

Anexa 10, analizor automat de urina, Urixon Relaxx, Macherey Nagel, Germania

Parametri ceruti	Parametri ofertati
Analizator semi-automat, de urină Cod 150100 Descriere Analizator semi-automat de urină pentru efectuarea analizelor chimice ale urinei, care determină prezența anumitor substanțe și estimează concentrațiile lor într-o probă de urină. Parametrul Specificația Productivitate în regim normal ≥ 60 teste/ora Teste chimice Bilirubin da Sînge (hematii) da Glucoză da Corpi cetonici da Esterază leucocitară da Nitrați da pH da Proteine da Greutatea specifică da Urobilinogen da Data management Interfață LIS bidirecțională Memorie internă da Monitor LCD sau LED da Imprimantă da Alimentarea 220 V, 50 Hz Consumabile Să fie inclus benzi pentru teste cu toți parametrii solicitați mai sus ≥ 1000 benzi Termenul de valabilitate din ziua livrării ≥ 6 luni	Analizator semi-automat, de urină Cod 150100 Descriere Analizator semi-automat de urină pentru efectuarea analizelor chimice ale urinei, care determină prezența anumitor substanțe și estimează concentrațiile lor într-o probă de urină. Parametrul Specificația Productivitate în regim normal - 50 teste/ora Teste chimice Bilirubin da Sînge (hematii) da Glucoză da Corpi cetonici da Esterază leucocitară da Nitrați da pH da Proteine da Greutatea specifică da Urobilinogen da Data management Interfață LIS bidirecțională Memorie internă da, 200 rezultate inclusive ID pacient. Touch screen LCD Display Imprimantă da Alimentarea 220 V, 50 Hz Consumabile Să fie inclus benzi pentru teste cu toți parametrii solicitați mai sus ≥ 1000 benzi Termenul de valabilitate din ziua livrării ≥ 6 luni

Anexa 11 Analizator semiautomat, de urină cu masurare continue, Model: URIXXON 500, Macherey Nagel

Cod 150120

Descriere

Analizator semiautomat de urină pentru efectuarea analizelor chimice ale urinei, care determină prezența anumitor substanțe și estimează concentrațiile lor într-o probă de urină.

Parametrul		Specificația Ceruta	Specificatia oferita
	Productivitate	≥ 500 teste/ora	400
Analize chimice			
	Bilirubin	da	da
	Sînge	da	da
	Glucoză	da	da
	Corpi cetonici	da	da
	Esterază leucocitară	da	da
	Nitrați	da	da
	pH	da	da
	Proteine	da	da
	Greutatea specifică	da	da
	Urobilinogen	da	da
Data management	Interfață LIS	bidirecțională	bidirecțională
	Cititor bar cod	da	da
	Memorie interna	da	da
Monitor	LCD sau LED	da	Ecran tactil LCD
Imprimantă		da	da
Alimentarea		220 V, 50 Hz	220 V, 50 Hz
Consumabile			
Consumabile	Să fie inclus benzi pentru teste cu toti parametrii solicitati mai sus ≥ 1000 analize	≥ 1000 analize	Da 1000 analize
Termenul de valabilitate din ziua livrării		≥ 6 luni	6 luni

EC Declaration of Conformity for In-vitro-diagnostics

according to directive 98/79/EC

The procedure for EC declaration established a quality assurance system according to EN ISO 9001:2008 and EN ISO 13485:2003+AC:2009.



We

Name of manufacturer: MACHEREY-NAGEL GmbH & Co. KG
Address: MACHEREY-NAGEL GmbH & Co. KG
Neumann-Neander-Strasse 6-8
D - 52355 Dueren
Germany

confirm that the following reflectometer for professional use

Name of product
URYXXON[®] 500

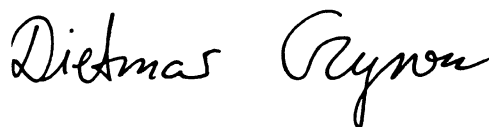
Reference numbers
930 080

Type: URINE MULTI-CONSTITUENT TEST STRIPS
EDMS 11-70-02-02-00

Registration number: DE/CA21/MACHEREY/2003/11/IVD/0005

is manufactured in compliance with the European Directive 98/79/EC.

