DocUReader 2 Pro

Compact Urine Chemistry Analyzer

The new DocUReader 2 Pro is the ideal choice for point-of-care urinalysis testing in physician's offices and hospital wards and for testing in small laboratories. The compact design of this lightweight instrument offers the broadest features and highest flexibility available in any desktop size urine analyzer. The system offers excellent accuracy, simple operation, high flexibility and connectivity as well as enhanced security and quality control functions.

- Up to 50 tests/hour in normal mode or 120 tests/hour in fast mode
- Patented high-precision photometric measurement technology
- Suitable for near-patient testing and laboratory uses equally
- Easy operation via advanced graphical interface
- Wide range of testing and user customization
- Easy and flexible integration, streamlined documentation through LIS2, HL7 and POCT1-A2
- Advanced QC and security functions help in laboratory compliance

Accurate and fast processing of
LabStrip U11 PLUS & **LabStrip mALB/CREA**

CE For professional Use IVD

UD2-9301-7

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Features & Functions

Measurement features and clinical utility:

- Suitable for point-of-care testing and laboratory uses
- Permanent standby and hygienic touchless operation with the autostart function
- Easy-to-use software with high level of user customization
- Intuitive GUI and logical menu structure
- Multiple language options
- Multiple operator options with different authorization levels
- Flexible, customized testing and reporting options
- Manual entry of color, turbidity and other comments (e.g. sediment results)
- Automatic start of measurement by strip detection
- Up to 50 tests/hour in normal mode or 120 tests/hour in fast mode
- Flagging of results and recommendation for additional sediment evaluation
- Easy software upgrade
- Minimal maintenance and convenient cleaning

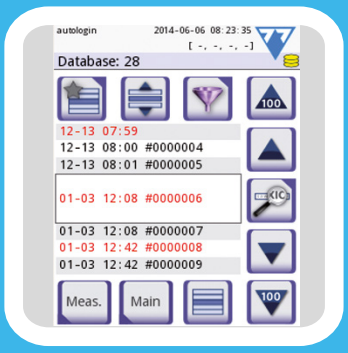
Effective data management & extended connectivity:

- Automated result transfer through LIS2, HL7 and POCT1-A2 protocols or via USB disk
- Worklist transmission through LIS2, HL7 and POCT1-A2
- Large memory capacity with sophisticated filtering criteria
- Automatic result printout
- Settings and operator list import/export via USB disk for facilitating large installations
- Optional barcode reader and external keyboard
- Optional external Wi-Fi connection

Advanced Quality Control and system security functions:

- Automated QC analysis (2 or 3 levels)
- QC test reminders and optional QC lockout function
- Support of strip & QC LOT code information
- Programmable operator management provides customized access levels & prevents unauthorized use
- Power management (screen, logout, power off)

Urinalysis in the easiest and most efficient way



LabStrip U11 Plus & LabStrip U mALB/CREA

High quality and reliable urine test strip

Pack size: 150 tests
Shelf life: 24 months
Parameters: Blood, Glucose, Spec. gravity, Bilirubin, Protein, Nitrite, Urobilinogen, Leucocytes, Ketones, pH, Ascorbic Acid

The early detection of albuminuria

Pack size: 25 tests
Shelf life: 18 months
Parameters: Albumin,Creatinine, ACR

About 77 Elektronika

77 Elektronika Kft. is a major global developer, manufacturer and supplier of in vitro diagnostic medical devices, mainly urine analyzers, rapid test readers blood glucose meters and their consumables. The products are supplied throughout the world under the 77 Elektronika brand and as OEM products for market-leading multinational companies. 77 Elektronika was established in 1986 and is headquartered in Budapest, Hungary (EU). The company is committed to providing superior products and services to the complete satisfaction of its customers.

Technical specifications

Technology:	reflectance photometer wavelengths 505, 530, 620, 660nm
Throughput:	Up to 50 tests/hour in normal mode Up to 120 tests/hour in fast mode
Memory capacity:	3000 patient test results 1000 QC test results
Display: (resolution: 240x320)	3.5" LCD QVGA color touch-screen
Printer:	internal thermal printer
Interfaces:	Ethernet port, RS232 serial port USB A, USB B, PS2, support of USB Wi-Fi adapter
Communication protocols:	LIS2-A2, HL7, POCT1-A2
Dimensions:	190 x 236 x 77mm (W x D x H)
Weight:	1.5 kg
Electrical rating:	100...240V AC, 50/60Hz, external mains adapter
Operating conditions:	15-32°C Relative humidity: 30-80% (without condensation)

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77 ELEKTRONIKA

U11Plus
LabStrip
URINALYSIS

Urinalysis

GB IVD CE

Test strip for semi-quantitative urine analysis from fresh urine. Use only with urine analyzer **DocUReader**, **DocUReader 2**, **DocUReader 2 Pro**, **LabUReader**, **LabUReader Plus**, **LabUReader Plus 2**, **HandUReader** or **LabUMat** or for visual reading. The **LabStrip U11 Plus** is an *in vitro* diagnostic medical device for professional laboratory use only in conformity with the Directive 98/79/EC.

150 pcs urine test strips for rapid determination of Bilirubin, Urobilinogen, Ketones (Acetoacetic acid), Ascorbic acid, Glucose, Protein (albumin), Blood, pH value, Nitrite, Leukocytes and Specific gravity in urine. Refer to the carton and label for specific parameter combination on the product you are using.

Summary and Explanation:

Screening test for recognition of liver disease, biliary and hepatic obstructions, diabetes, and haemolytic diseases, urological, and nephrological diseases associated with haematuria or haemoglobinuria, diseases of the kidneys and urinary tract, pathological shifts in the pH value, as well as for investigation of the sediment.

Clinical Utility:

Bilirubin: Intended to measure the levels of bilirubin conjugates in urine. Measurements of urinary bilirubin and conjugates are used in the diagnosis and treatment of certain liver and bile diseases.
Urobilinogen: Intended to detect and estimate urobilinogen (a bile pigment degradation product of red blood cell haemoglobin) in urine. Estimations obtained by this device are used in the diagnosis and treatment of liver diseases and haemolytic (red blood cells) disorders.
Ketones: Intended to detect ketones in urine. Identification of ketones is used for in the diagnosis and treatment of acidosis (a condition characterized by abnormally high acidity of body fluids) or ketosis (a condition characterized by increased production of ketone bodies) and for monitoring patients with diabetes.
Ascorbic acid: Intended to measure the level of ascorbic acid (vitamin C) in urine.
Glucose: Intended to measure glucosuria (glucose in urine). Urinary glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus and hyperglycemia.
Protein: Intended to identity protein in urine. Identification of urinary protein is used in diagnosis and treatment of renal diseases.
Blood: Intended to detect occult blood in urine. Occult blood indicates serious urological or kidney diseases.
pH: Intended to estimate the pH of urine. Estimations of pH are used to evaluate the acidity or alkalinity of urine as it relates to numerous renal and metabolic disorders and in the monitoring of patients with certain diets. Persisting high pH values indicate urinary tract infections.
Nitrite: Intended to identify nitrite in urine. Nitrite identification is used in the diagnosis and treatment of urinary tract infections of bacterial origin.
Leukocytes: Intended to detect leucocytes in urine. Leucocytes indicate inflammatory diseases of the kidney and the urinary tract, and suggest need of further investigation.
Specific gravity: Intended to provide an estimation of renal ability of urine concentration or urine dilution. The specific gravity of urine varies in accordance with the drinking quantity as well as different disorders.

Principle of the Procedure:

Bilirubin: A red azo compound is obtained in the presence of acid by coupling of bilirubin with diazonium salt.
Urobilinogen: The test is based on the coupling of urobilinogen with a stabilised diazonium salt to a red azo compound.
Ketones: Acetone and acetoacetic acid react with sodium nitroprusside in alkaline solution to give violet coloured complex (Legal's test).
Ascorbic acid: The detection is based on the decolouration of Tillman's reagent.
Glucose: The detection is based on the glucoseoxidase-peroxidase-chromogen reaction. Apart from glucose no other compound in urine is known to give a positive reaction.
Protein: The test is based on the „protein error" principle of the indicator. The test is especially sensitive in the presence of albumin. Other proteins are indicated with less sensitivity.
Blood: The detection is based on the pseudoperoxidative activity of haemoglobin and myoglobin, which catalyze the oxidation of an indicator by organic hydroperoxide and chromogene producing a green colour.
pH: The test paper contains indicators which clearly change colour between pH 5 and pH 9 (from orange to green to turquoise).
Nitrite: The colour test is based on the principle of Griess reaction. Any degree of pink-orange colouration should be interpreted as a positive nitrite test suggestive of $\geq 10^5$ organisms/ml urine.
Leucocytes: The test is based on the esterase activity of granulocytes. This enzyme splits heterocyclic carboxylates. The component released reacts with a diazonium salt producing a violet colour.
Specific gravity: The test is based on a colour change of the reagent from blue-green to greenish yellow depending on the concentration of ions in the urine. The test permits the determination of urine density between 1.000 and 1.030.

Kit Components:

Each kit contains everything needed to perform 150 tests:

- 150 pcs **LabStrip U11 Plus** test strips,
- Label with colour scale for visual reading,
- 1 pc Calibration card for checking and setting of analyzers **LabUReader** and **LabUReader Plus**, and **LabUReader Plus 2**,
- 1 pc Calibration card for checking and setting of analyzers **HandUReader** and **LabUMat**,
- 1 pc Calibration card for checking and setting of analyzer **DocUReader 2** and **DocUReader 2 Pro** 1 pc Instructions for use
- 1 pc Instructions for use

Other required appliances for urine analysis:

- Urine analyzer **DocUReader**, **DocUReader 2**, **DocUReader 2 Pro**, **LabUReader**, **LabUReader Plus**, **LabUReader Plus 2**, **HandUReader** or **LabUMat** with instructions for use
- Clean, detergent free and dry container for urine collection

Reagents Composition:

The reagents in the individual test fields are formulated to contain the following:

Bilirubin:	Diazonium salt	3.1 %
Urobilinogen:	Diazonium salt	3.6 %
Ketones:	Sodium nitroprusside	2.0 %
Ascorbic acid:	2,6-dichloro-phenol-indophenol	0.7 %
Glucose:	Glucose oxidase	2.1 %
	Peroxidase	0.9 %
	O-Toluidine hydrochloride	5.0 %
Protein:	Tetra-bromophenol blue	0.2 %
Blood:	Isopropylbenzol-hydroperoxide	21.0 %
	Tetramethylbenzidine-dihydrochloride	2.0 %
pH:	Bromthymol blue	10.0 %
	Methyl red	2.0 %
Nitrite:	Sulfanilic acid	1.9 %
	Tetrahydrobenzol[h]quinolon-3-ol	1.5 %
Leukocytes:	Carboxylic acid ester	0.4 %
	Diazonium salt	0.2 %
Specific gravity:	Bromothymol blue	2.8 %

Concentrations given are based on reagent composition (w/w) at time of production and may vary within manufacturing tolerances.

Warning!

- Every item in the package can be handled as household waste. As reactive materials are present at very low quantity, the product does not come under the scope of the relevant EU regulations for dangerous materials.
- Keep away from swallowing, touching with skin or mucous membranes of chemicals!
- For in vitro diagnostic use only!
- The vial cap containing a non toxic, molecule-sieve based drying agent blocks the test strips from air-humidity. In case of swallowing the drying agent chemicals, drink substantial amount of liquid.
- If you have any questions, please turn to your local distributor!

Arrangements for urine analysis:

Warning!

Use only urine analyzer **DocUReader**, **DocUReader 2**, **DocUReader 2 Pro**, **LabUReader**, **LabUReader Plus**, **LabUReader Plus 2**, **HandUReader** or **LabUMat** for **LabStrip U11 Plus** test strip urine analysis.
If you open a new **LabStrip U11 Plus** test strip package you can find a calibration card for checking and setting of the urine analyzer **LabUReader** and **LabUReader Plus**, **DocUReader 2** (**DocUReader 2 Pro**) and **LabUReader Plus 2**, another one for **HandUReader** and **LabUMat**. You can find the instructions for settings in the user manual of the meter. Adjustment of the meter is not required until the start of next strip vial.

Follow the user manual of the urine analyzer **DocUReader**, **DocUReader 2**, **LabUReader**, **LabUReader Plus**, **LabUReader Plus 2**, **HandUReader** or **LabUMat**.

Specimen Collection and Preparation:

- Collect urine in a clean, dry container which allows complete immersion of all the fields on the test strip.
- Do not add preservatives.
- Test the specimen as soon as possible, with the sample well mixed but not centrifuged.
- The use of fresh morning urine is recommended for optimal nitrite tests, as well as for the valid determination of bilirubin and urobilinogen, since these compounds are unstable when exposed to light and room temperature (+15 to +25 °C).
- If immediate testing is not possible, the sample should be stored in the refrigerator (+2 to +8 °C) and then brought to room temperature (+15 to +25 °C) before used in the test.
- Non-preserved urine at room temperature may undergo pH changes due to microbial proliferation, which may interfere with protein determination.
- If cleanly voided specimens are not collected from females, positive results for leukocytes may be found due to contamination from outside the urinary tract.
- Skin cleansers containing chlorhexidine may affect protein test results if specimen positive contamination occurs.

Procedure and Notes:

- Use only fresh, mixed, not centrifuged urine. First morning urine is recommended. Perform the urine analysis in 4 hours after sample collection! Keep urine away from light.
- Collect specimen in clean, rinsed containers, free of detergents. Do not use preservatives!
- After removing the required number of strips, close immediately the container securely with the vial cap containing drying agent.
- Do not touch test areas of the reagent strip.

In case of instrumental reading

- Read carefully the instructions for use of the analyzer **DocUReader**, **DocUReader 2**, **DocUReader 2 Pro**, **LabUReader**, **LabUReader Plus**, **LabUReader Plus 2**, **HandUReader** or **LabUMat**.
- Immerse the test strip into urine for approx. 2 sec, so that all reagent areas are covered.
- Remove excess urine from the strip by wiping the edge of the strip on the edge of the urine container or on absorbent paper.
- Place the test strip into the urine analyzer **DocUReader**, **DocUReader 2**, **DocUReader 2 Pro**, **LabUReader**, **LabUReader Plus, LabUReader Plus 2** or **HandUReader** according to the instructions for use. 1 minute after starting reading the meter displays the result.
- In case of reading with **LabUMat**, the meter feeds the strips and dips them into the sample automatically then displays the result after 1 minute incubation period.

In case of visual reading

- Immerse the test strip into the urine for approx. 2 sec, so that all reagent areas are covered.
- Remove excess urine from the strip by wiping the edge of the strip on the edge of the urine container or on absorbent paper.
- To prevent interference from adjacent test areas, incubate the strip in horizontal position.
- Compare the reagent areas on the strip with the corresponding color charts on the container about 60 sec (between 60-120 sec for the Leucocyte test) after immersion. Do not read later than 2 minutes.
- Colours on the colour chart are representing the nominal values of the test fields. Actual results are located around nominal values.
- The white field between the specific weight and leukocyte test field is for instrument measurements and is used to compensate for the intrinsic colour of urine.

Warning!

- Do not take the strip out of the meter during reading procedure.
- Prior to measuring always make sure that the process is performed according to the instructions for use of the urine analyzer **DocUReader**, **DocUReader 2**, **DocUReader 2 Pro**, **LabUReader**, **LabUReader Plus**, **LabUReader Plus 2**, **HandUReader** or **LabUMat**.
- Do not perform urine analysis at temperatures below +15 °C or above +35 °C.
- Strips must be kept away from heat and direct sunlight.
- Do NOT ever reuse test strips. After measurement completed eliminate the strip carefully.
- Until usage, store the test strips in original packages. Strips in each vial should not be mixed.
- Diagnoses and therapies can not be derived from one single test result only, instead should be based on all available medical diagnoses.
- Never use the strip if more than 5 minutes spent from the moment of its removing from the vial.

Biological risk!

Handle all specimens and strips as if they contamined infectious agents. When the assay procedure is completed, dispose of specimens and strips carefully follow the relevant, local instructions.

- In rare occasions, the varying test conditions, due to the heterogenity of the different urine (for reasons of different levels of activators, inhibitors, or different ion concentrations) may cause variation in the intensity and contrast of the colors.
- Not all cases of interference with every component of any medicines are known. The color reaction of the pads might change. We, therefore, recommend another test at the end of any medication with drugs.
- Always follow the general working instructions for laboratories as well.
- The test strips do NOT contain toxic materials!

Results:

Results are determined visually by direct comparison of reacted test fields with the colour chart on the container label. Visual colour charts represent nominal test values for each test field-actual values may vary around the nominal values.
The leucocyte and blood (erythrocyte) tests are not quantitative determinations, but serve as screening methods for the presence of Leucocytes and blood (erythrocytes) in urine. Microscopic examination of specimens with a positive Leucocyte or blood test result should be performed if quantitative results are required.
Ascorbic acid may interfere with the glucose, nitrite, bilirubin and blood test results (see Limitations below). If a positive Ascorbic acid result is found, either repeat the test at least 10 hours one day after discontinuation of Vitamin C administration or use a photometric test unaffected by Ascorbic acid.
When using **LabUReader, DocUReader**, **DocUReader 2**, **DocUReader 2 Pro**, **LabUReader Plus, LabUReader Plus 2, HandUReader** or **LabUMat** please refer the user manual of those instrument.

System operation:

Each test strip has 11 measuring zones. These zones contain sensitive reagents. Colour of the test field is changing as a result of chemical reaction of urine contact. The urine analyzer **DocUReader**, **DocUReader 2**, **DocUReader 2 Pro**, **LabUReader**, **LabUReader Plus**, **LabUReader Plus 2, HandUReader** or **LabUMat** detects the colouration and displays the result.

Limitations of the Procedure:

Note: Diagnostic or therapeutic decisions should not be based on any single result or method.
Bilirubin: The reaction is unaffected by pH of urine. False low or negative results may be simulated by large amounts of vitamine C or nitrite or by longer exposure of the sample to direct light. Increased concentration of urobilinogen can reinforce the sensitivity of the field. Different urine constituents (e.g. urine indicane) can lead to atypical coloration. For metabolites of drugs see urobilinogen.
Urobilinogen: The reaction is unaffected by pH of urine. Higher concentration of formaldehyde or exposure of the urine to light for a longer period of time may lead to lowered or falsely negative results. Beetroot (excreted pigments) or metabolites of drugs which give a colour at low pH (phenazopyridine, azo dyes, p-aminobenzoic acid or other medicaments which have a red intrinsic coloration in acidic medium) may produce false positive results. Prolonged exposure to light is to be avoided.
Ketones: Phthalein compounds and derivatives of anthrachinone interfere by producing a red coloration in the alkaline range which may mask the coloration of ketones.
Ascorbic acid: As ascorbic acid already in low concentrations can disturb various test fields, especially the glucose assay in low concentrations, the test must be repeated if the ascorbic acid reaction is positive, however, at the earliest 10 hours after the last vitamin C intake (medication, fruit and vegetables).

Glucose: High concentrations of ascorbic acid in urines with a low glucose concentration (up to 100 mg/dL (5.5 mmol/L)) may inhibit the reaction and lead to lower or false negative results. Repeat the test 10 hours one day after stopping the intake of vitamin C. Pay attention to the ascorbic acid field. In addition an inhibitory effect is produced by gentisic acid, a pH value of <5 and high specific gravity. False positive reactions can also be produced by a residue of peroxide containing cleansing agents or others.
Protein (albumin): Falsely positive results are possible in high alkaline urine samples (pH >9) and in the presence of high specific gravity, after infusions with polyvinylpyrrolidone (blood substitute) after intake of medicaments containing quinine and also by disinfectant residues containing quaternary ammonium groups in the urine sampling vessel.
Blood: Microhaematuria does not affect the colour of urine and is only detectable by microscopic or chemical tests. From a level approx. 25 Ery/μL and above, even at high concentrations of ascorbic acid normally no negative results are observed. Falsely positive reactions can also be produced by a residue of peroxide containing cleansing agents, activities of microbial oxidase due to infections of the urogenital tract or by formaline.
For establishing an individual diagnosis, it is therefore indispensable to take into consideration also the clinical manifestations.
The number of erythrocytes which are detected by sediment analysis may be lower than the result of the test strip, because lysed cells are not detected by sediment analysis.
pH: No interferences are known.
Nitrite: Before testing the patient should ingest vegetable-rich meals, reduce fluid intake and discontinue antibiotic and vitamin C therapy 3 days prior to the test. False positive results may occur in stale urine samples, in which nitrite has been formed by contamination of the specimen and in urines containing dyes (derivatives of pyridinium, beetroot). A negative result even in the presence of bacteriuria can have the following reasons: bacteria not containing nitrate reductase, antibiotic treatment diet with low nitrate content, high diuresis, high content of ascorbic acid or insufficient incubation of the urine in the bladder.
Leukocytes: Strongly coloured compounds (e.g. nitrofurantoin) may disturb the colour of the reaction. High concentrations of glucose, oxalic acid, drugs containing cephalexin, cephalothine or thetracycline can lead to weakened reaction. False-positive reactions may be caused by contamination of vaginal secretion. The number of leucocytes which are detected by sediment analysis may be lower than the result of the strip, because lysed cells are not detected by sediment analysis. Partial cytolysis intensifies the colour response, particularly in the region of the maximum analytical sensitivity. Leucocyte esterase results may be positive in the absence of observable cells if the leucocytes have lysed. False-positive reactions may be caused by formaldehyde (preservative). Protein concentrations above 5 g/L or a high specific gravity may diminish the colour response. Bacteria, trichomonas and erythrocytes do not, however, react with the test field.
Specific gravity: Highly acidic urines (pH <6) yield slightly elevated results whereas highly alkaline urines (pH >8) yield diminished results. Glucose and urea do not interfere.

Expected values:

Bilirubin: Normally, no bilirubin is detectable in urine. Concentration of 0.5 mg/dl and more lead to a colour of red-orange peach and indicate the early stage of a liver disease. The colour fields correspond to the following bilirubin concentrations: neg. (negative), 1 (+), 3 (++), 6 (+++) mg/dL or neg. (negative), 17 (+), 50 (++), 100 (+++) μmol/L. Values of 0.5-1 mg/dL bilirubin are indicated.
Urobilinogen: The normal concentration of urobilinogen in urine goes from 0.1-1.8 mg/dL (1.7-30 μmol/L). Concentrations of >2 mg/dL (35 μmol/L) are considered to be pathological. Absolute absence of urobilinogen in the urine, which is also pathological, cannot be demonstrated using test strips. The colour fields correspond to the following urobilinogen concentrations: norm. (normal), 2 (+), 4 (++), 8 (+++), 12 (++++) mg/dL or norm. (normal), 35 (+), 70 (++), 140 (+++), 200 (++++) μmol/L.
Ketones: Normally, the urine is free of ketones. Detectable concentrations of ketones can originate from physiological stress (fasting, pregnancy, excessive sport). Phenylketones in higher concentrations will produce variable colours. β-Hydroxibutyric acid is not detected. The colour fields correspond to the following acetoacetic acid values: neg. (negative), 15 (+), 50 (++), 150 (+++) mg/dL or neg. (negative), 1.5 (+), 5 (++), 15 (+++) mmol/L. Values of 5 mg/dL acetoacetic acid or 50 mg/dL acetone are indicated.
Ascorbic acid: In the presence of ascorbic acid a colour change takes place from grey blue to orange. The colour fields correspond to the following ascorbic acid concentrations: neg. (negative), 20 (+), 40 (++) mg/dL or neg. (negative), 1.14 (+), 2.28 (++) mmol/L. Values of 5-10 mg/dL or 0.6-1.1 mmol/L are indicated.
Glucose: Normally, glucose cannot be detected in the urine although small amounts are secreted also by the healthy kidney. Changes in the colorations less than 50 mg/dL (2.8 mmol/L) are to be considered normal. The colour fields correspond to the following ranges of glucose concentrations: norm. (normal), 50 (+), 150 (++), 500 (+++), 1000 (++++) mg/dL or norm. (normal), 2.8 (+), 8 (++), 28 (+++), 56 (++++) mmol/L. Values of 40 mg/dL glucose are indicated.
Protein (albumin): Normally, no protein is detectable in the urine of healthy subjects. Colour intensities for the protein (albumin) field which match the intensity of the 0.3 g/L colour field are to be classed as pathological. The colour fields correspond to the following ranges of albumin concentrations: neg. (negative), 30 (+), 100 (++), 500 (+++) mg/dL or neg. (negative), 0.3 (+), 1.0 (++), 5.0 (+++) g/L. Values of approx. 15 mg/dL albumine are indicated.
Blood: Intact erythrocytes are reported by punctual colorations on the test pad, haemoglobin and myoglobin are reported by a homogeneous green coloration. The color fields correspond to the following values: neg. (negative), approx. 5-10 (+), approx. 50 (++), approx. 300 (+++) Ery/μL. Values of approx. 5 erythrocytes/μL are indicated.
pH: Normal fresh urine of healthy people varies between 5 to 6 pH values. The colour fields correspond to the following pH values: 5, 6, 7, 8, 9.
Nitrite: Negative results do not exclude significant bacteriuria (insufficient incubation, urinary tract infections due to bacteria not containing nitrate reductase). Red or blue borders or edges which may be present must not be interpreted as a positive result. Values of 0.05-0.1 mg/dL nitrite are indicated.
Leucocytes: Urines of healthy subjects do not contain any leucocytes. Positive results, even when constantly varying from negative to 25, are to be considered as clinically relevant. Discolorations which no longer match the negative colour field are to be classed as positive. The colour fields correspond to the following values: neg. (negative), approx.25 (+), approx. 75 (++), approx. 500 (+++) leucocytes/μL. Values of 10-20 leucocytes/μL are indicated.

Specific gravity: Normal fresh urine of healthy people varies between 1.015 to 1.025 values. The colour scale has optimized at a pH of the urine of 6. The colour fields correspond to the values 1.000, 1.005, 1.010, 1.015, 1.020, 1.025, 1.030.

Measuring Ranges:

Parameters	neg.	trace*	+	++	+++	++++			
Bilirubin (mg/dL)	neg.	0,5	1	3	6				
Urobilinogen (mg/dL)	norm.	-	2	4	8	12			
Ketones (mg/dL)	neg.	5	15	50	150				
Ascorbic acid (mg/dL)	neg.	-	20	40					
Glucose (mg/dL)	norm.	25	50	150	500	1000			
Protein (mg/dL)	neg.	15	30	100	500				
Blood (Ery/μL)	neg.	-	ca. 5-10	ca. 50	ca. 300				
pH	5	5.5	6	6.5	7	7.5	8	8.5	9
Nitrite	neg.	-	pos.						
Leukocytes(Leu/μL)	neg.	-	ca. 25	ca. 75	ca. 500				
Compensation field									
Specific gravity	1000	1005	1010	1015	1020	1025	1030		

* **DocUReader 2**, **DocUReader 2 Pro** and **LabUReader Plus 2** are able to detect trace categories in case of Bilirubin, Ketones, Glucose and Protein, and half unit in case of pH.

