The PyroTec® PRO System

Overview and Specifications

Move from Manual Benchtop Processes to an Automated Workflow

Driven by new technologies in product platforms and scientific advancement, the PyroTec® PRO Robotic Solution is an automated, plate-based system that offers users the ability to move away from manual benchtop processes associated with endotoxin testing. The PyroTec® PRO System is directly integrated with the WinKQCL® Version 6 Software, achieving high-throughput sample testing in three simple steps, offering a fully automated workflow for higher volume QC labs.

This Data Sheet will help users gain insight into the specifications and components of the PyroTec® PRO System.

System Dimensions

Dimensions	
Height	87 cm (34.3 inches)
Width	145 cm (57.0 inches) (add 65 cm (25.6 inches) to the right side of the robot for a PyroWave® XM Reader add-on)
Depth	78 cm (30.7 inches)
Weight (base unit only)	130 kg (286 lbs)
Weight (full build with labware)	187 kg (412 lbs) – 200 kg (441 lbs) dependent on configuration (add 37.5 kg (83 lbs) for a PyroWave® XM Reader add-on)
Floor and table minimum load capacities	Table or bench: 300 kg (662 lbs)
	Floor: 365 kg (805 lbs) (add 50 kg (110 lbs) load capacity for a PyroWave® XM Reader add-on)
Minimum space requirement around the instrument	20 cm (8 inches) in all directions

Additional space consideration should be made for the PC workstation

General Overview

PyroTec® PRO System	
Throughput per run	42 samples (21 per plate in duplicate w/ duplicate PPC) when using 5-point standard curve and negative controls in duplicate on a 2 reader system
Sample handling	Yes: 48 sample tube locations
Sample pre-mixing	Yes
Prepares sample dilutions	Yes: 80 locations for sample dilution tubes available to make multiple simple to complex sample dilutions
Prepares auxiliary dilutions	Yes: for samples requiring other diluents than LAL reagent water, e.g. Beta-Glucan blocker, Tris buffer, etc.
Reconstitution of RSE/CSE	No: this is done off deck manually
Vortex of reconstituted RSE/CSE	No: this is done off deck manually
Prepares endotoxin standards	Yes: flexibility to make up to 8 standards per assay by serial dilution
Prepares positive product controls	Yes
Prepares negative controls	Yes
Pipettes controls and samples to the plate	Yes
Pre-incubates plate on deck	Yes
Reconstitutes LAL reagents	Yes
Prepares and mixes rFC reagent working solution	Yes
Pipettes reagent to plate	Yes
Places plate in reader	Yes
Barcode scanning	On deck 1D LoadingID barcode scanner for sample positioning. A handheld barcode scanner (1D/2D) can be used whilst creating WinKQCL® Software templates to populate reagent and sample details. Various standard barcode formats supported
Sample tube types	Endotoxin-free, 13 x 100 mm tubes with max volume of 8 mL per tube, e.g. Lonza P/N N207
Technician deck setup time	Fully loaded plate: 5 minutes minimum
Automated plate build including 10 minute incubation	Fully loaded plate: 30 minutes minimum After reagent addition: 43 minutes
Runtime in reader	~ 1 hour
Total time to result including preparation and run	~ 1 hour 40 minutes for 21 samples and 2 hours 40 minutes for 42 samples, all tested neat with PPC
Sample volume in each well	100 µL

General Overview continued on next page.

General Overview (continued)

PyroTec® PRO System	
Methods supported	Kinetic-QCL® Kinetic Chromogenic LAL Assay
	PYROGENT® 5000 Kinetic Turbidimetric LAL Assay
	PyroGene® rFC Assay
Safety features	User activated, interlocking door prevents non-intentional access to work area or non-intentional system halt. Runs cannot be started until door is closed and the lock prevents it from being opened during the run. There is an opening in the front safety panel (113 x 17 cm /44.5 x 6.7 inches) which can be further protected by purchase of an optional Restricted Access Door, PN 272448
Noise Emission (EN 61010-1)	<85 dBA (61.3 dBA sound pressure, measured at 1 meter from the instrument)
Compliance	The PyroTec® PRO System is CE and CSA marked and compliant with Directives 2014/35/EU, 2014/30/EU, 2011/65/EU and 21 CFR 1040.10 Not for Human *in vitro* Diagnostic Use

System Environment

Conditions	
Optimal system operating conditions	Temp. 20 to 27°C/ 68 to 80.6°F Relative humidity 30 to 60% (non-condensing) at 25°C (77°F) or below Altitude ≤2000 m, above sea level No excessive ambient light Clean environment
Storage conditions	Temp. 1 to 60°C/ 34 to 140°F Relative humidity 5 – 80% (non-condensing) at 30°C (86°F) or below
General liquid handling conditions	Avoid subjecting the system to • Vibration • Electrical interference • Magnetic fields

