

Dokumentnamn/Document name Phadia® 100 Data Sheet	Dokumentnummer/Document number
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Physical Specifications

Item	Specification	Comment
Instrument	Width: 680 mm Depth: 600 mm Height: 440 mm	
Packed instrument	Width: 1200 mm Depth: 800 mm Height: 680 mm	- - -
Instrument	Weight: 46 kg Weight: 49 kg Weight: 86 kg	Empty Loaded Packaged
Consolidated footprint	N/A	-
Sound level	57 dBA	At 1 meter (in operation and measured in compliance to ISO 3744)
Heat Contribution	200 W (average) or 683 Btu/h	-

Environmental Requirements

Item	Specification	Comment
Operational temperature	18 - 32 °C 37 °C	Ambient temperature Processing Chambers
	2 °C / hour	Allowed ambient temperature change (maximum change)
Operational air humidity	10 – 85 %RH	Ambient air humidity
Operational air pressure	750 – 1060 millibar	Ambient air pressure
Non-operational temperature	5 – 42 °C	
Transportation and storage requirements	Transportation temperature	-20 – 60 °C
	Storage temperature	-20 – 70 °C
	Allowed thermal shock	1 °C / 10 minutes
	Storage air humidity	10% - 95 % RH



At installation

Item	Specification	Comment
Grounded electric outlet	Instrument must be connected to a grounded electric outlet.	-

Electrical specifications

Item	Specification	Comment
Mains Power supply	<ul style="list-style-type: none"> • AC 100 V ($\pm 10\%$), 50/60 Hz • AC 120 V ($\pm 10\%$), 50/60 Hz • AC 230 V ($\pm 10\%$), 50/60 Hz • AC 240 V ($\pm 10\%$), 50/60 Hz 	Main voltage tolerances + 10% / - 15% Main frequency tolerances +/- 1 %
Primary fuses	<ul style="list-style-type: none"> • T 5 A L: 100-120 V • T 2,5 A L: 230-240 V 	-
Power Consumption	550 VA (0,55 kVA)	-
Signal Interface	<p><u>Instruments with USB ports:</u> Interface ports for USB memories, USB harddrive, IDM and bar code reader.</p> <p><u>Instruments with diskette drive:</u> Interface ports for external computer, Phadia Daisychain communication and bar code reader are available.</p>	These serial ports must be connected only to external equipment meeting the appropriate EMC and electrical safety standards.



Fluorometer Specifications

Item	Specification	Comment
Excitation filter	Center wavelength: 367 ± 5 nm Full width half max: 16 ± 5 nm Transmission: $30\% \pm 4\%$	-
Emission filter	Center wavelength: 445 ± 5 nm Full width half max: 30 ± 5 nm Transmission: 65% min	-
Lamp	12 V, 50 W Halogen lamp	-

Performance

Item	Specification	Comment
Features	Automated dispensing, processing and measuring	-
	Batch process	-
	Test result rate	48 tests/ 3 hour
	Random access	-
	Calibration Stability	28 days
Number of tests/day	Approx 100 tests/day	1 work shift (6-8 hours)
Number of tests/year	Approx. 25000 tests/year	-
Process times	150 minutes to first result	ImmunoCAP Technology EliA Technology
Sample Types	Serum, Plasma (EDTA)	-
Methods	Specific IgE Total IgE Specific IgA Specific IgG Specific IgG4 Tryptase ECP EliA IgA EliA IgG EliA IgM EliA Calprotectin	>600 allergens/mixes/components >80 components Autoimmunity panel for over 20 diseases
Maximum number of methods to run in one assay	4	Due to the fact that there are 4 conjugate positions in conjugate loading position.
Hands-on time		
From “stand-by” to operation	25 minutes	15-20 minutes for loading of reagents and samples. 5 minutes for priming of instrument (automatic).
From “stand-by” to first result (ImmunoCAP & EliA)	ca. 175 minutes	Loading: ~15 - 20 min Priming (automatic): ~5 min Processing time: 150 min

Loading capacity of instrument

Item	Specification	Comment
Samples	48 samples maximum loaded at the same time	-
Conjugate	4 Conjugate positions	In Conjugate loading positions



Item	Specification	Comment
		on the Sample carousel.
Development Solution	1 Development solution position.	In Development loading position on the Sample carousel.
Stop Solution	1 Stop solution position.	In Stop loading position on the Sample carousel.
Fluoro C Solution	1 Fluoro C position.	In Fluoro C loading position on the Sample carousel.
Calibration Curves, Curve Controls	Positions in the Sample carousel for one dose vials.	
Diluent	Diluent positions in Sample carousel.	On diluent vial/sample to be diluted depending on which dilution factors to be utilized.
Washing Solution	1 Washing Solution bottle	1 l
Rinse Solution	1 Rinse Solution bottle	1 l Water quality for the Rinse is purified water (specification according to Eur. Pharmacopeia 3d ed. suppl. 2000 “water, purified”)
Liquid Waste	1 Waste bottle	2 l

