inpeco

FlexLab™ X

Automation System

Operations manual

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Original instructions

Abbreviations and conventions

ACR	Active Carrier Rotation
ATR	Active Track Return
CAB	CANopen Antenna Board
CDB	Compact Driver Board
CLB	Compact Logic Board
DAS	Data Analysis System Software
DMS	Data Management Software
FDB	Full Driver Board
FSE	Field Service Engineer
UI	User Interface
LAS	Laboratory Automation System
LIS	Laboratory Information System
NSD	No Stop Divert
PNM	Pass Node Module
SMS	Sample Management Software
VS	Vision System

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1 Important User information

For the correct operation of the Automation System it is important that this manual is read completely and carefully and all instructions are observed.

Failure to read, understand and follow the instructions may result in personal injury. It can also lead to damage to the Automation System and/or poor equipment performance.

⚠ WARNING

Failure to observe the safety instructions.

Injuries and Automation System damage.

- Observe the safety instructions in this operations manual.
- Carefully read the complete operations manual.

1.1 Disclaimer

All printouts, graphics and screens depicted in this manual are reproduced only for information and illustration purposes and shall not be used for any clinical or maintenance evaluation. Data shown in such printouts, graphics and screens are not in any case related with actual patient names or test results.

Inpeco makes no representations or warranties as to the accuracy and reliability of any information provided in this manual.

The information contained herein is based on the experience and knowledge relating to the product gained by Inpeco prior to publication. Such information was therefore intended to be used only by Inpeco fully trained personnel, or eventually by other persons experienced or knowledgeable with the operation and service of the product, operating under the direct supervision and in cooperation with Inpeco technical sales or service representatives.

In no event shall Inpeco be liable for any damage or loss caused by the use of the information contained in this manual by personnel not properly trained by Inpeco or qualified Inpeco representatives. This limitation shall not apply to those persons experienced or knowledgeable with the operation and service of the product, operating under the direct supervision and in cooperation with Inpeco technical sales or service representatives.

Inpeco does not provide any kind of medical advice or service.

Inpeco reserves the right to change this manual without notice. Any eventual update to the manual may be provided in either paper or electronic format. Always refer to the latest version of the manual for the most up-to-date information.

Incremental updates provided to the present manual may cause the Table of Contents page numbering to change.

Inpeco Automation System is connected to Third Parties' instruments. Inpeco is not the Manufacturer and is not legally responsible for the Third-Party Analytical instruments nor the reagents. The diagnostic results produced by Third Parties' instruments are not under Inpeco's responsibility.

The Hettich Centrifuge and the Aliquoter Secondary Tubes and Caps distributed with the Automation System are not under Inpeco's responsibility.

In case of any problem related to the use of Third Parties devices please refer to the Legal Manufacturer of the specific device.

Inpeco device allows the users to configure many options and functionality for the management of results and samples in accordance to their needs. The laboratory personnel are responsible for the correctness of these parameters configuration and the tests ordered for the sample tubes loaded on the Automation System from the clinical point of view. The configuration of the software parameters is done by Service personnel once the devices are already on the field and the configured rules are defined according to the specific instructions provided by the laboratory director/professionals. The FSE, who configures Inpeco software according with the specific needs of each customer, is responsible for the data entry.

Also in case of configurations set to modify the test results received for the connected instruments, Inpeco software always allows to display and transmit also the raw data.

1.2 Intended use

The Automation System is a modular system designed to automate Pre-Analytical and Post-Analytical processing, sample handling in order to automate sample processing in the Laboratory.

The system consolidates multiple Analytical instruments into a unified workstation.

1.3 Warranty and liability

Warranty and liability rights expire if:

- the Automation System is not used according to the intended use
- the damage of the Automation System is due to failure to follow the instructions for use
- the operating staff has not been properly trained
- changes of any kind not specifically authorized and qualified by Inpeco have been made (e.g. replacement or addition of components, options, etc.)

If the Automation System is used in ways other than those specified in the present manual, safety conditions provided by the System are no longer guaranteed and samples could be subject to irreparable damages.

1.4 Precautions and requirements

Follow these precautions and requirements when operating the Automation System. Failure to do so could cause damage to the Automation System and may adversely affect test results.

