

Analizator biochimic cu cuva , semiautomat, cu sistem de tip deschis			
Descriere	Analizator semiautomat destinat analizelor biochimice cu sistem de tip deschis de reactivi		Specificatii tehnice Stat Fax Stat Fax 1904+Mosquito
Parametrul		Specificația	
Tip sistem		Sistem deschis de reactivi	Sistem deschis de reactivi
Tip probă	Ser	da	Da
	Plasmă	da	Da
	Urina	da	da
Reagenți	Lichid	da	Da
	Cu posibilitatea de a fi substituiți	da	Da
Incubator	Temperatura termostatare	37°C	37°C
	Capacitatea	minim 8 tuburi	12 tuburi
Cuva absorbanta	cuva	da	Da (Mosquito)
	tip	reutilizabila	reutilizabila
	Volum reactiv/investigatie	≤500 mcl	≤500 mcl
	Temperatura termostatare	37°C	37°C
Regimuri de masurare	Punct final	da	da
	Cinetic	da	da
	Multipoint cinetic	da	da
Sursa de lumină		Minim 6 lungimi de undă	6 lungimi de unda - 340, 405, 450, 505, 545, 600nm
Data management	Display	da	Da, LCD
	Memorie internă	da	da
	Imprimantă integrată	da	Da, termica
Calibrarea	automată	da	Da
Alimentarea	Rețeaua electrică 220 V, 50 Hz	da	220 V, 50 Hz
	Cuva absorbanta tip	Reutilizabila, 2 buc	Reutilizabila, 2 buc
Accesorii	Bec	≥3 buc	3 buc
Consumabile	Eprubete (cuve) pentru incubarea reactivelor compatibile cu incubatorul analizatorului	≥1000 buc	Eprubeta pentru Stat Fax 1000 buc

Analizator biochimic, semiautomat, cu sistem de tip deschis			
Descriere	Analizator semiautomat destinat analizelor biochimice cu sistem de tip deschis de reactivi		Specificatii tehnice Stat Fax Stat Fax 1904
Parametrul		Specificația	
Tip sistem		Sistem deschis de reactivi	Sistem deschis de reactivi
Tip probă	Ser	da	Da
	Plasmă	da	Da
	Urina	da	da
Reagenți	Lichid	da	Da
	Cu posibilitatea de a fi substituiți	da	Da
Incubator	Temperatura termostatare	37°C	37°C
	Capacitatea	minim 8 tuburi	12 tuburi
Regimuri de masurare	Punct final	da	da
	Cinetic	da	da
	Multipoint cinetic	da	da
Sursa de lumină		Minim 6 lungimi de undă	6 lungimi de unda - 340, 405, 450, 505, 545, 600nm
Data management	Display	da	Da, LCD
	Memorie internă	da	da
	Imprimantă integrată	da	Da, termica
Calibrarea	automată	da	Da
Alimentarea	Rețeaua electrică 220 V, 50 Hz	da	220 V, 50 Hz
Accesorii	Bec	≥3 buc	3 buc
Consumabile	Eprubete (cuve) pentru incubarea reactivelor compatibile cu incubatorul analizatorului	≥1000 buc	Eprubeta pentru Stat Fax 1000 buc

Anexa nr.62. Cititor de microplaci (Elisa) , Cod 250410, Stat Fax 4200, Awareness Technologies