Dueren, 2013-07-30



i.A. D. Czyron (QA Manager)

Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 1038121-1

Organization: MACHEREY-NAGEL GmbH & Co. KG
Neumann-Neander-Str. 6-8
52355 Düren
Germany

Scope: Design and development, manufacture and distribution of in vitro diagnostic test strips including self-testing devices and reflectometers used in the field of urine, gastric and vaginal fluid analysis, as well as in vitro diagnostic products for bioanalytical sample preparation.

(see attachment for sites included)

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 3309079-90

Effective date: 2020-05-29

Expiry date: 2023-05-28

Issue date: 2020-05-28

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1038121-1

Organization: MACHEREY-NAGEL GmbH & Co. KG
Neumann-Neander-Str. 6-8
52355 Düren
Germany

No.	Facility	Scope
/02	MACHEREY-NAGEL GmbH & Co. KG Valencienner Str. 11 52355 Düren Germany	Design and development, manufacture, quality control, distribution and customer service
/03	MACHEREY-NAGEL GmbH & Co. KG Bahnstr. 120 52355 Düren Germany	Warehousing and logistics

Report No.: 3309079-90

Effective date: 2020-05-29

Expiry date: 2023-05-28

Issue date: 2020-05-28



Dipl.-Ing. S. Hoffmann
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

EC Declaration of Conformity

The procedure for EC declaration was established according to the IVD directive 98/79/EC on the basis of a full quality assurance system according to EN ISO 9001:2008 and EN ISO 13485:2012+AC:2012.



We

Name of manufacturer	MACHEREY-NAGEL GmbH & Co. KG
Address:	MACHEREY-NAGEL GmbH & Co. KG Neumann-Neander-Strasse 6-8 D - 52355 Dueren Germany

confirm that the following reflectometer for professional use

Name of product:	URYXXON® Relax
Reference number:	930 88
Type:	URINE MULTI-CONSTITUENT TEST STRIPS EDMS 11-70-02-02-00
Registration number:	DE/CA21/MACHEREY/2003/11/IVD/0005

is manufactured in compliance with the European Directive 98/79/EC.

Dueren, 27.08.2014



i.A. Markus Meusel (QAM, Reg. Affairs)

MACHEREY-NAGEL

Urine Analysis



URYXXON® Relax

- Non-touch operation – easy and clean
- Optimized patient data management
- Great design – great functionality

Automated urinalysis at the point of care

The URYXXON® Relax provides dependable urine status results to detect early stages of many diseases such as diabetes, kidney disease and urinary tract infections. Instrument-read results have long proven to be advantageous for both, busy health care professionals and patients. URYXXON® Relax readings eliminate the subjectivity of visual color interpretation. The comprehensive interface options and the optimized printouts minimize risks associated with manual transcriptions. Reliable results can be obtained virtually immediate at the point of care. The URYXXON® Relax makes urinalysis simpler and more reliable.



Found to be the most user friendly device by six out of nine first time users within an analytical performance study.

Source:

Schot MJC, van Delft S, Kooijman-Buiting AMJ, et al. Analytical performance, agreement and userfriendliness of six point-of-care testing urine analysers for urinary tract infection in general practice. *BMJ Open* 2015;5:e006857. doi:10.1136/bmjopen-2014-006857



Technical specifications

Instrument memory	200 patient test results including name or patient ID
Interface	User: Touchscreen display, alphanumeric input, password protection Computer: USB interface for connection to PC alternatively RS232 interface for connection to PC PS/2 interface for connection of keyboard and / or barcode reader
Power requirements	110–240 V AC, automatic Battery powered operation (optional) with 6 AA batteries
Dimensions / Weight	Depth: 20 cm (7.9 inches) Width: 16 cm (6.3 inches) Height: 7.5 cm (3.0 inches) Weight: 710 g (1.90 lb) (without batteries and power supply)
Operation	Temperature range: 10–40 °C (50–104 °F) Humidity range: 20–80 % relative humidity, non condensing Calibration: automatic, self calibrating
Capacity	50 strips per hour
CE	CE certified