Power Requirements

Specifications	
Power	1200 VA UPS recommended (2500 watts, short circuit proof) Power outlets required for each reader and HeatPlate, the robot and PC workstation modules
Line voltage	100 to 120, 220 – 240 volts AC
Frequency	50/60 MHz (auto-sensing)
Fuses	2 x T10A
Electrical Safety Overvoltage category	II – IEC 60664-1
Electrical Safety Pollution Degree	2 – (EN) IEC 61010-1

LoadingID Barcode Scanner

Specifications	
Description	1D barcode scanner mounted on the left hand side of the PyroTec® PRO System deck. Retrofitting is possible to modify existing installed systems but will require deck rebuilding and re-execution of system configuration and IQOQPQ procedures.
Part number: 25-PTP-LID	LoadingID 1D fixed barcode scanner
	LoadingID tube carrier 13 mm diameter x 5 carriers
Laser scanning beam	Low-power collimated beam in the visible spectrum: Wavelength: 655 nm Pulse duration: 150 µs Maximum power of energy output: 1.0 mW
Classification	The LoadingID is a class 1 laser product pursuant to IEC 60825-1:2014 that emits laser radiation
Dimensions	
Height:	166.2 mm (6.5 in.)
Length:	422 mm (16.6 in.)
Width:	124.6 mm (4.9 in.)
Weight:	3.21 kg (7.08 lb.)
Supported barcode	
Density:	≥ 6.6 mil
Height:	≥ 8 mm
Length:	≤ 80 mm (including quiet zone)
Quiet zone	10 times the narrow bar width or 2.5 mm, whichever is greater
Barcode minimum distance	From the bottom of the tube: ≥ 20 mm (0.79 in.) including the quiet zone
	From the top of the tube: ≥ 14 mm (0.55 in.) including the quiet zone
Number of characters	≤ 64
Compatibilities	Barcode type Code 128 is recommended for optimum reading efficiency and reliability. This is the only format currently qualified for use with the LoadingID module on the PyroTec® PRO System
	The following codes are not recommend but may possibly be used with defined length, check digit and wide-narrow bar-width ratio of at least 1:2.5: Codes 39, Codabar, and Interleaved 2 of 5
Connection to the PyroTec® PRO System	The LoadingID connects to the instrument's system power (24 V / 4 W) and to its system communication (CAN) with a D-Sub connector (A)
Operating Conditions	
Temperature:	15–32°C (59–90°F)
Humidity:	30–80% relative at 30°C (86°F)
Altitude Max.:	2000 m above sea level
Transport Conditions	
Temperature:	-20 to 60°C (-4 to 140°F)
Humidity:	20–80% relative
Capabilities	Determines sample location by 1D barcode on sample tubes in LoadingID tube carrier(s) and cross references with the selected WinKQCL® Software template(s)
	Alerts users to missing samples, duplicate samples and unreadable barcode labels ensuring all samples in the selected WinKQCL® Software template are included in the run

Liquid Handling Components

LiHa Liquid Handling	Specifications		
General description	Air LiHa (Air displacement liquid handling) arm with 8 channels; independent Z-movement		
Precision movement	Air LiHa: ± 0.4 mm on X, Y, Z axes		
Y-tip spacing	Automatic 9 – 38 mm between tips (0.31 – 1.5 inches) between tips		
Volume range	10 – 1000 µL (max. volume used in PyroTec® PRO System processing 800 µL)		
Disposable tips	1000 µL conductive pyrogen-free tips with filter (tested < 0.005 EU/mL)		
Tip ejection system	Ejection of disposable tips using lower DiTi eject feature to prevent aerosols		
Liquid level detection	Capacitive for conductive liquids and pressure based technology for non-conductive liquids		
Tip occlusion detection	Part of integrated liquid detection		
Pressure monitored pipetting	Real-time quality control of the liquid transfer process		
	Detects pipetting faults like clots and air aspiration		
Disposable tip sensing	Confirmation of tip pickup and tip ejection		
Liquid handling conditions used to determine performance	Tap water with a conductivity of 0.3 mS/ cm to 1 mS/ cm, 8 channels, 12 replicates. CV and accuracy calculated over each channel and complete 96-well plate		
	Tip volume DiTi1000	Precision	Accuracy
Pipetting performance (Precision, CV)	100 µL	0.50%	± 1.0%
	500 µL	0.50%	± 1.0%
	1,000 µL	0.50%	± 1.0%
	6 x 100 µL multi-dispense	2.50%	± 2.0%
Theoretical resolution		0.1 µL	