<i>Specificarea tehnică deplină solicitată, Standarde de referință</i>	<i>Specificarea tehnică deplină oferita, Standarde de referință</i>
Cititor de microplăci Cod 250410 Descriere Permite efectuarea testelor pentru boli autoimune si pentru alergologie prin metode cantitative și calitative. Parametrul Specificația Tip sistem Sistem deschis Lungimi de undă de la ≤ 400 până la ≥ 750 nm Sursa de lumină Minim 5 lungimi de undă Centrul acuratețea lungimii de undă +/- 2 nm Sensibilitate ≤ 0.1 fluor/μm^2 Acuratețe 2% Precizie ≤ 0.3 % Linearitatea +/- 2% Timpul de măsurare ≤ 8 sec Sursa de lumină halogen Fotodetector ≥ 8 Agitare 3 moduri Afișarea LCD Incubator Inclus da Temperatura + 5°C până la + 40°C Data management Display da Memorie internă da Interfață PC da Imprimantă da Calibrarea automată da Alimentarea Rețeaua electrică 220 V, 50 Hz da	Cititor de microplăci Cod 250410 Descriere Permite efectuarea testelor pentru boli autoimune si pentru alergologie prin metode cantitative și calitative. Parametrul Specificația Tip sistem Sistem deschis Lungimi de undă de la 405 până la 700 nm Sursa de lumină Minim 5 lungimi de undă Centrul acuratețea lungimii de undă +/- 2 nm Sensibilitate ≤ 0.1 fluor/μm^2 Acuratețe 1% Precizie ≤ 0.3 % Linearitatea +/- 2% Timpul de măsurare 10 sec Sursa de lumină halogen Fotodetector ≥ 8 Agitare - nu Afișarea LCD Incubator Inclus da Temperatura + 5°C până la + 40°C Data management Display da Memorie internă da Interfață PC da Imprimantă da Calibrarea automată da Alimentarea Rețeaua electrică 220 V, 50 Hz da

Anexa nr.63. Spalator pentru microplaci (Elisa) , Cod 250420, Stat Fax 2600, Awareness Technologies

<i>Specificarea tehnică deplină solicitată, Standarde de referință</i>	<i>Specificarea tehnică deplină oferita, Standarde de referință</i>
Spălător pentru microplăci Cod 250420 Descriere Este fabricat pentru curățarea diferitor tipuri de microplăci, complet programabil asigurând soluții de diferite concentrații, aspirație, aspirație/combinare/dozare. Parametru Specificația Canale de la 8 până la 12 Capabile să spele toate tipurile de microplăci da Dotat cu calibrator da Afișare LCD Programabil da Alarmă da Control automat Numărul ciclurilor de spălare 1...15 Alimentare 220-240 V, 50 Hz	Spălător pentru microplăci Cod 250420 Descriere Este fabricat pentru curățarea diferitor tipuri de microplăci, complet programabil asigurând soluții de diferite concentrații, aspirație, aspirație/combinare/dozare. Parametru Specificația Canale de la 8 până la 12 Capabile să spele toate tipurile de microplăci da Dotat cu calibrator da Afișare LCD Programabil da Alarmă da Control automat Numărul ciclurilor de spălare 1...15 Alimentare 220-240 V, 50 Hz



Awareness Technology, Inc.



Declaration of Conformity

Product name :	Product identification
Model/Type :	Stat-Fax®, Chemistry Analyzer P1904
Name :	Manufacturer
Address :	Awareness Technology, Inc. 1935 S.W. Martin Hwy. Palm City, Florida 34990
Country :	USA
Representative:	Authorized Representative in Europe
Name :	Emergo Europe
Address :	Prinsessegracht 20 2514 AP The Hague
Country :	The Netherlands
tel:	+31 70 345 8570
fax:	+31 70 346 7299

Means of Conformity

Awareness Technology, Inc. declares that the product listed is in conformity with the Annex III, essential requirements and provisions of Council Directive:

98/79/EC

And is in conformance with the following standards:

*EN 61326-1 / EN 55022
EN 61010-1*

Place and Date:	Signature Awareness Technology, Inc.
Signature :	
Name :	Steve Andrus Quality Manager

December 01, 2003
Revised May 7th, 2018



Stat Fax[®] 1904Plus - Chemistry Analyzer

Inset - shown with Mosquito[®] Aspiration Flow Cell accessory

Features

- ⇒ Bichromatic optical system with six wavelengths including 340nm.
- ⇒ Pre-programmed calculations for both kinetic and endpoint assays.
- ⇒ Twelve-station 37°C incubation block and temperature-controlled read cell.
- ⇒ Easy to use with step-by-step prompting and built-in thermal printer with graphics capability.
- ⇒ Large, non-volatile memory to store more than 50 curves and test parameters.

