

# Security

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## General Security

Personnel operating the automation must be proficient in its operation, maintenance, and procedures. To ensure safety, follow basic precautions.

### Security Notes

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

**WARNING:** Defined as a physical, mechanical, or procedural condition that could result in moderate to serious personal injury.



**CAUTION:** Defined as a condition that could result in minor injury or interfere with proper functioning of the Automation System.



**IMPORTANT:** Defined as precautions which, if not followed, could cause a negative impact on system operations or assay results.

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

## Safety Labels

The following labels are affixed to the Automation System to alert the operator to safety considerations.

Icon	Description
	The operator should refer to the FlexLab 3.6 Operations Manual before performing procedures on the Automation System.
	Indicates the Automation System I was manufactured in the European Union in compliance with European regulations.
	Manufacturing location. Manufactured by Inpeco S.p.A. Segrate (MI) - Italy in Borgone di Susa Factory Plan.
	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.
	Rotate the knob to lock or unlock the cover
	Identifies the In Vitro Diagnostic device.
	Identifies for the U.S. and Canada: An <b>Nemko-CCL</b> mark that means the product is certified for both U.S. and Canadian markets to applicable U.S. and Canadian standards.

**Table Section 2.1: Labels**

Icon	Description
	Identifies an area where operators can be exposed to moving parts. Be careful around these parts when performing diagnostics and maintenance operations with safety shield and covers removed.
	Identifies an activity that may present a safety-related hazard and advises the operator to consult the associated caution or warning instructions provided.
	Identifies an activity or area where operators may be exposed to potentially infectious material.
	Identifies an activity or area where the operator may be exposed to hot surfaces (> 70°C/158°F).
	Identifies an area containing cutting parts. Follow manufacturer instructions written in this guide when performing maintenance.
	Identifies the warn of electrical hazards. Identifies that hazardous voltage is present behind the protective cover.

**Table Section 2.1: Labels**

Icon	Description
	<p>Avoid eye exposure to laser light. Do not stare into beam. Warns against direct viewing of the beam or reflections from the beam.</p>
	<ul style="list-style-type: none"> <li>Input Output Module, Centrifuge Module and Storage and Retrieval Module cover lids should be opened completely to engage the locking mechanism.</li> <li>When closing the Input Output Module, Centrifuge Module and Storage and Retrieval Module safety shields, pull out the lock and lower the safety shield.</li> </ul>
	<p>Use caution when opening the Input Output Module, Centrifuge Module and Storage and Retrieval Module safety shields to ensure they are fully open. Do not place objects on the top surface.</p>

## Environmental and power specifications

### Environmental conditions

Description	Value
Operating altitude up to	2000 meters above sea level
Operating temperature range	16° to 30° C
Operating humidity	Max 80% at 30°C
Overvoltage	Category I
Pollution	Degree 2

**Table 2.2: Storage Conditions**

Description	Value
Non Operating altitude up to	12,000 meters above sea level
Non Operating Humidity	5% to 90%
Non Operating Temperature	-20°C to +60°C

### Power requirements

Description	Value
Mains Line Frequency	50/60 Hz
Mains Line voltages fluctuation	Up to $\pm 10\%$
• Mains Line Voltages depending on system configuration as follow:	
Single phase configuration with UPS	230 V ~ 3680 VA
Single phase configuration without UPS	230 V ~ 9200 VA
Three phases configuration without UPS	400 V 3N ~ 27600
Mains Line voltages fluctuations	Up to $\pm 10\%$

### Compressed Air Requirements

Description	Specification
Compressed air must be clean	Oil free and dry
Compressed air pressure range	7 to 9 bar

## Manufacturer

This equipment is manufactured by Inpeco S.p.A. in Borgone di Susa factory plant.

[www.inpeco.com](http://www.inpeco.com)

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## Waste Disposal

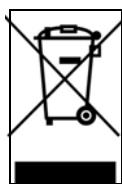
Dispose of all waste produced during the workcell operation according to local, state, and country regulations.

Treatment of waste electrical and electronic equipment.

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

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

**Figure 2.1: Waste symbol**



Indicates that the product meets the requirements of the new guidelines introduced to protect the environment (2002/95/EC, 2002/96/EC, 2003/108/EC) 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.

## Hazardous substances

Precaution should be taken handling tubes. Tube handling must be done using protective gloves and protective goggles. Automation system operators should follow Clinical Laboratory Safety (i.e: NCCLS document GP17-A2-Clinical Laboratory Safety; Approved Guideline-Second Edition).



**IMPORTANT:** Do not allow bleach or soapy water to spill through the Automation cover, or set any bleach solution or soapy water containers on the Automation surface. This could lead to contamination of samples, possibly causing erroneous patient results.

## Installation Specifications

The **FlexLab 3.6** Automation system must be installed by a qualified Inpeco representative.

System installation includes a complete checkout to ensure the equipment is fully operational.

This equipment is intended only for internal use.

## Bar Code Reader Lasers

The Automation system has one or more Bar Code Readers emitting laser beams. All bar code reader laser beams are protected by means of a metallic shield. There are no laser beams that are accessible and visible to the operator. Laser beam metallic shields must be left in place.

## Moving Parts

Due to the necessity to insert the sample tube racks in the Automation system modules (i.e.: IOM, RIM, etc) there are moving parts that are unavoidably exposed during the normal use. Automation system operators should be adequately warned and trained. The residual potential risk is mitigated by means of warning labels.

## Equipment Protection

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

## FCC warning statements

This device complies with Part 15 of the FCC rules subject to the following two conditions:

- 1) This device may not cause harmful interference
- 2) This device must accept all interference received, including interference that may cause undesired operation.

The antenna CANBUS antenna wirings incorporated in this equipment has been modified to comply with the Part 15 of the FCC rules.

Ferrite Fair Rite 046117645 Bin H4 has been added on transponder cables.