Storage and Stability:

Keep diagnostic test strips in tightly closed original tubes in a dry, dark and cool place (between +2 to +30 °C). After removing the required number of strips, close immediately the container securely. Do not remove the desiccant from the original cap.

The strips must be kept away from moisture, direct sunlight, elevated temperature and chemical fumes. Under proper conditions test strips are stable up to the stated expiry date even after opening. Do not touch the test pads.

System quality control:

During quality control, the legal requirements and guidelines shall be observed regarding frequency of tests, target values and target ranges, as well as the documentation of the results.
Corrective actions shall be taken if the results are out of the target range.
For periodically checking your strips and system we offer the QC the Dipper (Quantimetrix Corporation, REF: 1440-01), the Dropper (Quantimetrix Corporation, REF:1440-02) or DipAndSpin (Quantimetrix Corporation, REF:1470-01) urine dipstick control solutions.
Dip the test strip into control solution instead of urine sample!

Read the chapter „Checking of the system" in the instructions for use of the urine analyzer.

Specific Performance Characteristics:

The performance characteristics of **LabStrip U11 Plus** test strips are based on both clinical and analytical studies. Sensitivity is dependent upon the colour perception of the reader, the presence or absence of interfering specimens, and the lighting conditions for visual reading.
Each colour block on the chart corresponds to a range of analyte concentrations.
Bilirubin: In 90 % of urines tested, bilirubin concentrations of 0.5 mg/dL produced a positive result. After a longer reaction time an unspecific yellow colour may develop, which can create positive interference.
Urobilinogen: Based on the work of Kutter [10], a concentration of 1 mg/dl urobilinogen will yield a positive result. The test is sufficiently sensitive so that normal specimens will produce a slight pink colour.
Ketones: In 90 % of urines tested, acetoacetic acid at 8 mg/dL produced a positive result. The test field reacts less sensitively with acetone. Hydroxybutyric acid is not detected.
Ascorbic acid: In 90 % of urines tested, ascorbic acid at 20 mg/dL yielded a positive result.
Glucose: The maximum sensitivity is 20 mg/dL. The test field response is adjusted so that pathological glucose concentrations of 30 mg/dL (Fine) [11] are recognized. Sugars other than glucose and other reducing substances do not react in this test. Possible interference by ascorbic acid can be detected by the adjoining test field which reacts with the ascorbic acid.
Protein: In 90 % of urines tested, albumin concentrations of 12 mg/dL produced a positive result. The test is more sensitive to albumin than to globulin, Bence-Jones proteins and mucoproteins. A negative result does not exclude the presence of these other proteins.
Blood: The test permits the differentiation of intact erythrocytes from hemoglobin or myoglobin. Erythrocytes react as diffuse patches on the field. The practical sensitivity of the test lies between 5 and 10 Ery/μL.
A study of 625 fresh urine specimens, comparing results with those using another test strip for blood demonstrated a clinical specificity of 90.2 % and sensitivity of 81 %.
pH: pH values are determined to within 1 unit over the range from 5 to 9. Readings are not affected by variations in the urine buffer concentration.
Nitrite: The maximum sensitivity is 0.05 mg/dL, which is equivalent to about 100,000 bacteria/ml. In early morning urine, 90 % of all infections are detected by the nitrite test. Although most uropathogenic bacteria are able to reduce nitrate to nitrite (e. g. Klebsiella, E. coli, Proteus, Aerobacter, Citrobacter, etc.), results depend on the number of bacteria, the nitrate content, and the retention time of the urine.
Leucocytes: In 90 % of urines tested, concentrations of 20 leucocytes/μL produced positive results. Any pink coloration of the test field should be considered clinically significant. When result from this method were compared with those using another test strip for leucocytes for 822 fresh urines, clinical specificity of 80 % and sensitivity of 89.2 % were determined.
Specific gravity: In 86 % of 102 urines tested, the finds based on the colour chart were found to be within the acceptable range of ±1 colour increment compared to the findings of the reference refractometer.

Intra-assay

Within run precision was determined by using 10 replicas of two levels (normal, abnormal) of control urine. The negative and positive values were correctly identified 100 % of time for all the parameters.

Inter-assay

Between run precision was determined by using two levels (normal, abnormal) of control urine in 10 independent assays and with three different lots of reagent over a 6 months period. The negative and positive values were correctly identified 100 % of time for all the parameters.

U11Plus
LabStrip URINALYSIS

Reagenzstreifen für Harnanalyse

D IVD CE

Teststreifen für semiquantitative Harnanalyse vom frischen Urin. Ausschliesslich zur Auswertung in Urinanalysegeräten **DocUReader**, **DocUReader 2**, **DocUReader2 Pro**, **LabUReader**, **LabUReader Plus**, **LabUReader Plus 2**, **HandUReader** oder **LabUMat** oder zum visuellen Ablesen. **LabStrip U11 Plus** Teststreifen nur zur professionellen in-vitro-diagnostischen Anwendung nach Richtlinie 98/79/EC über In-vitro-Diagnostika.

LabStrip U11 Plus Teststreifen nur für professionellen Gebrauch in Laboren

Teststreifen für die schnelle Bestimmung von Bilirubin, Urobilinogen, Keton, Ascorbinsäure, Glucose, Protein (Albumin), Blut, pH-Wert, Nitrit, Leukozyten, spezifischem Gewicht aus Harn. Die Kombination der Parameter auf dem Streifen ist dem Packungsaufdruck zu entnehmen.

Anwendung

Schnelltest zur Diagnostik und Früherkennung von Leberschäden, Verschlussformen, Diabetes, hämolytischen, urologischen und nephrologischen Erkrankungen, die mit Hämaturie und Hämoglobinurie verbunden sind. Erkrankungen im Bereich der Nieren und Harnwege, pathologischen pH-Wert-Verschiebungen und zur Untersuchung des Sediments.

Klinische Bedeutung

Bilirubin: Zur Bestimmung von Bilirubin im Harn. Bestimmungen von Bilirubin und ihren Konjugatum dienen zur Diagnose von Leber- und Gallenerkrankungen.
Urobilinogen: Zur Bestimmung von Urobilinogen im Harn. Die Bestimmung dient zur Diagnose von Lebererkrankungen und gesteigertem Hämoglobinabbau infolge von hämolytischen Erkrankungen.
Keton: Zur Bestimmung von Ketonkörpern im Harn. Die Bestimmung dient zur Diagnose von Ketoacidose sowie zur Behandlung und Kontrolle von Diabetes-Patienten.
Ascorbinsäure: Zur Bestimmung von Ascorbinsäure (Vitamin C) im Harn.
Glucose: Zur Bestimmung von Glucose im Harn. Bestimmungen von Glucose im Harn dienen zur Diagnose und Behandlung von Störungen des Kohlenhydratstoffwechsels, wie Diabetes mellitus und Hyperglycaemie.
Protein (Albumin): Zur Bestimmung von Protein im Harn. Der Nachweis dient zur Diagnose und Behandlung von Nierenerkrankungen.
Blut: Zur Bestimmung von okkultem Blut im Harn. Okkultes Blut im Harn weist auf Erkrankungen des Urogenitalbereichs und der Niere hin.
pH-Wert: Zur Bestimmung des pH-Wertes im Harn. Die Bestimmung dient zur Bewertung der Acidität oder Alkalität des Harns, die im Zusammenhang mit Stoffwechselstörungen auftreten können, und zur Überwachung von Diäten. Anhaltend hohe pH-Werte deuten auf eine Infektion des Urogenitalbereichs hin.
Nitrit: Zur Bestimmung von Nitrit im Harn. Nitrit im Harn deutet auf bakteriell verursachte Infektionen des Urogenitalbereichs hin.
Leukozyten: Zur Bestimmung von Leukozyten im Harn. Leukozyten im Harm deuten auf Entzündungen der Niere oder des Urogenitalbereichs hin.
Spezifisches Gewicht/Dichte: Zur Bestimmung der Dichte von Harn. Die Bestimmung dient zur Kontrolle der Nierenfunktion und zur allgemeinen Bewertung der Konzentration der Harnprobe. Je nach aufgenommener Flüssigkeitsmenge und äußeren Umständen kann die Dichte des Harnes schwanken.

Testprinzipien

Bilirubin: Der Test basiert auf einer Kupplungsreaktion von Bilirubin mit Diazoniumsalz in einem sauren Medium.
Urobilinogen: Das Testfeld für Urobilinogen enthält ein stabiles Diazoniumsalz. Durch Kupplungsreaktion entsteht ein roter Azofarbstoff.
Keton: Es handelt sich um eine Variante der Probe nach Legal. Acetessigsäure und Aceton reagieren mit Natrium-Nitroprussid in alkalischem Medium zu einem violetten Farbkomplex.
Ascorbinsäure: Der Nachweis beruht auf der Entfärbung von Tillmans-Reagenz.
Glucose: Der Nachweis basiert auf der Glucoseoxidase-Peroxidase-Chromogen Reaktion. Außer Glucose ist kein Harninhaltsstoff bekannt, der eine positive Reaktion liefert.
Protein (Albumin): Der Test beruht auf dem „Eiweißfehler" des Indikators. Der Test reagiert besonders empfindlich gegenüber Albumin. Andere Urinproteine reagieren weniger stark.
Blut: Die Pseudoperoxidase-Aktivität des Hämoglobins und Myoglobins führt in Anwesenheit organischer Hydroperoxyde und eines Chromogens zu einem grünen Farbstoff.
pH: Das Testpapier enthält einen Mischindikator, der im pH-Bereich von 5 bis 9 deutlich unterscheidbare Reaktionsfarben (von orange über gelb nach türkis) zeigt.
Nitrit: Farbtest auf Grundlage der Probe nach Grieß. Jede Rosafärbung gilt als positiv und weist auf ≥105 Keime/ml Harn hin.
Leukozyten: Granulozytenesterasen spalten einen heterozyklischen Karbonsäureester, das Spaltprodukt reagiert mit einem Diazoniumsalz zu einem violetten Farbstoff.
Spezifisches Gewicht/Dichte: Der Test beruht auf einem Farbumschlag des Wirkstoffes von blaugrün nach grüngelb in Abhängigkeit der Konzentration ionischer Bestandteile im Harn. Der Test erlaubt die Bestimmung der Harndichte zwischen 1.000 und 1.030.

Der Inhalt der Schachtel

Packungen mit 150 Teststreifen:
- 150 Stück **LabStrip U11 Plus** Teststreifen,
- Farbenskala für visuelle Auswertung

- 1 Stück Kalibrierstreifen zur Kontrolle und zum Kalibrieren der Urinanalysegeräte **LabUReader**, **LabUReader Plus**, **LabUReader Plus 2**
- 1 Stück Kalibrierstreifen zur Kontrolle und zum Kalibrieren der Urinanalysegeräte **HandUReader** und **LabUMat**
- 1 Stück Kalibrierstreifen zur Kontrolle und zum Kalibrieren der Urinanalysegerät **DocUReader2** und **DocUReader 2 Pro**
- 1 Stück Gebrauchsanleitung

Sonstige Mittel zur Urinanalyse

- Urinanalysegeräte **DocUReader**, **DocUReader2**, **DocUReader 2 Pro**, **LabUReader**, **LabUReader Plus**, **LabUReader Plus 2**, **HandUReader** oder **LabUMat** mit Gebrauchsanleitung
- Trockenes, chemikalienfreies und sauberes Gefäß zum Auffangen von Urin.

Inhaltsstoffe

Die Reagenzien auf den einzelnen Testfeldern setzen sich wie folgt zusammen:

Bilirubin:	Diazoniumsalz	3.1 %
Urobilinogen:	Diazoniumsalz	3.6 %
Keton:	Nitroprussid-Natrium	2.0 %
Ascorbinsäure:	2.6-Dichlorophenolindophenol	0.7 %
Glucose:	Glucoseoxidase	2.1 %
	Peroxidase	0.9 %
	O-Tolidin - Hydrochloride	5.0 %
Protein (Albumin):	Tetrabromphenolblau	0.2 %
Blut:	Isopropylbenzol-Hydroperoxide	21.0 %
	Tetramethylbenzidin - Dihydrochloride	2.0 %
pH:	Bromthymolblau	10.0 %
	Methylrot	2.0 %
Nitrit:	Sulfanilsäure	1.9 %
	Tetrahydrobenzol[h]quinolon-3-ol	1.5 %
Leukozyten:	Karbonsäureester	0.4 %
	Diazoniumsalz	0.2 %
Spezifisches Gewicht:	Bromthymolblau	2.8 %

Die Prozentangaben basieren auf den Reagenz-Zusammensetzungen (w/w) zum Herstellungszeitpunkt und können im Rahmen der Herstellungs-Toleranz variieren.

Vorsicht!

- Alle Mittel im Paket können im Haushaltsmüll entsorgt werden. Wegen geringes Anteils an reaktiven Werkstoffen ist die EU Regelung über gefährliche Stoffe nicht anwendbar.
- Verschlucken und Kontakt mit Haut und Schleimhäuten vermeiden.
- Nur zur in-vitro-diagnostischen Anweisung.
- Im Originalstopfen der Teststreifen gibt es einen nicht giftigen, saugfähigen Stoff auf Molekularfilterbasis, der die Teststreifen vor Nässe schützt. Beim zufälligen Verschlucken ergiebig Flüssigkeit trinken.
- Bei Fragen wenden Sie sich bitte an Ihren Distributor.

Vorbereitung zur Harnanalyse:

Vorsicht!

Zur Harnanalyse mit Teststreifen **LabStrip U11 Plus** nur Harnanalysegerät **DocUReader**, **DocUReader 2**, **DocUReader 2 Pro**, **LabUReader**, **LabUReader Plus**, **LabUReader Plus 2**, **HandUReader** oder **LabUMat** verwenden.

In der Originalflasche **LabStrip U11 Plus** sind zwei Kalibrierstreifen zugepackt, jeweils ein zum Kalibrieren der Geräte **LabUReader** und **LabUReader Plus**, **LabUReader Plus 2**, und **DocUReader 2** (**DocUReader 2 Pro**) bzw. **HandUReader** und **LabUMat**. Zur Einstellung bitte die ausführliche Gebrauchsanleitung zum Gerät beachten. Das Gerät ist beim Einsatz einer neuen Originalflasche neu zu kalibrieren.

Bitte die ausführliche Gebrauchsanleitung zum Harnanalysegerät **LabUMat** beachten.

Probengewinnungen und Testvorbereitung

- Eine frische Harnprobe in einem sauberen, trockenen Gefäß sammeln.
- Keine Konservierungsmittel zufügen.
- Den Test sollte so bald als möglich in der unzentrifugierten, gut durchmischten Probe erfolgen.
- Für optimale Nitrittestungen wird die Verwendung von frischem Morgenharn empfohlen, genauso wie für die gültige Bestimmung von Bilirubin und Urobilinogen, da diese Analyse bei Einfluss durch Licht und Raumtemperatur instabil sind (+15 bis +25 °C).
- Wenn die Austestung nicht sofort durchgeführt werden kann, ist die Probe im Kühlschrank (+2 bis +8 °C) aufzubewahren und vor Testung wieder auf Raumtemperatur (+15 bis +25 °C) zu bringen.
- Bei Raumtemperatur können im Harn ohne Konservierungsstoffe durch mikrobielle Vermehrung pH-Veränderungen auftreten, die die Proteinbestimmung stören.
- Falls die Entnahme von Harn bei Damen nicht einwandfrei durchgeführt wird, können durch Kontaminationen vom äußeren Genitalbereich positive Ergebnisse für Leukozyten erhalten werden.
- Chlorhexidinhaltige Reinigungsmittel können bei Verunreinigung der Probe positive Proteinergebnisse vortäuschen.

Durchführung

- Nur gut gemischten, unzentrifugierten Harn, der nicht länger als 4 Stunden gestanden hat, verwenden. Empfohlen wird der erste Morgenurin. Vor Licht schützen.
- Zur Harnsammlung nur gut gespülte, saubere Gefäße verwenden. Keine Konservierungsmittel zusetzen.
- Stets nur die notwendige Anzahl an Teststreifen entnehmen. Packung nach der Entnahme sofort wieder mit dem Originalstopfen fest verschließen.
- Reaktionszone nicht berühren!

Instrumentelle Auswertung

- Bei Auswertung mit **DocUReader**, **DocUReader 2**, **DocUReader 2 Pro**, **LabUReader**, **LabUReader Plus**, **LabUReader Plus 2**, **HandUReader** oder **LabUMat** bitte vorher die ausführliche Gebrauchsanweisung zum Gerät beachten.
- Den Teststreifen ins Urinanalysegerät **DocUReader**, **DocUReader 2**, **DocUReader 2 Pro**, **LabUReader**, **LabUReader Plus**, **LabUReader Plus 2** oder **HandUReader** einlegen. Die Testergebnisse werden nach Ablauf von 60 Sekunden auf dem Display angezeigt.
- Im Urinanalysegerät **LabUMat** werden die Teststreifen automatisch weiterleitet und in die Urinprobe getaucht. Die Testergebnisse werden nach Ablauf von 60 Sekunden auf dem Display angezeigt.

Visuelle Auswertung

- Teststreifen kurz (ca. 2 Sek.) in die Urinprobe eintauchen. Alle Testfelder benetzen.
- Überschüssigen Harn über die Kante des Streifens am Rand des Sammelgefäßes oder auf saugfähigem Papier abstreifen.
- Teststreifen während der Inkubationszeit waagerecht halten, um Interferenzen zwischen den Reaktionszonen zu vermeiden.
- Reaktionsfarben nach 60 Sek. (Leukozyten nach 60-120 Sek.) mit der Farbskala vergleichen. Verfärbungen, die nur am Rand der Testfelder oder nach mehr als 2 Minuten nach Testbeginn auftreten, sind ohne Bedeutung.
- Die Farbfelder stellen Nennwerte dar. Istwerte schwanken um die Nennwerte.
- Das Kompensationsfeld zwischen dem spezifischen Gewicht und den Leukozyten ist frei von Chemikalien und dient ausschließlich der reflektrometrischen Auswertung der Testfelder.

Vorsicht!

Grundsätzlich ist eine definitive Diagnose nicht auf der Basis einzelner Teststreifenresultate, sondern erst im Zusammenhang mit anderen ärztlichen Befunden zu erstellen, und infolge gezielter Therapie einzuleiten.

Biologische Gefahr

Entsorgen Sie die benutzten Teststreifen unter Beachtung der geltenden Sicherheitsbestimmungen.

- Durch die nicht konstante Zusammensetzung des Harns (z.B. wechselnder Gehalt von Probe zu Probe an Aktivatoren oder Inhibitoren, wechselnde Ionekonzentration) sind die Reaktionsbedienungen nicht immer gleich, so dass Intensität und Farbton in seltenen Fällen variieren können.
- Die Auswirkung von Medikamenten oder deren Metaboliten auf den Test ist nicht in allen Fällen bekannt. Im Zweifelsfall wird deshalb empfohlen, den Test nach Absetzen der Medikation zu wiederholen.
- Für den Umgang mit Teststreifen sind die allgemeinen Arbeitsvorschriften für das Labor zu beachten.
- Die Teststreifen enthalten KEINE Giftstoffe.

Resultate

Alle Teststreifen können visuell ausgewertet werden, oder auch instrumentell, unter Verwendung eines Harnanalysengerätes. Die visuellen Farbskalen ergeben Nominalwerte für jedes Testfeld, die tatsächlichen Werte können von den Nominalwerten etwas abweichen.
Leukozytentest und Bluttest sind keine quantitativen Bestimmungen, sondern sie dienen als Filterverfahren für den Nachweis von Leukozyten und Blut im Harn. Mit einem positiven Ergebnis sollten mikroskopische Untersuchungen durchgeführt werden, wenn quantitative Ergebnisse erforderlich sind.
Ascorbinsäure in hohen Konzentrationen kann insbesondere den Glucose-, Nitrite-, Bilirubin- und Blutnachweis beeinflussen (Grenzen). Der Test muss bei positiver Ascorbinsäurereaktion wiederholt werden, frühestens 10 Stunden nach der letzten Vitamin C-Aufnahme (Obst, Gemüse, Medikation).
Näheres erfahren Sie bei Ihrem zuständigen Medizinproduktberater, wenn Sie **LabUReader**, **DocUReader**, **DocUReader 2**, **DocUReader 2 Pro**, **LabUReader Plus**, **LabUReader Plus 2**, **HandUReader** oder **LabUMat** benutzen.

Durchführung

Jeder Teststreifen hat 11 Reagenzzonen, die empfindliche chemische Stoffe enthalten. Wenn diese Testfelder mit Urin benetzt werden, entsteht eine chemische Reaktion, wobei sich die Farbe der Reagenzzone ändert. In den Harnanalysegeräten **DocUReader**, **DocUReader 2**, **DocUReader 2 Pro**, **LabUReader**, **LabUReader Plus**, **LabUReader Plus 2**, **HandUReader** oder **LabUMat** werden die Reaktionsfarben bestimmt und die Messwerte ermittelt.

Grenzen

Grundsätzlich ist eine definitive Diagnose nicht auf der Basis einzelner Teststreifenresultate gestellt werden.
Bilirubin: Die Reaktion ist pH-unabhängig. Falsch niedrige oder negative Resultate können durch hohe Konzentrationen an Vitamin C oder Nitrit auftreten und durch längeres Stehen am Licht. Erhöhte Urobilinogen-Konzentrationen können die Empfindlichkeit des Testfeldes verstärken. Versch. Harnbestandteile (z.B. Harnindikant) können zu atypischen Verfärbungen führen. Bzgl. Pharmakametaboliten siehe Urobilinogen.
Urobilinogen: Die Reaktion ist pH-unabhängig. Formaldehyd oder Sonnenlicht kann zu falsch niedrigen oder negativen Werten führen. Rote Beete und Pharmakametabolite, die bei niedrigem pH-Wert eine rote Färbung geben (Phenazopyridine, Azofarbstoffe, p-Aminobenzoesäure) können falsch positive Ergebnisse verursachen. Sonnenlicht kann zu falsch negativen Werten führen.
Keton: Phthaleinverbindungen und Anthrachinonderivate zeigen im alkalischen Bereich rötliche Farbtöne, die den Nachweis überdecken können.
Ascorbinsäure: Da sich Ascorbinsäure die verschiedenen Testfeldern störend auswirkt, muss der Test bei pos. Ascorbinsäurereaktion wiederholt werden, frühestens 10 Stunden nach der letzten Vitamin C-Aufnahme (Obst, Gemüse, Medikation).
Glucose: Bis einer Glucosekonzentration von ca. 100 mg/dl (5,5 mmol/l) werden bei hohen Ascorbinsäurekonzentrationen falsch negative Ergebnisse beobachtet. Der Test muss bei pos. Ascorbinsäurereaktion frühestens 10 Stunden nach der letzten Vitamin C-Aufnahme wiederholt werden. Hemmwirkung zeigen weiterhin Gentisinsäure, pH<5 und hohes spez. Gewicht. Falsch positive Reaktionen können durch Reste peroxydhaltiger oder anderer Reinigungsmittel hervorgerufen werden.
Protein (Albumin): Falsch positive Befunde können bei stark alkalischem Harn (pH>9) und hohem spezifischem Gewicht, nach Infusionen mit Polyvinylpyrrolidon (Blutersatzmittel), bei der Behandlung mit chininhaltigen Präparaten und durch Reste Desinfektionsmittel mit quartären Ammoniumgruppen im Sammelgefäß auftreten.
Blut: Durch Mikrohämaturie wird die Farbe des Harns nicht beeinflusst, eine Bestimmung ist daher nur mit chemischem Test oder mikroskopisch möglich. Ab einer Konzentration von ca. 25 Ery/μl oder höher werden auch bei hohen Ascorbinsäurekonzentrationen normalerweise keine falsch negativen Ergebnisse beobachtet. Falsch positive Reaktionen können durch Reste peroxydhaltiger oder anderer Reinigungsmittel, mikrobielle Oxidase-Aktivitäten bei Urogenitaltraktinfektionen oder Formalin hervorgerufen werden. Die Aussagekraft eines positiven Ergebnisses schwankt von Patient zu Patient, zur Erstellung einer individuellen Diagnose ist daher das klinische Bild unerlässlich. Die Anzahl der im Sediment ermittelten Erythrozyten kann niedriger sein als das Teststreifenresultat, da bereits lysierte Zellen im Sediment nicht erfasst werden.
pH-Wert: Keine Interferenzen sind bekannt.
Nitrit: Vor der Untersuchung sollte der Patient gemüsereiche Nahrung zu sich nehmen, die Flüssigkeitsaufnahme reduzieren und eine Antibiotica- oder Vitamin C-Therapie 3 Tage vor Probennahme absetzen. Falsch positive Resultate können bei alten Urinen auftreten (Nitritbildung auf Grund von Sekundärkontamination) und in Urinen, die Farbstoffe enthalten (Pyridiniumderivate, rote Beete). Negative Anzeige bei vorliegender Bakterieurie kann folgende Ursachen haben: Keime ohne Befähigung zur Nitratreduktion, Antibiotica-Therapie, nitratarme Kost, starke Diurese, hoher Ascorbinsäuregehalt oder zu geringe Verweilzeit des Urins in der Blase.
Leukozyten: Stark gefärbte Proben (z.B. Nitrofurantoin) können die Farbe auf dem Testfeld beeinträchtigen, Glucose oder Oxalsäure in höheren Konzentrationen, Medikamente mit Cephalexin, Cephalothin oder Tetracyclin können zu einer schwächeren Reaktion führen. Die Anzahl der im Sediment ermittelten Leukozyten kann niedriger sein als das Teststreifenresultat, da bereits lysierte Zellen im Sediment nicht erfasst werden. Granulozytenesterasen spalten einen heterozyklischen Karbonsäureester, wenn die Leukozyten lysieren werden. Falsch positive Reaktionen können durch Formaldehyd verursacht werden. Stark erhöhte (5 g/l) Konzentrationen an Protein können die Farbreaktion abschwächen. Bakterien, Trichomonaden und Erythrozyten reagieren dagegen nicht mit dem Testfeld.
Spezifisches Gewicht/Dichte: Stärker alkalischer (pH >8) Harn führt zu leicht erniedrigten, stärker saurer (pH <6) Harn zu leicht erhöhten Befunden. Glucose und Harnstoff haben keinen Einfluss.