Options & Accessories

- ⇒ Redi-Check[®] to monitor accuracy, linearity, and repeatability of Stat Fax[®] Chemistry Analyzer.

Mosquito[®] Aspiration Flow Cell

- ⇒ Powered from the Stat Fax[®] Chemistry Analyzer.
- ⇒ Keyboard selectable read volume from 250mL to 500 mL.
- ⇒ Software controlled with user prompts.
- ⇒ Internal extra-quiet vacuum pump.
- ⇒ All cables and connectors included.

Distributed by:



AWARENESS TECHNOLOGY, Inc. PO Box 1679, Palm City, FL 34991 (772) 283 6540 fax (772) 283 8020
 web: <http://www.awaretech.com> email: info@awaretech.com

Cost Effective by Design[®]

Stat Fax® 1904 Chemistry Analyzer Specifications

Photometric

Linear Measurement Range:	0.0 to 2.5 Absorbance units (A).
Photometric Accuracy:	+/- (1% of the reading + 0.005A).
Stability:	Drift of no more than 0.005A in 8 hours/bichromatic.
Light Source:	Tungsten lamp with lamp saver feature.
Standard Wavelengths:	340, 405, 450, 505, 545 and 600nm. (alternate filters available from 340 to 700nm)
Filter Type:	IAD hardcoat interference, 10nm half bandpass.
Tube Size:	12 mm round is standard.
Minimum sample volume:	1mL for 12mm round tube, 250mL with Mosquito accessory.

Electronic

Display:	Alphanumeric, 16 character LCD.
Printer:	Thermal dot matrix, 20 characters per line, plus graphics.
Keyboard:	16-key, domed membrane switch, enunciating.
Power Requirements:	115V or 230V AC, 50-60Hz (switch selectable).

Software

Speed:	Reads, calculates and prints results - 3 seconds per tube.
Calculation Modes:	Single point calibration by standard or factor, multipoint calibration with point-to-point curve fit, rate by standard or factor (batch or singly).
Test Menu:	More than 60 open channels to store tests. Stores all parameters including wavelengths, calculations, unit codes, linear and normal ranges, rate timing, standard values, test names, and previous standard curve.

Other

Temperature	37°C, block stays on, cell has on/off switch.
Enclosure:	Painted flame-retardant ABS plastic cover with metal base.
Dimensions:	Approx. 9x13.5x5in. (24x34x13cm) weighs 10 lbs.(4.5kg).
Certifications:	NRTL listed, CE mark.

Mosquito® Aspiration Flow Cell specifications

Cell

Minimum aspiration volume:	250mL at 7"Hg vacuum.
Other Volume Options:	300, 350, 400, 450, 500mL.
Illuminated Volumes:	21mL.
Equivalent Pathlength:	1cm.
Cell Body:	Surgical grade stainless.
Windows:	1mm Pyrex.

Control Module

Power Input:	12V DC/0.7A from analyzer.
Valve:	Silicone pinch type.
Vacuum Sensor:	Piezoresistive bridge type.
Vacuum Regulation:	Better than 0.25" Hg.
Vacuum Pump:	Self contained.
Full Sensor:	Stainless conductivity probe.

Mosquito® is compatible with 1900 series chemistry analyzers with 12mm round read cell manufactured by Awareness Technology, Inc.



Stat Fax[®] 2600 - Microplate Washer

Features

Washes flat, round, and v-bottom plates and strips.

No user adjustments required, automatic calibration, alignment, and last row detection.

Large, non-volatile memory for up to 50 user-entered wash protocols; Six factory-programmed wash/rinse modes.

Programmable automatic rinse cycle.

Precision operation with constant monitoring of vacuum and pressure. For extra quiet operation, internal pump cycles on only when needed.

Ready to run; 3 bottles, aerosol shield, and 8-probe manifold included.

Options & Accessories

12-probe and 16-probe manifolds.