1.4.1 Precautions before operation

Before you begin operating the Automation, you should:

- Contact the Service Assistance to install the Automation System.
- Ensure the Automation is out of direct sunlight, heat and drafts, and away from any heat generating device. Exposure to heat and drafts can interfere with the ability of the Automation System to maintain an operating temperature that is within the acceptable range.
- Leave the Automation System power on continuously unless instructed otherwise in a maintenance or troubleshooting procedure, or unless an emergency situation occurs.
- Read this manual thoroughly to understand full functionality of the Automation System and associated hazards.
- Read the sections of the reagent manufacturer's assay-specific documentation (e.g., a package insert or reagent application sheet) that are associated with:
  - Warnings and precautions
  - Safety precautions
  - Handling precautions
- Ensure that all the covers of the Automation System are close before processing

1.4.2 Precautions during operation

While operating the Automation, take the following precautions.

- Keep all module covers and safety shields closed unless instructed otherwise in a maintenance or troubleshooting procedure.
- Do not disconnect any electrical connection while the power is on.
- Shutdown the Automation if the main power source is interrupted. A maximum of 10 minutes is available to perform shutdown before losing the backup power from the UPS.
- Respond to Automation notifications relating to waste levels during processing. Dispose of all waste according to local, state, and country regulations.
- The lab staff is not allowed to use the covers of the Automation System as a storage area.
- Perform maintenance procedures as outlined in this manual.
- Do not attempt any maintenance or repairs that are not specified in documentation provided.

- Do not connect devices to any power outlets or connector plugs of the Automation System.

1.5 Adverse event report

Any serious incident that has occurred in relation to the Automation System shall be reported to the manufacturer and the Competent Authority of the State in which the user and/or the patient is established in accordance to the local regulations.

1.6 Signal word panel

Warnings, cautions, and notes are included throughout this manual to emphasize important instructions.

⚠ WARNING

Indicates a hazardous situation which, if not avoided, could result in moderate to serious personal injury.

⚠ CAUTION

Indicates a hazardous situation which, if not avoided, could result in minor injury or damage to the Automation System.

NOTICE

Defined as precautions which, if not followed, could cause a negative impact on Automation System operations or assay results.

NOTE

Defined as supplemental information that is relevant to the current subject matter.

1.7 Manufacturer information

Inpeco SA

Via Torraccia, 26 - 6883 Novazzano - Switzerland

Phone +41 (91) 9118200 - Fax +41 (91) 9118299

www.inpeco.com

This equipment is manufactured by Inpeco S.p.A. in Val della Torre factory plant

Via Givoletto, 15 - 10040 Val della Torre (To) - Italy

Phone +39 (011) 7548000 - Fax +39 (011) 7548099

1.8 User training

The Automation System shall be installed only by qualified Inpeco representatives or properly trained personnel.

The Automation System shall be used only by properly trained personnel.

Inpeco or qualified Inpeco representatives provide user training for use of Automation System.

The Automation System is intended for professional use only and not for private use.

1.9 Regulatory requirements

1.9.1 Applicable Directives and Regulations

The Automation System is designed and manufactured to comply with the applicable Directives and Regulations described in the next paragraphs.

Changes made on the Automation System may void compliance with one or more of these applicable standards.

Changes to the System include replacing a part or adding components, options, or peripherals not specifically authorized and qualified by Inpeco.

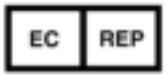
To ensure continued compliance with applicable standards, replacement parts and additional components, options, and peripherals must be ordered from Inpeco or one of its authorized representatives.

1.9.2 Regulations and Directives for the European Union

1.9.2.1 Regulation (EU) 2017/746 – IVD Regulation

The Automation System is an In Vitro Diagnostics Device in compliance with the provisions of the Regulation (EU) 2017/746.

Inpeco SA appointed QARAD as EU Authorized Representative.



Qarad EC-REP BV
Pas 257
2440 Geel
Belgium

1.9.2.2 Directive 2014/53/EU – RED Directive

The RFID antenna system mounted in this equipment is in compliance with the essential requirements and other relevant provisions of RED 2014/53/EU.

NB 2051

1.9.2.3 Directives 2011/65/EU and 2015/863/EU – RoHS Directives

Directives 2011/65/EU and 2015/863/EU of the European Parliament on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

1.9.2.4 Directive 2012/19/EU - WEEE Directive

Directive WEEE 2012/19/EU of the European Parliament and of the Council on waste electrical and electronic equipment.

This directive refers to the definitions in that Directive, including the definitions of waste and general waste management operations.

Dispose of all waste produced during the Automation System operation according to local, State, and Country regulations.

Refer to the rules concerning the treatment of electrical and electronic equipment waste.

The product, at the end of its useful life, should be disposed of following the rules for disposing differentiated and cannot be treated as a simple urban waste.

