand and HiFISH capabilities for labs who seek higher efficiency and more cost-effective solution for both chromosome analysis and FISH on the same system as well as spectral image acquisition.

6.1.3.1 Product Platform

Scan & Analysis platform:

- PC: Dell Precision T3660
- Camera: Basler 5 MP Monochrome
- Scanning Stage: Marzhauser 9-slide motorized stage
- Optional: High Throughput Tray Loader 99 slides. Certified to use with automatic microscope (Olympus BX61/BX63, Zeiss AXIO Imager Z2).

Related hardware components:

- ASI Controller
- Barcode Reader
- Barcode Printer
- Oil Dispenser

Capture & Analysis platform:

- PC: Dell 3660/ Other- which comply with the defined PC minimal specifications
- Camera: Basler 5 MP Monochrome

Review & Analysis platform:

- PC: Dell 3660/ Other- which comply with the defined PC minimal specifications

Hyperspectral Platform:

- PC: Dell Precision T5820
- Spectra Cube and VDS 1.3 MP monochrome camera

AnyWhere review platform

- Server/ Virtual Server for VDI environment (VMWare), Citrix Virtual Apps and Desktops, or Microsoft Remote Desktop Services (RDS)
- Thin client application for remote connection

ScanLink Cyto Conversion Platform:

- PC: Dell 3660/ Other- which comply with the defined PC minimal specifications

6.1.4 HiPath Pro

Comprehensive solution for pathology brightfield imaging and analysis through whole slide imaging, computer assisted analysis of IHC membrane and nuclear as well as CISH.

6.1.4.1 Product Platform

Scan & Analysis platform:

- PC: Dell Precision T3660
- Camera: Basler 5 MP Color
- Scanning Stage: Marzhauser 9-slide motorized stage
- Optional: High Throughput Tray Loader 99 slides. Certified to use with automatic microscope (Olympus BX61/BX63, Zeiss AXIO Imager Z2).

Related hardware components:

- ASI Controller
- Barcode Reader
- Barcode Printer
- Oil Dispenser

Capture & Analysis platform:

- PC: Dell 3660/ Other- which comply with the defined PC minimal specifications
- Camera: Basler 5 MP Color

Review & Analysis platform:

- PC: Dell 3660/ Other- which comply with the defined PC minimal specifications

AnyWhere review platform

- Server/ Virtual Server for VDI environment (VMWare), Citrix Virtual Apps and Desktops, or Microsoft Remote Desktop Services (RDS)
- Thin client application for remote connection

ScanLink Pathology Conversion Platform:

- PC: Dell 3660/ Other- which comply with the defined PC minimal specifications

6.1.5 PathFusion

Full pathology imaging suite which includes whole slide imaging, tissue matching, FISH imaging and analysis for both tissue samples and cell suspension.

6.1.5.1 Product Platform

Scan & Analysis platform:

- PC: Dell Precision T3660
- Camera: Basler 5 MP Color
- Scanning Stage: Marzhauser 9-slide motorized stage
- Optional: High Throughput Tray Loader 99 slides. Certified to use with automatic microscope (Olympus BX61/BX63, Zeiss AXIO Imager Z2).

Related hardware components:

- ASI Controller
- Barcode Reader
- Barcode Printer
- Oil Dispenser

Capture & Analysis platform:

- PC: Dell 3660/ Other- which comply with the defined PC minimal specifications
- Camera: Basler 5 MP Color

Review & Analysis platform:

- PC: Dell 3660/ Other- which comply with the defined PC minimal specifications

AnyWhere review platform

- Server/ Virtual Server for VDI environment (VMWare), Citrix Virtual Apps and Desktops, or Microsoft Remote Desktop Services (RDS)
- Thin client application for remote connection

ScanLink Pathology Conversion Platform:

- PC: Dell 3660/ Other- which comply with the defined PC minimal specifications

6.2 Workspace Requirements (Automatic Systems)

To ensure the proper functioning of the system, specific environment conditions are required.

6.2.1 Table Recommendations

- The Scan & Analysis platform requires a steady table to avoid vibrations which may lead to low image quality.
- High Throughput system weighs 100Kg. Since we are dealing with moving parts and a system that requires fine tuning and calibration, the steadiness of the table is essential.
- The 99-slide Tray Loader, including the Microscope requires a space of 100cm in length/ 90cm in width/ 90 cm in height. Please note that extra space should be kept for other equipment, such as: screen, barcode printer and so on.

6.2.2 Electrical Outlets

The following electrical equipment requires a connection to the electricity network:

- Computer monitor
- Barcode printer
- Computer
- Fluorescent lamp controller
- Microscope controller
- ASI controller

Some of the above items are preferred to be connected to a UPS* network to avoid problems in the case of a power failure: computer, microscope controller & Tray Loader controller.

Unless you have a UPS network, we can recommend purchasing UPS specifications. In this case, (using external UPS), all relevant equipment can be connected to the UPS by using extension electrical sockets.