Extra wash, rinse, and waste bottles.

2600 Plus added features:
Dual wash bottle system for added versatility and convenience.
Individual row selection for partial plate washing.
Built-in plate mixing function.

Distributed by:



Awareness Technology, Inc. PO Drawer 1679, Palm City, FL 34991 (772) 283 6540, fax (772) 283 8020
 web site: <http://www.awaretech.com>, email: info@awaretech.com

Cost Effective by Design[®]

Stat Fax[®] 2600

Microplate Washer Specifications

Fluid Performance (with 8-probe head)

Residual Volume: <3µl.
Dispense accuracy: <3% CV at 300µl.
Processing time (full plate): 55 seconds aspirate/dispense with single or double aspirate.
Liquid Contact Materials: Stainless steel, Delrin, silicone, nylon, PVC, polypropylene, HDPE.

Electronic

Display: Two-line LCD, alphanumeric, 24 characters per line.
Keyboard: 16-key, domed membrane switch, 4x4, enunciating.
Power Requirements: 115V or 230V AC, 50-60Hz (switch selectable).
Microprocessor: Z80A or Z180.
Non-volatile Memory: Battery supported RAM, holds approx. 50 wash protocols.

Software

Washing Programs: Aspirate, dispense, mix, soak - up to 99 minutes 99 secs.
Special Menu Options: *Auto alignment* - senses physical geometry of the head, plate, and carrier mechanism.
Standby - disables pumps and releases vacuum and pressure.
Self Check - performs internal performance tests and auto alignment.
Auxiliary - selection of well type, select auto/manual well depth and dispense depth, constant plate cycle time, viewing of pre-programmed tests, configure auto-rinse, set the time and date.