Stability Reagents when used in Phadia 100

Reagent	ImmunoCAP	EliA
Calibrator/Curve Control	One dose vials	One dose vials
Conjugate	+8 °C in 16 h and +32 °C in 8 h for 6 days.	Single use reagent
Development Solution	According to DfU	According to DfU
Stop Solution	According to DfU	According to DfU
Washing Solution (prepared solution)	7 days at room temperature	7 days at room temperature
Diluent	According to DfU	According to DfU
ImmunoCAP/EliA well carrier	Until expiration date	28 days at 2-8 °C or 24 h at room temperature



Pipetting volumes

Sample	ImmunoCAP EliA	40 µl 90 µl CV ≤ 1%
	Dead volume	Depends on the tube used
Conjugate	ImmunoCAP EliA	50 µl 90 µl CV ≤ 1%
	Dead volume	200 µl
Development Solution	ImmunoCAP EliA	50 µl 90 µl CV ≤ 1%
	Dead volume	500 µl
Stop Solution	ImmunoCAP EliA	200 µl (3 times → 600 µl) 200 µl CV ≤ 1%
	Dead volume	6500 µl

Washing volumes

Washing Solution	ImmunoCAP EliA	130-145 µl 210-250 µl
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Sample bar code and bar code reader

Item	Specification	Comment
Positive sample identification	Bar code reader is an optional feature that is not marketed by Phadia.	Mandatory to be utilized when performing EliA runs.



Sample tubes

Item	Specification	Comment
Possible to use bar code labeled primary tubes.	Yes	
Dimensions of tubes	Height: 36-100 mm Diameter: 10-16 mm	Inner diameter must not be less than 9 mm's.
Possible to use tubes for capillary blood samples.	No	It will be a too narrow situation when both pipette tips shall have enough space in the tube.
Dead volume	Depends on the tube.	The dead volume in a sample tube is dependent on the tubes diameter and bottom shape. To be able to optimize least possible dead volume settings for sample tubes and instrument calibrations is crucial. For some tube types it is possible to achieve lesser dead volumes than stated below. For round bottom Ellerman tubes with an inner diameter of 9-11 mm a normal dead volume is around 100-150 µl.
Dead volume pediatric tube	Depends on the tube.	For a pediatric tube (1 ml conical tube with an inner diameter of 8 mm or more) the normal dead volume is 50-70µl.
Level detection	Yes	Level detection is performed automatically when aspirating from sample tube. Samples and reagents should always be inspected regarding the presence of bubbles and/or foam since the instrument cannot handle this. Tube should always stand straight up in the rack
Clot detection	No	



Sample Dilution	Sample can be diluted (automatic)	Instrument dilutions are: 1 2 5 10 20 50 100
Re-running of samples below or above the measuring range.	Possible	
Closed-tube sampling	Not possible.	

Other

Item	Specification	Comment
System can communicate with a number of LIS via two-way communication and when connected to Phadia IDM.		System handles ASTM via RS-232 or TCP/IP (both genuine two-way communication forms). Available communication protocols are ASTM, Phamas, MasterCAP, DataCAP and HL7.
Instrument Software (ISW)	<p>Stand alone instrument</p> <p>Enter request: Requests are entered from the inbuilt keypad. Easy and logically routine when entering.</p> <p>Load reagents: Reagents are loaded with an easy and logical order from the inbuilt keypad.</p> <p>Assay: control and confirmation of loaded reagents. Start of assay. Process status and message status possible to view during assay run.</p> <p>Utilities: Maintenance, test programs, service programs</p>	-



Item	Specification	Comment
	inbuilt.	
Reflex-testing	Available when Phadia IDM is utilized.	-



Automatic approval	Automatic approval can be selected by settings in the Phadia Information Data Manager (IDM) software. Approval of results can also be set to manual. Transfer/Export of approved results to LIS can be manual or automatic.	-
STAT (urgency) samples	Not possible.	-
Qualitative or quantitative results	Both are available.	-
On-line communication with LIS	On-line communication with LIS is possible to choose if instrument is connected to Phadia IDM computer.	-
Operation of Instrument Software (ISW) is via inbuilt keypad.	Yes	-
Excellent QC package with online tracking and trending (Levey-Jennings plot) is available.	Yes	-
Flexible and customizable patient reports.	Available in Phadia IDM and a standard format for printing is utilized in the stand alone instrument.	-
Multilingual support	6 languages to choose from: English, Spanish, Italian, Portuguese, French, German.	User manuals also in Swedish, Danish and Dutch.
Remote Diagnostics	LabCommunity supplied by Phadia that can be utilized when instrument is connected to Phadia IDM computer.	This feature provides enhanced support and troubleshooting assistance that can reduce the downtime of the system
Correction of results using slope or intercept	Correction of results using slope or intercept is not possible. Calibration function is non-linear. It is a 4 or 5 parameter logistic function.	-