* For one Scanning system which includes

- Computer with camera (660W)
- ASI Controller with 9-slide stage (150W)
- Microscope Olympus BX63 (less then 100W)
- Fluorescent light source (150W)
- Display (80W max)

Total = 1,140W

For Scanning system recommended UPS not less than 1500VA

Recommended: Maximum backup time between 10 to 45 minutes

For Capture and Review system (4 systems)

- Computer with camera (660W)
- Display (80W max)

Total = 370W

For Capture and Review systems recommended UPS not less than 600VA

Recommended: Maximum backup time 25 minutes.

6.2.3 Power Consumption

- ASI Controller: 150W (Maximum)
- Dell Precision T3660: 500W (Maximum)
- Dell Precision T5820: 425W (Maximum)
- Dell 27” monitor: 150W(Maximum)
- Fluorescent lamp: 160W (Maximum)
- Microscope Olympus BX61: 350W (Maximum)
- Microscope Olympus BX63: 440W (Maximum)
- Microscope Zeiss Axio Imager Z2: 225W

7 Footprint of GenASIs Platform Systems

System configuration	Accessories	WxLxH [cm]	Notes
Capture & Analysis Platform	Microscope	According to microscope model	Allow approximately 30cm extra height for the camera and C-mount.
	Lamp Power supply	According to Lamp and Microscope model	In case the Microscope is equipped with fluorescent illumination, allow additional space on the table for the lamp's power supply.
	PC	17 x 42 x 37 cm	PC supplied with keyboard/mouse pad.
	Monitor	According to monitor model	ASI recommends min 25" LCD monitors
	Sockets		4 Sockets are required per each station of 16m amp per socket
Analysis & Review Platform	PC	17 x 42 x 37 cm	PC supplied with keyboard and mouse pad.
	Monitor	According to monitor model	ASI recommends min 25" LCD monitors
	Sockets		2 Sockets are required per each station of 16m amp per socket
Scan & Analysis Platform with High Throughput Platform	PC	17 x 42 x 37 cm	PC supplied with keyboard / mouse pad.
	Monitor	According to monitor model	ASI recommends min 25" LCD monitors
	Stage controller	25 x 35 x 10 cm	All the controllers may be placed on top of each other. The controller supplied with Joystick that should be placed on the working table.
	Tray Loader	100 x 90 x 90 cm	Including Microscope
	Barcode Printer	20 x 30 x 20 cm	The printer may be located on the system's table. If you wish to place it on a different table, please ask before heading for a longer cable.
	Sockets		7 Sockets are required per each station of 16m amp per socket
	Table Surface		Requires a stable, sturdy table for holding the tray loader, and microscope and monitor – there must be no vibrations with this table.

Weight of the following components

- High-Throughput Tray Loader 35kg
- BX61 with 9 slide stage 42kg
- Zeiss Axio Imager Z2 with 9 slide stage 44kg
- BX63 with 9 slide stage 40kg
- Dell Precision T3660 8.5kg
- Dell Precision T5820 15.4kg
- Dell 27” monitor 7.3kg

NOTE

PRIOR TO INSTALLATION, THE SUPPLIER NEEDS TO BE NOTIFIED AS TO IF ALL STATIONS WILL BE LOCATED IN ONE ROOM OR WILL BE SCATTERED AMONG SEVERAL ROOMS IN THE LABORATORY.

- If all stations are not in the same room- the laboratory IT needs to ensure that the network infrastructure is secure.
- If all stations in the same room, a minimum of 5-meter cables need to be available between each station
- If all stations in the same room a switch with 16 ports needs to be available.
- The laboratory needs to ensure that electric power is sufficient for 13 stations.
- A UPS is recommended in the case of a power failure.

Contact Information

The information below may be used for contacting ASI in the event that service is required, or clarification is necessary for any part of the system. Read the separate warranty document included in the product shipment for information about the product warranty.

Any disregard of instructions in this guide may void the product warranty.

Manufacturer:

Applied Spectral Imaging Ltd.

2 HaCarmel Street P.O.Box 262,

2069204 Yokneam, Israel

Tel: +972 (4) 654-7567

Fax: +972 (4) 654-7507

Email: support@spectral-imaging.com

Web: http://www.spectral-imaging.com

European Authorized Representative:

CEpartner4U

BV, Esdoornlaan 13, 3951

DB Maarn, The Netherlands

Tel: +(31) 343 442 524

Fax: +(31) 343 442 162

E-Mail: office@cepartner4u.com

USA and Canada Distributor:

Applied Spectral Imaging Inc.

6160 Innovation Way

Carlsbad, CA

92009 USA

Tel.: (760) 929-2840

Fax: (760) 929-2842

Email: support@spectral-imaging.com

Web: http://www.spectral-imaging.com

UK Responsible Person (UKRP):

Obelis UK

Sandford Gate, East Point Business Park

OX4 6LB – Oxford

UK

Tel: +44 1491 378 012

Email: sales-uk-swiss@obelis.net

Web: https://www.obelis.co.uk

Applied Spectral Imaging

6160 Innovation Way, Carlsbad, CA 92009, USA
Office: (760) 929 2840 Fax: (760) 929 2842

www.spectral-imaging.com