

Anexa 20 Cititor de microplaci, Stat Fax 4700, Awarness Technology, SUA

Specificatie tehnica solicitata	Specificatie tehnica oferita
<p>Cititor de microplaci</p> <p>Permite efectuarea testelor pentru boli autoimune si pentru alergologie prin metode cantitative și calitative.</p> <p>Parametrul Specificația</p> <p>Tip sistem Sistem deschis</p> <p>Lungimi de undă de la 300 până la 750 nm</p> <p>Sursa de lumină Minim 5 lungimi de undă</p> <p>Centrul acuratețea lungimii de undă +/- 2 nm</p> <p>Sensibilitate ≤ 0.1 fluor/μm^2</p> <p>Acuratețe 2%</p> <p>Precizie ≤ 0.3 %</p> <p>Linearitatea +/- 2%</p> <p>Capacitatea de incarcare: de la 3 stripuri de 8/12 godeuri</p> <p>Timpul de măsurare ≤ 5 sec</p> <p>Sursa de lumină halogen/xenon</p> <p>Afișarea LCD</p> <p>Display: da</p> <p>Memorie internă da</p> <p>Interfață PC da</p> <p>Imprimantă da</p> <p>Automata: da</p> <p>Alimentarea Rețeaua electrică 220 V, 50 Hz da</p>	<p>Cititor de microplaci</p> <p>Permite efectuarea testelor pentru boli autoimune si pentru alergologie prin metode cantitative și calitative.</p> <p>Parametrul Specificația</p> <p>Tip sistem Sistem deschis</p> <p>Lungimi de undă de la 340 până la 700 nm</p> <p>Sursa de lumină Minim 5 lungimi de undă</p> <p>Centrul acuratețea lungimii de undă +/- 2 nm</p> <p>Sensibilitate ≤ 0.1 fluor/μm^2</p> <p>Acuratețe 2%</p> <p>Precizie ≤ 0.3 %</p> <p>Linearitatea : 0.00-3.0 unitati de absorbtie</p> <p>Capacitatea de incarcare: de la 3 stripuri de 8/12 godeuri</p> <p>Timpul de măsurare: Citește, calculează și tipărește rezultatele, câte 3 secunde pe tub.</p> <p>Sursa de lumină halogen/xenon</p> <p>Afișarea LCD</p> <p>Display: da</p> <p>Memorie internă da</p> <p>Interfață PC da</p> <p>Imprimantă da</p> <p>Automata: da</p> <p>Alimentarea Rețeaua electrică 220 V, 50 Hz da</p>



Awareness Technology, Inc.

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
Microplate Reader	ChemWell Fusion 4800 series
	Stat Fax 2100 series
	Stat Fax 3200 series
Incubator / Shaker	Stat Fax 4200 series
Microplate Washer	Stat Fax 2200 series
Electrolyte Analyzer	Stat Fax 2600 series
Luminometer	ISE 3900 series
	LumiStat 4100 series
	LuMate 4400 series
Microplate Reader	LumiStat 4900 series
	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 : Molenstraat 15
2513 BH The Hague
Country : The Netherlands
Telephone : +31 70 345 8570
Fax Number : +31 70 346 7299

*Self-certified under the principles of ISO 13485:2003
Registered Medical Device Quality System under ISO 13485:2003*

Place and date:

Awareness Technology, Inc.

October 26, 2016

Signature:

Name:

Steve Andrus

Title:

Quality Manager

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



Calin Moldovean

President

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





Stat Fax[®] **4700**

Microstrip Reader

The Stat Fax[®] 4700 is a compact, standalone microstrip reader. Its streamlined design offers touch screen interface, superb optics, on-board curve-fitting software, and built-in printer to meet the requirements of modern laboratories.



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

Cost Effective by Design[®]

Stat Fax[®] 4700

Microstrip Reader Specifications

Photometric

Linear Measurement Range:	0.0 to 3.0 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:	Standard: 405, 450, 492, and 630nm. 6-VIS: 405, 450, 492, 545, 600, and 630nm. 6-UV: 340, 405, 450, 492, 545, and 630nm. (alternate filters available from 340 to 700nm).
Filter Type:	IAD hardcoat interference, 10nm half bandpass.
Vessel:	Single, double, or break-apart strips up to 12 wells long. 3-strip loading capacity with 2 options: <input checked="" type="checkbox"/> 3x12 carrier for single break-apart or 12 well strips. <input checked="" type="checkbox"/> 3x8 carrier for non-break-apart (rigid) or 2x8 strips.