The product should be disposed of at dedicated collection centers or shall be returned to the dealer if you want to replace it with another equivalent new.

Figure 1: Waste symbol

The Waste symbol indicates that the product meets the requirements of the new guidelines introduced to protect the environment (WEEE 2012/19/EU) and must be disposed of properly at the end of his life cycle.

Request information from local authorities about the areas devoted to waste disposal.

Who does not dispose of the product by following the instructions in this section responds according to current regulations.

1.9.2.5 Directive 2006/42/EC - Directive Machine

The Directive has the dual aim of harmonizing the health and safety requirements applicable to machinery on the basis of a high level of protection of health and safety, while ensuring the free circulation of machinery on the EU market.

1.9.2.6 Regulation (EC) No 1907/2006 - REACH Regulation

Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) is a European Union regulation. REACH addresses the production and use of chemical substances, and their potential impacts on both human health and the environment.

1.9.3 Regulations for the United States and Canada

The device complies:

- UL Std. No. 61010-1 3rd Edition + AM1:2018
- CAN/CSA-C22.2 No. 61010-1-12 Third Edition + AM1:2018
- UL 61010-2-011:2021
- CAN/CSA C22.2 No. 61010-2-011:2019
- UL 61010-2-51:2019
- CSA C22.2 No. 61010-2-051:2019
- UL Std.No. 61010-2-101:2019 3rd Edition
- CAN/CSA C22.2 No. 61010-2-101:2019

1.9.3.1 FCC – Use restrictions and warnings

- Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
- Device models and FCC IDs:

CANopen Antenna Board single – 13 MHz	2BALJ-CAB1C13M01
CANopen Antenna Board double – 13 MHz	2BALJ-CAB2C13M01

- US Agent’s contact located in the United States:

Company Name	Inpeco North America Inc.
Physical U.S. Company Address	50 Broad Street New York 10004
Agent name	Rachel Tice
Agent Email Address	rachel.tice@inpeco.com

- This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
- This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
  - reorient or relocate the receiving antenna;
  - increase the separation between the equipment and receiver;
  - connect the equipment into an outlet on a circuit different from that to which the receiver is connected;

- consult the dealer or an experienced radio/TV technician for help.

1.9.3.2 RF Radiation Exposure statement

This product complies with FCC and ISED radiation exposure limits set forth for an uncontrolled environment. The antenna should be installed and operated with minimum distance of 20 cm between the radiator and your body.

1.10 Trademarks

All third party trademarks are the property of their respective owners.

The names of companies and/or products used in this manual are trademarks. The indications of ® and ™ are omitted.

1.11 Patents

Products and technologies from Automation System are covered by one or more patents and/or proprietary intellectual property rights.

All infringements are prohibited and will be prosecuted.

1.12 Technical and environmental information

1.12.1 Transporting and storage data

Description	Value
Non operating altitude	Up to 12000 m [39370.08 ft] above sea level
Non operating humidity	5% to 90%
Non operating temperature	-20°C [-4°F] to +60°C [+140°F]

1.12.2 Operational data

Description	Value
Operating altitude	Up to 2000 m [6561.68 ft] above sea level
Operating temperature range	16°C [60.8°F] to 30°C [86°F]
Safe temperature range	5°C [41°F] to 40°C [104°F]
Operating humidity	Maximum relative humidity 80% for temperatures up to 30°C [86°F]
Overvoltage	Category II (IEC 61010-1)
Pollution	Degree 2 (IEC 61010-1)
Environment	The Automation System is intended for internal use only
Heat	Heat is dependent on the Automation System configuration
Noise	The emission sound pressure level of the Automation System is ≤ 70 dBA
Belts speed	172.5 ± 2.5 mm/s [6.8 ± 0.1 in/s]
External light illuminance (in case of Modules equipped with Vision System)	Max 30 klux

1.12.3 Technical data

1.12.3.1 Power requirements

Description	Value
Mains Line Frequency	50/60 Hz
Mains Line voltages fluctuation	Up to ± 10%
Power consumption	Power consumption is dependent on the Automation System configuration

Mains Line Voltages depend on system configuration as follows:

Description	Value
Single-phase configuration	230V ~ 11500VA
Three-phase configuration	400V ~ 34500VA

1.12.3.2 Compressed air requirements

Description	Value
Characteristics	With reference to ISO 8573-1: 2010: • Class ≤3 for Table 1 • Class 3-4 for Table 2 • Class ≤3 for Table 3
Pressure	0.7 MPa [7 bar]
Consumption	Air volume is dependent on the Automation System configuration

1.12.3.3 Disposal

Observe the following during disposal:

- decontaminate all components of the Automation System
- adhere to the country-specific regulations
- separate the material groups (e.g. packaging, consumables, etc.)
- dispose of the materials in an environmentally friendly way
- recycle waste if possible

2 Safety information

This chapter reports the safety rules to be observed when using the Automation System.