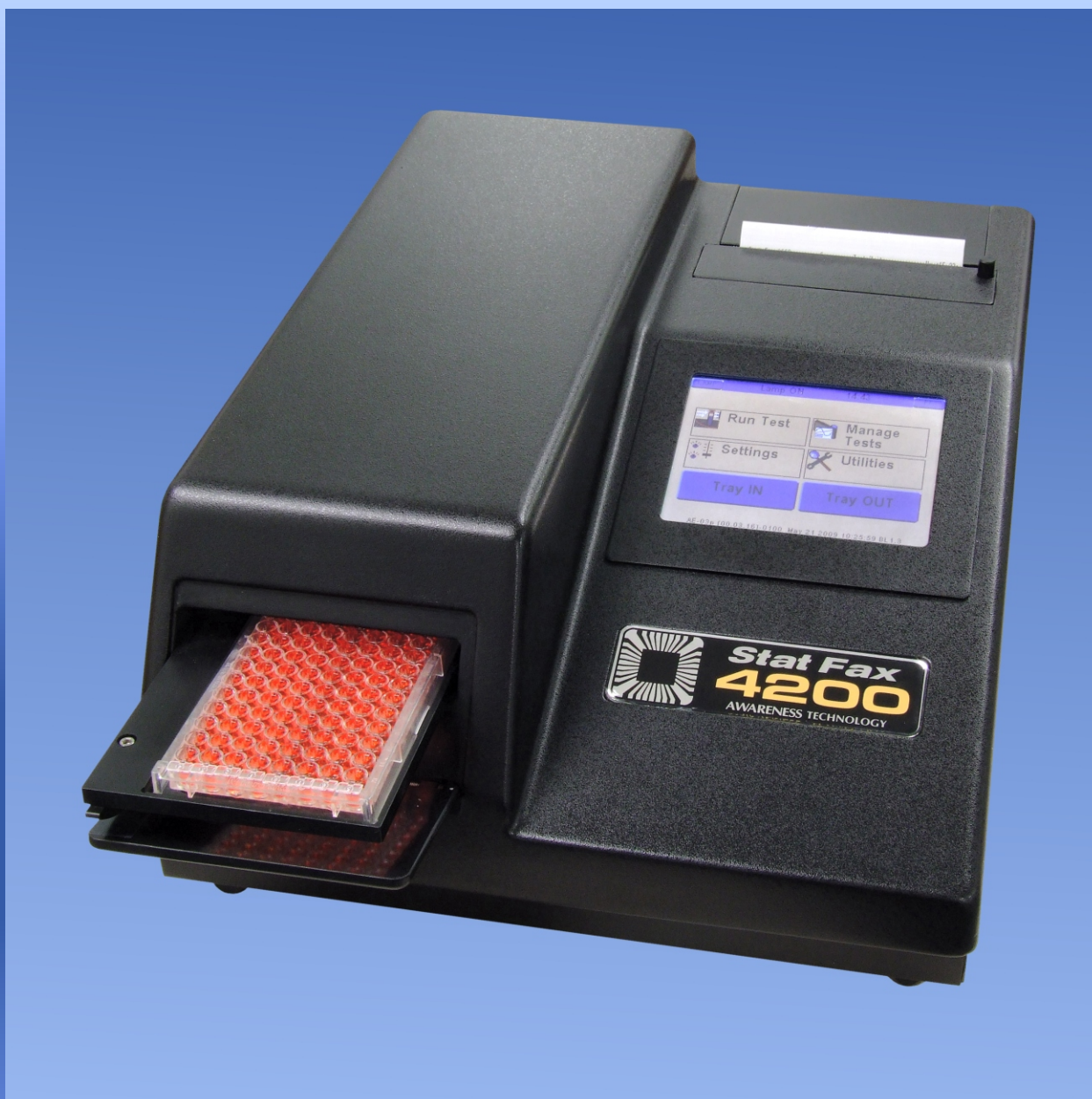
Other

Bottles: Wash and waste 2L, rinse 1L, plastic with volume sensor probes.
Enclosure: Fire retardant ABS plastic cover with metal base.
Dimensions: Approx. 15.5 x 13.5 x 7.5in (39 x 34 x 19cm). Weight 19 lbs. (8.6kgs).
Certifications: NRTL Listed, CE Mark.



2600 Plus model - added features

Bottles: Wash-1, Wash-2, and Waste (2L), Rinse (1L), plastic with volume sensor probes.
Mix function: Programmable mix time during soak cycle.
Row selection: User may select individual rows to wash, skipping used wells.



***Stat Fax*[®] 4200**

Microplate Reader

The Stat Fax[®] 4200 is a compact, standalone 8-channel microplate reader. Its streamlined design offers touch screen interface, rapid reading, superb optics, on-board curve-fitting software, and built-in printer to meet the requirements of modern laboratories.



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web: <http://www.awaretech.com> email: info@awaretech.com

Cost Effective by Design[®]

Stat Fax® 4200

Microplate Reader Specifications

Photometric

Linear Measurement Range:	0.0 to 4.0 Absorbance units (A).
Photometric Accuracy:	+/- 1% .
Stability:	Drift of no more than 0.005A in 8 hours.
Light Source:	Remote halogen lamp source with lamp saver feature.
Wavelengths:	Standard: 405, 450, 492, and 630nm. 6-filter: 405, 450, 492, 545, 600, and 630nm. Filter options from 405nm to 700nm.
Filter Type:	IAD hardcoat interference, 10nm half bandpass.
Vessel:	Standard 96-well microtiter plates, or strip trays.

Electronic

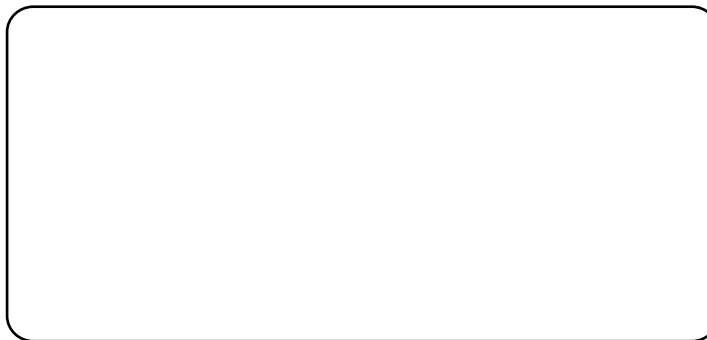
Display:	Interactive 5.7" (14.5cm) graphical touch-screen LCD.
Printer:	Thermal dot matrix, 20 characters per line, plus graphics.
Power Requirements:	115V or 230V AC, 50-60Hz (auto-sensing).
Interface:	USB mouse.
Speed:	Reads absorbances of 96 wells in about 10 seconds.
Plate Transport:	Stepper motor.
Certifications:	NRTL listed, CE mark.