Erwartungswerte

Bilirubin: Normalerweise ist Bilirubin im Harn nicht nachweisbar. Werte ab 0.5 mg/dl führen zur rötlich-orangen Pfirsichfarbe und weisen auf das Frühstadium einer Lebererkrankung hin. Die Farbfelder sind folgenden Konzentrationen zugeordnet: neg. (negativ), 1 (+), 3 (++), 6 (+++) mg/dl bzw. neg. (negativ), 17 (+), 50 (++), 100 (+++) μmol/l. Konzentrationen ab 0.5-1 mg/dl Bilirubin werden angezeigt.
Urobilinogen: Die normale Urobilinogenkonzentration im Harn reicht von 0.1-1.8 mg/dl (1.7-30 μmol/l), Konzentrationen >2 mg/dl (35 μmol/l) gelten als pathologisch. Die Farbfelder entsprechen folgenden Urobilinogenkonzentrationen: norm. (normal), 2 (+), 4 (++), 8 (+++), 12 (++++) mg/dl bzw. norm. (normal), 35 (+), 70 (++), 140 (+++), 200 (++++) μmol/l.
Keton: Normalerweise enthält Harn keine Ketonkörper. Nachweisbare Ketonkonzentrationen können durch physiologische Anstrengung (Fasten, Schwangerschaft, Sport) verursacht werden. Phenylketone können in höheren Konzentrationen eine abweichende Färbung ergeben. β-Hydroxibuttersäure wird nicht erfasst. Die Farbfelder sind folgenden Acetessigsäurekonzentrationen zugeordnet: neg. (negativ), 15 (+), 50 (++), 150 (+++) mg/dl bzw. neg. (negativ), 1.5 (+), 5 (++), 15 (+++) mmol/l. Konzentrationen ab 5 mg/dl Acetessigsäure bzw. 50 mg/dl Aceton werden angezeigt.
Ascorbinsäure: Die Anwesenheit von Ascorbinsäure wird durch einen Umschlag von graublau nach orange angezeigt. Die Farbfelder entsprechen: neg. (negativ), 20 (+), 40 (++) mg/dl bzw. neg. (negativ), 1.14 (+), 2.28 (++) mmol/l. Konzentrationen von 5-10 mg/dl bzw. 0.6-1.1 mmol/l Ascorbinsäure wird angezeigt.
Glucose: Glucose ist normalerweise im Harn nicht nachweisbar, obwohl minimale Mengen auch durch die gesunde Niere ausgeschieden werden. Farbänderungen schwächer als 50 mg/dl (2.8 mmol/l) sind als normal einzustufen. Die Farbfelder entsprechen folgenden Konzentrationen: norm. (normal), 50 (+), 150 (++), 500 (+++), 1000 (++++) mg/dl bzw. norm. (normal), 2.8 (+), 8 (++), 28 (+++), 56 (++++) mmol/l. Konzentrationen ab 40 mg/dl Glucose werden angezeigt.
Protein (Albumin): Normalerweise ist Bilirubin im Harn nicht nachweisbar.
Farbwerte für Protein (Albumin), die eine Intensität des 0,3 g/l Farbfeldes erreichen, sind als pathologisch zu bewerten. Die Farbfelder sind folgenden Albuminkonzentrationen zugeordnet: neg. (negativ), 30 (+), 100 (++), 500 (+++) mg/dl bzw. neg. (negativ), 0.3 (+), 1.0 (++), 5.0 (+++) g/l. Konzentrationen ab ca. 15 mg/dl Albumin werden angezeigt.
Blut: Intakte Erythrozyten werden durch punktförmige Verfärbungen des Testfeldes Hämoglobin bzw. Myoglobin durch eine homogene grüne Färbung angezeigt. Die Farbfelder entsprechen: neg. (negativ), ca. 5-10 (+), ca. 50 (++), ca. 300 (+++) Ery/μl. Konzentrationen ab 5 Erythrozyten/μl werden angezeigt.
pH-Wert: Bei Gesunden liegt der pH-Wert des frischen Harns meist zwischen pH 5 und 6. Die Farbvergleichsfelder entsprechen einem pH-Wert von: 5, 6, 7, 8, 9.
Nitrit: Negative Ergebnisse schließen eine signifikante Bakteriurie nicht aus (kurze Verweilzeit des Harns in der Blase, Infektionen mit Bakterien ohne Nitratreduktase). Gelegentlich auftretende rote oder blaue Ränder oder Ecken sind nicht als positive zu bewerten. Konzentrationen ab 0.05-0.1 mg/dl Nitrit werden angezeigt.
Leukozyten: Proben des Gesundens enthalten keine Leukozyten. Positive Ergebnisse, auch wenn wiederholt zwischen negativ und 25, sind als klinisch relevant zu betrachten. Die Farbvergleichsfelder entsprechen: neg. (negativ), ca .25 (+), ca. 75 (++), ca. 500 (+++) Leukozyten /μl. Konzentrationen ab 10-20 Leukozyten /μl werden angezeigt.
Spezifisches Gewicht/Dichte: Der Normalwert liegt etwa zwischen 1.015 und 1.025. Die Farbskala ist auf einen mittleren pH-Wert von Harn von 6 optimiert. Die Farbfelder sind Konzentrationen von 1.000, 1.005, 1.010, 1.015, 1.020, 1.025, 1.030.

Messgrenzen

Parameter	neg.	trace*	+	++	+++	++++			
Bilirubin (mg/dl)	neg.	0,5	1	3	6				
Urobilinogen (mg/dl)	norm.	-	2	4	8	12			
Keton (mg/dl)	neg.	5	15	50	150				
Ascorbinsäure (mg/dl)	neg.	-	20	40					
Glucose (mg/dl)	norm.	25	50	150	500	1000			
Protein (mg/dl)	neg.	15	30	100	500				
Blut (Ery/µl)	neg.	-	ca. 5-10	ca. 50	ca. 300				
pH-Wert*	5	5.5	6	6.5	7	7.5	8	8.5	9
Nitrit	neg.	-	pos.						
Leukozyten (Leu/µl)	neg.	-	ca. 25	ca. 75	ca. 500				
Kompensationsfeld									
Spezifisches Gewicht	1000	1005	1010	1015	1020	1025	1030		

* **DocUReader 2**, **DocUReader 2 Pro** und **LabUReader Plus 2** vermögen Plus Kategorien von Bilirubin, Ketones, Glucose, Protein und pH zu erweisen.

Haltbarkeit

Teststreifen kühl und trocken aufbewahren (Lagertemperatur +2 to +30 °C). Stets nur die notwendige Anzahl an Teststreifen entnehmen. Packung nach der Entnahme sofort wieder fest verschließen. Dose nach Entnahme sofort wieder mit dem Originalverschluss verschließen.

Teststreifen vor Licht und Feuchtigkeit schützen. Bei sachgemäßer Lagerung sind die Teststreifen bis zum aufgedruckten Verfalldatum haltbar. Reaktionszone nicht berühren.

Qualitätskontrollsystem

Jedes Labor sollte eigene Zielwerte für die adäquaten Leistungsstandards ermitteln. Bei der Durchführung der Qualitätskontrolle sind bezüglich der Häufigkeit der durchgeführten Analysen, der Zielwerte und Zielbereiche sowie der Dokumentation der Ergebnisse die gesetzlichen Vorgaben und Richtlinien einzuhalten.
Korrekturmaßnahmen für den Fall von Ergebnissen außerhalb des Zielbereiches sollten festgelegt werden.
Wie empfehlen Ihnen QC Dipper (Quantimetrix Corporation, REF: 1440-01), Dropper (Quantimetrix Corporation, REF: 1440-02) oder DipAndSpin (Quantimetrix Corporation, REF: 1470-01). Den Teststreifen in die Kontrolllösung statt des Urins eintauchen.

Bitte „Systemkontrolle" der ausführlichen Gebrauchsanweisung zum Harnanalysegerät beachten.

Spezifische Leistungsangaben

Die Leistungsangaben des **LabStrip U11 Plus** Teststreifens basieren auf klinischen und analytischen Studien. Die Empfindlichkeit ist von verschiedenen Faktoren abhängig, sowie den Unterschieden in der Farbwahrnehmung, Anwesenheit oder Abwesenheit von normalerweise im Harm anzutreffenden Inhibitoren und Matrixfaktoren.
Bilirubin: 90 % der Teste ergaben positive Resultate auf Bilirubinkonzentration ab 0.5 mg/dl. Farbveränderungen, die nach Stellung auftreten, sind ohne Bedeutung.
Urobilinogen: Nach Kutter [10], führen Werte ab 1 mg/dl von Urobilinogen zu positiven Resultaten.
Keton: 90 % der Teste ergaben positive Resultate auf Acetessigsäure ab 8 mg/dl. Der Test reagiert nicht mit Aceton. Hydroxibuttersäure wird nicht erfasst.
Ascorbinsäure: 90 % der Teste ergaben positive Resultate auf Ascorbinsäure ab 20 mg/dl.
Glucose: Konzentrationen ab 20 mg/dl Glucose werden angezeigt. Die Empfindlichkeit der Testfelder ermöglicht pathologische Glucosekonzentrationen von 30 mg/dl (Fine) [11] zu erfassen. Außer Glucose ist kein Harninhaltsstoff bekannt, der eine positive Reaktion liefert. Ascorbinsäure in hohen Dosen kann in Proben mit niedrigem Glucosegehalt die Reaktion hemmen. Ascorbinsäurefeld beachten!
Protein (Albumin): 90 % der Teste ergaben positive Resultate auf Albuminkonzentrationen ab 12 mg/dl. Der Proteintest ist gegenüber Mucoproteinen und Globulinen weniger empfindlich. Ein negatives Ergebnis schließt also das Vorhandensein dieser Proteine nicht aus.
Blut: Der Test ist gleichermaßen empfindlich für Myoglobin und Hämoglobin. Der Test erfasst Werte ab 5 bis 10 Erythrozyten/µl Harn. Eine Studie von 625 frischen Harnproben, wobei die Resultate mit denen von anderen Teststreifen verglichen wurden, ermittelt eine klinische Spezifität von 90,2% und eine Empfindlichkeit von 81%.
pH-Wert: Die Farbskala erlaubt eine deutliche Differenzierung des pH-Wertes zwischen pH 5 und 9. Die Werte werden nicht durch Änderungen der Urinpufferkonzentration beeinträchtigt.
Nitrit: Der Nachweis erfasst Werte ab 0.05 mg Nitrit/dl Harn, das bedeutet 100.000 Keime/ml Harn. In dem ersten Morgenurin wird 90 % der Ansteckung positives Nitritergebnis ergeben. Das Prinzip dieses Tests beruht auf der Umwandlung von Nitrat (aus Nahrung) in Nitrit durch gram-negative Bakterien im Harn. Der Test ist nitritspezifisch und reagiert keiner anderen normalerweise im Harn ausgeschiedenen Substanz. Bakterien werden nicht aufgeführt.
Leukozyten: 90 % der Teste ergaben positive Resultate auf Konzentrationen ab 20 Leukozyten/µl. Eine rosa Verfärbung am Testfeld wird als klinisch signifikant beurteilt. Klinische Empfindlichkeit aus 822 Harnproben befunden zwischen 80 % und 89,2 %.
Spezifisches Gewicht/Dichte: Bei 86% von 102 Harnproben befunden die Werte am Farbskala im Bereich von + oder – eins im Vergleich zu den durch die Refraktometer-Methode gemessenen Werten.

Impräzision während der Analyse

Die Wiederholbarkeit während der Analyse wurde durch 10 wiederholte Messungen mit zwei Harnkontrolllösungen (normal, abnormal) definiert. Die negativen and positiven Resultate wurden zu 100% der Zeit auf alle Parameter richtig identifiziert.

Impräzision zwischen Analysen

Die Reproduzierbarkeit zwischen den Analysen wurde durch 10 unabhängige Messungen mit zwei Harnkontrolllösungen (normal, abnormal) definiert. Die Messungen wurden 6 Monate lang mit drei verschiedenen Chargen von Reagenzien duchgeführt. Die negativen and positiven Resultate wurden zu 100% der Zeit auf alle Parameter richtig identifiziert.

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Stripping/Streifen

REF ANA-9901-1

Manufacturer/Hergestellt von

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Markings/Symbole

IVD — In vitro diagnostic medical device / In vitro Diagnostikum

REF — Catalogue Number / Artikelnummer

LOT — Lot Number / Chargenbezeichnung

CE — The CE mark identifies that the product complies with the applicable directives of the European Union / Das CE-Zeichen gibt an, dass das Gerät die geltenden Richtlinien der Europäischen Union erfüllt

Use by / Verwendbar bis

2°C 30°C — Temperature Limitation / Lagerung bei

Manufacturer / Hergestellt von

Keep away from sunlight / Teststreifen vor Licht und Feuchtigkeit schützen!

Consult instructions for use / Packungsbeilage beachten.

Caution / Vorsicht!

Biological Risks / Biologische Gefahr

Σ 150 — Contains sufficient for 150 tests / Packungen mit 150 Teststreifen

Do NOT Reuse / Für den Einmalgebrauch.

Do not use if package is damaged / Nicht benützen, wenn die Verpackung beschädigt ist!

GB — English language

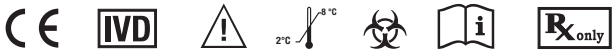
D — Deutsche Sprache

ANA-9201-6 GB/D 2014. 03.

Quantimetrix®
Dip&Spin®

Urinalysis Dipstick & Microscopics Control
Level 1&2

LOT 252881 252882 | REF 1470-01 1470-02 | 2026-11-30



English

Intended Use
The Quantimetrix Dip&Spin Urinalysis Dipstick & Microscopics Control is intended as a control for urinalysis reagent strips, microalbumin, and creatinine by the listed test methods, and as a control for confirmatory tests such as **K-CHECK** and **Ictotest®** reagent tablets, and for **hCG** methods.

In addition, the Dip&Spin Control is intended as a means of validating the processing and centrifugation of patient urine samples prior to the microscopic evaluation of urine sediment. For professional use only.

Summary and Explanation
Control materials having known component concentrations are an integral part of diagnostic procedures. Daily monitoring of control values establishes intralaboratory parameters for accuracy and precision of the test method.

Microscopic QC controls must be run each day the test is performed. Standardized microscopic evaluation or urine sediment is an important part of routine analysis or urine. Along with physical and chemical analysis, microscopic examination of urine can provide valuable information regarding not only renal and urinary tract disease, but also metabolic diseases unrelated to the kidney. Urinary sediment microscopy generally includes the detection and identification of red blood cells, leukocytes, epithelial cells, bacteria, casts, and crystals.

Product Description
The Quantimetrix Dip&Spin Urinalysis Dipstick & Microscopics Controls are supplied liquid, ready-to-use in two levels. They do not require reconstitution or dilution. They are prepared from human urine to which stabilized human red and white blood cells, calcium oxalate crystals, and other compounds have been added to produce the desired reactions when tested by the methods indicated in the **Intended Use** section. Preservatives have been added to inhibit microbial growth.

Caution
Contains human urine, human blood cells and human Chorionic Gonadotropin (hCG) from pregnancy urine. The human hCG source material and all blood donor units comprising the human cell source material used in the manufacture of this product have been tested and found nonreactive for Hepatitis B Surface Antigen and Hepatitis C and HIV 1 & 2 antibody when tested by FDA accepted methods. No known test method can assure that a product derived from human material does not contain Hepatitis or HIV virus. Handle the QC material as you would a patient sample. QC materials should be used and disposed of in accordance with regulatory and accreditation requirements.

Warning ⚠ Hazard (H) and Precautionary (P) Statements
Contains Mixture, 3(2H)-isothiazolone, 5-chloro-2-methyl- with 2-methyl-3(2H)-isothiazolone, 1,2-Propylene Glycol, Level 1; 2,4-Pentanedione, Level 2.
H317 – May cause an allergic skin reaction.
P261 – Avoid breathing vapors, mist, or spray.
P272 – Contaminated work clothing should not be allowed out of the workplace.
P280 – Wear protective gloves, protective clothing, and eye protection.
P302+P352 – IF ON SKIN: Wash with plenty of water.
P333+P313 – If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 – Take off contaminated clothing and wash it before reuse.
P501 – Dispose of contents/container in accordance with local, regional, national, and international regulations.
Safety Data Sheet (SDS) available for professional users at **quantimetrix.com.**

Storage and Stability
The Dip&Spin Control Kit should be at 2°C–8°C when not in use. **Do not freeze.** When stored at 2°C–8°C the controls are stable until the expiration date stated on the label. After opening, the controls will remain stable until the expiration date stated on the label when stored at 2°C–8°C between uses. Discard the control if it becomes more turbid or develops a stronger odor. Discard controls in the same manner as other biological specimens, according to local guidelines.

Procedure for Dipstick Urinalysis and Microscopic Evaluation of Urine Sediment
Remove the controls from the refrigerator and replace the cap on the control bottle with the spout cap included in the control box. Allow the control to come to room temperature (18°C–25°C) for approximately 15-90 minutes depending on the volume remaining in the bottle. Mix the controls thoroughly by inverting the bottle at least 20 times to assure homogeneity of the contents. Avoid foaming. Thorough mixing with each use is important in order to obtain reproducible results. Pour 12 mL of the controls into a standard 15 mL centrifuge tube.

For urinalysis, microalbumin and creatinine testing, immerse the reagent strip in the centrifuge tubes containing the control as if they were patient specimens. Read the urinalysis reagent strips, visually or with an instrumental reader, in accordance with the manufacturer's instructions.

For microscopic evaluation of urine sediment, treat the controls as you would patient samples in accordance with the manufacturer's instructions for the standardized microscopic urinalysis system you are using. The National Committee for Clinical Laboratory Standards (NCCLS) recommends the use of standardized systems in order to yield standardized, reproducible results and to enable the reporting of abnormal sediment elements per unit volume.[1]

Procedure for hCG Tests and Confirmatory Tests
Note: The bottles of Level 1 Control are to be used as negative controls for hCG methods. The bottles of Level 2 Control are to be used as positive controls for hCG methods.

Most manufacturers of pregnancy test kits specify the volume of sample to be used with their kits. Many kits include transfer pipets to be used to deliver a certain sample volume onto the test device. It is important that sufficient volume be used to produce the correct test result.

If dispensing the control for hCG tests and confirmatory tests directly from the control bottles, each user should validate that the volume (number of drops) dispensed by the included spout cap is sufficient to meet the pregnancy test kit's and confirmatory tests' requirement for sample volume.

Remove the controls from the refrigerator. Allow the controls to come to room temperature (18°C–25°C) for approximately 15-90 minutes depending on the volume remaining in the bottle. Mix the control thoroughly by inverting the bottle at least 20 times to assure homogeneity of the contents. Avoid foaming. Use the negative and positive controls as if they were patient specimens in accordance with the test kit manufacturer's instructions. If using the same bottle of control dispensed for urinalysis testing and microscopic evaluation, remove the volume of sample to be used for hCG tests and confirmatory tests after centrifugation, before discarding the supernatant and without disturbing the sediment. Immediately close the spout cap and store the controls at 2°C–8°C when not in use.

Expected Values
For visual readings, the expected ranges have been established from interlaboratory data by comparing the dipstick reaction that occurs with the controls to the color comparison chart with multiple lots of each manufacturers' dipsticks or reagent tablets. For expected values for urinalysis reagent strips not listed, please contact Quantimetrix Technical Services.

For instrument readings, the expected ranges have been established from interlaboratory data from multiple lots of each manufacturers' dipsticks. Each laboratory should establish its own precision parameters.

For specific gravity, the expected ranges by refractometer have been established from interlaboratory data.

For hCG, the positive and negative results were obtained by testing each lot number of the controls with multiple lot numbers of different hCG test kits with sensitivities of ≥ 25 mIU/mL.

For microscopic evaluation of urine sediment, the expected ranges for each type of formed element were determined by assay of multiple bottles of the indicated lot by the methods listed. A 12 mL sample volume of the samples were centrifuged at 400 RCF (relative centrifugal force) for 5 minutes. After centrifugation, urine sediment was resuspended in either ~0.5 or ~1.0 mL of remaining supernatant according to the plasticware manufacturer's directions. The ranges listed are based on the range of elements observed in 10 high power fields. Use of other systems or protocols may yield differing results. Each laboratory should establish its own precision parameters.

Limitations
Any future changes made by the manufacturer of a test method may give different values from the indicated range. Detailed information on the limitations of each test method is included in the limitations section of the manufacturers' package insert. Technical updates can be found on our website. The Quality Control Log can be downloaded from the Quantimetrix website at **quantimetrix.com** or contact Tech Support at (310) 536-0006, option 3.

Chemstrip/CombiScreen/Combur/Multistix/Urocheck Users
Colors produced by the **urobilinogen** and/or **bilirubin** reactions on these dipsticks with the Urinalysis Dipstick Control may not be characteristic of those shown on the manufacturer's label when reading the dipstick reactions visually. The urobilinogen reactions are consistent and intensify with the increase in the urobilinogen concentration but may not provide an exact color match to those displayed on the label.

Note: Siemens® CLINITEK 50 and Siemens® STATUS or CLINITEK STATUS PLUS may see an Albumin/Creatinine ratio result of "Abnormal" with the Level 1 control.

The appearance of a macroscopic crystalline precipitate in the product will not affect performance.

Deutsch

Verwendungszweck
Die Quantimetrix Dip&Spin Urinalysis Dipstick & Microscopics Control ist als Kontrolle für Urinanalyse-Reagenzstreifen, Mikroalbumin und Kreatinin gemäß den aufgeführten Testmethoden sowie als Kontrolle für Bestätigungstests wie z. B. **K-CHECK** und **Ictotest®** Reagenz-Tabletten und für **hCG**-Methoden bestimmt.

Darüber hinaus dient die Dip&Spin Control zur Bewertung der Verarbeitung und Zentrifugierung von Patienten-Urinproben vor der mikroskopischen Beurteilung des Urinsediments. Nur für den professionellen Gebrauch.

Zusammenfassung und Erklärung
Kontrollmaterialien mit bekannten Konzentrationen von Komponenten sind ein integraler Bestandteil diagnostischer Verfahren. Im Rahmen der täglichen Überwachung von Kontrollwerten werden laborinterne Parameter für die Genauigkeit und Präzision der Testmethode festgelegt.

An jedem Tag, an dem der Test durchgeführt wird, müssen mikroskopische Qualitätskontrollen (QC) laufen. Die standardisierte mikroskopische Beurteilung von Urinsediment ist ein wichtiger Bestandteil der routinemäßigen Urinanalyse. Zusammen mit der physikalischen und chemischen Analyse kann die mikroskopische Untersuchung des Urins wertvolle Informationen nicht nur über Erkrankungen von Nieren und Harnwegen, sondern auch über von der Niere unabhängige Stoffwechselerkrankungen liefern.Zur mikroskopischen Untersuchung von Urinsediment gehört grundsätzlich der Nachweis und die Identifizierung von roten Blutkörperchen, Leukozyten, Epithelzellen, Bakterien, Ausgüssen und Kristallen.

Produktbeschreibung
Die Quantimetrix Dip&Spin Urinalysis Dipstick & Microscopics Controls werden gebrauchsfertig in zwei Stufen ausgeliefert. Es ist keine Rekonstitution oder Verdünnung erforderlich. Sie werden aus menschlichem Urin hergestellt, der mit stabilisierten roten und weißen Blutkörperchen, Kalziumoxalatkristallen und anderen Substanzen angereichert wurde, um die gewünschte Reaktion zu erzeugen, wenn das Produkt gemäß den unter **Verwendungszweck** beschrieben Verfahren eingesetzt wird. Das Produkt wurde mit Konservierungsstoffen angereichert, um mikrobiellem Keimwachstum entgegenzuwirken.

Warnhinweis
Enthält menschlichen Urin, menschliche Blutkörperchen und menschliches Choriongonadotropin (hCG) aus Urin bei Schwangerschaft. Das menschliche hCG-Quellenmaterial und alle bei der Produktherstellung verwendeten Blutspenden, die das menschliche Zellenquellenmaterial beinhalten, wurden unter Einhaltung anerkannter FDA-Methoden auf Hepatitis B-Oberflächenantigene, Hepatitis C und Antikörper gegen HIV 1 & 2 getestet. Die Testergebnisse waren nicht-reaktiv. Es sind keine Testmethoden bekannt, mit denen garantiert werden kann, dass die aus menschlichem Material gewonnenen Produkte frei von Hepatitis- oder HIV-Viren sind. Die Materialen für die Qualitätskontrolle sollten wie Patientenproben gehandhabt werden. Die Materialien müssen im Einklang mit den gesetzlichen Bestimmungen und Zulassungsvorschriften verwendet und entsorgt werden.

Achtung ⚠ Gefahrenhinweise (H) Sicherheitshinweise (P)
Gemisch, 3(2H)-isothiazolone, 5-chloro-2-methyl- mit 2-methyl-3(2H)-isothiazolone, 1,2-Propylene Glycol, Stufe-1; 2,4-Pentanedione, Stufe-2.
H317 – Kann allergische Hautreaktionen verursachen.
P261 – Einatmen von Nebel, Dämpfen, Aerosol vermeiden.
P272 – Kontaminierte Arbeitskleidung nicht außerhalb des Arbeitsplatzes tragen.
P280 – Schutzhandschuhe, Schutzkleidung und Augenschutz tragen.
P302+P352 – BEI KONTAKT MIT DER HAUT: Mit viel Wasser waschen.
333+P313 – Bei Hautreizung oder -ausschlag: Ärztlichen Rat einholen/ärztliche Hilfe hinzuziehen.
P362+P364 – Alle kontaminierten Kleidungsstücke sofort ausziehen und vor erneutem Tragen waschen.
P501 – Inhalt/Behälter entsprechend örtlichen, regionalen, nationalen und internationalen Richtlinien der Entsorgung zuführen.
Sicherheitsdatenblatt (SDB) steht ihnen im Internet unter **quantimetrix.com** zur Verfügung.

Lagerung und Stabilität
Das Dip&Spin Control Kit sollte bei Nichtgebrauch bei 2°C bis 8°C gelagert werden. **Nicht einfrieren**. Bei Lagerung bei 2°C bis 8°C sind die Kontrollen bis zum auf dem Etikett angegebenen Verfallsdatum stabil. Nach dem Öffnen bleiben die Kontrollen bis zum auf dem Etikett angegebenen Verfallsdatum stabil, wenn sie zwischen den Verwendungen bei 2°C bis 8°C gelagert werden. Falls die Kontrolle trüb wird oder einen starken Geruch ausströmt, sollte sie entsorgt werden. Kontrollen auf gleiche Weise wie andere biologische Proben gemäß den örtlichen Richtlinien entsorgen.

Verfahren für Dipstick Urinanalyse und mikroskopische Beurteilung von Urinsediment
Nehmen Sie die Kontrollen aus dem Kühlschrank, und tauschen Sie die Kappe des Kontrollfläschchens gegen den in der Kontrollbox enthaltenen Ausgießverschluss aus. Lassen Sie die Kontrollen je nach der noch im Fläschchen verbleibenden Menge ca. 15 bis 90 Minuten lang auf Raumtemperatur (18°C bis 25°C) aufwärmen. Mischen Sie die Kontrollen gründlich, indem Sie das Fläschchen mindestens 20 Mal umdrehen und so einen homogenen Inhalt sicherstellen. Nicht schäumen lassen. Ein gründliches Mischen vor jeder Verwendung ist unerlässlich, um reproduzierbare Resultate zu erhalten. Gießen Sie 12 ml der Kontrollen in ein standardmäßiges 15 ml Zentrifugenröhrchen.

Zur Urinanalyse, Mikroalbumin- und Creatinin-Testung tauchen Sie den Reagenzstreifen wie bei einer Patientenprobe in das Zentrifugenröhrchen mit der Kontrolle. Die Urinanalyse-Teststreifen visuell oder in einem Lesegerät gemäß den Herstelleranweisungen ablesen.