2.1 Information on equipment protection

Automation System is equipped with safety shields for protecting Users.

There are two different types of safety shields:

- Fixed guards: safety shields fixed by screws, not openable by the operator with the exception of special cases expressly indicated. They require a tool to be open.
- Interlocking movable guards: safety shields openable by the operator and controlled by a safety switch that prevents the start of hazardous machinery functions until they are closed and gives a stop command whenever they are no longer closed. They do not require a tool to be open.

⚠ WARNING

If the equipment is used in manner not specified in this manual the protection provided by the equipment may be impaired.

⚠ WARNING

Data Privacy and Security.

Access of unauthorized personnel may cause loss of confidentiality/integrity/availability of data.

Access the Automation System or Automation servers is restricted to authorized personnel.

⚠ WARNING

Electrical hazard.

Operator or service injury due to liquid spilled over the Module.

Do not place any container on the Automation System surface that could be overturned and spill liquid over the parts of the Automation System covered by safety shields.

NOTICE

Failure to electronic components.

Do not place any containers that could be overturned and spill liquid on the Automation System covers.

NOTICE

The Automation System covers are not impermeable to liquids.

2.1.1 Moving Parts

Users are exposed to moving parts during normal use due to the necessity of interaction with the Automation System modules (i.e. IOM, RIM, etc.). Users should be adequately warned and trained. The residual potential risk is highlighted by means of warning labels.

⚠ CAUTION

Do not open or remove safety shields and covers during sample processing or if the Automation Module is on-line.

⚠ CAUTION

Do not use the Automation System with the safety shields or covers removed.

2.1.2 Sharp edges

The internal parts of the Modules can have sharp edges that can result in injury if reached.

⚠ WARNING

Sharp edges.

Use caution when accessing parts of the module normally protected by covers: after removing the cover or opening an access door, sharp surfaces can be reached.

⚠ WARNING

Potential Biohazard.

Operator injury due to contact with sharp parts potentially contaminated.

Use Personal protective equipment (e.g. gloves) when accessing parts normally protected by safety shields.

2.1.3 Hazardous/Biohazardous substances

Precaution should be taken when handling sample tubes or operating in proximity of specific areas reported with biohazard labels. Use personal protections, including protective gloves and goggles. Laboratory personnel should follow recommendations in Clinical Laboratory Safety (i.e: CLSI document: GP17-A3 - Clinical Laboratory Safety; Approved Guideline-Third Edition).

2.2 Labels

The following labels are affixed to the Automation System to alert the User to safety or functional considerations or to provide the users with general information about the manufacturer and the device.

⚠ WARNING

Failure to observe the safety informations on labels.

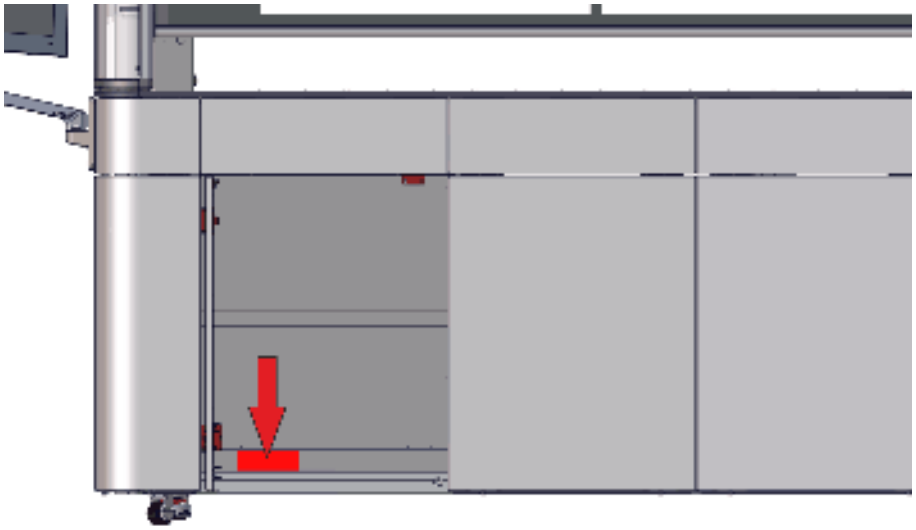
Serious injuries and System damage in case of failure to observe the safety informations on labels.