Robotic Plate Manipulation

Robotic Manipulator Arm	Specifications
Purpose	To transport plate(s) to and from HeatPlate(s) to Tecan® Sunrise™ and Lonza PyroWave® XM Reader devices
Gripper space range	58 – 140 mm (2.28 inches – 5.5 inches)
Maximum transport load	0.4 kg (0.88 lbs)
Precision movement	± 0.4 mm (0.0157 inches) X axis ± 0.5 mm (0.0197 inches) on Y axis ± 0.3 mm (0.0118 inches) on Z axis

Software

Requirements	
User operating software	WinKQCL® Endotoxin Detection and Analysis Software Version 6
Background Robotic Control	Via Tecan® EVOWare™ Application Programming Interface and Tecan® EVOWare™ v2.8 SP1
Engineer hardware configuration and testing software	Tecan® Set-up and Service™ Tecan® Sunset™ Tecan® QCPac™ Tecan® SunDiag™ Microsoft® Excel® TTP II spreadsheet Tera Term
Server database and client workstation requirements	Please refer to WinKQCL® Software Enterprise Deployment Guide (EDG-25-611) Note: Each Sunrise™ Reader and HeatPlate™ require RS232 ports (via USB to RS232 adapters and driver PN 25-361 if necessary) USB ports are required for a PyroWave® XM Reader add-on and for the PyroTec® PRO System robotic deck

Plate Readers

Tecan® Sunrise™ Reader	Specifications
Optical system	12 measurement channels, 1 reference channel
Wavelength range	340 – 750 nm
Bandwidth @ 50% transmission	10 ± 2 nm
Read position	Top read
Power consumption	Max. 110 VA
Fuse rating	2 x F 2.0 A / 250 V (Fast Blow)
Measurement range	340 – 399 nm, 0 to 3.000 OD
	400 – 750 nm, 0 to 4.000 OD
Measurement time	Single wavelength: 6 seconds
Accuracy	0.0 to 2.0 OD/492 nm better than ± 1.0 % ± 0.010 OD
	2.0 to 3.0 OD/492 nm better than ± 1.5 % ± 0.010 OD)
Linearity	340 – 399 nm, 0.0 – 2.0 OD: better than ± 2 %, R2 ≥ 0.999
	400 – 750 nm, 0.0 – 2.0 OD: better than ± 1 %, R2 ≥ 0.999
	2.0 – 3.0 OD: better than ± 1.5 %, R2 ≥ 0.999
Precision	0.0 – 2.0 OD/492 nm < (± 0.5 % ± 0.005 OD)
	2.0 – 3.0 OD/492 nm < (± 1.0 % ±0.005 OD)
Resolution	0.001 OD
Shaking	Yes, shaking function used to mix plate contents prior to initial read
Interface	RS-232C (remote control)/parallel
Filters supplied	340 nm and 405 nm
Filter wavelength accuracy	Central wavelength ± 2 nm
Light source	Halogen lamp 20 W
Temperature range	Room temperature to 42°C (resolution 0.1°C) Peltier-based temperature control
Temperature accuracy	Typical ± 0.2°C (max. ± 0.5°C)
Temperature uniformity	± 0.5°C at 37°C
Pre-heating time	30 minutes
Width	28.5 cm (11.22 inches)
Depth	34.0 cm (13.39 inches)
Height	14.5 cm (5.71 inches)
Weight	8.6 kg (19 lbs)
Plate carriage height limit	Maximum height 14.35 mm ± 0.76 mm (0.5650 inches ± 0.0299 inches)

Plate Reader continued on next page.

Plate Readers (continued)

PyroWave® XM Reader	Specifications
Optical system	Fluorescence
Wavelength range	200 – 850 nm
Read position	Top read
Detection	High performance photo multiplier tube
Fluorescence sensitivity	Fluorescein at 1 pM/ well in a 96-well plate
Shaking	Yes, shaking function used to mix plate contents prior to initial read
Interface	RS-232 or USB
Interference filters and Dichroic mirrors supplied	Blue: Excitation 380/20 nm, Emission 440/30 nm, 400 nm mirror for PyroGene® Assay
	Green: Excitation 440/30 nm, Emission 528/20 nm, 510 nm mirror for Sodium Fluorescein testing
Power	24V external power supply
	Compatible with 100 – 240 Volts AC 50/60 Hz
	250W max. power consumption
Light source	Xenon flash light source (not user change-able)
	5W maximum average power
Temperature range	4°C above ambient to 45°C
Temperature accuracy	± 0.2°C at 37°C
Temperature uniformity	± 0.5°C at 37°C
Pre-heating time	30 minutes
Width	39.1 cm (15.4 inches)
Depth	47.2 cm (18.6 inches)
Height	32.8 cm (12.9 inches)
Weight	22.5 kg (50 lbs)
Plate carriage height limit	Maximum height 22.6 mm (0.89 inches)
Space requirement	Allow 15.2 cm (6 inches) clearance at rear for air flow

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