Zur mikroskopischen Beurteilung von Urinsediment behandeln Sie die Kontrollen wie Patientenproben entsprechend den Herstelleranweisungen für das von Ihnen verwendete, standardisierte, mikroskopische Urinanalysesystem. Das National Committee for Clinical Laboratory Standards (NCCLS) empfiehlt die Verwendung standardisierter Systeme, um standardisierte, reproduzierbare Ergebnisse zu erhalten und die Angabe abnormaler Sedimentbestandteile pro Volumeneinheit zu ermöglichen.[1]

Verfahren für hCG-Tests und Bestätigungstests

Hinweis: Die Fläschchen mit der Level-1-Kontrolle sind bei hCG-Methoden als negative Kontrollen vorgesehen. Die Fläschchen mit der Level-2-Kontrolle sind bei hCG-Methoden als positive Kontrollen vorgesehen.

Die meisten Hersteller von Schwangerschaftstests geben die für ihre Tests benötigte Probenmenge an. Viele Testkits enthalten Pipetten zum Übertragen einer bestimmten Probenmenge auf das Testgerät. Es ist wichtig, dass eine ausreichende Probenmenge verwendet wird, um das richtige Testergebnis zu erzielen.

Falls die Kontrolle für die hCG-Tests und die Bestätigungstests direkt von den Kontrollfläschchen aus verabreicht wird, muss der Benutzer bestätigen, dass die über den Tropfverschluss verabreichte Menge (Anzahl der Tropfen) ausreicht, damit sie die Anforderungen an die Probenmenge für den Schwangerschaftstest und für die Bestätigungstests erfüllt.

Die Kontrollen aus dem Kühlschrank nehmen. Die Kontrollen ca. 15 bis 90 Minuten lang auf Raumtemperatur (18°C bis 25°C) aufwärmen lassen, je nach der noch im Fläschchen verbliebenen Menge. Mischen Sie die Kontrollen gründlich, indem Sie das Fläschchen mindestens 20 Mal umdrehen und so einen homogenen Inhalt sicherstellen. Nicht schäumen lassen. Verwenden Sie die negativen und positiven Kontrollen entsprechend den Herstelleranweisungen des Testkits wie Patienten-Proben. Bei Verwendung der gleichen Flasche der Kontrolle für die Harnanalyse und die mikroskopische Auswertung sollte das für die hCG-Tests bzw. die Bestätigungstests verwendete Probenvolumen nach der Zentrifugierung entfernt werden, bevor der Überstand entsorgt wird. Die Sedimente dürfen dabei nicht aufgeschüttelt werden. Ausgießverschluss sofort verschließen und Kontrollen bei Nichtgebrauch bei 2°C bis 8°C lagern.

Erwartete Werte

Für **visuelle Messungen** wurden die erwarteten Bereiche aus den Daten verschiedener Labors bestimmt, indem die mit den Kontrollen erhaltene Teststäbchenreaktion mit der Farbvergleichstabelle verglichen wurde, die Farben für mehrere Chargen der Teststäbchen bzw. Reagenztabletten jedes Herstellers enthält. Erwartete Werte für nicht aufgeführte Urinanalyse-Reagenzstreifen sind von Quantimetrix Technical Services erhältlich.

Für **Gerätemessungen** wurden die erwarteten Werte anhand von Daten verschiedener Labors und mehreren Chargen von Teststäbchen jedes Herstellers bestimmt. Jedes Labor sollte seine eigenen Präzisionsparameter bestimmen.

Für die **relative Dichte** wurden die mit dem Refraktometer ermittelten, erwarteten Bereiche aus Daten von verschiedenen Labors bestimmt.

Für **hCG** wurden die positiven und negativen Ergebnisse durch Testen jeder Chargennummer der Kontrollen mit mehreren Chargennummern verschiedener hCG-Test-Kits mit Sensitivitäten von ≥ 25 mIE/ml erzielt.

Für die **mikroskopische Beurteilung** von Urinsediment wurden die erwarteten Werte für jede Art von geformten Elementen durch Nachweis mehrerer Fläschchen der angegebenen Charge durch die aufgeführten Methoden bestimmt. Ein Volumen von 12 ml der Probe wurde bei 400 RCF (relative Zentrifugalkraft) 5 Minuten lang zentrifugiert. Nach dem Zentrifugieren wurde das Urinsediment in entweder ~0,5 oder ~1,0 ml des verbleibenden Überstands entsprechend den Herstelleranweisungen resuspendiert. Die angegebenen Bereiche basieren auf dem Bereich von Elementen, die in 10 stark vergrößerten Feldern beobachtet wurden. Die Verwendung anderer Systeme oder Verfahren kann zu abweichenden Resultaten führen. Jedes Labor sollte seine eigenen Präzisionsparameter bestimmen.

Einschränkungen

Alle zu einem späteren Zeitpunkt vom Hersteller einer Testmethode vorgenommenen Änderungen können Abweichungen von dem angegebenen Bereich zur Folge haben. Detaillierte Informationen zu den Einschränkungen der einzelnen Testmethoden sind im Abschnitt Einschränkungen auf der Packungsbeilage des Herstellers aufgeführt. Technische Neuigkeiten entnehmen Sie bitte unserer Website. Sie erhalten das Qualitätskontrollprotokoll durch Herunterladen über die Website von Quantimetrix unter **quantimetrix.com**, oder indem Sie sich an den technischen Support unter der Rufnummer +1 (310) 536-0006, Option 3 wenden.

Chemstrip/CombiScreen/Combur/Multistix/Urocheck-Benutzer

Farben, die durch das **Urobilinogen** erzeugt werden, und/oder **Bilirubin**reaktionen auf diesen Teststäbchen mit der Urinteststäbchen-Kontrolle sind möglicherweise nicht charakteristisch für die auf dem Etikett des Herstellers aufgeführten Werte, wenn die Teststäbchen-Reaktionen visuell abgelesen werden. Die Urobilinogen-Reaktionen sind konsistent und nehmen bei Zunahme der Urobilinogenkonzentration an Intensität zu, stimmen farblich jedoch möglicherweise nicht exakt mit den auf dem Etikett angegebenen Farben überein.

Hinweis: Siemens® CLINITEK 50 und Siemens® STATUS oder CLINITEK STATUS PLUS können bei der Stufe-1-Kontrolle unter Umständen ein „anormales" Albumin/Kreatinin-Verhältnis anzeigen.

Das Auftreten eines makroskopischen kristallinen Niederschlags im Produkt beeinträchtigt die Leistung nicht.

Français

Utilisation prévue

Le Quantimetrix Dip&Spin Urinalysis Dipstick & Microscopics Control a pour fonction de vérifier les bandes de réactif d'analyse d'urine et le dosage de la micro-albumine et de la créatinine selon les méthodes de test indiquées et, de contrôler les tests de confirmation tels ceux des tablettes de réactif **K-CHECK** et **Ictotest®** ainsi que les méthodes **hCG**.

De plus, le contrôle Dip&Spin est conçu comme un moyen de valider le traitement et la centrifugation d'échantillons d'urine de patients avant l'évaluation microscopique du sédiment urinaire. Réservé à un usage professionnel.

Résumé et explication

Les contrôles dont les concentrations d'un composant sont connues font partie intégrante des procédures diagnostiques. Le relevé quotidien des valeurs du contrôle permet d'établir des paramètres de comparaison intralaboratoire garantissant la précision et l'exactitude de la méthode de test.

Les contrôles de qualité microscopiques doivent être effectués chaque jour qu'un test est réalisé. L'évaluation microscopique standardisée du sédiment urinaire représente une part importante de l'analyse d'urine de routine. De même que l'analyse physique et chimique, l'examen microscopique de l'urine peut fournir de précieuses informations concernant non seulement les pathologies rénales et urinaires, mais aussi les maladies métaboliques non liées aux reins. L'examen microscopique du sédiment urinaire comprend généralement la détection et l'identification de globules rouges, de leucocytes, de cellules épithéliales, de bactéries, de cylindres et de cristaux.

Description du produit

Les Quantimetrix Dip&Spin Urinalysis Dipstick & Microscopics Controls sont disponibles en deux niveaux sous forme de liquides prêts à l'emploi. Ils ne nécessitent ni reconstitution, ni dilution. Ces contrôles sont élaborés à partir d'urine humaine à laquelle ont été ajoutés des globules rouges et des globules blancs humains stabilisés, des cristaux d'oxalate calcite et d'autres composés afin d'obtenir les réactions désirées lors de tests effectués avec les méthodes indiquées à la section **Utilisation prévue**. Des conservateurs ont également été ajoutés pour inhiber la prolifération microbienne.

Mise en garde

Contient de l'urine humaine, des cellules sanguines humaines et de l'hormone chorionique gonadotrope humaine (hCG) provenant d'urine de femmes enceintes. Les matériels humains de la source d'hCG ainsi que toutes les unités de donneurs de sang composant les matériels sanguins humains utilisés pour la fabrication de ce produit ont fait l'objet de tests conformes aux méthodes approuvées par la FDA. Ils se sont révélés non réactifs à l'antigène de surface de l'hépatite B, ainsi qu'aux anticorps de l'hépatite C et du VIH 1 et 2. Aucune méthode de test connue n'est en mesure de garantir qu'un produit dérivé de matérial humain ne contient pas le virus de l'hépatite ou du VIH. Manipuler les matériels du contrôle de qualité de la même façon que pour un échantillon de patient. Ces matériaux doivent être utilisés et éliminés conformément aux exigences réglementaires et critères d'accréditation.

Attention ⚠ Mentions de danger (H) Conseils de prudence (P)

Mélange , 3(2H)-isothiazolone, 5-chloro-2-methyl- avec 2-methyl-3(2H)-isothiazolone,
1,2-Propylene Glycol, niveau 1; 2,4-Pentanedione, niveau 2.
H317 – Peut causer une réaction allergique cutanée.
P261 – Éviter de respirer les vapeurs, les brouillards ou les aérosols.
P272 – Les vêtements de travail contaminés ne doivent pas quitter le lieu de travail.
P280 – Porter des gants de protection, des vêtements de protection et un dispositif de protection des yeux.
P302+P352 – EN CAS DE CONTACT AVEC LA PEAU : laver à grande eau.
P333+P313 – En cas d'irritation ou d'éruption cutanée : consulter un médecin.
P362+P364 – Enlever les vêtements contaminés et les laver avant réutilisation.
P501 – Éliminer le contenu/contenant conformément aux réglementations locales, régionales, nationales et internationales.
Une ficha de sécurité (SDS) est à disposition des vutilisateurs professionnels sur la site **quantimetrix.com**.

Stockage et stabilité

Le contrôle Dip&Spin doit être entreposé à une température de 2°C–8°C entre deux utilisations. **Ne pas congeler.** Stockés à la température indiquée, les contrôles sont stables jusqu'à la date de péremption figurant sur l'étiquette. Après ouverture, les contrôles resteront stables jusqu'à la date de péremption figurant sur l'étiquette s'ils sont conservés à une température de 2°C–8°C entre deux utilisations. eter le contrôle en cas de traces de turbidité ou d'apparition d'une odeur forte. Jetez les contrôles en procédant comme pour d'autres spécimens biologiques, conformément aux directives locales en vigueur.

Procédure pour analyse d'urine par bandelette réactive et examen microscopique du sédiment urinaire

Sortez les contrôles du réfrigérateur et remettez la capsule sur la bouteille de contrôle, le bouchon verseur étant rangé dans la boîte du contrôle. Patientez pendant 15-90 minutes, en fonction du volume restant dans la bouteille, que le contrôle soit à température ambiante (18°C–25°C). Mélangez bien les contrôles en retournant la bouteille au moins 20 fois pour assurer l'homogénéité de son contenu. Évitez de faire mousser. Il est important de bien mélanger le contrôle avant chaque utilisation pour obtenir des résultats reproductibles. Versez 12 ml de contrôle dans un tube de centrifugation standard de 15 ml.

Pour l'analyse d'urine, de microalbumine et de créatinine, immergez la bandelette réactive dans les tubes de centrifugation contenant le contrôle comme s'il s'agissait d'échantillons de patients. Interprétez les bandelettes réactives d'analyse d'urine, visuellement ou à l'aide d'un lecteur prévu à cet effet, conformément aux instructions du fabricant.

Pour l'évaluation du sédiment urinaire, procédez de la même manière qu'avec des échantillons de patients conformément aux instructions du fabricant pour le système standardisé d'analyse d'urine que vous utilisez. Le National Commitee for Clinical Laboratory Standards (NCCLS) recommande l'utilisation de systèmes standardisés afin de produire des résultats standardisés, reproductibles et de permettre de relever les éléments sédimentaires anormaux par volume unitaire.[1]

Procédure pour tests hCG et test de confirmation

Remarque: Les bouteilles de contrôle de niveau 1 peuvent servir de contrôles négatifs pour les méthodes hCG. Les flacons de contrôle de niveau 2 peuvent servir de contrôles positifs pour les méthodes hCG.

La plupart des fabricants de tests de grossesse précisent le volume d'échantillon à utiliser avec leurs kits. La plupart de ces tests contiennent des pipettes de transfert permettant de déposer un volume précis d'échantillon sur le dispositif de test. Il est important d'utiliser un volume suffisant pour obtenir des résultats de test adéquats.

Si le contrôle des tests hCG et des tests de confirmation est versé directement à partir des flacons de contrôle, chaque utilisateur doit s'assurer que la quantité (nombre de gouttes) distribuée par le bouchon verseur qui est fourni est suffisante pour répondre aux exigences du kit de test de grossesse et des tests de confirmation pour le volume de l'échantillon en question.

Sortez les contrôles du réfrigérateur. Patientez pendant 15-90 minutes, en fonction du volume restant dans la bouteille, jusqu'à ce que le contrôle soit à température ambiante (18°C–25°C). Mélangez bien le contrôle en retournant la bouteille au moins 20 fois pour assurer l'homogénéité de son contenu. Évitez de faire mousser. Traitez les contrôles positif et négatif comme s'il s'agissait d'échantillons prélevés sur des patients conformément aux instructions du fabricant du kit de test hCG. Si vous utilisez le même flacon de contrôle pour les tests d'analyse urinaire et l'évaluation microscopique, retirez le volume d'échantillon qui servira aux tests hCG et aux tests de confirmation après la centrifugation avant de jeter le supernageant et ce, sans troubler les sédiments. Refermez immédiatement le bouchon verseur et entreposez les contrôles à 2°C–8°C entre deux emplois.

Valeurs attendues

Pour les relevés visuels, les plages de valeurs attendues ont été établies à partir de données interlaboratoires en comparant la réaction de la bandelette utilisée pour le contrôle à l'échelle colorimétrique illustrant les lots de bandelettes et de tablettes réactives de chaque fabricant. Pour les valeurs attendues dans le cas des bandelettes réactives d'analyse d'urine non listées, veuillez contacter les services techniques de Quantimetrix.

Pour les relevés d'instruments, les plages de valeurs attendues ont été établies à partir de données interlaboratoires portant sur plusieurs lots de bandelettes réactives de chaque fabricant. Il incombe à chacun de ces laboratoires de déterminer ses propres paramètres de précision.

Pour la densité, les plages de valeurs attendues par réfractomètre ont été établies à partir de données interlaboratoires.

Pour le hCG, les résultats positifs et négatifs ont été obtenus en testant des lots de contrôles de tous types avec des lots de kits de divers test hCG ayant des sensibilités de ≥ 25mUI/ml.

Pour l'analyse microscopique du sédiment urinaire, les plages de valeurs attendues par Chaque type d'élément cellulaire figuré a été déterminé en testant plusieurs bouteilles des lots indiqués par la méthode indiquée. Un volume de 12 ml a été prélevé sur les échantillons et centrifugé à 400 RCF (relative centrifugal force) pendant 5 mn. Après centrifugation, le sédiment urinaire a été remis en suspension dans soit 0,5 soit 1,0 ml du surnageant restant les directives du fabricant de matériel plastique. Les plages de valeurs indiquées sont basées sur les éléments observés dans 10 champs
(hpf). Le recours à d'autres systèmes ou protocoles peut produire des résultats différents. Il incombe à chacun de ces laboratoires de déterminer ses propres paramètres de précision.

Limitations

Tout futur changement apporté par le fabricant d'une méthode de test peut donner lieu à des valeurs différentes de la plage indiquée. Le détail des limites inhérentes à chaque kit de test est décrit à la section Limites de la notice fournie par le fabricant du kit. Les mises à jour techniques sont disponibles sur notre site Web. Vous pouvez télécharger le journal de contrôle de la qualité sur le site Web de Quantimetrix (**quantimetrix.com**) ou contacter l'assistance technique au +1 (310) 536-0006, option 3.

Utilisateurs de bandes Chemstrip/CombiScreen/Combur/Multistix/Urocheck

Les colorations développées par les réactions de **l'urobilinogène** et/ou de la **bilirubine** sur ces bâtonnets avec le contrôle de bâtonnet d'analyse d'urine ne sont pas forcément caractéristiques de celles illustrées sur l'étiquette du fabricant lorsque les réactions des bâtonnets sont interprétées visuellement. Les réactions à l'urobilinogène sont homogènes et s'intensifient si la concentration en urobilinogène augmente, mais il se peut que la couleur ne soit pas exactement celle indiquée sur l'étiquette.

Remarque: les analyseurs CLINITEK 50 Siemens® et STATUS ou CLINITEK STATUS PLUS Siemens® peuvent indiquer un rapport albumine/créatinine « anormal » avec le témoin de niveau 1.

L'apparition d'un précipité cristallin macroscopique dans le produit n'affecte pas la performance.

Italiano

Finalità d'uso

Il Quantimetrix Dip&Spin Urinalysis Dipstick & Microscopics Control è pensato per essere impiegato come un controllo per strisce reattive per l'analisi delle urine, come un controllo per la microalbumina e la creatinina ottenute dai metodi di analisi elencati, e come un controllo per test di conferma a reagenti in compresse quali **K-CHECK** e **Ictotest®**, e per metodi **hCG**.

Inoltre Dip&Spin Control è inteso come mezzo di valutazione del trattamento e della centrifugazione dei campioni di urina del paziente prima dell'esame microscopico del sedimento urinario. Solo per uso professionale.

Riepilogo e spiegazione
Sostanze di controllo con concentrazioni note dei componenti sono parte integrante delle procedure diagnostiche. Il monitoraggio giornaliero dei valori di controllo stabilisce i parametri di accuratezza e di precisione del metodo di analisi del laboratorio.

I controlli microscopici QC devono essere effettuati ogni giorno in cui si esegue il test. La valutazione microscopica standardizzata del sedimento dell'urina è una fase importante dell'analisi di routine o delle urine. Insieme all'analisi fisica e chimica, l'esame microscopico delle urine può fornire un'informazione attendibile non solo sulle patologie renali e del tratto urinario, ma anche su quelle metaboliche non correlate ai reni. L'esame microscopico del sedimento urinario, in genere, comprende la ricerca dei globuli rossi, dei leucociti, delle cellule epiteliali, dei batteri, dei cilindri e dei cristalli.

Descrizione del prodotto
I Quantimetrix Dip&Spin Urinalysis Dipstick & Microscopics Controls sono forniti in forma di controlli liquidi e pronti all'uso in due livelli. Non richiedono ricostituzione né diluizione. I controlli sono preparati partendo da urina umana, a cui vengono aggiunti globuli rossi e bianchi umani stabilizzati, cristalli di ossalato di calcio e altri composti, per produrre le reazioni desiderate all'analisi mediante i metodi indicati nella sezione **Finalità d'uso**. Sono stati aggiunti dei conservanti per inibire la crescita microbica.

Attenzione
Contiene urina umana, cellule ematiche umane e gonadotropina corionica umana (hCG) derivante da urina di donne gravide. Il materiale di origine della hCG umana e tutte le unità di sangue di donatore che compongono il materiale di origine a base di cellule umane utilizzato per preparare questo prodotto sono stati testati e trovati non reattivi per l'antigene di superficie dell'epatite B e gli anticorpi contro l'epatite C e l'HIV 1 e 2 quando analizzati con metodi approvati dalla FDA. Non si conoscono metodi di analisi che possano assicurare che un prodotto derivato da materiale umano non contenga i virus dell'epatite o dell'HIV. Trattare il material per CQ come si tratterebbero i campioni di pazienti, I materiali di CQ vanno usati e smaltiti attenendosi ai requisiti normativi e di accreditazione.

Attenzione ⚠ Indicazioni di pericolo (H) Indicazioni precauzionali (P)
Miscela, 3(2H)-isothiazolone, 5-chloro-2-methyl- con 2-methyl-3(2H)-isothiazolone,
1,2-Propylene Glycol, livello 1; 2,4-Pentanedione, livello 2.
H317 – Può provocare una reazione allergica cutanea.
P261 – Evitare di respirare i vapori, la nebbia o le particelle nebulizzate.
P272 – Gli indumenti di lavoro contaminati non devono essere portati fuori dal luogo di lavoro.
P280 – Indossare guanti protettivi, indumenti protettivi e protezioni per gli occhi.
P302+P352 – IN CASO DI CONTATTO CON LA PELLE: lavare abbondantemente con acqua.
P333+P313 – In caso di irritazione o eruzione della pelle: consultare/chiamare un medico.
P362+P364 – Togliere gli indumenti contaminati e lavarli prima del riutilizzo.
P501 – Smaltire i contenuti/il contenitore in conformità alle normative locali, regionali, nazionali e internazionali.
Scheda infomativa sulla sicurezza (SDB) ad uso professionale disponibile al sito **quantimetrix.com**.

Conservazione e stabilità
Il kit Dip&Spin Control deve essere conservato a una temperatura compresa tra 2°C–8°C se non utilizzato. **Non congelare.** Se conservati a temperature comprese fra 2°C e 8°C i controls rimangono stabili fino alla data di scadenza indicata sull'etichetta. Dopo l'apertura della confezione, i controls restano stabili fino alla data di scadenza indicata sull'etichetta, se conservati a temperature comprese tra 2°C–8°C. Smaltire il controllo se acquista ulteriore torbidità o un odore più forte. Eliminare i controlli allo stesso modo degli altri campioni biologici secondo le linee guida, locali.

Procedure di esame delle urine con dipstick e di valutazione microscopica del sedimento urinario
Togliere i controlli dal frigorifero e sostituire il tappo del flacone con il beccuccio in dotazione nella confezione. Lasciare scaldare il controllo a temperatura ambiente (18°C–25°C) per ca. 15-90 minuti in base al contenuto del flacone. Agitare capovolgendo delicatamente il flacone, per garantire l'omogeneità del contenuto. Evitare la formazione di schiuma. È importante miscelare bene il prodotto prima di ogni uso per ottenere risultati riproducibili. Inserire 12 ml di controllo in una provetta da centrifuga standard da 15 ml.

Per effettuare l'esame delle urine, il test della microalbumina e della creatinina, immergere la striscia di reagente nelle provette con il control come se si trattasse di campioni del paziente. Leggere le strisce di esame delle urine o utilizzare uno strumento di lettura in base alle istruzioni del fabbricante.

Per la valutazione microscopica del sedimento urinario trattare i controls come fossero campioni di paziente, in base alle istruzioni del fabbricante e in base al sistema di esame delle urine standardizzato utilizzato. Il National Committee for Clinical Laboratory Standards (NCCLS) consiglia l'uso di sistemi standardizzati al fine di ottenere risultati standardizzati riproducibili e per consentire il rilevamento di elementi di sedimentazione anomali per unità di volume.[1]

Procedure per test hCG e test di conferma
Nota: i flaconi di Control Level 1 devono essere utilizzati come controlli negativi nei metodi hCG. I flaconi di Control Level 2 devono essere utilizzati come controlli positivi nei metodi hCG.

La maggior parte dei fabbricanti di kit di test di gravidanza specifica il volume di campione da usare con i loro kit. Molti kit includono pipette di trasferimento da usare per erogare un determinato volume di campione sul dispositivo di analisi. È importante usare un volume sufficiente per produrre il corretto risultato del test.

Se si eroga il controllo per i test hCG e di conferma direttamente dalle flaconi del controllo, ogni utente dovrebbe convalidare che il volume (numero di gocce) erogato dal beccuccio incluso sia sufficiente per soddisfare il requisito di volume del campione per il kit di test di gravidanza e per i test di conferma.

Togliere i controlli dal frigorifero. Lasciare scaldare i controlli a temperatura ambiente (18°C–25°C) per ca. 15-90 minuti in base al contenuto del flacone. Agitare capovolgendo delicatamente il flacone per almeno 20 volte, al fine di garantire l'omogeneità del contenuto. Evitare la formazione di schiuma. Utilizzare i controlli negativi e positivi come se si trattasse del campione del paziente, in base alle istruzioni del fabbricante del kit di test. Se si usa lo stesso flacone del controllo erogato per le analisi delle urine e per la valutazione microscopica, rimuovere il volume del campione da usare per i test hCG e di conferma dopo la centrifugazione, prima di eliminare il supernatante e senza disturbare il sedimento. Chiudere immediatamente il beccuccio e conservare i controlli a temperature comprese tra 2°C–8°C fra i vari impieghi.

Valori previsti
Per le letture visive, i range previsti sono stati stabiliti attraverso dati di diversi laboratori, confrontando la reazione dei disticks con quelli della carta dei colori, utilizzando diversi lotti di ogni dipstick o di pastiglia reagente dei vari fabbricanti. Per conoscere i valori previsti delle strisce per l'esame delle urine non in elenco, contattare il servizio tecnico Quantimetrix.

In relazione alle letture con appositi strumenti i range previsti sono stati stabiliti da dati di vari laboratori su diversi lotti di ogni fabbricante di dipstick. Ogni laboratorio dovrà stabilire i propri parametri di precisione.

In relazione alla gravità specifica, gli ambiti previsti con l'uso del rifrattometro sono stati stabiliti attraverso i dati di diversi laboratori.

In relazione a hCG, i risultati positivi e negativi sono stati ottenuti testando ogni numero di lotto dei controlli con molteplici numeri di lotto di diversi kit di test hCG con sensibilità di ≥ 25 mIU/ml.

In relazione alla valutazione microscopica del sedimento urinario, gli ambiti previsti per ogni tipo di elemento formato è stato determinato mediante analisi di molteplici flaconi del lotto indicato, utilizzando il metodo elencato. 12 ml di campione sono stati centrifugati a 400 RCF (forza centrifuga relativa) per 5 minuti. Dopo la centrifugazione il sedimento urinario è stato risospeso in ~0,5 o ~1,0 ml del supernatante restante, in base alle istruzioni del fabbricante dell'articolo di plastica. Gli ambiti elencati fanno riferimento al range degli elementi osservati in 10 campi ad alto ingrandimento. L'impiego di altri sistemi o protocolli può portare a risultati differenti. Ogni laboratorio dovrà stabilire i suoi propri parametri di precisione.