Intended use

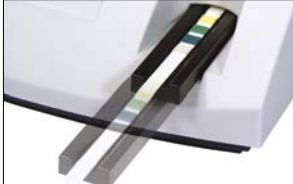
URYXXON® Relax is for the instrumental evaluation of URYXXON® Stick 10 urine test strips. It is for the semi-quantitative detection of blood (occult), urobilinogen, bilirubin, protein, nitrite, ketones, glucose, pH, specific gravity and leukocytes.

URYXXON® Relax and URYXXON® Stick 10 are CE marked according to the IVD directive 98/79/EG.

Now also suitable for the evaluation of microalbumin test strips.



7 convincing features for optimized usability



Non-touch operation

After placing the strip on the instrument, the measurement is started automatically. No further action is needed which makes the operation easy and clean.



Graphic display

On the 128 x 128 pixel graphic screen results for all 10 parameters are conveniently displayed on one page. Pathological results are clearly marked which makes further diagnostic decisions straightforward.



Touchscreen

Operation with touchscreen makes using the instrument a real pleasure. All functions can easily be accessed with a dip on the screen. Optionally an external keyboard can also be connected, so patient names can be comfortably introduced.



Interface options

The instrument carries an USB as well as an RS232 interface. It can easily be connected to existing laboratory information systems.



Small footprint for mobile operation

Due to the small footprint of only 16 x 20 cm mobile use of the device is highly comfortable. Combined with the option for battery operation this is the ideal instrument for near-patient-testing.



Power supply with batteries possible

Optional battery operation enables to use the instrument wherever it is needed. Of course the instrument can also be powered using a 110/240 V autoswitch mains adaptor.



Memory for 200 measurements

Up to 200 measurements can be stored. Using internal functions positive readings can easily be filtered out, enabling further diagnosis when necessary.

Medi-Test ordering information

REF	REF	Type	with test fields for determination of												
50 strips per pack	100 strips per pack		Glucose	Ketones	Ascorbic acid	Protein/Albumin	Blood	Leukozytes	Nitrite	Density	pH value	Bilirubin	Urobilinogen	Creatinine	
930 01	930 24	Glucose ¹⁾	▪												
930 25	930 20	Glucose / Ketone ¹⁾	▪	▪											
930 04	930 27	Protein ²⁾				▪					▪				
930 05	930 28	Ketone ¹⁾		▪											
930 06	930 29	Nitrite ¹⁾							▪						
930 12	–	Urbi										▪	▪		
930 15	930 37	Combi ²⁾	▪			▪									
930 07	930 30	Combi 3 A®	▪		▪	▪					▪				
930 09	930 32	Combi 5	▪		▪	▪	▪				▪				
930 35	930 36	Combi 5 N®	▪		▪	▪	▪		▪		▪				
930 55	–	Combi 5 S	▪	▪		▪	▪				▪				
930 18	930 78	Combi 6	▪			▪	▪	▪	▪				▪		
930 13	930 34	Combi 6 A	▪	▪	▪	▪	▪				▪	▪			
930 10	930 22	Combi 7	▪	▪	▪	▪	▪		▪		▪				
–	930 21	Combi 8 L	▪		▪	▪	▪	▪	▪	▪	▪				
930 11	930 23	Combi 9®	▪	▪	▪	▪	▪		▪		▪	▪	▪		
–	930 56	Combi 10®	▪	▪	▪	▪	▪		▪	▪	▪	▪	▪		
930 79	930 58	Combi 10® L	▪	▪	▪	▪	▪	▪	▪		▪	▪	▪		
930 77	930 67	Combi 10® SGL	▪	▪		▪	▪	▪	▪	▪	▪	▪	▪		
–	930 68	URYXXON® Stick ^{2) 3)}	▪	▪		▪	▪	▪	▪	▪	▪	▪	▪		
930 874	–	Microalbumin ^{3) 5)}				▪								▪	