Electronic

Display:	Interactive touch-screen 3.5" LCD, color graphic display.
Printer:	Thermal dot matrix, with graphic capability.
Power Requirements:	115V or 230V AC, 1.5A, 50-60Hz (universal input).
Interface:	USB mouse.

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, linear regressions with log, lin, and log-logit selections, non-linear regressions with 4-parameter and cubic spline selections.
Test Menu:	More than 50 open channels to store tests. Stores all parameters including wavelengths, calculations, unit codes, ranges, interpretations, calibrator values, test names, and previous curve.

Other

Enclosure:	Painted flame-retardant ABS plastic cover and base.
Dimensions:	Approx. 9x13.5x5in. (24x34x13cm) weighs 10lbs.(4.5kg).
Certifications:	NRTL listed, CE mark.

Dri-Dye[®] Check Strips

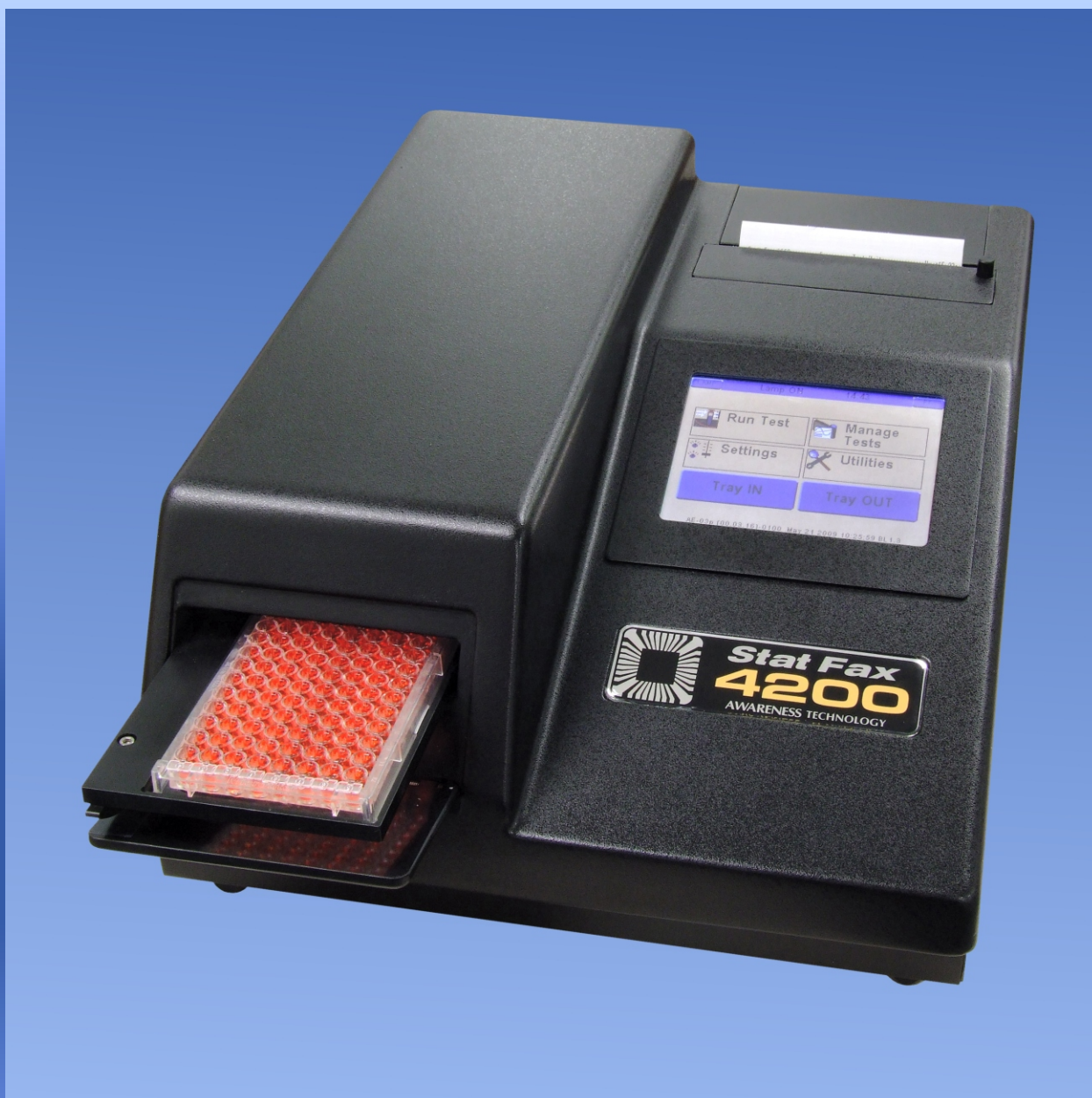
For performance verification of Stat Fax[®], ChroMate[®], and other microstrip and microplate readers



Awareness Technology products are designed and manufactured in the U.S.A.