Limiti
Eventuali futuri cambiamenti apportati dal fabbricante di un metodo di analisi potrebbero dare valori diversi dall'intervallo di valori indicato. Informazioni dettagliate sui limiti di ciascun metodo di analisi sono incluse nella sezione Limiti dell'inserto informativo del fabbricante. Aggiornamenti tecnici sono reperibili sul nostro sito web. Il registro del controllo della qualità si può ottenere scaricandolo dal sito web Quantimetrix all'indirizzo **quantimetrix.com** oppure contattando il team del Supporto tecnico al numero +1 (310) 536-0006, opzione 3.

Utilizzatori di Chemstrip/CombiScreen/Combur/Multistix/Urocheck
I colori prodotti dalle reazioni di **urobilinogeno** e/o **bilirubina** su questi dipstick con il Controllo dipstick urina potrebbero non rispecchiare quelli illustrati sull'etichetta del fabbricante quando le reazioni del dipstick vengono lette visivamente. Le reazioni dell'urobilinogeno sono costanti e aumentano di intensità all'aumentare della concentrazione di urobilinogeno ma è possibile che non vi sia un'esatta corrispondenza di colore con quelle mostrate sull'etichetta.

Nota: Siemens® CLINITEK 50 e Siemens® STATUS o CLINITEK STATUS PLUS potrebbero riscontrare risultati "Anomali" per il rapporto albumina/creatinina con il controllo di Livello 1.

La comparsa di precipitato cristallino macroscopico nel prodotto non ne pregiudica le prestazioni.

Español
Uso previsto
El Quantimetrix Dip&Spin Urinalysis Dipstick & Microscopics Control se utiliza como control para las tiras reactivas de análisis de orina, microalbúmina y creatinina por los métodos indicados, y como control de pruebas de confirmación como las tabletas reactivas **K-CHECK** e **Ictotest®** y para los métodos de detección de **hCG**.

Además, el Dip&Spin Control se utiliza para validar el procesado y centrifugado de muestras de orina de pacientes antes de la evaluación microscópica de la sedimentación presente en la orina. Solo para uso profesional.

Resumen y explicación
Los materiales de control que tienen concentraciones conocidas del componente forman parte integral de los procedimientos diagnósticos. La monitorización diaria de los valores de control establece los parámetros de exactitud y precisión del método de análisis en cada laboratorio.

Los controles microscópicos de control de calidad deben realizarse cada día que se lleva a cabo la prueba. La evaluación microscópica normalizada de la sedimentación presente en la orina es una parte importante del análisis rutinario de la orina. Junto con el análisis físico y químico, el estudio microscópico de la orina puede aportar valiosa información no sólo sobre enfermedades renales y del tracto urinario, sino también sobre enfermedades metabólicas que no tengan relación alguna con el riñon. El estudio microscópico de la sedimentación presente en la orina generalmente incluye la detección e identificación de hematíes, leucocitos, células epiteliales, bacterias, cilindros y cristales.

Descripción del producto
Los Quantimetrix Dip&Spin Urinalysis Dipstick & Microscopics Controls se suministran líquidos, listos para usar en dos niveles. No requieren reconstitución o dilución. Están preparados a partir de orina humana a la que se han agregado glóbulos humanos rojos y blancos estabilizados, cristales de oxalato de calcio y otros compuestos para producir las reacciones deseadas cuando se prueban con los métodos indicados en la sección **Uso previsto**. Se han agregado conservantes para inhibir la proliferación microbiana.

Precaución
Contiene orina humana, células sanguíneas humanas y gonadotropina coriónica humana (hCG) de la orina del embarazo. El material fuente del hCG humano y de todas las unidades donantes de sangre que comprenden el material fuente de células humanas utilizado en la fabricación de este producto se ha probado y no se ha detectado ningún reactivo para el antígeno de superficie de la Hepatitis B ni anticuerpos de Hepatitis C y VIH 1 y 2 cuando las pruebas se realizan con métodos aceptados por la FDA. Ningún método de prueba conocido puede asegurar que un producto derivado de material humano no contenga hepatitis o virus VIH. Trabaje con el material QC como lo haría con una muestra de paciente. Los materiales QC deben usarse y eliminarse de acuerdo con los requisitos reglamentarios y de acreditación.

Atención ⚠ Indicaciones de peligro (H) Consejos de precaución (P)
Mezcla, 3(2H)-isothiazolone, 5-chloro-2-methyl- con 2-methyl-3(2H)-isothiazolone,
1,2-Propylene Glycol, nivel 1; 2,4-Pentanedione, nivel 2.
H317 – Puede causar una reacción alérgica cutánea.
P261 – Evite respirar vapores, niebla o aerosol.
P272 – La ropa de trabajo contaminada no debe sacarse del lugar de trabajo.
P280 – Lleve guantes, prendas y gafas de protección.
P302+P352 – EN CASO DE CONTACTO CON LA PIEL: lave con agua abundante.
P333+P313 – Si aparece irritación o erupción cutánea: consulte a un médico.
P362+P364 – Quítese la ropa contaminada y lávela antes de volver a utilizarla.
P501 – Elimine el contenido/contenedor conforme a la normativa local, regional, nacional e internacional vigente.
Le hoja de datos de seguridad (SDB) está disponible para los usarios profesionales en **quantimetrix.com**.

Almacenamiento y estabilidad
El Dip&Spin Control Kit deberá almacenarse a 2°C–8°C cuando no se utilice. **No congelar.** Cuando se almacenan a 2°C–8°C, los controles permanecen estables hasta la fecha de caducidad que figura en la etiqueta. Una vez abiertos, los controles permanecerán estables hasta la fecha de caducidad que figura en la etiqueta cuando se almacenen a 2°C–8°C después de cada uso. Deseche el control si se vuelve más turbio o si desarrolla un olor más fuerte. Desechar los controles de la misma forma que cualquier otra muestra biológica, conforme a las normativas locales.

Procedimiento para el análisis de orina con tira reactiva y la evaluación microscópica de la sedimentación presente en la orina
Extraiga los controles de la nevera y sustituya la tapa del frasco de control por la tapa del surtidor incluida en la caja de control. Deje que el control se estabilice a temperatura ambiente (18 °C–25 °C) durante aproximadamente 15-90 minutos, dependiendo del volumen que quede en el frasco. Mezcle bien los controles invirtiendo el frasco por lo menos 20 veces para garantizar la homogeneidad del contenido. Evite la formación de espuma. Para poder obtener resultados reproducibles, es importante mezclar bien los controles cada vez que se utilicen. Vierta 12 ml de los controles en un tubo de centrífuga estándar de 15 ml.

Para los análisis de orina, microalbuminuria y creatinina, sumerja la tira reactiva en los tubos de centrífuga que contienen el control, igual que si fueran muestras de pacientes. Lea las tiras reactivas de análisis de orina, visualmente o con un instrumento lector, de acuerdo con las instrucciones del fabricante.

Para la evaluación microscópica de la sedimentación presente en la orina, los controles deberán tratarse como si fueran muestras de pacientes, de acuerdo con las instrucciones del fabricante para el sistema microscópico normalizado de análisis de orina que esté utilizando. El National Committee for Clinical Laboratory Standards (NCCLS) recomienda el empleo de sistemas normalizados con el fin de obtener resultados reproducibles y normalizados, y poder detectar e informar acerca de la presencia de elementos anormales en la sedimentación en cada volumen unitario.[1]

Procedimiento para los ensayos de hCG y los ensayos de confirmación
Nota: Los frascos de control de concentración 1 se deben usar como controles negativos de los métodos de hCG. Los frascos de control de concentración 2 se deben usar como controles positivos de los métodos de hCG.

La mayoría de los fabricantes de kits de prueba de embarazo especifican el volumen de muestra a utilizar en sus kits. Muchos kits incluyen pipetas de transferencia que se utilizan para suministrar un determinado volumen de muestra en el dispositivo de prueba. Es importante que se use suficiente volumen para producir el resultado correcto de la prueba.

Si el control para pruebas hCG y pruebas confirmatorias se dispensa directamente desde de los frascos de los controles, cada usuario debe validar que el volumen (cantidad de gotas) dispensado por la tapa del surtidor sea suficiente para cumplir con los requisitos del kit de prueba de embarazo y las pruebas confirmatorias.

Extraiga los controles de la nevera. Deje que los controles se estabilicen a temperatura ambiente (18 °C–25 °C) durante aproximadamente 15-90 minutos, dependiendo del volumen que quede en el frasco. Mezcle bien los controles invirtiendo el frasco por lo menos 20 veces para garantizar la homogeneidad del contenido. Evite la formación de espuma. Use los controles positivo y negativo como si fueran muestras de paciente, de acuerdo con las instrucciones del fabricante del kit de análisis. Si el mismo frasco de control dispensado se utiliza para las pruebas de análisis de orina y la evaluación microscópica, retire el volumen de muestra a utilizar en las pruebas de hCG y las pruebas de confirmación después del centrifugado, antes de descartar el sobrenadante y sin perturbar el sedimento. Cierre inmediatamente la tapa del surtidor y almacene los controles a 2 °C–8 °C cuando no se utilicen.

Valores esperados

En el caso de lecturas visuales, los intervalos esperados se han establecido a partir de datos de varios laboratorios, comparando la reacción de la tira reactiva que se produce con los controles, con la carta de comparación de colores de varios lotes de tiras reactivas o tabletas de reactivo de cada fabricante. En cuanto a los valores esperados de las tiras de reactivo para análisis de orina que no figuren, póngase en contacto con el Servicio Técnico de Quantimetrix.

En el caso de lecturas con instrumento, los intervalos esperados se han establecido a partir de datos obtenidos en varios laboratorios con múltiples lotes de tiras reactivas de cada fabricante. Cada laboratorio deberá establecer sus propios parámetros de precisión.

En el caso del peso específico, los intervalos esperados con el refractómetro se han establecido a partir de datos obtenidos en varios laboratorios.

En el caso de hCG, los resultados positivo y negativo se obtuvieron analizando cada número de lote de los controles con múltiples números de lote de diferentes kits de análisis de hCG con sensibilidades de ≥ 25 mUI/ml.

En el caso de la evaluación microscópica de la sedimentación presente en la orina, los intervalos esperados para cada tipo de elemento formado se determinaron mediante valoración de varios frascos del lote indicado por medio de los métodos listados. Se centrifugó un volumen de las muestras de 12 ml a 400 RCF (fuerza centrífuga relativa) durante 5 minutos. Tras la centrifugación, la sedimentación presente en la orina se volvió a suspender en ~0,5 o ~1,0 ml del sobrenadante restante, de acuerdo con las instrucciones del fabricante de los plásticos. Los intervalos listados se basan en el intervalo de elementos observados en 10 campos de gran aumento. El uso de otros sistemas o protocolos puede arrojar resultados distintos. Cada laboratorio deberá establecer sus propios parámetros de precisión.

Limitaciones

Cualquier cambio futuro realizado por el fabricante de un método de prueba puede dar valores diferentes del rango indicado. En la sección de limitaciones del prospecto del fabricante se incluye información detallada sobre las limitaciones de cada método de prueba. En nuestro sitio web se pueden encontrar las actualizaciones técnicas. El registro de control de calidad se puede descargar en el sitio web de Quantimetrix en **quantimetrix.com** o poniéndose en contacto con el Soporte técnico en el +1 (310) 536-0006, opción 3.

Usuarios de Chemstrip/CombiScreen/Combur/Multistix/Urocheck

Los colores producidos por las reacciones al **urobilinógeno** y/o a la **bilirrubina** en esas tiras reactivas con el Control de tiras reactivas en orina podrían no ser características de las que se indican en la etiqueta del fabricante al leer visualmente las reacciones en la tira reactiva. Las reacciones de urobilinógeno son coherentes y se intensifican cuando aumenta la concentración de urobilinógeno, pero puede que no den colores exactamente iguales a los que se muestran en la etiqueta.

Nota: Siemens® CLINITEK 50 y Siemens® STATUS o CLINITEK STATUS PLUS pueden ver un resultado en la proporción de albúmina/creatinina calificado de "Anormal" con el control de Nivel 1.

La aparición de un precipitado cristalino macroscópico en el producto no afecta al rendimiento.

Polski

Przeznaczenie

Kontrole Quantimetrix Dip&Spin Urinalysis Dipstick & Microscopics Control są przeznaczone do stosowania jako kontrole dla pasków odczynnikowych do badania ogólnego moczu, oznaczania mikroalbuminy i kreatyniny za pomocą wymienionych metod testowych oraz jako kontrole do oznaczeń potwierdzających, takich jak **K-CHECK** i tabletki odczynnikowe **Ictotest®** oraz dla metod **hCG**.

Ponadto kontrola Dip&Spin Control może być także stosowana jako środek służący do walidacji przetwarzania i wirowania próbek moczu pacjenta przed mikroskopową oceną osadu moczu. Tylko do użytku profesjonalnego.

Podsumowanie i wyjaśnienie

Materiały kontrolne o znanych stężeniach składnika stanowią integralną część procedur diagnostycznych. Codzienne monitorowanie wartości kontrolnych pozwala ustalić wewnątrzlaboratoryjne parametry dokładności i precyzji dla metody testu.

Mikroskopowe kontrole KJ należy wykonywać każdego dnia, kiedy wykonywane są badania. Standaryzowana mikroskopowa ocena osadu moczu stanowi ważną część rutynowej analizy moczu. Obok analizy fizycznej i chemicznej badanie mikroskopowe moczu może dostarczyć cennych informacji nie tylko na temat chorób nerek i dróg moczowych, lecz także na temat chorób metabolicznych niezwiązanych z nerkami. Mikroskopowe badanie osadu moczu obejmuje zazwyczaj wykrywanie oraz identyfikację krwinek czerwonych, leukocytów, komórek nabłonka, bakterii, wałeczków i kryształów.

Opis produktu

Kontrole Quantimetrix Dip&Spin Urinalysis Dipstick & Microscopics Controls są dostarczane w postaci płynnej, gotowej do użycia w dwóch poziomach. Nie wymagają one rekonstytucji ani rozcieńczania. Odczynniki te są przygotowywane z moczu ludzkiego, do którego dodano stabilizowane ludzkie krwinki czerwone i białe, kryształy szczawianu wapnia oraz inne substancje w celu uzyskania pożądanych reakcji po wykonaniu oznaczenia z użyciem metod opisanych w punkcie „Przeznaczenie". Do produktu dodano także środki konserwujące, aby zahamować wzrost drobnoustrojów.

Przestroga

Zawiera mocz ludzki, ludzkie krwinki oraz ludzką gonadotropinę kosmówkową (hCG) uzyskaną z próbek moczu kobiet w ciąży. Ludzki materiał źródłowy hCG oraz wszystkie jednostki krwi pobrane od dawców i tworzące materiał źródłowy komórek ludzkich stosowany do wytwarzania tego produktu został przetestowany z użyciem metod akceptowanych przez FDA i uznany za niereaktywny w przypadku antygenu powierzchniowego wirusa zapalenia wątroby typu B i C oraz przeciwciała przeciwko wirusowi HIV 1 i 2. Żadna znana metoda testowa nie daje pewności, że produkt uzyskiwany z materiału pochodzenia ludzkiego nie zawiera wirusów zapalenia wątroby lub HIV. Z materiałem KJ należy postępować tak samo jak z próbką pobraną od pacjenta. Materiały KJ należy stosować i usuwać zgodnie z wymaganiami przepisów i wymaganiami dotyczącymi akredytacji.

Ostrzeżenia ⚠ o zagrożeniach (H) i zwroty wskazujące środki ostrożności (P)

Zawiera mieszaninę, 3(2H)-izotiazolonu, 5-chloro-2-metylo- z 2-metylo-3(2H)-izotiazolonem, 1,2-propylenowy glikol, poziom 1; 2,4-pentanedion, poziom 2.
H317 – Może powodować reakcję alergiczną skóry.
P261 – Unikać wdychania gazu / mgły / rozpylonej cieczy.
P272 – Zanieczyszczonej odzieży ochronnej nie wynosić poza miejsce pracy.
P280 – Stosować rękawice ochronne / odzież ochronną / ochronę oczu.
P302+P352 – W PRZYPADKU KONTAKTU ZE SKÓRĄ: umyć dużą ilością wody.
P333+P313 – W przypadku wystąpienia podrażnienia skóry lub wysypki: zasięgnąć porady / zgłosić się pod opiekę lekarza.
P362+P364 – Zdjąć zanieczyszczoną odzież i uprać ją przed ponownym użyciem.
P501 – Zawartość/pojemnik usuwać zgodnie z przepisami miejscowymi, regionalnymi, krajowymi i międzynarodowymi.
Karta charakterystyki substancji (SDS) jest dostępna dla użytkowników profesjonalnych na stronie **quantimetrix.com.**

Przechowywanie i stabilność

Nieużywany zestaw kontroli Dip&Spin powinien być przechowywany w temperaturze 2–8°C. **Nie zamrażać**. W przypadku przechowywania w temperaturze 2–8°C kontrole zachowują stabilność do daty ważności wskazanej na etykiecie. Po otwarciu kontrole zachowują stabilność do daty ważności podanej na etykiecie pod warunkiem ich przechowywania w temperaturze 2–8°C pomiędzy kolejnymi zastosowaniami. Kontrolę należy wyrzucić, jeśli dojdzie do jej zmętnienia lub pojawi się silniejszy zapach. Kontrole należy wyrzucać tak samo jak inne próbki biologiczne, zgodnie z lokalnymi wytycznymi.

Procedura paskowego badania ogólnego moczu i mikroskopowego badania osadu moczu

Należy wyjąć kontrole z lodówki, zdjąć zatyczkę z butelki i założyć na nią zatyczkę do wylewek dołączoną do opakowania kontroli. Pozostawić kontrolę do osiągnięcia temperatury pokojowej (18–25°C) przez mniej więcej 15-90 minut, w zależności od ilości odczynnika pozostającej w butelce. Dokładnie wymieszać kontrole, odwracając butelkę co najmniej 20 razy, aby zapewnić jednorodność jej zawartości. Unikać tworzenia piany. Dokładne wymieszanie przed każdym użyciem jest ważne dla zapewnienia powtarzalności wyników. Wlać 12 ml kontroli do standardowej probówki wirówkowej o pojemności 15 ml.
W przypadku badania ogólnego moczu, oznaczenia mikroalbuminy i kreatyniny zanurzyć pasek odczynnikowy w probówkach wirówkowych zawierających kontrolę tak, jakby były to próbki pobrane od pacjentów. Paski z odczynnikami do badania ogólnego moczu należy odczytać wzrokowo lub za pomocą czytnika, zgodnie z instrukcjami wydanymi przez producenta.
W przypadku mikroskopowej oceny osadu moczu kontrole należy traktować tak jak próbki pobrane od pacjenta, zgodnie z instrukcjami wydanymi przez producenta stosowanego standaryzowanego systemu mikroskopowego badania ogólnego moczu. Krajowa Komisja ds. Laboratoryjnych Norm Klinicznych (National Committee for Clinical Laboratory Standards, NCCLS) zaleca stosowanie standaryzowanych systemów w celu uzyskiwania standaryzowanych, powtarzalnych wyników oraz aby umożliwić podawanie nieprawidłowego składu osadu w przeliczeniu na jednostkę objętości[1].

Procedura badań w kierunku hCG i badań potwierdzających

Uwaga: Butelki z kontrolą poziomu 1 są przeznaczone do stosowania jako kontrole ujemne w przypadku metod oznaczania hCG. Butelki z kontrolą poziomu 2 są przeznaczone do stosowania jako kontrole dodatnie w przypadku metod oznaczania hCG.

Większość producentów testów ciążowych określa objętość próbki, jakiej należy użyć. Wiele zestawów zawiera pipety, których należy użyć do przeniesienia określonej objętości próbki na urządzenie testowe. Do uzyskania prawidłowego wyniku testu konieczne jest użycie wystarczającej objętości próbki.

W przypadku pobierania kontroli do testu w kierunku hCG i testów potwierdzających bezpośrednio z butelek z odczynnikiem kontrolnym każdy użytkownik powinien potwierdzić, że objętość (liczba kropli) pobrana za pomocą dołączonej zatyczki do wylewek jest wystarczająca, aby spełnić wymaganie w zakresie objętości próbki dla zestawów testów ciążowych i testów potwierdzających.

Wyjąć kontrole z lodówki. Pozostawić kontrole do osiągnięcia temperatury pokojowej (18–25°C) przez mniej więcej 15–90 minut, w zależności od ilości odczynnika pozostającej w butelce. Dokładnie wymieszać kontrolę, odwracając butelkę co najmniej 20 razy, aby zapewnić jednorodność jej zawartości. Unikać tworzenia piany. Kontroli ujemnej i dodatniej należy użyć tak jak próbek pobranych od pacjenta, zgodnie z instrukcjami dołączonymi przez producenta do zestawu testu. W przypadku korzystania z tej samej butelki z kontrolą do badania ogólnego moczu i badania mikroskopowego, należy usunąć objętość próbki, jaka ma zostać użyta do badań w kierunku hCG i badań potwierdzających po wirowaniu i przed wyrzuceniem supernatantu, uważając, aby nie poruszyć osadu. Natychmiast zamknąć zatyczkę do wylewek i przechowywać kontrole w temperaturze 2–8°C (kiedy nie są używane).

Wartości oczekiwane

W przypadku odczytów wizualnych oczekiwane zakresy ustalono na podstawie danych z różnych laboratoriów, porównując reakcję paskową, która występuje w przypadku kontroli z kartą porównawczą kolorów dla wielu partii pasków lub tabletek odczynnikowych każdego producenta. Aby uzyskać informacje na temat oczekiwanych wartości dla niewymienionych pasków odczynnikowych do badania ogólnego moczu, należy skontaktować się z serwisem technicznym firmy Quantimetrix.

W przypadku odczytów instrumentu oczekiwane zakresy ustalono na podstawie danych z różnych laboratoriów dla wielu partii pasków każdego producenta. Każde laboratorium powinno ustalić własne parametry precyzji.

W przypadku ciężaru właściwego oczekiwane zakresy według refraktometru ustalono na podstawie danych z różnych laboratoriów.

W przypadku hCG wyniki dodatnie i ujemne uzyskano, oznaczając każdą partię kontroli z wieloma partiami różnych zestawów w kierunku oznaczenia hCG o czułości ≥ 25 mIU/ml.

W przypadku mikroskopowej oceny osadu moczu oczekiwane zakresy dla każdego typu elementów morfotycznych ustalono na podstawie oznaczenia z użyciem wielu butelek wskazanej partii za pomocą wymienionych metod. Próbka o objętości 12 ml została odwirowana z prędkością 400 RCF (względna siła wirowania) przez 5 minut. Po wirowaniu osad moczu ponownie zawieszono w mniej więcej 0,5 lub 1,0 ml pozostałego supernatantu zgodnie ze wskazówkami producenta naczyń plastikowych. Wymienione zakresy są oparte na zakresach elementów obserwowanych pod 10-krotnym powiększeniem. Użycie innych systemów lub protokołów może dać odmienne wyniki. Każde laboratorium powinno ustalić własne parametry precyzji.

Ograniczenia

Wszelkie zmiany wprowadzone w przyszłości przez producenta metody testowej mogą doprowadzić do uzyskania wartości spoza wskazanego zakresu. Szczegółowe informacje na temat ograniczeń poszczególnych metod testowych można znaleźć w punkcie „Ograniczenia" w ulotce dołączonej do opakowania przez producenta. Informacje o aktualizacjach technicznych można znaleźć w naszej witrynie internetowej. Dziennik kontroli jakości można pobrać z witryny internetowej firmy Quantimetrix pod adresem **quantimetrix.com** lub kontaktując się z działem pomocy technicznej pod numerem telefonu (310) 536-0006, opcja 3.

Użytkownicy Chemstrip/CombiScreen/Combur/Multistix/Urocheck

Zabarwienie generowane przez reakcje **urobilinogenu** i/lub **bilirubiny** na tych paskach testowych po użyciu kontroli do paskowego badania ogólnego moczu mogą być niecharakterystyczne dla przedstawionych na etykiecie przez producenta w przypadku wzrokowego odczytywania wyniku reakcji na paskach testowych. Reakcje urobilinogenu są powtarzalne i ulegają intensyfikacji ze wzrostem stężenia urobilinogenu, ale mogą nie dać dokładnie takiego zabarwienia, jakie zostało wskazane na etykiecie.

Uwaga: W przypadku kontroli poziomu 1 urządzenia Siemens® CLINITEK 50 i Siemens® STATUS lub CLINITEK STATUS PLUS mogą wyświetlić wynik dla stosunku albumina/kreatynina jako „nieprawidłowy".

Obecność makroskopowego osadu krystalicznego nie ma wpływu na działanie produktu.