Software

Calculation Modes:	Single point calibration, point-to-point curve fit, polynomial regression, linear and sigmoidal regressions (log & linear), cutoff absorbance, multipoint % absorbance.
Additional Features:	User-programmable open system, selectable plate formatting, alphanumeric test naming, automatic interpretation options, duplicate well options, curve plotting and editing, flags and error messages.

Other

Enclosure:	Flame-retardant ABS plastic cover and base.
Dimensions:	Approx. 7.5"x13.0"x16.5" (19x20.3x42cm). Weighs 15lbs. (6.8kg).



CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Awareness Technology, Inc.

Main Site: 1935 SW Martin Highway

Palm City, Florida 34990 USA

Additional site: 2325 SW Martin Highway, Palm City, Florida 34990 USA

has been assessed by Intertek as conforming to the requirements of:

ISO 13485:2016

The quality management system is applicable to:

The design, development, manufacture, distribution, installation and service of IVDD General Laboratory Instruments.

Additional site: Manufacturing, Quality Control, Distribution, Shipping, Installation and Service.

Certificate Number:

9362-8

Initial Certification Date:

March 28, 2012

Date of Certification Decision:

March 24, 2021

Issuing Date:

March 27, 2021

Valid Until:

March 27, 2024



Intertek



A handwritten signature in black ink, appearing to read "Calin Moldovean".

Calin Moldovean
President

Intertek Testing Services NA Ltd.,
1829, 32nd avenue, Lachine, QC, H8T 3J1,
Canada





Awareness Technology, Inc.



Intertek

Declaration of Conformity

Product Identification

Product name	Model/Type
Microstrip Reader	Stat Fax 300 series
	Stat Fax 4700 series
Chemistry Analyzer	Stat Fax1900 series
	ChemWell 2900 series
	Stat Fax 3300 series
	Stat Fax 4500 series
	ChemWell-T 4600 series
	ChemWell Fusion 4800 series
ELISA Analyzer	ChemWell2 5100 series
Automated Analyzer	ChemWell-RPR 5800 series
Microplate Reader	Stat Fax 2100 series
	Stat Fax 3200 series
	Stat Fax 4200 series
Incubator / Shaker	Stat Fax 2200 series
Microplate Washer	Stat Fax 2600 series
Electrolyte Analyzer	ISE 3900 series
Luminometer	LumiStat 4100 series
	LuMate 4400 series
	LumiStat 4900 series
Microplate Reader	ChroMate 4300 series

Manufacturer

Name : Awareness Technology, Inc.
Address : 1935 SW Martin Hwy
Palm City, Florida 34991
Country : USA

Means of Conformity

Awareness Technology, Inc. declares that the product listed is in conformity with the Annex III, essential requirements and provisions of Council Directive: 98/79/EC and is in conformance with the following standards: EN 61326-1 EMC / EN 61010-1 Safety

Representative: Authorized Representative in Europe

Name : Emergo Europe
Address : Prinsessegracht 20
2514 AP The Hague
Country : The Netherlands
Telephone : +31 70 345 8570
Fax Number : +31 70 346 7299

*Self-certified under the principles of ISO 13485:2016
Registered Medical Device Quality System under ISO 13485:2016*

Place and date:

Awareness Technology, Inc.

October 26, 2016

Revised May 7 2018

Signature:

Name:

Steve Andrus

Title:

Quality Manager