Further Medi-Test urine test strips

Test strips for veterinary applications														
–	930 870	Combi 10® VET ⁴⁾	▪	▪		▪	▪	▪	▪	▪	▪	▪	▪	▪
Test strips for detection of urine adulteration														
930 19	–	Medi-Test Adulteration Stick ⁴⁾ for the detection of urine adulteration prior to drugs-of-abuse tests with test fields for Creatinine, Glutaraldehyde, Nitrite, pH, Oxidants and Density												

All products (except ⁴⁾) are CE-marked according to the directive 98/79/EC

¹⁾ suitable for patient self-testing ²⁾ for evaluation with reflectometer URYXXON® 500 ³⁾ for evaluation with reflectometer URYXXON® Relax

⁴⁾ not an IVD product (no CE-mark) ⁵⁾ pack of 24 test strips

Instruments for urine test strips	
930 88	URYXXON® Relax, automated urine analysis at the point of care
930 080	URYXXON® 500, high performance automated urine analysis
Accessories and spare parts	
930 38	Medi-Test Control, solution to check Medi-Test urine test strips and URYXXON® instruments
930 65	Printer paper for URYXXON® Relax, pack of 5 rolls
930 890	Strip adaptor for URYXXON® Relax
930 71	Printer paper for URYXXON® 300 and URYXXON® 500, pack of 5 rolls
930 74	Barcode scanner for URYXXON® instruments

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MACHEREY-NAGEL

Urine analysis



URYXXON® 500

- Quick – Reads 400 strips per hour
- Easy – Touch screen operation
- Hygienic – Automatic strip detection

Medi-Test

High performance urine analysis

The URYXXON® 500 is an automatic reader for URYXXON® Stick 10 urine test strips. With a capacity of 400 strips per hour, it is ideal for use in hospitals and practices. The “easy-to-use-features” allow hygienic operation with hardly any training.

The URYXXON® 500 provides dependable urine status results to detect early stages of many diseases such as urinary tract infections, kidney diseases or diabetes. The device eliminates the subjectivity of visual strip evaluation and minimizes risks associated with manual result transcription.

The URYXXON® 500 makes urine analysis quicker, easier and more reliable.



Technical specifications

Instrument memory	500 patient test results including name or patient ID	
Sediment	30 user defined sediment parameters	
Interface	User:	Touchscreen display, alphanumeric input, password protection
	Computer:	1 x USB (type B) and 2 x RS232 interfaces for connection to PC
		PS/2 interface for keyboard / barcode reader
Power requirements	110–240 V AC, automatic	
Dimensions /Weight	240 x 280 mm x 150 mm (D x W x H)	
	3.9 kg (10.5 lb)	
Operation	Temperature range:	5–40 °C (41–104 °F)
	Humidity range:	20–80 % relative humidity, non condensing
	Calibration:	automatic, self calibrating
Capacity	400 strips per hour	
CE	CE labeling according to IVDD 98/79/EC	

URYXXON® 500

Field of application

The URYXXON® 500 is intended for the automatic evaluation of URYXXON® Stick 10 urine test strips. It provides reliable results for the semi-quantitative detection of the following parameters in urine: blood, urobilinogen, bilirubin, protein, nitrite, ketones, glucose, pH, specific gravity and leukocytes. URYXXON® 500 and URYXXON® Stick 10 are CE marked according to the IVD-directive 98/79/EC.

Improvements for your lab

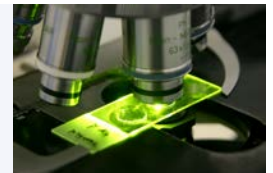
Easy and intuitive

Operating the URYXXON® 500 is easy. Access all functions using the easy-to-follow menu on the touch screen. It nearly eliminates the need for training and makes urine analysis more reliable.



Informative and unique

Add microscopic evidence to the urine chemistry results using the sediment options. Powerful user defined filter functions only admit those samples to sediment analysis that need further diagnostic.