Analytes/Method	Level 1 - 252881	Level 2 - 252882	Units
Red Blood Cells (Erythrocytes)			
77 Elektronika UriSed Variants / Analyticon Urilyzer® Cell	0 - 30	4 - 115	p/µL
Teco UriScope 50 / COBIO Variants	3 - 28	43 - 99	p/µL
Mindray EU-5600, EU-5300, EU-3000	0 - 25	20 - 90	p/µL
Mindray EH-2090B, EH-2090C, EH-2090B Pro, EH-2090C Pro	0 - 25	30 - 83	p/µL
Mindray EU-5300 Pro, EU-5600 Pro	0 - 25	35 - 94	p/µL
YD Diagnostics URiSCAN PluScope	0 - 50	0 - 200	p/µL
ROCHE cobas 6500 (cobas u 701)	0 - 25	22 - 68	p/µL
KOVA® GLASSTIC® SLIDE 10 with GRIDS	0 - 13	37 - 94	p/µL
Non-grid slides (~0.5 mL)	0 - 5	6 - 39	p/hpf
Non-grid slides (~1.0 mL)	0 - 5	3 - 21	p/hpf
Slide & Coverslip (~0.5 mL)	0 - 5	1 - 33	p/hpf
Slide & Coverslip (~1.0 mL)	0 - 4	1 - 15	p/hpf
FisherBrand UriSystem DeciSlide	0 - 4	3 - 24	p/hpf
White Blood Cells (Leukocytes)			
77 Elektronika UriSed Variants / Analyticon Urilyzer® Cell	0 - 30	10 - 90	p/µL
Teco UriScope 50 / COBIO Variants	0 - 29	19 - 57	p/µL
Mindray EU-5600, EU-5300, EU-3000	0 - 25	0 - 60	p/µL
Mindray EH-2090B, EH-2090C, EH-2090B Pro, EH-2090C Pro	0 - 20	10 - 50	p/µL
Mindray EU-5300 Pro, EU-5600 Pro	0 - 20	10 - 50	p/µL
YD Diagnostics URiSCAN PluScope	0 - 50	0 - 200	p/µL
ROCHE cobas 6500 (cobas u 701)	0 - 50	27 - 83	p/µL
KOVA® GLASSTIC® SLIDE 10 with GRIDS	1 - 10	19 - 58	p/µL
Non-grid slides (~0.5 mL)	0 - 4	2 - 26	p/hpf
Non-grid slides (~1.0 mL)	0 - 4	0 - 12	p/hpf
Slide & Coverslip (~0.5 mL)	0 - 4	0 - 16	p/hpf
Slide & Coverslip (~1.0 mL)	0 - 4	1 - 12	p/hpf
FisherBrand UriSystem DeciSlide	0 - 4	1 - 12	p/hpf
Casts			
77 Elektronika UriSed Variants / Analyticon Urilyzer® Cell	may be present	may be present	
Teco UriScope 50 / COBIO Variants	none	none	
ROCHE cobas 6500 (cobas u 701)	none	none	
Mindray EU-5600, EU-5300, EU-3000	none	none	
Mindray EH-2090B, EH-2090C, EH-2090B Pro, EH-2090C Pro	none	none	
Mindray EU-5300 Pro, EU-5600 Pro	none	none	
YD Diagnostics URiSCAN PluScope	none	none	
KOVA® GLASSTIC® SLIDE 10 with GRIDS	none	none	
Non-grid slides (~0.5 mL)	none	none	
Non-grid slides (~1.0 mL)	none	none	
Slide & Coverslip (~0.5 mL)	none	none	
Slide & Coverslip (~1.0 mL)	none	none	
FisherBrand UriSystem DeciSlide	none	none	
Crystals			
77 Elektronika UriSed Variants / Analyticon Urilyzer® Cell	may be present	present	
Teco UriScope 50 / COBIO Variants	none	may be present	
Mindray EU-5600, EU-5300, EU-3000	none	present	
Mindray EH-2090B, EH-2090C, EH-2090B Pro, EH-2090C Pro	may be present	present	
Mindray EU-5300 Pro, EU-5600 Pro	none	present	
YD Diagnostics URiSCAN PluScope	none	may be present	
ROCHE cobas 6500 (cobas u 701)	negative	positive	
KOVA® GLASSTIC® SLIDE 10 with GRIDS	none	present	
Non-grid slides (~0.5 mL)	none	present	
Non-grid slides (~1.0 mL)	none	present	
Slide & Coverslip (~0.5 mL)	none	present	
Slide & Coverslip (~1.0 mL)	none	present	
FisherBrand UriSystem DeciSlide	none	present	
Bacteria			
77 Elektronika UriSed Variants / Analyticon Urilyzer® Cell	may be present	present	
Teco UriScope 50 / COBIO Variants	may be present	may be present	
Mindray EU-5600, EU-5300, EU-3000	may be present	present	
Mindray EH-2090B, EH-2090C, EH-2090B Pro, EH-2090C Pro	may be present	present	
Mindray EU-5300 Pro, EU-5600 Pro	may be present	present	
KOVA® GLASSTIC® SLIDE 10 with GRIDS	may be present	present	
Non-grid slides (~0.5 mL)	may be present	present	
Non-grid slides (~1.0 mL)	may be present	present	
Slide & Coverslip (~0.5 mL)	may be present	present	
Slide & Coverslip (~1.0 mL)	may be present	present	
FisherBrand UriSystem DeciSlide	may be present	present	

Analytes	Level 1 - 252881	Level 2 - 252882
Accutest® URS 11 • URS 10 • URS 4 Urine Reagent Strips (VISUAL)		
Leukocytes	Negative	15 - 500 cells/µL (Tr - Lg)
Nitrite	Negative	Positive
Urobilinogen	Normal (0.2 - 1 mg/dL)	1 - 8 mg/dL [7]
Protein	Negative	30 - 300 mg/dL (1+- 3+)
pH	5.0 - 6.5	7.5 - 8.5
Blood	Negative	25 - 200 cells/µL (Sm - Lg)
Specific Gravity	1.015 - 1.030	1.000 - 1.015
Ketones	Negative	5 - 160 mg/dL (Tr - Lg)
Bilirubin	Negative	Small - Large
Glucose	Negative	100 - 1000 mg/dL (Tr - 3+)
Ascorbic Acid [12]	Negative	Negative
Accustrip® URS Reader/Visual		
Bilirubin	Negative	1 - 4 mg/dL (1+ - 3+) (17 - 70 µmol/L) [7]
Blood	Negative	10 - 250 Ery/µL
Glucose	Negative	20 - 1000 mg/dL (1.1 - 55.6 mmol/L)
Ketones	Negative	25 - 300 mg/dL (1+ - 3+) (2.5 - 30.0 mmol/L)
Leukocytes	Negative	75 - 500 Leu/µL
Nitrite	Negative	Positive
pH	5.0 - 6.0	7.0 - 9.0
Protein	Negative	30 -500 mg/dL (0.3 - 5.0 g/L)(1+ - 3+)
Specific Gravity (Density)	1.010 - 1.025	1.000 - 1.015
Urobilinogen	Normal	2 - 8 mg/dL [7]
Beckman Coulter IRIS Diagnostics® iChem®VELOCITY™ Analyzer		
	NOT AVAILABLE	
Confirmatory and Other Tests		
K-CHECK (Ketones)	Negative	Small - Large
Ictotest (Bilirubin)	Negative	Positive
Refractometer (Specific Gravity)	1.019 - 1.025	1.011 - 1.017
hCG	Negative	Positive
pH Paper	4.0 - 6.0	7.0 - 9.0
Sulfosalicylic Acid (Total Protein)	Negative (≤ 0.05) [10]	Positive (≥0.50) [10]
Germaine® Laboratories • AimStrip® and FisherBrand® 10-SG Urine Reagent Strips • Visual		
Leukocytes	Negative	70 - 500 Leu/µL (1+ - 3+)
Nitrite	Negative	Positive
Urobilinogen	0.2 mg/dL (Normal)	2 - 4 mg/dL [11]
Protein	Negative - Trace	30 - 300 g/dL (1+ - 3+)
pH	5.0 - 6.5	7.0 - 9.0
Blood	Negative	1+ - 3+
Specific Gravity	1.015 - 1.025	1.005 - 1.015
Ketones	Negative - Trace	5 - 160 mg/dL (Tr – 4+)
Bilirubin	Negative	1 - 4 mg/dL(1+ - 3+)
Glucose	Negative	100 - 500 mg/dL (± - 2+)
Germaine® Laboratories • AimStrip® and FisherBrand® 10-SG Urine Reagent Strips • AimStrip® Urine Analyzer II		
Leukocytes	Negative	70 - 500 Leu/µL (1+ - 3+)
Nitrite	Negative	Positive
Urobilinogen	Normal (0.2 E.U./dL)	0.2- 2 mg/dL [11]
Protein	Negative	Tr - 300 g/dL (± - 3+)
pH	5.0 - 6.0	7.0 - 9.0
Blood	Negative	1+ - 3+
Specific Gravity	1.015 - 1.025	1.005 - 1.015
Ketones	Negative	5 - 80 mg/dL (Tr – 3+)
Bilirubin	Negative	1 - 4 mg/dL (1+ - 3+)
Glucose	Negative	250 - 1000 mg/dL (1+ - 3+)
Henry Schein One Step Plus/Urispec Plus Analyzer (Visual)		
Bilirubin	Negative	1 - 4 mg/dL (1+ - 3+) (17 - 70 µmol/L) [7]
Blood	Negative - 10 Ery/µL	10 - 250 Ery/µL
Glucose	Negative - Normal	50 - ≥500 mg/dL (8.3 - ≥27.8 mmol/L) [8]
Ketones	Negative	25 - 300 mg/dL (1+ - 3+) (2.5 - 30 mmol/L)
Leukocytes	Negative	25 - 500 Leu/µL
Nitrite	Negative	Positive
pH	5.0 - 7.0	7.0 - 9.0
Protein	Negative	30 - 500 mg/dL (0.3 - 5.0 g/L) (1+ - 3+)
Specific Gravity (Density)	1.005 - 1.025	1.000 - 1.020
Urobilinogen	Normal	2 - 12 mg/dL (34 - 200 µmol/L) [7]
Ascorbic Acid [12]	Negative	Negative

Analytes	Level 1 - 252881	Level 2 - 252882
Henry Schein Urispec® 10SG (Visual)		
Leukocytes	Negative	15 - 500 Cells/µL (Tr - 3+)
Nitrite	Negative	Positive
Urobilinogen	Normal (0.2 E.U./dL)	1 - 8 E.U./dL
Protein	Negative	30 - 300 mg/dL (1+ - 3+)
pH	5.0 - 6.0	7.5 - 9.0
Blood	Negative - 10 Ery/µL	1+ - 3+
Specific Gravity (1.0~)	1.015 - 1.030	1.000 - 1.015
Ketones	Negative	5 - 160 mg/dL (Tr - Lg)
Bilirubin	Negative	Sm - Lg (1+ - 3+)
Glucose	Negative	100 - 500 mg/dL (Tr - 2+)
MACHEREY-NAGEL® URYXXON® Relax/300/500 Analyzer / VISUAL		
Bilirubin	Negative	1 - 4 mg/dL (1+ - 3+) (17 - 70 µmol/L)[7]
Blood	Negative	10 - 250 Ery/µL
Glucose	Negative - Normal	50 -≥500 mg/dL (8.3 - ≥27.8 mmol/L)[8]
Ketones	Negative	25 - 300 mg/dL (1+ - 3+) (2.5 - 30 mmol/L)
Leukocytes	Negative	25 - 500 Leu/µL
Nitrite	Negative	Positive
pH	5.0 - 7.0	7.0 - 9.0
Protein	Negative	30 - 500 mg/dL (0.3 - 5.0 g/L) (1+ - 3+)
Specific Gravity	1.005 - 1.025	1.000 - 1.020
Urobilinogen	Normal	2 - 12 mg/dL (34 - 200 µmol/L)[7]
Ascorbic Acid[12]	Negative	Negative
McKesson® Consult Diagnostics 10SG Urine Reagent Strips Visual		
Glucose	Negative	100 - 1000 mg/dL (± - 3+)
Bilirubin	Negative	1 - 4 mg/dL (1+ - 3+)
Ketones	Negative	5 - 160 mg/dL (± - 4+)
Specific Gravity	1.015-1.025	1.000 - 1.015
Blood	Negative	1+ - 3+
pH	5.0-6.0	7.5 - 9.0
Protein	Negative	30 - 300 mg/dL (1+ - 3+)
Urobilinogen	Normal (0.2 E.U./dL)	1 - 8 mg/dL
Nitrite	Negative	Positive
Leukocytes	Negative	15 - 500 Leu/µL (± - 3+)
McKesson® 120 Urine Analyzer •Consult Diagnostics® 10SG & M-ALB/CRE Strips		
Leukocytes	Negative	15 - 500 Leu/µL (± - 3+)
Nitrite	Negative	Positive
Urobilinogen	Normal (0.2 E.U./dL)	0.2- 2.0 mg/dL[11]
Protein	Negative	Tr - 300 mg/dL (± -3+)
pH	5.0 - 6.5	7.0 - 9.0
Blood	Negative	25 - 200 Ery/µL (1+ - 3+)
Specific Gravity	1.010 - 1.025	1.000 - 1.015
Ketones	Negative	5 - 80 mg/dL (Tr - 3+)
Bilirubin	Negative	1 -4 mg/dL (1+ - 3+)
Glucose	Negative	100 - 1000 mg/dL (Tr - 3+)
Microalbumin	10 - 30 mg/L	30 - 300 mg/L
Creatinine	10 - 50 mg/dL	50 - 300 mg/dL
ROCHE VISUAL TESTING (Visual Test Strips Only)		
Specific Gravity	1.015 - 1.030	1.000 - 1.010
pH	5 - 6	7 - 9
Leukocytes	Negative	1+ - 2+
Nitrite	Negative	Positive
Protein	Negative	30 - 100 mg/dL (1+ - 2+)
Glucose	Normal	250 - 1000 mg/dL
Ketones	Negative	1+ - 3+
Urobilinogen[8]*	Normal	1 - 12 mg/dL (1+ - 4+)
Bilirubin[8]*	Negative	1+ - 3+
Blood	Negative	50 - 250 Ery/µL
Microalbumin[5]	Negative	50 - 100 mg/L
ROCHE Chemstrip 101 Urine Analyzer or ROCHE Urisys 1100 Urine Analyzer		
Blood	Negative	50 - 250 Ery/µL (1+ - 2+)
Bilirubin	Negative	3 - 6 mg/dL (2+ - 3+)*
Urobilinogen	Normal	1 - 8 mg/dL (1+ - 3+)[7]*
Ketones	Negative	50 - 150 mg/dL (2+ - 3+)
Glucose	Normal	250 - 1000 mg/dL (2+ - 3+)
Protein	Negative[6]	30 - 100 mg/dL (1+ - 2+)[7]
Nitrite	Negative	Positive
Leukocytes	Negative	75 - 500 Leu/µL (1+ - 2+)
pH	5 - 6.5	7 - 9
Specific Gravity	1.015 - 1.025	1.000 - 1.015
ROCHE Cobas 6500 (cobas u 601)		
Blood	Negative	150 - 250 Ery/µL
Leukocytes	Negative	100 - 500 Leu/µL
Nitrite	Negative	Positive
Ketones	Negative	50 - 150 mg/dL
Glucose	Normal	250 - 1000 mg/dL
Protein	Negative[6]	30 - 100 mg/dL[7]
Urobilinogen	Normal	1 - 8 mg/dL[7]*
Bilirubin	Negative	3 - 6 mg/dL*
pH	5 - 6.5	7 - 9
Specific Gravity	1.016 - 1.028	1.008 - 1.020
Color	Yellow - Pale Yellow	Brown
Clarity	Clear	Clear

Analytes	Level 1 - 252881	Level 2 - 252882
ROCHE cobas u 411		
Blood	Negative	150 - 250 Ery/µL (4+ - 5+)
Bilirubin	Negative	3 - 6 mg/dL (2+ - 3+)*
Urobilinogen	Normal	1 - 8 mg/dL (1+ - 3+)[7]*
Ketones	Negative	50 - 150 mg/dL (3+ - 4+)
Glucose	Normal	250 - 1000 mg/dL (3+ - 4+)
Protein	Negative[6]	30 - 100 mg/dL (2+ -3+)[7]
Nitrite	Negative	Positive
Leukocytes	Negative	100 - 500 Leu/µL (2+ - 3+)
pH	5 - 6.5	7 - 9
Specific Gravity	1.015 - 1.025	1.000 - 1.020
ROCHE Urisys 1800		
Blood	Negative	150 - 250 Ery/µL (4+ - 5+)
Bilirubin	Negative	3 - 6 mg/dL (2+ - 3+)*
Urobilinogen	Normal	1 - 8 mg/dL (1+ - 3+)[7]*
Ketones	Negative	50 - 150 mg/dL (3+ - 4+)
Glucose	Normal	300 - 1000 mg/dL (3+ - 4+)
Protein	Negative[6]	75 - 150 mg/dL (2+ -4+)[7]
Nitrite	Negative	Positive
Leukocytes	Negative	100 - 500 Leu/µL (2+ - 3+)
pH	5 - 6.5	7 - 9
Specific Gravity	1.015 - 1.025	1.000 - 1.020
SIEMENS VISUAL TESTING (Visual Test Strips Only)		
Glucose	Negative	100 - 1000 mg/dL
Bilirubin	Negative	Sm - Lg (1+ - 3+)
Ketones	Negative	5 - 160 mg/dL (Tr - Lg)
Specific Gravity	1.015 - 1.025	1.005 - 1.015
Blood	Negative	Sm - Lg (1+ - 3+)
pH	5.0 - 6.5	7.5 - 8.5
Protein	Negative	15 - ≥2000 mg/dL (Tr - 4+)
Urobilinogen	Normal (0.2 E.U./dL)[6]	1.0 - 8.0 E.U./dL*
Nitrite	Negative	Positive
Leukocytes	Negative	Tr - Lg (Tr - 3+)
Creatinine[2]	10 - 50 mg/dL	100 - 300 mg/dL
SIEMENS® CLINITEK 50		
Glucose	Negative	100 - 500 mg/dL (Tr - 2+)
Bilirubin	Negative	Small - Large (1+ - 3+)
Ketones	Negative	Trace - ≥80 mg/dL (Tr - 3+)
Specific Gravity	1.010 - ≥ 1.030	≤1.005 - 1.020
Blood	Negative	Small - Large (1+ - 3+)
pH	5.0 - 6.5	7.0 - 8.5
Protein	Negative	30 - ≥300 mg/dL (1+ - 3+)
Urobilinogen	Normal (0.2 E.U./dL)	1.0 - 4.0 E.U./dL
Nitrite	Negative	Positive
Leukocytes	Negative	Trace - Large (Tr - 3+)
Microalbumin[1]	10 - 30 mg/L	30 - 300 mg/L
Creatinine[3]	10 - 100 mg/dL	50 - 300 mg/dL
SIEMENS® CLINITEK 500		
NOT AVAILABLE		
SIEMENS® CLINITEK ADVANTUS		
Glucose	Negative	100 - 500 mg/dL (Tr - 2+)
Bilirubin	Negative	Small - Large (1+ - 3+)
Ketones	Negative	Trace - ≥80 mg/dL (Tr - 3+)
Specific Gravity	1.015 - ≥1.030	≤1.005 - 1.025
Blood	Negative	Small - Large (1+ - 3+)
pH	5.5 - 6.5	7.0 - ≥9.0
Protein	Negative	30 - ≥300 mg/dL (1+ - 3+)
Urobilinogen	Normal (0.2 E.U./dL)	1.0 - ≥8.0 E.U./dL
Nitrite	Negative	Positive
Leukocytes	Negative	Small - Large (1+ - 3+)
Creatinine[2]	10 - 50 mg/dL	100 - 300 mg/dL
SIEMENS CLINITEK STATUS/ STATUS PLUS/STATUS CONNECT		
Glucose	Negative	100 - 500 mg/dL (Tr - 2+)
Bilirubin	Negative	Small - Large (1+ - 3+)
Ketones	Negative	Trace - ≥160 mg/dL (Tr - 4+)
Specific Gravity	1.010 -1.025	1.010 - 1.025
Blood	Negative	Small - Large (1+ - 3+)
pH	5.0 - 6.5	7.0 - ≥9.0
Protein	Negative	30 - ≥300 mg/dL (1+ - 3+)
Urobilinogen	Normal (0.2 E.U./dL)	2.0 - ≥8.0 E.U./dL
Nitrite	Negative	Positive
Leukocytes	Negative	Trace - Large (Tr - 3+)
Microalbumin[1]	10 - 30 mg/L	30 - 300 mg/L
Creatinine[3]	10 - 100 mg/dL	100 - 300 mg/dL
hCG	Negative	Positive

Analytes	Level 1 - 252881	Level 2 - 252882
Teco Diagnostics (Visual)		
Glucose	Negative	100 - 1000 mg/dL (Tr - 3+)
Bilirubin	Negative	Small - Large (1+ - 3+)
Ketones	Negative	Trace - 80 mg/dL
Specific Gravity	≤1.005 - 1.015	≤1.005 - 1.015
Blood	Negative	Small - Large (1+ - 3+)
pH	5.0 - 6.5	7.0 - 8.5
Protein	Negative	30 - 300 mg/dL (1+ - 3+)
Urobilinogen	Normal (0.2 E.U./dL)	1 - ≥8 E.U./dL
Nitrite	Negative	Positive
Leukocytes	Negative	Trace - Lg (Tr - 3+)
Albumin	10 - 30 mg/L	80 - 150 mg/L
Creatinine	10 - 50 mg/dL	100 - 300 mg/dL
Teco Diagnostics TC-101 • TC-201 • TC-720 Urine Analyzer		
Glucose	Negative	100 - 1000 mg/dL
Bilirubin	Negative	Sm - Lg (1+ - 3+)
Ketones	Negative	Trace - ≥80 mg/dL
Specific Gravity	≤1.005 - 1.020	≤1.005 - 1.015
Blood	Negative	Small - Large (1+ - 3+)
pH	5.0 - 6.5	7.0 - 8.5
Protein	Negative	Trace - ≥300 mg/dL (Tr - 3+)
Urobilinogen	Normal (0.2 E.U./dL)	0.2 - ≥8 E.U./dL
Nitrite	Negative	Positive
Leukocytes	Negative	Tr - Mod (Tr - 2+)
Albumin	10 - 30 mg/L	80-150 mg/L
Creatinine	10 - 50 mg/dL	50 - 200 mg/dL
Uriscan™ • 10 SGL Strips (Visual)		
Blood	Negative	10 - 250 RBC/µL (1+ - 3+)
Bilirubin	Negative	0.5 - 3.0 mg/dL (1+ - 3+)
Urobilinogen	Negative - Normal	4 - 12 mg/dL (2+ - 4+)
Ketones	Negative	5 - 100 mg/dL (± - 3+)
Protein	Negative	30 - 1000 mg/dL (1+ - 4+)[7]
Nitrite	Negative	Positive
Glucose	Negative	250 - 2000 mg/dL (1+ - 4+)
pH	5.0 - 6.5	7.5 - 8.5
Specific Gravity	1.015 - 1.030	1.000 - 1.015
Leukocytes	Negative	25 - 500 WBC/µL (1+ - 3+)
Uriscan™ Optima Urine Analyzers • 10 SGL Strips		
Blood	Negative - Trace	10 - 250 RBC/µL (1+ - 3+)
Bilirubin	Negative	0.5 - 3.0 mg/dL (1+ - 3+)
Urobilinogen	Negative - Normal	1 - 12 mg/dL (1+ - 4+)
Ketones	Negative	5 - 100 mg/dL (± - 3+)
Protein	Negative	10 - 300 mg/dL (± - 3+)[8]
Nitrite	Negative	Positive
Glucose	Negative	100 - 2000 mg/dL (± - 4+)
pH	5.0 - 6.0	7.0 - 8.0
Specific Gravity	1.005 - 1.025	1.000 - 1.015
Leukocytes	Negative	25 - 500 WBC/µL (1+ - 3+)

INTERNATIONAL USE ONLY

This Section is for International Use only and contains data for methods that are not available or cleared for diagnostic use in the United States.

Method	Level 1 - 252881	Level 2 - 252882	Units
Red Blood Cells (Erythrocytes)			
77 Elektronika UriSed Variants / Analyticon Urilyzer® Cell	0 - 30	4 - 115	p/µL
Teco UriScope 50 / COBIO Variants	3 - 28	43 - 99	p/µL
Mindray EU-5600, EU-5300, EU-3000	0 - 25	20 - 90	p/µL
Mindray EH-2090B, EH-2090C, EH-2090B Pro, EH-2090C Pro	0 - 25	30 - 83	p/µL
Mindray EU-5300 Pro, EU-5600 Pro	0 - 25	35 - 94	p/µL
YD Diagnostics URiSCAN PluScope	0 - 50	0 - 200	p/µL
ROCHE cobas 6500 (cobas u 701)	0 - 25	22 - 68	p/µL
KOVA® GLASSTIC® SLIDE 10 with GRIDS	0 - 13	37 - 94	p/µL
Non-grid slides (~0.5 mL)	0 - 5	6 - 39	p/hpf
Non-grid slides (~1.0 mL)	0 - 5	3 - 21	p/hpf
Slide & Coverslip (~0.5 mL)	0 - 5	1 - 33	p/hpf
Slide & Coverslip (~1.0 mL)	0 - 4	1 - 15	p/hpf
FisherBrand UriSystem DeciSlide	0 - 4	3 - 24	p/hpf
White Blood Cells (Leukocytes)			
77 Elektronika UriSed Variants / Analyticon Urilyzer® Cell	0 - 30	10 - 90	p/µL
Teco UriScope 50 / COBIO Variants	0 - 29	19 - 57	p/µL
Mindray EU-5600, EU-5300, EU-3000	0 - 25	0 - 60	p/µL
Mindray EH-2090B, EH-2090C, EH-2090B Pro, EH-2090C Pro	0 -20	10 - 50	p/µL
Mindray EU-5300 Pro, EU-5600 Pro	0 -20	10 - 50	p/µL
YD Diagnostics URiSCAN PluScope	0 - 50	0 - 200	p/µL
ROCHE cobas 6500 (cobas u 701)	0 - 50	27 - 83	p/µL
KOVA® GLASSTIC® SLIDE 10 with GRIDS	1 - 10	19 - 58	p/µL
Non-grid slides (~0.5 mL)	0 - 4	2 - 26	p/hpf
Non-grid slides (~1.0 mL)	0 - 4	0 - 12	p/hpf
Slide & Coverslip (~0.5 mL)	0 - 4	0 - 16	p/hpf
Slide & Coverslip (~1.0 mL)	0 - 4	1 - 12	p/hpf
FisherBrand UriSystem DeciSlide	0 - 4	1 - 12	p/hpf

Method	Level 1 - 252881	Level 2 - 252882	Units
Casts			
77 Elektronika UriSed Variants / Analyticon Urilyzer® Cell	may be present	may be present	
Teco UriScope 50 / COBIO Variants	none	none	
ROCHE cobas 6500 (cobas u 701)	none	none	
Mindray EU-5600, EU-5300, EU-3000	none	none	
Mindray EH-2090B, EH-2090C, EH-2090B Pro, EH-2090C Pro	none	none	
Mindray EU-5300 Pro, EU-5600 Pro	none	none	
YD Diagnostics URiSCAN PluScope	none	none	
KOVA® GLASSTIC® SLIDE 10 with GRIDS	none	none	
Non-grid slides (~0.5 mL)	none	none	
Non-grid slides (~1.0 mL)	none	none	
Slide & Coverslip (~0.5 mL)	none	none	
Slide & Coverslip (~1.0 mL)	none	none	
FisherBrand UriSystem DeciSlide	none	none	
Crystals			
77 Elektronika UriSed Variants / Analyticon Urilyzer® Cell	may be present	present	
Teco UriScope 50 / COBIO Variants	none	may be present	
Mindray EU-5600, EU-5300, EU-3000	none	present	
Mindray EH-2090B, EH-2090C, EH-2090B Pro, EH-2090C Pro	may be present	present	
Mindray EU-5300 Pro, EU-5600 Pro	none	present	
YD Diagnostics URiSCAN PluScope	none	may be present	
ROCHE cobas 6500 (cobas u 701)	negative	positive	
KOVA® GLASSTIC® SLIDE 10 with GRIDS	none	present	
Non-grid slides (~0.5 mL)	none	present	
Non-grid slides (~1.0 mL)	none	present	
Slide & Coverslip (~0.5 mL)	none	present	
Slide & Coverslip (~1.0 mL)	none	present	
FisherBrand UriSystem DeciSlide	none	present	
Bacteria			
77 Elektronika UriSed Variants / Analyticon Urilyzer® Cell	may be present	present	
Teco UriScope 50 / COBIO Variants	may be present	may be present	
Mindray EU-5600, EU-5300, EU-3000	may be present	present	
Mindray EH-2090B, EH-2090C, EH-2090B Pro, EH-2090C Pro	may be present	present	
Mindray EU-5300 Pro, EU-5600 Pro	may be present	present	
KOVA® GLASSTIC® SLIDE 10 with GRIDS	may be present	present	
Non-grid slides (~0.5 mL)	may be present	present	
Non-grid slides (~1.0 mL)	may be present	present	
Slide & Coverslip (~0.5 mL)	may be present	present	
Slide & Coverslip (~1.0 mL)	may be present	present	
FisherBrand UriSystem DeciSlide	may be present	present	