- Keep safety labels complete and legible.
- Replace safety labels that are no longer legible.

2.2.1 Product label

The product label is applied on the internal panel of the Input/Output Module (IOM) and contains general information about the manufacturer and the device.

Figure 2: Product label

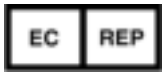


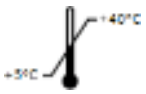
2.2.2 Safety labels

Icon	Description
	Identifies an activity that may present a safety-related hazard and advises the User to consult the associated caution or warning instructions provided.
	Identifies an activity or area where Users may be exposed to potentially infectious material.
	Identifies an activity or area where the User may be exposed to hot surfaces (> 65°C/149°F).
	Identifies an area containing cutting or stinging parts. Follow manufacturer instructions written in this guide when performing maintenance.
	Identifies an area where Users can be exposed to moving parts. Be careful around these parts when performing diagnostics and maintenance operations with safety shield and covers removed.
	Identifies the presence of electrical hazards. Identifies that hazardous voltage is present behind the protective cover.
	Identifies low temperature or freezing conditions.
	Strong magnetic field hazard warning labels to notify people not to bring sensitive equipment near the device.
	Identifies the vicinity of counterrotating rollers.

Icon	Description
	No access. Identifies an area where Users can be exposed to moving parts. Do not insert the hands in this area.
	No access for unauthorized personnel.
	This symbol notifies that the area access can cause risks to persons wearing a pacemaker. Any person with a pacemaker must keep a safety distance of: • at least 200 mm from the Module robot axes. • at least 80 mm from the magnets of the Module safety shields.

2.2.3 Standardized symbols present in the labels

Icon	Description
	Refer to the Operations Manual before performing procedures on the Automation System.
	Certification mark that indicates the conformity with the IVD Regulation.
	Label that identifies the Authorized Representative in the European Union for Inpeco SA.
	Manufacturing location.
	The Waste Electrical and Electronic Equipment (WEEE) indicates separate collections for electrical and electronic equipment. Dispose of electrical or electronic components in a separate container in accordance with local legislation.
	In Vitro Diagnostic device.
	Device intended for professional use only and not for private use.

Icon	Description
	Maximum and minimum temperature limits at which the item shall be stored, transported or used.
	To indicate that the item shall not be exposed to sunlight.
	Do not reuse.
	Box containing 1000 pieces.

3 Specimen preparation and management

The sample management consists of activities addressed to collect and prepare the specimen for its processing by the Automation System.

Operational requirements, precautions, and limitations are provided to ensure User safety and accurate assay results. Not following these requirements or not taking these precautions could impact Automation and assay performance and may cause damage to the Automation or adversely affect assay results

NOTICE

Do not run sample tubes if the requirements are not met. Patient result could be affected.

For detailed information about samples collection, preparation and storage based on the specific tests to run, it is important to refer to the documentation provided by the reagent manufacturers. Errors due to inappropriate use of sample tubes may cause errors in test results.

NOTICE

Automation System does not ensure sample integrity after centrifugation, before the sample is routed to the Analyzer. It is the Laboratory responsibility to determine an acceptable process for sample preparation and evaluation of its integrity. Hemolysis, Icterus and Lipemia in the sample can be measured semi-quantitatively by some Analyzers. It is possible to route samples requiring inspection by the User to sorting rack configured on Input Output Module or to Rack Output Module. Contact the Service Assistance for more details.

Sample carryover requirements for some Clinical Chemistry analyzers may be less stringent than Immunoassay analyzers. The possibility of sample carryover should be considered when samples are processed on multiple analyzers. Automation System routes sample tubes to maximize throughput and balance the workload between Modules and Analyzers.

Sample carryover cannot be controlled by the order of the analyzers in the Automation System configuration since it is not possible to guarantee the sample processing order. It is Laboratory's responsibility to verify sample carryover is acceptable among all Analyzers connected to the Automation System.

The Laboratory should determine the acceptable processing time for priority samples. If this time is not being met by loading the tubes in Rack Input Module or in priority lanes of the Input/Output Module, it would be necessary to load tubes directly on the Analyzers.

⚠ WARNING

Potential Biohazard.

Sample tubes are potentially biohazardous. Follow Laboratory standard procedures and guidelines when handling and disposing of tubes.

⚠ WARNING

Potential Biohazard.

Possible sample contamination and spillage when handling racks containing sample tubes.