Clean and hygienic

Start the measurement without touching the instrument. Simply place the strip on the transport tray, the detector will recognize it and automatically start the measurement.



Fast and efficient

Once turned on, the URYXXON® 500 is immediately ready for use. It reads up to 400 strips per hour ensuring fast urine chemistry results.



Accurate and convenient

Use a barcode reader to enter patient IDs. Set up lists of samples with ease and convenience and quickly add urine chemistry results to the patient file in your laboratory information system.



Reliable and safe

Use the QC menu to maintain clinical reporting standards with ease and convenience. Medi-Test Control solutions are ideal to ensure correct results at any time.



Small and practical

Free up space with the smallest instrument in its class. With a size of only 28 x 24 cm (11 x 9,4 in) the URYXXON® 500 fits onto every bench. The clear design allows access to all parts and makes cleaning easy.



Medi-Test ordering information

REF	REF	Type	with test fields for determination of												
50 strips per pack	100 strips per pack		Glucose	Ketones	Ascorbic acid	Protein/Albumin	Blood	Leukozytes	Nitrite	Density	pH value	Bilirubin	Urobilinogen	Creatinine	
93001	930 24	Glucose ¹⁾	■												
93025	930 20	Glucose / Ketone ¹⁾	■	■											
93004	930 27	Protein 2 ¹⁾				■					■				
93005	93028	Ketone ¹⁾		■											
93006	93029	Nitrite ¹⁾							■						
93012	–	Urbi										■	■		
93015	93037	Combi 2 ¹⁾	■			■									
93007	93030	Combi 3 A®	■		■	■					■				
93009	93032	Combi 5	■		■	■	■				■				
93035	93036	Combi 5 N®	■		■	■	■		■		■				
93055	–	Combi 5 S	■	■		■	■				■				
93018	93078	Combi 6	■			■	■	■	■				■		
93013	93034	Combi 6 A	■	■	■	■	■				■	■			
93010	93022	Combi 7	■	■	■	■	■		■		■				
–	93021	Combi 8 L	■		■	■	■	■	■	■	■				
93011	93023	Combi 9®	■	■	■	■	■		■		■	■	■		
–	93056	Combi 10®	■	■	■	■	■		■	■	■	■	■		
93079	93058	Combi 10® L	■	■	■	■	■	■	■		■	■	■		
–	93060	Combi 11	■	■	■	■	■	■	■	■	■	■	■		
93077	93067	Combi 10® SGL	■	■		■	■	■	■	■	■	■	■		
–	93068	URYXXON® Stick 10 ^{2) 3)}	■	■		■	■	■	■	■	■	■	■		
930874	–	Microalbumin ^{3) 5)}				■								■	

Further Medi-Test urine test strips

Test strips for veterinary applications

–	930870	Combi 10® VET ⁴⁾	■	■		■	■	■	■	■	■	■	■	
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Test strips for detection of urine adulteration

93019	–	Medi-Test Adulteration Stick ⁴⁾	for the detection of urine adulteration prior to drugs-of-abuse tests with test fields for Creatinine, Glutaraldehyde, Nitrite, pH, Oxidants and Density											
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All products (except 4) are CE-marked according to the directive 98/79/EC

¹⁾ suitable for patient self-testing ²⁾ for evaluation with reflectometer URYXXON® 500 ³⁾ for evaluation with reflectometer URYXXON® Relax ⁴⁾ not an IVD product (no CE-mark) ⁵⁾ pack of 24 test strips

Instruments for evaluation of urine test strips URYXXON® Stick 10

93088	URYXXON® Relax, suitable for the evaluation of MT URYXXON® Stick 10
930080	URYXXON® 500, suitable for the evaluation of MT URYXXON® Stick 10

Accessories and spare parts

93038	Medi-Test Control, solution to check Medi-Test urine test strips and URYXXON® instruments
93071	Printer paper for URYXXON® 300 and URYXXON® 500, pack of 5 rolls
93074	Barcode scanner for URYXXON® instruments

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