Analytes	Level 1 - 252881	Level 2 - 252882
77 Elektronika (Visual / Analyzers)		
Bilirubin	Negative	1 - 6 mg/dL (17 - 100 µmol/L)[8]
Urobilinogen	Normal	2 - 12 mg/dL (35 - 200 µmol/L)[8]
Ketones	Negative	15 - 150 mg/dL (1.5 - 15 mmol/L)
Ascorbic Acid[12]	Negative	Negative
Glucose	Normal	50 - 1000 mg/dL (2.8 - 56 mmol/L)
Protein	Negative	15 - 500 mg/dL (0.15 - 5 g/L)
Blood	Negative	50 - 300 Ery/µL
pH	5 - 6	7 - 8
Nitrite	Negative	Positive
Leukocytes	Negative	75 - 500 Leu/µL
Specific Gravity	1.010 - 1.030	1.000 - 1.025
Creatinine	10 - 50 mg/dL (0.9-4.4 mmol/L)	50 - 300 mg/dL (4.4 - 26.5 mmol/L)
Microalbumin	≤ 10 mg/L	150 - 500 mg/L
Analyticon® Combi Screen (Visual)		
Bilirubin	Negative	1+ - 3+
Urobilinogen	Normal	2 - 12 mg/dL (35 - 200 µmol/L)[8]*
Ketones	Negative	(+) - 3+
Ascorbic Acid[12]	Negative	Negative
Glucose	Normal	50 - 1000 mg/dL (2.8 - 56 mmol/L)
Protein	Negative	30 - 500 mg/dL
Blood	Negative[6]	10 - 300 Ery/µL (1+ - 3+)
pH	5 - 6	6 - 9
Nitrite	Negative[6]	Positive
Leukocytes	Negative	25 - 500 Leu/µL
Specific Gravity	1.010 - 1.020	1.000 - 1.010
Creatinine	10 - 100 mg/dL (0.9 - 8.8 mmol/L)	100 - 300 mg/dL (8.8 - 26.5 mmol/L)
Microalbumin	10 - 80 mg/L	150 - 500 mg/L

Analytes	Level 1 - 252881	Level 2 - 252882
Analyticon® Urilyzer® 100 Pro and Urilyzer® Auto		
Bilirubin	Negative	1 - 4 mg/dL, 17 - 70 µmol/L (1+ - 3+)
Urobilinogen	Normal	2 - 12 mg/dL 35-200 µmol/L (1+ - 4+)[8*]
Ketones	Negative	10 - 300 mg/dL, 1.0 - 30 mmol/L (+) - 3+
Ascorbic Acid[12]	Negative - 20 mg/dL, Negative - 1+	Negative - 20 mg/dL, Negative- 1+
Glucose	Normal	50 - 1000 mg/dL, 2.8 - 56 mmol/L (1+ - 5+)
Protein	Negative	30 - 500 mg/dL, 0.3 - 5 g/L (1+ - 3+)
Blood	Negative[6]	10 - 300 Ery/µL (1+ - 3+)
pH	5 - 7	6 - 8
Nitrite	Negative[6]	Positive
Leukocytes	Negative	25 - 500 Leu/µL (1+ - 3+)
Specific Gravity	1.010 - 1.030	1.000 - 1.020
Creatinine	10 - 50 mg/dL (0.9 - 4.4 mmol/L)	50 - 300 mg/dL, (4.4 - 26.5 mmol/L)
Microalbumin	10 - 80 mg/L	150 - 500 mg/L
CHUNGDO Visual / Analyzers		
Blood	Negative	10 - 250 RBC/µL (1+ - 3+)
Bilirubin	Negative	Neg - 1.0 mg/dL (Neg - 2+)
Urobilinogen	Normal (0.1)	1 - 8 mg/dL (1+ - 3+)
Ketones	Negative	5 - 100 mg/dL (± - 3+)
Protein	Negative	10 - 100 mg/dL (± - 2+)
Nitrite	Negative	Positive
Glucose	Negative	100 - 500 mg/dL (± - 2+)
pH	5.0 - 6.0	7.0 - 8.5
Specific Gravity	1.015 - 1.030	1.005 - 1.015
Leukocytes	Negative	75 - 500 WBC/µL (1+ - 3+)
Ascorbic Acid[12]	Normal	Normal
CYPRESS DIAGNOSTICS Urine Strips • CYANStrip • CYANStrip Mini • Visual		
Urobilinogen	Normal (0.1~1 mg/dL)	1~8 mg/dL (16~131 µmol/L)[11]
Glucose	Negative	50~2000 mg/dL (2.8~111 mmol/L)
Bilirubin	Negative	Small~Large (1+~3+)
Ketones	Negative	5~160 mg/dL (0.5~16 mmol/L)
Specific Gravity	1.015~1.030	1.005~1.020
Blood	Negative	10~250 RBC/uL (1+~3+)
pH	5~6.5	7~9
Protein	Negative	15~300 mg/dL (0.15~3.0 g/L) (Trace~ 3+)
Nitrite	Negative	Positive
Leukocytes	Negative	15~500 WBC/uL (Trace~3+)
Microalbumin	10~50 mg/dL (0.9~4.4 mmol/L)	50~300 mg/dL (4.4~26.5 mmol/L)
Creatinine	10 mg/L	30~150 mg/L
DiaLab Urine Strip Analyzer 500/Urine Strip 10C/Urine Strip 2MC		
	NOT AVAILABLE	
DFI CYBOW • ComboStik • DUS Urine Reagent Strips (Visual)		
Urobilinogen	Normal (0.1~1 mg/dL)	1~8 mg/dL (16~131 µmol/L)[11]
Glucose	Negative	50~2000 mg/dL (2.8~111 mmol/L)
Bilirubin	Negative	Small~Large (1+~3+)
Ketones	Negative	5~160 mg/dL (0.5~16 mmol/L)
Specific Gravity	1.015~1.030	1.005~1.020
Blood	Negative	10~250 RBC/uL (1+~3+)
pH	5~6.5	7~9
Protein, Total	Negative	15~300 mg/dL (0.15~3.0 g/L) (Trace~3+)
Nitrite	Negative	Positive
Leukocytes	Negative	15~500 WBC/uL (Trace~3+)
Creatinine	10~50 mg/dL (0.9~4.4 mmol/L)	50~300 mg/dL (4.4~26.5 mmol/L)
Microalbumin	10 mg/L	30~150 mg/L
DFI CYBOW R-50 (50S) • ComboStik R-50 (50S) • DUS R-50 (50S)		
Urobilinogen	Normal (0.1~1 mg/dL)	1~8 mg/dL (16~131 µmol/L)[11]
Glucose	Negative	50~2000 mg/dL (2.8~111 mmol/L)
Bilirubin	Negative	Small~Large (1+~3+)
Ketones	Negative	5~160 mg/dL (0.5~16 mmol/L)
Specific Gravity	1.015~1.030	1.005~1.020
Blood	Negative	10~250 RBC/µL (1+~3+)
pH	5~6.5	7~9
Protein, Total	Negative	15~300 mg/dL (0.15~3.0 g/L) (Trace~3+)
Nitrite	Negative	Positive
Leukocytes	Negative	15~500 WBC/µL (Trace~3+)
Creatinine	10~50 mg/dL (0.9~4.4 mmol/L)	50~300 mg/dL (4.4~26.5 mmol/L)
Micoalbumin	10 mg/L	30~150 mg/L
DFI CYBOW Reader 300 • ComboStik R-300 • DUS R-300		
Urobilinogen	Normal (0.1~1 mg/dL)	1~8 mg/dL (16~131 µmol/L)[11]
Glucose	Negative	50~2000 mg/dL (2.8~111 mmol/L)
Bilirubin	Negative	Small~Large (1+~3+)
Ketones	Negative	5~160 mg/dL (0.5~16 mmol/L)
Specific Gravity	1.015~1.030	1.005~1.020
Blood	Negative	10~250 RBC/µL (1+~3+)
pH	5~6.5	7~9
Protein, Total	Negative	15~300 mg/dL (0.15~3.0 g/L) (Trace~3+)
Nitrite	Negative	Positive
Leukocytes	Negative	15~500 WBC/µL (Trace~3+)
Creatinine	10~50 mg/dL (0.9~4.4 mmol/L)	50~300 mg/dL (4.4~26.5 mmol/L)
Micoalbumin	10 mg/L	30~150 mg/L

Analytes	Level 1 - 252881	Level 2 - 252882
DFI CYBOW Reader 600S • ComboStik R-600S • DUS R-600S • Reader 720 • Combostik R-700 • DUS R-720 • DFI CYBOW Reader 720 • ComboStik R-700 • DUS R-720		
Urobilinogen	Normal (0.1~1mg/dL)	1~8 mg/dL (16~131 µmol/L)[11]
Glucose	Negative	50~2000 mg/dL (2.8~111 mmol/L)
Bilirubin	Negative	Small~Large (1+~3+)
Ketones	Negative	5~160 mg/dL (0.5~16 mmol/L)
Specific Gravity	1.015~1.030	1.005~1.020
Blood	Negative	10~250 RBC/uL (1+~3+)
pH	5~6.5	7~9
Protein, Total	Negative	15~300 mg/dL (0.15~3.0 g/L) (Trace~3+)
Nitrite	Negative	Positive
Leukocytes	Negative	15~500 WBC/uL (Trace~3+)
Creatinine	10~50 mg/dL (0.9~4.4 mmol/L)	50~300 mg/dL (4.4~26.5 mmol/L)
Microalbumin	10 mg/L	30~150 mg/L
DFI's CYBOW R-60(60S)/ComboStik R-60(60S)/DUS R-60(60S)		
Urobilinogen	Normal (0.1~1 mg/dL)	1~8 mg/dL (16~131 µmol/L)
Glucose	Negative	50~2000 mg/dL (2.8~111 mmol/L)
Bilirubin	Negative	Small~Large (1+~3+)
Ketones	Negative	5~160 mg/dL (0.5~16 mmol/L)
Specific Gravity	1.015~1.030	1.005~1.020
Blood	Negative	10~250 RBC/µL (1+~3+)
pH	5~6.5	7~9
Protein, Total	Negative	15~300 mg/dL (0.15~3.0 g/L) (Trace~3+)
Nitrite	Negative	Positive
Leukocytes	Negative	15~500 WBC/µL (Trace~3+)
Creatinine	10~50 mg/dL (0.9~4.4 mmol/L)	50~300 mg/dL (4.4~26.5 mmol/L)
Microalbumin	10 mg/L	30~150 mg/L
ERBA LACHEMA DekaPHAN LAURA STRIPS & LAURA Urine Analyzer ERBA Mannheim Uro-dip 10e STRIPS & Uro-dipcheck 400e Urine Analyzer		
Bilirubin	Negative	1 - 6 mg/dL (17 - 103 µmol/L) (1+ - 3+)
Blood	Negative	50 - 250 Ery/µL (2+ - 3+)
Glucose	Negative	100 - 1000 mg/dL (5.5 - 55 mmol/L) (2+ - 4+)
Ketones	Negative	16 - 156 mg/dL (1.5 - 15 mmol/L) (1+ - 3+)
Leukocytes	Negative	75 - 500 Leu/µL (2+ - 3+)
Nitrite	Negative	Positive
pH	5 - 6.5	7 - 9
Protein	Negative	30 - 500 mg/dL (0.3 - 5 g/L) (1+ - 3+)
Specific Gravity	1.015 - 1.030	1.000 – 1.015
Urobilinogen	Normal	1 - 3 mg/dL (17 - 51 µmol/L) (1+ - 2+)
ERBA LACHEMA DekaPHAN LAURA STRIPS & LAURA M Urine Analyzer ERBA Mannheim Uro-dip 10e STRIPS & LAURA M Urine Analyzer		
Bilirubin	Negative	1 - 6 mg/dL (17 - 103 µmol/L) (1+ - 3+)
Blood	Negative	50 - 250 Ery/µL (2+ - 3+)
Glucose	Negative	100 - 1000 mg/dL (5.5 - 55 mmol/L) (2+ - 4+)
Ketones	Negative	16 - 156 mg/dL (1.5 - 15 mmol/L) (1+ - 3+)
Leukocytes	Negative	75 - 500 Leu/µL (2+ - 3+)
Nitrite	Negative	Positive
pH	5 - 6.5	7 - 9
Protein	Negative	30 - 500 mg/dL (0.3 - 5 g/L) (1+ - 3+)
Specific Gravity	1.020 - 1.030	1.000 - 1.015
Urobilinogen	Normal	Norm - 3 mg/dL (Norm - 51 µmol/L) (Norm - 2+)
ERBA LACHEMA DekaPHAN LAURA STRIPS & LAURA Smart Urine Analyzer ERBA Mannheim Uro-dip 10e STRIPS & Uro-dipcheck 240e Urine Analyzer		
Bilirubin	Negative	1 - 6 mg/dL (17 - 103 µmol/L) (1+ - 3+)
Blood	Negative	50 - 250 Ery/µL (2+ - 3+)
Glucose	Negative	100 - 1000 mg/dL (5.5 - 55 mmol/L) (2+ - 4+)
Ketones	Negative	16 - 156 mg/dL (1.5 - 15 mmol/L) (1+ - 3+)
Leukocytes	Negative	75 - 500 Leu/µL (2+ - 3+)
Nitrite	Negative	Positive
pH	5 - 6.5	7 - 9
Protein	Negative	30 - 500 mg/dL (0.3 - 5 g/L) (1+ - 3+)
Specific Gravity	1.020 - 1.030	1.000 - 1.015
Urobilinogen	Normal	Norm - 3 mg/dL (Norm - 51 µmol/L) (Norm - 2+)

Analytes	Level 1 - 252881	Level 2 - 252882
ERBA LACHEMA DekaPHAN LAURA STRIPS (Visual) ERBA Mannheim Uro-dip 10e STRIPS (Visual)		
Bilirubin	Negative	3 - 6 mg/dL (51 - 103 µmol/L) (2+ - 3+)
Blood	Negative	10 - 250 Ery/µL (1+ - 3+)
Glucose	Negative	300 - 1000 mg/dL (17 - 55 mmol/L) (3+ - 4+)
Ketones	Negative	52 - 156 mg/dL (5 - 15 mmol/L) (2+ - 3+)
Leukocytes	Negative	75 - 500 Leu/µL (2+ - 3+)
Nitrite	Negative	Positive
pH	5 - 6	7 - 9
Protein	Negative	30 - 100 mg/dL (0.3 - 1 g/L) (1+ - 2+)
Specific Gravity	1.020 - 1.030	1.000 - 1.015
Urobilinogen	Normal	1 - 3 mg/dL (17 - 51 µmol/L) (1+ - 2+)
Mindray EU-5600, EU-5300, EU-3000		
Leukocytes	Negative	70~500 Leu/µL(1+~3+)
Urobilinogen	Normal	2~8 mg/dL(1+~3+)
Microalbumin	10~80mg/L	30~150 mg/L
Protein	Negative	30~300 mg/dL(1+~3+)
Bilirubin	Negative	1~6 mg/dL(1+~3+)
Glucose	Negative	100~500 mg/dL(1+~3+)
Specific Gravity	1.010~1.025	1.000~1.015
Ketones	Negative	15~80 mg/dL(1+~3+)
Nitrite	Negative	Positive
Creatinine	0.9~8.8 mmol/L	8.8~26.5 mmol/L
pH	5.0~6.5	7.0~9.0
Blood	Negative	25~200 Ery/µL(1+~3+)
Ascorbic Acid	Negative	Negative
Mindray UA-5600		
Leukocytes	Negative	70~500 Leu/µL(1+~3+)
Urobilinogen	Normal	2~8 mg/dL(1+~3+)
Microalbumin	10~80 mg/L	30~150mg/L
Protein	Negative	30~300 mg/dL(1+~3+)
Bilirubin	Negative	1~6 mg/dL(1+~3+)
Glucose	Negative	250~1000 mg/dL(2+~4+)
Specific Gravity	1.010~1.025	1.005~1.020
Ketones	Negative	15~80 mg/dL(1+~3+)
Nitrite	Negative	Positive
Creatinine	0.9~8.8 mmol/L	8.8~26.5 mmol/L
pH	5.0~6.5	6.5~8.5
Blood	Negative	25~200 Ery/µL(1+~3+)
Ascorbic Acid	Negative	Negative
Mindray EU-5300 Pro, EU-5600 Pro		
Leukocytes	Negative	70~500 Leu/µL(1+~3+)
Urobilinogen	Normal	2~8 mg/dL(1+~3+)
Microalbumin	10~80 mg/L	30~150mg/L
Protein	Negative	30~300 mg/dL(1+~3+)
Bilirubin	Negative	1~6 mg/dL(1+~3+)
Glucose	Negative	100~500 mg/dL(1+~3+)
Specific Gravity	1.010~1.025	1.005~1.020
Ketones	Negative	15~80 mg/dL(1+~3+)
Nitrite	Negative	Positive
Creatinine	0.9~8.8 mmol/L	8.8~26.5 mmol/L
pH	5.0~6.5	6.5~8.5
Blood	Negative	25~200 Ery/µL(1+~3+)
Ascorbic Acid	Negative	Negative
ROCHE VISUAL TESTING (Visual Test Strips Only)		
Specific Gravity	1.015 - 1.030	1.000 - 1.010
pH	5 - 6	7 - 9
Leukocytes	Negative	75 - 500 Leu/µL (2+ - 3+)
Nitrite	Negative	Positive
Protein	Negative	30 -100 mg/dL (1+ - 2+)
Glucose	Normal	300 - 1000 mg/dL (3+ - 4+)
Ketones	Negative	10 - 150 mg/dL (1+ - 3+)
Urobilinogen [8]*	Normal	1 - 12 mg/dL (1+ - 4+)
Bilirubin [8]*	Negative	1+ - 3+
Blood	Negative	50 - 250 Ery/µL (3+ - 4+)
Microalbumin [5]	Negative	50 - 100 mg/L
ROCHE cobas 6500 (cobas u 601)		
Blood	Negative	150 - 250 Ery/µL
Leukocytes	Negative	100 - 500 Leu/µL
Nitrite	Negative	Positive
Ketones	Negative	15 - 150 mg/dL
Glucose	Normal	300 - 1000 mg/dL
Protein	Negative [6]	75 - 150 mg/dL [7]
Urobilinogen	Normal	1 - 8 mg/dL [7]*
Bilirubin	Negative	3 - 6 mg/dL*
pH	5.0 - 6.5	8 - 9
Specific Gravity	1.016 - 1.028	1.008 - 1.020
Color	Yellow - Pale Yellow	Brown
Clarity	Clear	Clear

Analytes	Level 1 - 252881	Level 2 - 252882
ROCHE Urisys 1100 Urine Analyzer or ROCHE Urilux S Urine Analyzer		
Blood	Negative	50 - 250 Ery/µL (3+ - 4+)
Bilirubin	Negative	3 - 6 mg/dL (2+ - 3+)*
Urobilinogen	Normal	1 - 8 mg/dL (1+ - 3+) [7]*
Ketones	Negative	50 - 150 mg/dL (2+ - 3+)
Glucose	Normal	300 - 1000 mg/dL (3+ - 4+)
Protein	Negative [6]	25 - 150 mg/dL (1+ - 3+) [7]
Nitrite	Negative	Positive
Leukocytes	Negative	100 - 500 Leu/µL (2+ - 3+)
pH	5 - 6.5	8 - 9
Specific Gravity	1.015 - 1.025	1.000 - 1.015
ROCHE Cobas u 411 Urine Analyzer		
Blood	Negative	150 - 250 Ery/µL (4+ - 5+)
Bilirubin	Negative	3 - 6 mg/dL (2+ - 3+)*
Urobilinogen	Normal	1 - 8 mg/dL (1+ - 3+) [7]*
Ketones	Negative	50 - 150 mg/dL (3+ - 4+)
Glucose	Normal	300 - 1000 mg/dL (3+ - 4+)
Protein	Negative [6]	75 - 150 mg/dL (2+ - 3+) [7]
Nitrite	Negative	Positive
Leukocytes	Negative	100 - 500 Leu/µL (2+ - 3+)
pH	5 - 6.5	8 - 9
Specific Gravity	1.015 - 1.025	1.000 - 1.020
ROCHE Urisys 1800 Urine Analyzer		
Blood	Negative	150 - 250 Ery/µL (4+ - 5+)
Bilirubin	Negative	3 - 6 mg/dL (2+ - 3+)*
Urobilinogen	Normal	1 - 8 mg/dL (1+ - 3+) [7]*
Ketones	Negative	50 - 150 mg/dL (3+ - 4+)
Glucose	Normal	300 - 1000 mg/dL (3+ - 4+)
Protein	Negative [6]	75 - 150 mg/dL (2+ - 4+) [7]
Nitrite	Negative	Positive
Leukocytes	Negative	100 - 500 Leu/µL (2+ - 3+)
pH	5 - 6.5	8 - 9
Specific Gravity	1.015 - 1.025	1.000 - 1.020
YD Diagnostics URiSCAN Urine Test Strips (Visual)		
Blood	Negative	10~250 RBC/uL (1+~3+)
Bilirubin	Negative	0.5~3.0 mg/dL (1+~3+) *[7]
Urobilinogen	Normal	1~12 mg/dL (1+~4+)
Ketones	Negative	10~100 mg/dL (1+~3+)
Protein	Negative	30~1000 mg/dL (1+~4+)
Nitrite	Negative	Positive
Glucose	Negative	250~2000 mg/dL (1+~4+)
pH	5.0~6.5	6.5 - 8.5
Specific Gravity	1.015~1.030	1.005~1.020
Leucocytes	Negative	25~500 WBC/uL (1+~3+)
YD URiSCAN PRO, URiSCAN Optima & Optima II		
Blood	Negative	10~250 RBC/uL (1+~3+)
Bilirubin	Negative	0.5~3.0 mg/dL (1+~3+) *[7]
Urobilinogen	Normal	1~12 mg/dL (1+~4+)
Ketones	Negative	10~100 mg/dL (1+~3+)
Protein	Negative	30~1000 mg/dL (1+~4+)
Nitrite	Negative	Positive
Glucose	Negative	100~1000 mg/dL (±~3+)
pH	5.0~6.5	6.5~8.5
Specific Gravity	1.010~1.030	1.005~1.020
Leucocytes	Negative	25~500 WBC/uL (1+~3+)
Microalbumin	Negative~30 mg/L	30~150 mg/L
Creatinine	10~100 mg/dL	50~300 mg/dL
YD Diagnostics URiSCAN Super		
Blood	Negative	10~250 RBC/uL (1+~3+)
Bilirubin	Negative	0.5~3.0 mg/dL (1+~3+) *[7]
Urobilinogen	Normal	1~12 mg/dL (1+~4+)
Ketones	Negative	10~100 mg/dL (1+~3+)
Protein	Negative	30~1000 mg/dL (1+~4+)
Nitrite	Negative	Positive
Glucose	Negative	100~1000 mg/dL (±~3+)
pH	5.0~6.5	6.5~8.5
Specific Gravity	1.014~1.030	1.006~1.022
Leucocytes	Negative	25~500 WBC/uL (1+~3+)
YD Diagnostics URiSCAN Super +		
Blood	Negative	10~250 RBC/uL (1+~3+)
Bilirubin	Negative	0.5~3.0 mg/dL (1+~3+) *[7]
Urobilinogen	Normal	1~12 mg/dL (1+~4+)
Ketones	Negative	10~100 mg/dL (1+~3+)
Protein	Negative	30~1000 mg/dL (1+~4+)
Nitrite	Negative	Positive
Glucose	Negative	100~1000 mg/dL (±~3+)
pH	5.0~6.5	6.5~8.5
Specific Gravity	1.014~1.030	1.006~1.022
Leucocytes	Negative	25~500 WBC/uL (1+~3+)

ENGLISH
1 Values only apply to Clinitek Microalbumin Reagent Strips when read on the Clinitek 50 & Status.
2 Values only apply to Multistix Pro™ Reagent Strips
3 Values only apply to Multistix Pro and Clinitek Microalbumin Reagent Strips when read on Clinitek Urine Analyzers
4 VISUAL: Some customers may obtain false negatives.
5 Values apply to Chemstrip® Micral Reagent Strips
6 Some customers may obtain false positives.
7 Some customers may obtain false negatives.
8 Atypical color
10 Absorbance at 620 nm
11 The urobilinogen reaction produces an atypical color which may result in a normal (0.2 E.U./dL) reading. Should this occur, a visual observation of the intensification of the pad color indicates a positive response.
12 For information purposes only.
* See Limitations

DEUTSCH
1 Werte gelten nur für Clinitek Mikroalbumin-Reagenzstreifen wenn diese auf Clinitek 50 und Status
2 Werte gelten nur für Multistix Pro™ Reagenzstreifen
3 Werte gelten nur für Multistix Pro und Clinitek Mikroalbumin-Reagenzstreifen, wenn diese auf Clinitek Urin-Analysatoren gelesen werden
4 VISUAL: Manche Kunden erhalten möglicherweise falsch negative Ergebnisse.
5 Werte gelten für Chemstrip® Micral Reagenzstreifen
6 Manche Kunden erhalten möglicherweise falsch positive Ergebnisse.
7 Manche Kunden erhalten möglicherweise falsch negative Ergebnisse.
8 Atypische Farbe
10 Absorption bei 620 nm
11 Die Urobilinogen-Reaktion erzeugt eine atypische Farbe, die zu einem normalen Messwert (0,2 EU/dl) führen kann. In diesem Fall kann eine positive Reaktion anhand der sichtbar veränderten Farbintensität des Testfeldes festgestellt werden.
12 Nur für Informationszwecke.
* Siehe Einschränkungen

FRANÇAIS
1 Valeurs s'appliquant uniquement aux bandes de réactif Clinitek micro-albumine lues sur Clinitek 50 et Status
2 Valeurs s'appliquant uniquement aux bandes de réactif Multistix Pro™
3 Valeurs s'appliquant uniquement aux bandes de réactif Multistix Pro et Clinitek micro-albumine lues sur Clinitek Analyseurs d'urine
4 VISUAL: Certains clients sont susceptibles d'obtenir des faux négatifs.
5 Valeurs s'appliquant aux bandes de réactif Chemstrip® Micral
6 Certains clients sont susceptibles d'obtenir des faux positifs.
7 Certains clients sont susceptibles d'obtenir des faux négatifs.
8 Couleur atypique
10 Absorbance à 620 nm
11 La réaction de l'urobilinogène produit une couleur atypique pouvant donner lieu à une lecture normale (0,2 unité Ehrlich/dl). Si cela se produit, l'observation visuelle de l'intensification de la couleur de la zone de test indique une réponse positive.
12 Fourni uniquement à titre d'information.
* Voir Limitations