NOTICE

Follow the reagent manufacturer’s assay-specific documentation (such as a package insert or reagent application sheet) for detailed, assay-specific information about specimen collection, preparation and Storage. Failure to follow tube and assay manufacturer's recommendations for sample tube handling and type could result in erroneous and misleading results.

NOTICE

Use only tube types listed in section 3.2 *Automation System - allowable sample tube types*, page 24. The tube type used must satisfy the specifications in this document.

3.1 Sample requirements

The Automation System can process the following specimen types:

- serum
- plasma
- whole blood
- urine
- feces

NOTICE

Restrictions on the type of specimen processed depend on the Analyzers connected to the Automation System.

3.1.1 Requirements for specimen collection

Obey these requirements for collecting specimens.

- Refer to the reagent manufacturer's assay-specific documentation for sample analysis (for detailed information on the collection, preparation and storage of samples). Treat all samples, reagents, controls and calibrators containing human material as potentially infectious. Consider all the areas of Automation and components that may come into contact with human material as potentially infectious.

  ⚠ WARNING

  Potential Biohazard.

  Sample tubes are potentially biohazardous. Follow Laboratory standard procedures and guidelines when handling and disposing of tubes.

- Sealed sample tubes must be transported in racks only. No other type of transport (bags, bulk or other) is considered acceptable.
- Follow all usual precautions for collecting blood by venipuncture to avoid specimen hemolysis.

  NOTICE

  The Automation System does not assess integrity of a specimen for testing after centrifugation, after retrieval from Storage and before running on an Analyzer. It is the laboratory's responsibility to determine an acceptable process for specimen preparation and assessment of integrity. Hemolysis, icterus, and lipemia can be semi-quantitatively measured on some Chemistry Analyzers. Samples requiring User inspection can be routed to a Sorting lane. This can be done via the Host/Middleware by ordering an off-track inspection test.

- A sample tube can be glass or plastic with a removable cap on the open end. The tube surface must be smooth and free of any ridges or collars that could interfere with the removal of the tube cap.

- Sample tubes must be filled and handled according to laboratory guidelines and procedures. Do not fill over the filling volume of the sample tube. The filling volume is the nominal volume reported by the manufacturer on the tube label. The maximum volume of any sample loaded in the Automation must be the volume (expressed in milliliters [mL]) as indicated in the label of the tube (volume threshold) in accordance with the tube's manufacturer manual and/or specifications.
- Verify that the correct specimen type is used. The Automation System does not verify specimen type.
- Refer to the reagent manufacturer's assay-specific documentation (e.g., a package insert or reagent application sheet) and Analyzer Operations Manual for sample volume information.

3.1.2 Requirements for specimen preparation

Obey these requirements for preparing specimens.

- In serum specimens, ensure complete clot formation has taken place before centrifugation. Some specimens, especially those from patients receiving anticoagulant or thrombolytic therapy may exhibit increased clotting times. If the specimen is centrifuged before a complete clot forms, the presence of fibrin may cause erroneous results.
- Mix and centrifuge samples after any freeze/thaw cycle or to remove red blood cells or particulate matter. Refer to the reagent manufacturer's assay-specific documentation (e.g., a package insert or reagent application sheet) for limitations and interfering substances.
- Inspect the tubes and verify that they are not cracked or leaking before insertion into sample racks. Damaged tubes could result in Automation System contamination and/or sample carryover.
- Sample tubes must be barcode labeled.
- Ensure barcode label alignment is correct and meets the recommended specifications. For additional information refer to 3.4.2 *Label placement and length*, page 29.
- Ensure the label does not extend below the top of the tube carrier. The barcode must be completely visible once the tube is placed in tube carrier. For additional information refer to 3.4.2 *Label placement and length*, page 29.
- Do not load duplicate sample IDs on Automation System.
- Follow the Good Laboratory Practices for the use of unique sample IDs.
- Verify the sample tube meets specifications listed in 3.2 *Automation System - allowable sample tube types*, page 24.
- Ensure there is sufficient sample volume to run the ordered tests. Due to Automation System enclosed, automated processing of sample tubes, sample volume cannot be inspected visually after centrifugation and before sampling. It is the Laboratory responsibility to determine an acceptable process to assess sample volume.
- Follow the documentation provided by the reagent manufacturers for detailed information about sample collection, preparation and storage based on specific tests to be performed.
- Ensure complete clot formation in serum samples has taken place. Some samples, especially those from patients receiving anticoagulants and thrombolytic therapy, may exhibit increased clotting time.