Anexa 27 Cititor de placi, Stat Fax 4200, Awareness Technology

Parametri ceruti	Parametri oferati
"Lungime de undă 400-700 nm Sistem optic cu 8 canale Centrul acuratețea lungimii de undă ± 2 nm Stabilitate $\leq 0,005$ Abs/10 min, Acuratețe 2 %, Precizie $\leq 0,3\%$ Linearitatea $\pm 1\%$, Timpul de măsurare ≤ 5 sec Sursa de lumină halogen-tungsten Filtre 405 nm,450nm,492nm,630nm Agitare 2 moduri, Tip plată 96/48 probe, Afișare LCD Temperatura $+3^{\circ}\text{C}$ până la $+50^{\circ}\text{C}$ Display cu Touch screen , Memorie internă < 20000 rezultate Interfață PC,LIS, Imprimantă încorporată, Calibrare automată Alimentare la rețea electrică 220V 50Hz"	"Lungime de undă 400-700 nm Sistem optic cu 8 canale Centrul acuratețea lungimii de undă ± 2 nm Stabilitate $\leq 0,005$ Abs/10 min, Acuratețe 2 %, Precizie $\leq 0,3\%$ Linearitatea $\pm 1\%$, Timpul de măsurare ≤ 5 sec Sursa de lumină halogen-tungsten Filtre 405 nm,450nm,492nm,630nm Agitare 2 moduri, Tip plată 96/48 probe, Afișare LCD Temperatura $+5^{\circ}\text{C}$ până la $+40^{\circ}\text{C}$ Display cu Touch screen , Memorie internă - stochează 100 de teste; stochează toți parametrii, inclusiv lungimile de undă, calculele, codurile unității, intervalele liniare și normale, valorile standard, numele testelor și curba standard anterioară Interfață PC,LIS, Imprimantă încorporată, Calibrare automată Alimentare la rețea electrică 220V 50Hz"



***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.



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® 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

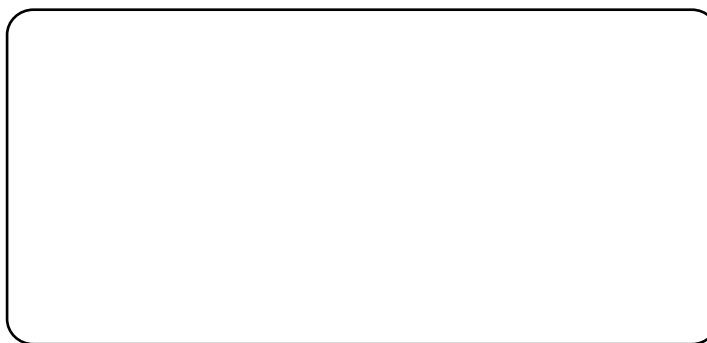
Display:	Interactive 5.7" (14.5cm) graphical touch-screen LCD.
Printer:	Thermal dot matrix, 20 characters per line, plus graphics.
Power Requirements:	115V or 230V AC, 50-60Hz (auto-sensing).
Interface:	USB mouse.
Speed:	Reads absorbances of 96 wells in about 10 seconds.
Plate Transport:	Stepper motor.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



Anexa 24 Microscop binocular, PW-BK2002, Proway

Specificatie tehnica solicitata	Specificatie tehnica oferita
Pentru lumină transmisă cu iluminare cu lampă Halogen. Măsuță mecanică pentru operare cu mâna dreaptă cu acționare coaxială pentru deplasare pe X și Y Fixator de probe universal pentru un singur specimen Revolver pentru 4 obiective, din sticlă Obiective Plan Achromat, fabricat din sticlă 4x,10x,40x,100x/1,25 ulei Condensator universal pre-centrat și pre-focusat, tip Abbe Diafragmă de câmp pentru iluminare Kohler Tub binocular cu unghi de înclinare 30° Cu ajustarea distanței interpupulare în diapazonul minim 52-75 mm Oculare 10x/20-2 buc(cele puțin unul cu focusare), Iluminare-halogen Unitate de alimentare-încorporată,	Pentru lumină transmisă cu iluminare cu lampă Halogen. Măsuță mecanică pentru operare cu mâna dreaptă cu acționare coaxială pentru deplasare pe X și Y Fixator de probe universal pentru un singur specimen Revolver pentru 4 obiective, din sticlă Obiective Plan Achromat, fabricat din sticlă 4x,10x,40x,100x/1,25 ulei Condensator universal pre-centrat și pre-focusat, tip Abbe Diafragmă de câmp pentru iluminare Kohler Tub binocular cu unghi de înclinare 30° Cu ajustarea distanței interpupulare în diapazonul minim 50-75 mm Oculare 10x/20-2 buc(cele puțin unul cu focusare), Iluminare-halogen Unitate de alimentare-încorporată,

