

Anexa 3, 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

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

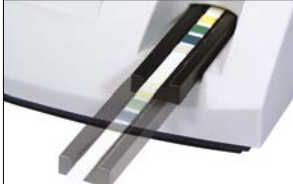
URYXXON® Relax is for the instrumental evaluation of URYXXON® Stick 10 urine test strips. It is for the semi-quantitative detection of blood (occult), urobilinogen, bilirubin, protein, nitrite, ketones, glucose, pH, specific gravity and leukocytes.

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

www.mn-net.com

MACHEREY-NAGEL



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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



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

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

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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)