- Ensure the tube surface is clean and not wet before loading sample tubes into the Automation System in order to avoid unexpected System behavior during sample tubes handling.
- In case a vacuum tube has erroneously been uncapped by the User, it shall not be manually recapped before loading into the Automation System. It shall be first centrifuged off-track (if needed), then loaded on the Automation System as uncapped.

3.2 Automation System - allowable sample tube types

Obey the following indications.

- The Automation System is capable to process either glass or plastic sample tubes with a removable cap.
- Use only sample tubes with plastic screwed, pressure or snap fit caps.
- The tube surface must be smooth and free of any ridges or collars that could interfere with the removal of the tube cap.
- The tubes must be filled and handled according to the Laboratory guidelines and procedures. Follow the usual procedures for the blood collection to avoid sample hemolysis.
- Use only plastic sample tubes when the Sealer Module is installed and in the on-line status. Acceptable types of plastic tubes that can be sealed using the Sealer Module include:
  - PET (Polyethylene terephthalate)
  - PS (Polystyrene)
  - PP (Polypropylene)

NOTICE
Glass tubes are not sealed properly. If glass tubes require to be processed, verify the Sealer Module is off-line.

- The glass tubes can be used on the Centrifuge Module. For restriction, refer to Hettich manual.
- Do not load glass tubes to the Bulk Input Module. The glass tubes could be broken during the movements in the tray, resulting in the loss of the sample.
- Do not load sample tubes with rubber cap to the Automation System if they require to be uncapped. Sample tubes with rubber cap damage the Decapper Module. If necessary processing uncapped tubes, remove caps manually prior to load these tubes to the Automation System.
- If sample volume is not adequate it could generate result errors. Make sure that the volume of the sample is sufficient for tests that must be performed on the tube. The sample volume present in the tube cannot be visually verified after centrifugation and before sampling. It is Laboratory's responsibility to determine an acceptable process for sample preparation and assessment of integrity.
- Remove Parafilm® film (or similar products) from caps before loading sample tubes to the Automation System.
- Do not thaw the secondary sample tubes by immersion in water.
- Manually recapped or sealed sample tubes must not be loaded to a lane requiring decapping or centrifugation. Manually recapped sample tubes must be manually decapped. Sealed tubes must be properly loaded to be routed to the Desealer module, otherwise manually desealed if the Desealer Module is not installed or not available.
- Do not load sample tubes that were capped off-track.

- Do not load sticky tubes on the Automation. Tubes cannot have any residual glue or other material that could cause stickiness and prevent the Automation to properly handle the tube itself.

Contact Inpeco for the list of sample tubes that can be processed by the Automation System.

3.3 Automation System - bad tubes

Here below a non-exhaustive list of bad tubes that are not allowable on the Automation System. These tubes do not comply with the Automation System requirements and can cause malfunctions of the Automation itself.

Bad tubes negatively impact the efficiency of the Automation System by reducing the uptime of Modules and third-party connections.

Table 1: Bad tubes

Description	Picture	Comments
Tube with extraneous labels. Protruding label residual.		N/A
Tube badly labelled.		Refer to Figure 6 *Incorrectly labeled sample tube*, page 31.
Misplaced labels.		Refer to Figure 6 *Incorrectly labeled sample tube*, page 31.
Tube with residual glue.		Do not load sticky tubes on the Automation. Tubes cannot have any residual glue or other material that could cause stickiness and prevent the Automation to properly handle the tube itself.

Table 1 Bad tubes (cont'd.)

Description	Picture	Comments
Tube badly recapped.		N/A
Tube badly recapped. Crooked cap.		In case a vacuum tube has erroneously been uncapped by the User, it shall not be manually re-capped before loading into the Automation System. It shall be first centrifuged off-track (if needed), then loaded on the Automation System as uncapped, by means of the correct Input lane or Module.
Tube with adhesive tape.		Do not wrap the tube with adhesive tape. Remove Parafilm® film (or similar products) from caps before loading sample tubes to the Automation System.

3.4 Sample barcode

3.4.1 Symbology and restrictions

Automation Modules support the following barcode symbologies:

- Code 128
- Code 39 with and without check digit
- Interleaved 2 of 5 with and without check digit
- USS Codabar

In addition, for some modules, the following barcode symbologies are supported:

- EAN-8 (JAN-8 for Japan)
- EAN-13 (JAN-13 for Japan)
- UPC-A
- UPC-E
- Code 93

NOTICE

As reported in Standard AUTO2-A2 Vol.25 No.29 “Laboratory Automation: Bar Codes for Specimen Container Identification; Approved Standard - Second Edition”, published by Clinical and Laboratory Standards Institute, Code 128 shall be the preferred symbology to be used in the Laboratory Automation System. Its use can reduce barcode reading errors.