Specification		Model		
		PW-BK2001	PW-BK2002	PW-BK2003
Viewing Head	Seidentopf binocular head, 30° inclined, 360° rotation	●	●	●
	Interpupillary distance: 50-75mm, diopter adjustment			
Eyepiece	WF10X/18mm	●		
	WF10X/20mm		●	●
Objective	Achromatic objective: 4x, 10x, 40x(s), 100x(s,oil)	●		
	Finity plan objective: 4x, 10x, 40x(s), 100x(s,oil)		●	
	Infinite plan objective: 4x, 10x, 40x(s), 100x(s,oil)			●
Stage	Double layers mechanical stage with 142mmX140mm			
	Travel area 76mmX50mm with a right-hand stage handle	●	●	●
	0.1mm provide; Double slide holder			
Condenser	Abbe type N.A.=1.25 with Iris Diaphragm	●	●	●
Focusing	Coaxial coarse/fine focusing knobs	●	●	●
Nosepiece	Inward Quadruple click-stop, Revolving mechanism with multiple ball bearing	●	●	●
Illumination	Built-in Koehler illuminator system 3W LED or Halogen 6V/20W, Adjust brightness, Field Diaphragm	●	●	●
Power Supply	85V~265V universal power supply	●	●	●
Optional Accessory				
* Digital Camera & Software * Trinocular Head * Phase Contrast Kit * Dark Field				

Mark "●" standard outfit, Mark "○" optional parts



Certificate of Registration

Certificate NO: 10131157Q

This is to Certify that the Quality Management System of

**Ningbo ProWay Optics & Electronics
Co., Ltd**

**No.301 Jingu Middle Road (west), Yinzhou Investment
& Business of Ningbo, China**

Has been audited to the following Quality Management System standard:

ISO9001:2008

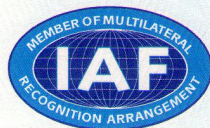
This system is valid for the

**Production, sales and service of microscopes,
lab equipments and accessories**

Date of issue: Aug. 20, 2014

Valid period: Aug. 19, 2017

This certificate will not remain valid only if the certified organization accepts at least one surveillance audit annually within the validity period of the certificate in which the surveillance audit conforming mark is in the designated position on the certificate.



Issued by:

Franso

9months	18months	27months
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Quality Management System

C E R T I F I C A T E



of Conformity Low Voltage Directive 2014/35/EU

Registration No.: AN 50500367 0001

Report No.: 14706948 003

Holder: Ningbo ProWay Optics & Electronics
Co., Ltd.
Room 8-1, Central Business, No.54 Dashani Street,
Ningbo
315010 Zhejiang
P.R. China

Product: Microscope
(Biological Microscope)

Identification: Type Designation: XSZ-PW104, XSZ-PW107, XSZ-PW105,
XSZ-PW109, XSZ-PW206, XSZ-PW207,
XSZ-PW208, PW-BK2000, PW-BK5000,
N-PW300Flu, N-PW300LCD, N-PW300
(Pro.Way)

Serial No.: n.a.

Remark: Refer to test report 14706948 003 for details.

This certificate of conformity is based on an evaluation of a sample of the above mentioned product. Technical Report and documentation are at the Licence Holder's disposal. This is to certify that the tested sample is in conformity with Annex I of Council Directive 2014/35/EU, referred to as the Low Voltage Directive. This certificate does not imply assessment of the series-production of the product and does not permit the use of a TÜV Rheinland mark of conformity. The holder of the certificate is authorized to use this certificate in connection with the EC declaration of conformity according to Annex IV of the Directive.



Date 12.04.2021

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

Ⓒ The CE marking may be used if all relevant and effective EC Directives are complied with. Ⓒ