Traceability of reagents	System has full automatic traceability of reagents if a bar code reader is utilized when preparing assay run and during loading of assay run.	Full automatic traceability regarding lot numbers for all components, samples and reagents. All Id's are logged and stored in a database. Samples/components can easily be traced. Options for how long the information should be saved can be chosen. Reports can be printed.
Traceability of lot no and expiry dates for Quality controls (QC) and calibrators (CAL).	System has full automatic traceability of reagents if a bar code reader is utilized when preparing assay run and during loading of assay run.	-
Information to operator of expiry dates	If the instrument has a bar code reader connected and all reagents are read during preparing and loading of the assay run the system has information about the expiry dates for all reagents.	-



System Computer Specifications

Computer	In order to fulfil EMC/Safety demands, the PC shall be from one of the following manufacturers:	Dell Compaq HP IBM
	Processor/memory:	Windows 2000 and Windows XP: Minimum processor speed: 1.4 GHz Minimum memory: 256 MB RAM Windows Vista: Minimum processor speed: 2.0 GHz Minimum memory: 1 GB RAM Windows 7: Minimum processor speed: 2.4 GHz Minimum memory: 2 GB RAM Minimum Processor type: Quad Core
	Storage:	Diskette drive. 3,5", 1,44 MB CD ROM or DVD: CD-R, CD-RW 8x Windows 2000 and Windows XP: Minimum hard-disk size: 20 GB Windows Vista: Minimum hard-disk size: 40 GB Windows 7: Minimum hard-disk size: 80 GB
	Display:	Screen resolution: 1024 x 768 pixels Minimum size using CRT: 17 " Graphics card: supporting 64K colors Touch screen (optional) Flat screen, 15" TFT (optional)
	Communication:	1 parallel port (printer) 1 USB port 1-8 serial ports (depending on



		<p>configuration)</p> <p>1-3 network adapters (10/100 MB Ethernet / RJ45 / TP)</p> <p>Switch w 3-6 connections RJ45 (optional)</p> <p>External V.90 modem (optional)</p>
	Other:	<p>Keyboard: National type or best suitable</p> <p>Mouse: 1 serial or bus mouse</p> <p>Sound card w speakers: Drivers for Windows 2000</p> <p>Bar code reader: RS232C serial reader, handling code 39, 93, 128</p> <p>Network cables: RJ45 / TP</p> <p>Printer (optional): B/W, A4-printer, 600 dpi, drivers for Windows 2000</p> <p>Power backup (UPS) or internal battery backup (optional)</p> <p>Backup unit for backup of hard-disk (optional)</p>
Operating System		<p>Windows 2000 Professional, SP3</p> <p>Windows XP Professional, SP1</p> <p>Windows Vista (<i>User Account Control must be disabled</i>).</p> <p>Windows 7 (<i>User Account Control must be disabled</i>).</p>
Electric Safety and Compatibility		<p>The system computer is CE marked. That means that, among others, the following directives are fulfilled:</p> <p>The EMC-directive (89/336/EEC)</p> <p>The low voltage directive (73/23/EEC)</p> <p>The CE directive (93/68/EEC)</p>



Environmental Requirements		Environmental requirements for the system computer are the same as for the ImmunoCAP instruments.
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Laboratory Automation System (LAS)

Phadia 100 cannot be connected to automatic track system (e.g. LAS).	-	-
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Compliance with directives and standards

Instrument and instrument software (ISW) is CE labelled in compliance with IVD directive (98/79/EG)		
Phadia 100 complies with: Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on <i>In Vitro</i> Diagnostic Medical Devices		
Phadia 100 complies with following EMC (Electromagnetic Compatibility) standards:		
EN 61000-6-2, (2001). "Electromagnetic Compatibility, Part 6:2: Generic standards, Immunity for industrial environment"		
EN 61326, (1997) with amendment A1 (1998) and A2 (2001) Electrical equipment for measurement, control and laboratory use – EMC requirements		
EN 61000-6-3, (2001). "Electromagnetic Compatibility (EMC) Part 6-3:"Emission standard for residential, commercial and light-industrial environments"		
The electrical safety properties of Phadia 100 complies with requirements in the European standards:		
IEC/EN 61010-1 second edition (2001) "Safety requirements for electrical equipment for measurement, control and laboratory use".		
IEC/EN 61010-2-101 ed. 1 (2002) Particular requirements for <i>In Vitro</i> Diagnostic (IVD) medical equipment.		
IEC/EN 61010-2-081 ed. 1 (2001) and A1, Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes.		
The electrical safety properties of Phadia 100 also complies with:		



UL 61010-1, 2004 incl. rev. 2005 and CAN/CSA-C22.2 No. 61010-1, 2004.



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