NOTICE

It is not possible to process sample tubes with and without check digit at the same time on the Automation . When the check digit is enabled, it is enabled for all symbologies that allow for check digit configuration.

EAN (JAN), UPC, Code 93 symbologies are always with check digit.

NOTE

Contact the Service Assistance for information and customizing the configuration.

3.4.2 Label placement and length

Automation System can process sample tubes prepared based on the Standard AUTO2-A2 Vol.25 No.29 “Laboratory Automation: Bar Codes for Specimen Container Identification; Approved Standard - Second Edition”, published by Clinical and Laboratory Standards Institute.

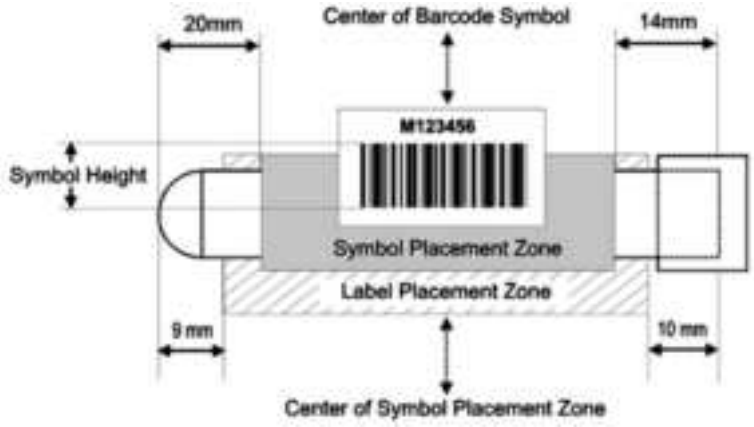
NOTICE

The User is responsible for placing the correct barcode label on the sample tube to ensure proper sample identification.

Obey the following indications.

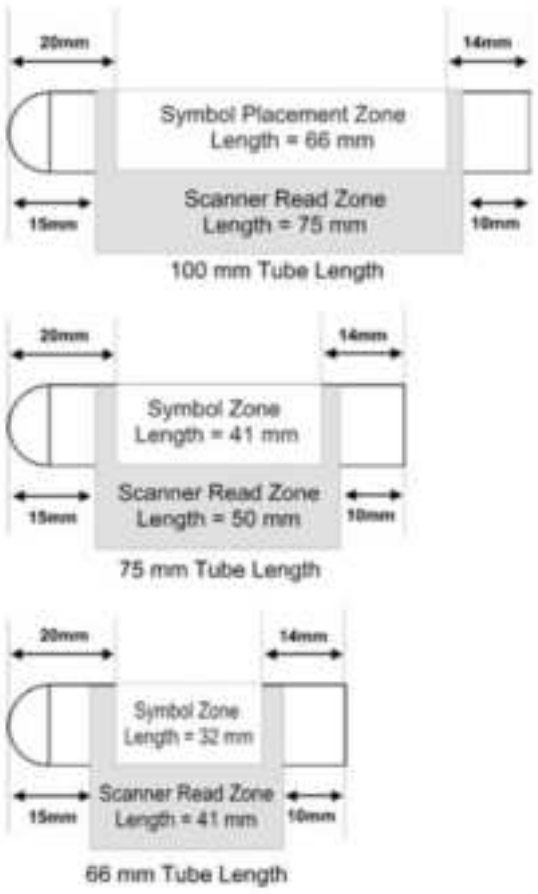
- The center of the symbol should be placed in the centre of the symbol placement zone. The height of the barcode symbol in the sample tube shall not be less than 10 mm (0.40 in.). The symbol placement zone (as referenced from the outside of the tube) is the area 20 mm (0.79 in.) above the bottom of the tube to a distance 14 mm (0.55 in.) below the top of the tube, excluding the cap.

Figure 3: Symbol and label placement zones



The size of the placement zone varies depending on the length of the tube.

Figure 4: Tube sizes and zone dimensions



- Do not to stick more than 3 labels on top of each other (included the manufacturer's label, if present).

NOTICE
When a new barcode label is added to a sample tube, ensure the original barcode label is covered entirely by the new barcode label.

- The barcode label shall be affixed to the sample tube in a "ladder" orientation, where the printed bars are horizontal.