ITALIANO
1 I valori si riferiscono esclusivamente alle Strisce reagenti per microalbumina Clinitek lette su Clinitek 50 e Status
2 I valori si riferiscono esclusivamente alle Strisce reagenti Multistix Pro™
3 I valori si riferiscono esclusivamente alle Strisce reagenti per microalbumina Multistix Pro e Clinitek lette su Clinitek Analizzatori urine
4 VISUAL: Alcuni pazienti possono ottenere risultati falsi negativi.
5 I valori si riferiscono alle Strisce reagenti Micral Chemstrip®
6 Alcuni pazienti possono ottenere risultati falsi positivi.
7 Alcuni pazienti possono ottenere risultati falsi negativi.
8 Colore atipico
10 Assorbanza a 620 nm
11 La reazione dell'urobilinogeno produce un colore atipico che può determinare una lettura normale (0,2 U.E./dl). In questo caso, se si nota visivamente un'intensificazione del colore del cuscinetto, questo indica una reazione positiva.
12 Solo a scopo informativo.
* Vedere limiti

ESPAÑOL
1 Los valores son aplicables únicamente a las tiras reactivas Clinitek Microalbumin cuando se leen en equipos Clinitek 50 y Status
2 Los valores son aplicables únicamente a las tiras reactivas Multistix Pro™
3 Los valores son aplicables únicamente a las tiras reactivas Multistix Pro y Clinitek Microalbumin cuando se leen en equipos Clinitek Analizadores de orina
4 VISUAL: Algunos pacientes pueden obtener resultados negativos falsos.
5 Los valores son aplicables a las tiras reactivas Chemstrip® Micral
6 Algunos pacientes pueden obtener resultados positivos falsos
7 Algunos pacientes pueden obtener resultados negativos falsos.
8 Color anormal
10 Absorbencia a 620 nm
11 La reacción del urobilinógeno genera un color atípico que puede dar lugar a una lectura normal (0,2 E.U./dL). Si ocurriera esto, la respuesta es positiva si se observa visualmente una intensificación del color de la almohadilla.
12 Solo para fines informativos.
* Ver las limitaciones

POLSKI
1 Wartości mają zastosowanie wyłącznie do pasków odczynnikowych Clinitek Microalbumin podczas odczytu za pomocą urządzenia Clinitek 50 lub Status.
2 Wartości mają zastosowanie wyłącznie do pasków odczynnikowych Multistix Pro™.
3 Wartości mają zastosowanie wyłącznie do pasków odczynnikowych Multistix Pro oraz Clinitek Microalbumin podczas odczytu za pomocą analizatorów moczu.
4 ODCZYT WIZUALNY: Niektórzy klienci mogą uzyskiwać wyniki pozornie ujemne.
5 Wartości dotyczą pasków odczynnikowych Chemstrip® Micral
6 Niektórzy klienci mogą uzyskiwać wyniki pozornie dodatnie.
7 Niektórzy klienci mogą uzyskiwać wyniki pozornie ujemne.
8 Nietypowe zabarwienie
10 Absorbancja przy długości fali 620 nm
11 Reakcja urobilinogenu powoduje nietypowe zabarwienie, co może doprowadzić do uzyskania prawidłowego (0,2 E.U./dl) odczytu. W takiej sytuacji obserwacja intensyfikacji zabarwienia wkładki wskazuje na odpowiedź dodatnią.
12 Wyłącznie do celów informacyjnych.
* Patrz „Ograniczenia"

European Conformity CE-Konformitätskennzeichnung Conformité aux normes européennes Conformità europea Conformidad europea Zgodność z przepisami UE	Catalog No. Bestellnr. N° de catalogue Catalogo n. Nº de catálogo Nr katalogowy	Manufactured by Hergestellt von Fabriqué par Fabbricato da Fabricado por Wyprodukowane przez	Authorized Representative Bevollmächtigter Représentant agréé Rappresentante autorizzato Representante autorizado Autoryzowany przedstawiciel	U.S. Federal law restricts this device to sale by or only on the order of a licensed healthcare practitioner. Gemäß US-Bundesgesetz darf dieses Gerät nur von einer lizenzierten Fachkraft im Gesundheitswesen bzw. in deren Auftrag verkauft. La loi fédérale des États-Unis restreint la vente de cet appareil par ou uniquement sur ordonnance d'un professionnel de santé agréé. Legge federale degli Stati Uniti limita la vendita del dispositivo da parte di o solo su prescrizione di medici specialisti. La ley federal de Estado Unidos permite la venta de este dispositivo exclusivamente a médicos o bajo prescripción facultativa. Amerykańskie prawo federalne określa, że urządzenie może być sprzedawane wyłącznie wykwalifikowanym pracownikom służby zdrowia lub na ich zamówienie.
Temperature limitation Temperaturbegrenzungen Limites de température limiti di temperatura límite de temperatura Ograniczenie temperaturowe	Lot Number Bezeichnung Désignation du lot Numero di lotto Denominación de lote Numer partii	Biological Risk Biogefährdung Risque biologique Rischio biologico Peligro biológico Ryzyko biologiczne	Contents of kit Inhalt der Packung Contenu du coffret Contenuto della confezione Contenido del estuche Zawartość zestawu	
Consult instructions for use Gebrauchsanweisung beachten Consulter les instructions d'utilisation Consultare le istruzioni l'uso Consulte las instrucciones de uso Patrz instrukcja użycia	For in vitro diagnostic use In-vitro Diagnosticum Pour diagnostic in vitro Per uso diagnostico in vitro De uso diagnóstico in vitro Do użytku diagnostycznego in vitro	Use by (last day of month) Verwendbar bis (letzter Tag des Monats) Utilisable jusqu'à (dernier jour du mois indiqué) Da utilizzare prima del (ultimo giorno del mese) Estable hasta (último día del mes) Termin ważności (ostatni dzień miesiąca)	Caution, See Product Insert Achtung, Siehe Packungsbeilage Attention, voir notice d'utilisation Attenzione, vedere il foglietto illustrativo del prodotto Atención, consulte el folleto del producto Uwaga, patrz ulotka dołączona do produktu	

Level 1 LOT **252881**

Level 2 LOT **252882**

Level 1&2 Expiration Date
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DocUReader 2 PRO

77 ELEKTRONIKA

Urine chemistry analyzer
User Manual

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CE IVD

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The information in this manual was correct at the time of printing. However, 77 Elektronika Kft. continues to improve its products and reserves the right to change specifications, equipment, and maintenance procedures at any time without notice.

Companies, names and data used in examples are fictitious unless otherwise noted. No part of this document may be reproduced or transmitted in any form or by any means, electronic, mechanical or otherwise, for any purpose, without the express written permission of 77 Elektronika. 77 Elektronika may have patents or pending patent applications, trademarks, copyrights or other intellectual or industrial property rights covering this document or subject matter in this document. The furnishing of this document does not give a license to these property rights except as expressly provided in any written license agreement from 77 Elektronika.

If this instrument is used in a manner differently than specified in this manual, the protection provided by the equipment may be impaired.

REF UD2-9902-1

CONTENT

1 INTRODUCTION

1.1 Modification history

Version	Date	Modification
UD2-9201-1 Rev F	02/2014	First version
UM_UD2-9201_EN_01	03/2022	New features added in software version. IVDR compliance.

ⓘ *You do not have to calibrate the analyzer in any way before performing measurements. The analyzer software checks the system each time the analyzer is turned on. During testing, the analyzer automatically checks and corrects its performance based on the independent internal sensor.*

ⓘ *Due to software changes, some screens on the instrument may appear slightly different from those in this manual.*

1.2 Intended purpose

The DocUReader 2 Pro is a semi-automatic urine test strip analyzer and provides qualitative and semi-quantitative parameter concentration values in human urine. The analyzer evaluates dedicated LabStrip urine test strips for preliminary screening.

The product is designed for professional use and may be used in a near-patient environment as an in vitro diagnostic medical device.

1.3 Indications for use

The DocUReader 2 PRO urine analyzer is a bench top IVDD for professional use designed to be used exclusively with LabStrip U11 Plus/LabStrip U mALB/CREA urine test strips manufactured by 77 Elektronika.

LabStrip U11 Plus

The system performs the qualitative measurement of relevant properties of Nitrite (Nit) and the semi-quantitative measurement of relevant properties of the following urine analytes of the samples:

Bilirubin (Bil), Urobilinogen (Ubg), Ketones (Ket), Ascorbic Acid (Asc), Glucose (Glu), Protein (Pro), Blood (Bld / Ery), pH, Leukocytes (Leu) and Specific Gravity (SG).

The system provides a screening test for the early detection of the following conditions:

- Liver disease
- Biliary and hepatic obstructions

- Carbohydrate metabolism disorders including Diabetes Mellitus
- Haemolytic disease
- Urological and nephrological diseases associated with haematuria or haemoglobinuria
- Diseases of the kidneys and the urinary tract
- Pathological shifts in the pH value.

LabStrip U mALB/CREA

The system performs the semi-quantitative measurement of relevant properties of the following urine analytes:

Albumin (mALB), Creatinine (CREA)

The system provides a screening test for the early detection of the following conditions:

- Symptoms of beginning nephropathy
- Cardio-vascular diseases

ⓘ *See the* **MedlinePlus Medical Encyclopedia** *article on urinalysis for further details.*

1.4 Limitation of use

Do not use the semi-quantitative results that the device provides to make diagnostic or therapeutic decisions without additional analysis.

The device was developed and manufactured for human diagnostics use only (original function). The manufacturer excludes all liability arising from or in connection with any use of the device that is different from its original function.

1.5 How to use this manual

This Operator's Manual contains all essential information for the user to make full use of the analyzer device. The manual describes system functions and includes step-by-step procedures for the access and use of the system.

For further assistance and feedback, visit **https://www.en.e77.hu/for-distributors.**

1.5.1 Symbols and formatting conventions

This manual uses the following symbols to highlight important information and help you navigate the text:

CAUTION: This symbol indicates maintenance procedures, operations, and other processes that can cause personal harm or equipment malfunction, equipment failure, or damage to the equipment if the instructions are not followed carefully. This symbol is also used to highlight situations that can compromise results.

Caution text appears in bold type.

BIOLOGICAL HAZARD: This symbol indicates maintenance procedures, operations, and other processes where hazardous biological agent are present. Instructions are to be followed carefully to avoid personal injury and/or adversed health effect.

Warning text appears in bold type.

NOTE: This symbol indicates important information or useful tips on servicing the device.

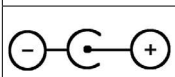
Note text appears in italic type.

This manual uses the following formatting conventions to highlight important information and help you navigate the text:

- **Bold grey text** indicates cross-references that point to related parts of the manual or to external hyperlinks.
- **`Bold monospace type`** indicates text that appears on the display
- **1.** (numbering) within procedures indicates steps that you should perform in sequence.
- Bullet points (•) indicate items on a list or steps that you do not need to perform in sequence.

The following symbols appear on the device, its AC Adapter, its packaging, and on the packaging of the reagent strip it was designed to read.

	Double insulated product or transformer. May also identify class 2 equipment (power supply only)
	Indicates that the instrument is listed by Underwriters Laboratories as meeting U.S. and Canadian requirements for safety
	Indicates that this product has been tested to the requirements of CAN/CSA-C22.2 No. 61010-1, second edition, including Amendment 1, or a later version of the same standard includes the same level of testing requirements
	Indicates that this system contains certain toxic or hazardous substances or elements. The environmental protection use period for this system is ten years. The system can be used safely during its environmental protection use period. The system should be recycled immediately after its environmental protection use period has expired.
	Manufacturer
	Power on/off
	Handle with care
	Temperature limitation
	Atmospheric pressure limitation
	Batch code
	The number of items that the contents of the package is sufficient for
	Protect from sunlight and heat
	Catalogue number
	Do not reuse
	Indoor use only

CE	The CE mark indicates that the product complies with the applicable directives of the European Union
	Indicates that this equipment is classified as Waste Electrical and Electronic Equipment under the European WEEE Directive. It must be recycled or disposed of in accordance with applicable local requirements
	Caution, consult accompanying documents
	Consult instructions for use
	Ethernet port symbol
IVD	In vitro diagnostic medical device
SN	Serial number
	Do not use if package is damaged
	USB port symbol
	DC Adaptor Polarity Centre Positive
	This way up
	Stack no more than four (4)
	Humidity limitation
	Use by date

1.6 Safety information

⚠ **See "Safety and compliance information" for detailed safety and compliance information.**

⚠ **Correct use: Any disregard of the instructions in the User Manual may result in a safety risk. Use DocUReader 2 PRO to analyze urine samples only: the device is not intended for any other application.**

⚠ **Environmental conditions: The DocUReader 2 PRO analyzer is approved for indoor use only. See "11 Maintenance" and "Appendix B Technical specifications" for further environmental limitations.**

☣ **All components of the urine analyzer may come into contact with human urine and are therefore possible sources of infection. Urine specimens should be handled at Biosafety Level 2. To prevent accidental contamination in a clinical laboratory, always wear disposable surgical gloves when handling reagents, fluids, or any part of the device. Use universal precautions and consult relevant sections of the Centers for Disease Control and Prevention manual, Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition and the World Health Organisation's Laboratory biosafety manual, Fourth edition.**

1.7 Approvals

The DocUReader 2 PRO system meets the requirements laid down in:

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

RoHS Restriction of hazardous substances The DocUReader 2 PRO system meets the requirements laid down in: Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Compliance with the applicable regulation and directive(s) is provided by means of the Declaration of Conformity.

2 SYSTEM DESCRIPTION

2.1 Principle of operation

A motor moves the test strip tray (a slide with a central channel and an embedded reference pad) that carries the test strip, under a fixed measurement unit. The analyzer reads the reference pad first, then each of the test pads on the strip in turn.

The optical unit contains four LEDs that emit light at various discrete wavelengths.

Figure 1 summarizes the electro-optical pad reading process.

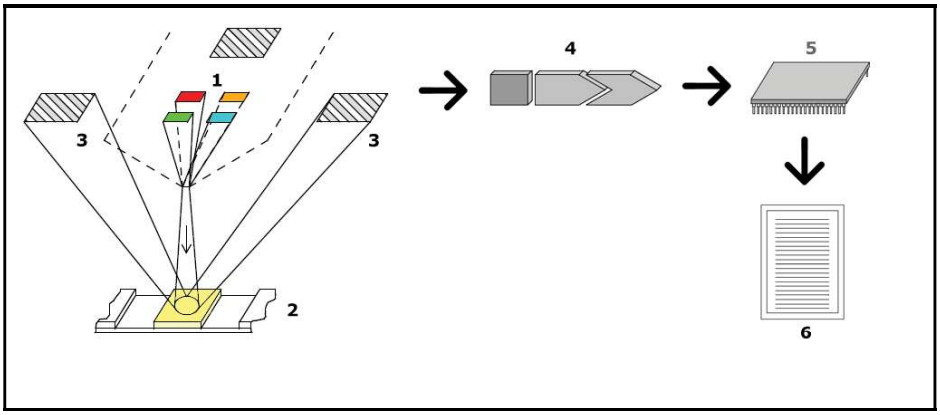


Figure 1: *Measurement principle*

Each LED (1) emits light of a predefined wavelength onto the surface of the test pad (2) from directly above the test zone. The test zone is a 3-mm circle in the center of each pad where the test reaction is optimal.

The light from the LEDs is reflected back from the test zone with more or less intensity. The intensity of the reflection is directly related to the concentration of the particular analyte in the urine that the pad absorbed. Photodiode detectors (3) positioned at optimum angles pick up the reflected light. The analogue electrical signals from the detectors are first boosted by an amplifier (4) before they arrive at the microcontroller (5). Here the A/D converter in the microcontroller changes the analogue signals into digital values. The microcontroller converts this digital data into an absolute reflectance value by comparing it to a calibration standard. Finally, the system calculates an evaluation value from the reflectance values, compares it to the predefined range limits and produces a semi-quantitative result (6).

A lead (incubation) time of about 55-65 seconds between the test strips coming into contact with the urine and the start of the measurement produce the most accurate results.

2.2 Components & functions

Figure 2: *Front and rear view of the analyzer, marked up*

Component	Function
1. Printer cover	Flips up to receive printer paper
2. Printer cover button	Opens printer cover when pressed
3. Touchscreen	Serves as an interface with the user
4. Test strip tray	Holds and moves the test strip during the analysis process
5. Power socket	Allows connection to the AC adapter
6. PS/2 socket	Allows connection to a barcode reader or a keyboard
7. Serial interface	Allows connection to a PC or a host computer
8. Type B USB port	Allows connection to a USB A-B cable and other peripheral devices
9. Ethernet socket	Allows connection to an Ethernet network
10. Type A USB port	Allows connection to various USB peripherals
11. On/Off switch	Allows switching the unit on and off.

⚠ **Use the On/Off switch to switch off the device only if the normal powering down procedure fails.**

⚠ **Use the connectors only with their appropriate plugs and operational cables.**

ⓘ *The USB ports are compatible with FAT32, ext2, and ext4 file systems, but not compatible with the NTFS file system.*

3 DEVICE INSTALLATION

3.1 Unpacking

⚠ **Read the DocUReader 2 PRO 2 User Manual carefully before installation, so as to ensure proper operation of the analyzer from the outset.**

⚠ **Follow the specified installation instructions carefully. Otherwise, inaccurate results or damage to the analyzer may occur.**

Check the carton and instrument for visible signs of damage; if seen, contact the carrier immediately.

Carefully remove the contents of the shipping carton, remove each of the wrappings and check for the following items:

3.2 Parts checklist

- Intact DocUReader 2 PRO analyzer device

ⓘ *DocUReader 2 PRO is tamper-evident: either there is a silicone seal in one of the four screw holes on the bottom panel, or there is a tamper-evident sticker next to the power socket where the two panels join. Operational elements of the device cannot be accessed without breaking the sticker or removing the silicone seal.*

ⓘ *If you find the tamper-evident silicone seal broken, you may want to cancel the warranty your company provides for the device. Follow your company's guidelines.*

- AC adapter

  (Mains requirements: AC 100-240 V, 50/60 Hz, 1.5 A Output: DC 7.5V, 3.0 A)

⚠ **Use only the AC adapter provided and always plug it into a grounded socket.**

- Mains cable

ⓘ *The shipped mains cable has a CEE 7/16 ('Europlug') plug that can be safely plugged only into a grounded CEE 7/4 socket. If your socket is incompatible with the power plug, use a plug converter or visit* **http://www.globtek.com/datasheets/pdfsnew/GTM91120-XXYY-T2T3A.pdf** *for a GTM91120-3007.5-T2 AC power supply that suits your socket.*

- Test strip tray with a clean white reference pad firmly in place.

⚠ **Do not touch the reference pad.**

- Grey check strip, two (2) pieces

⚠ **Do not touch the test area of the strip. Hold the strip by its handle.**

- Roll of printer paper

3.3 Setup considerations

⚠ **Do not use the device outdoors.**

- Make sure that you set up and operate the device on a solid level surface in an environment with fairly constant temperature and humidity.
- Do not operate the device in close proximity to sources of intense electromagnetic radiation (such as unshielded intentional RF sources).

ⓘ *The device is certified to meet the EMC requirements of IEC 61326-1:2005 and IEC 61326-2-6:2005. See* **"Appendix F Safety and compliance information"** *for further details.Do not operate the device in temperatures below 15°C (59°F) or above 32 °C (89.6 °F). See* **"Appendix A Technical specifications"***for further environmental considerations.*

ⓘ *The device displays a warning message (*"**W37**"*) if the ambient temperature is out of the operational range.*

- Do not expose the measuring head to intense light such as direct sunlight.

ⓘ *The device displays an error message (*"**E269**"*) if an external light source interferes with the strip reading process.*

- Do not set up and operate the device in an environment with vibration sources. Make sure that the strips sit and travel smoothly and stay level in the test strip tray at all times.

3.3.1 Clearance limits

⚠ **Make sure that there is enough room in front of the device for the test strip tray to move in and out of the machine freely. The DocUReader 2 PRO device can only make accurate measurements if nothing obstructs or touches the test strip tray during the measurement process.**

⚠ **Make sure that there is enough room at the back of the device to operate the On/Off switch. Make sure that there is enough room at the back of the device so that the power supply cable, the USB devices, and the cables of other peripherals are not bent, strained, or twisted.**

⚠ **Do not put anything on top of the device while it is in operation. Objects placed on top of the device may damage the touchscreen and block the printer cover.**

3.4 Setup

3.4.1 Inserting the test strip tray

⚠ **Never touch the top surface of the reference pad on the test strip tray.**

1. Handle the test strip tray by the end where the test strip channel opens, opposite the reference pad. Make sure that the test strip channel is facing upwards.
2. Push the test strip tray into the opening on the front of the device to the left of the touchscreen. Make sure that the serrated edge at the bottom of the tray engages with the stepper motor inside.

Figure 3: *Inserting the test strip tray*

3.4.2 Loading the printer

1. Push the printer cover button and open the printer cover.

⚠ **Do not touch the printer head; it may be hot.**

2. Place a roll of thermal paper into the printer roll compartment. The roll should sit straight inside the depression in the bottom. Positionthe loose end of the roll so that it is towards the printer head, not towards the rear of the device. This should ensure that the paper is aligned properly. Let a few centimeters (about an inch) of paper hang over the edge of the compartment.
3. Close the printer cover until click.

Figure 4: *Loading the printer*

ⓘ *By default, the analyzer prints measurement results automatically. You can turn off the automatic printing function on the* **Main » Options » User Options** *screen (See* **"8.3 Recalling QC results"***).*

3.4.3 Connecting the device to a computer

The device can interface with a computer via the female 9-pin D-sub serial port on its rear panel. The connections are the following:

DocUReader2		Host (PC 9-pin pinout)
1		1
2	TxD	2
3	RxD	3
4		4
5	GND	5
6		6
7		7
8		8
9		9

ⓘ ⓘ *The connected PC must comply with EN 60950 requirements.*

3.4.4 Switching the device on and off

Connect the device to the electric mains via the AC adapter and switch it on by pressing the On/Off switch at the back. The system starts up with a single beep and runs a self-check.

Figure 5: *Switching on the device*

Switch off the device by tapping the  button on the **Main** or the **Login** screen.

ⓘ *If necessary (in case the system freezes or the touchscreen fails), you can also switch off the device by pressing down on the On/Off switch for at least five (5) seconds.*

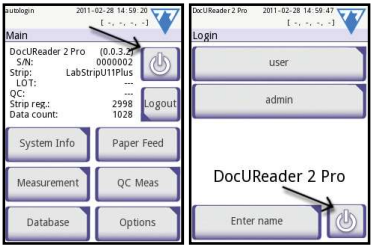


Figure 6: *Switching off the device*

⚠ **Do not disconnect the power cable while the device is in operation. Doing so can corrupt the data and damage the system.**

⚠ **Make sure that there is no strip on the test strip tray and that the tray is clean before switching off the device.**

3.4.5 Calibrating the touchscreen

⚠ **The touchscreen display is made of glass. Do not touch the screen if the glass is cracked or shattered. Glass screens are sensitive to drops and mechanical shocks.**

The touchscreen of the device is correctly calibrated in the factory, but you may want to recalibrate the display at least once a year. If you notice that the touchscreen is not responding or does not respond accurately, complete the following steps to calibrate it:

1. Switch on or restart the device.
2. While the device is booting, wait for the progress bar at the bottom of the screen to turn green. When it does, keep gently pressing down on the touchscreen until the yellow screen calibration alert screen appears.

⚠ **Do not use your finger to calibrate the Touchscreen. Use a pointing device or a pen.**

⚠ **Do not use a pointing device that could damage the touchscreen such as the tip of a pencil or the extended tip of a ballpoint pen.**

3. Wait for the actual black screen calibration screen to appear. Tap the display at the intersection of the crosshairs that appear in the corners and the center of the screen with your pointing device. Try to tap the display as close to the intersections as possible; this practice ensures the best possible alignment between the touchscreen coordinates and the LCD screen behind it.

3.5 Software updates

ⓘ *Only Adminstrator and higher access level operators can run a software update.*

The manufacturer is continuously upgrading the DocUReader 2 PRO user software, adding new features and improving usability. From time to time you will be sent a software update package for your device.

The most convenient way to enter software update files into the system is via a USB connection. When a software update package is developed, you will either receive the files via e-mail or as a downloadable, or copied onto a USB flash drive.

The following sections describe the software update procedure in each of the two cases.

ⓘ *The update process will not overwrite or delete the existing database or your active settings on the device.*

3.5.1 Using the ready-made USB flash drive

1. Switch on the DocUReader 2 PRO and wait until the system is ready.
2. Plug the USB flash drive with the software update into one of the USB A connectors at the back of the analyzer. Wait for a  (disk) icon to appear in the top right hand corner of the touchscreen.

ⓘ *The yellow disk icon indicates that the system recognized the USB device.*

3. On the **`Settings(2)`** » **`Update`** screen, wait for the **`Update`** button to light up and tap it to start the automatic update process.

ⓘ *The system detects the software update package and verifies its contents before the* `Update` *button becomes active. If no update is detected, the* `Update` *button changes to* `Refresh`*. Tap it to force the system to check the peripherals again for updates.*

4. Tap **`Restart`** when the update process is finished and remove the USB flash drive.

⚠ **You can safely remove the flash drive by tapping and pressing down for a few seconds on the logo in the top right corner of the display. The logo will turn grey and the disk icon will disappear when you lift your finger or pointing device.**

3.5.2 Using the online distributed software update package

ⓘ *You will need a USB flash drive, a PC or Macintosh to connect it to, and some basic computer skills.*

Complete the following steps to copy the software update package you received to an USB flash drive.

1. Create an 'update' directory in the root folder of your USB flash drive.
2. Unzip the software update package you received or downloaded and copy it into the 'update' directory you created.

ⓘ *The device will not be able to access the update files unless they are located in the root folder of the USB flash drive in a folder named 'update'.*

ⓘ *The following are the kind of file names you should expect to find in the update package:*

udr2base_x.x.x.tar.gz; udr2base_x.x.x.tar.gz.chk; iUD2vX, iUD2vX.chk. 'x' and 'X' stand for various numbers. 'pro' replaces 'base' in the file names if you have a DocUReader 2 PRO device.

3. Complete the steps in **"3.5.1 Using the ready-made USB flash drive".**

4 INTERACTING WITH THE DEVICE

If no bar code scanner or keyboard is connected to the device, you can interact with the system via the Touchscreen only.

4.1 Screens

The system displays messages, instructions, and options to choose from on the touchscreen to help you operate the device. You can respond to these by tapping the appropriate area onscreen.

The screen layout can be divided into three main areas:

Figure 7: *Display layout*

❶ **Header**: Displays important system information, like the date and time, current operator ID queue and status line messages.

The four placeholders below the date and time indicate, from left to right:

- the number of active errors
- the number of records in the printing queue
- the number of records in the output queue
- the number of items in the worklist

ⓘ ⓘ *The background color of the status bar is a basic notification about the system's status. It turns yellow to indicate a warning message and red to indicate an error.*

ⓘ ⓘ *Active error and warning messages can be listed by tapping the status bar area.*

❷ **Content navigation bar:** Indicates the current section of the system you are working in. The navigation bar lets you keep track of your location within the menu structure. **'»'** is the hierarchy separator character.

❸ **Content area:** The primary operation area of the Touchscreen. If the 'autologin' operator is enabled (See **"18.15.2 System security settings"**), the first main screen you see is the **Measure** screen. In the work area you can start a measurement, switch strip type, handle the worklist, cycle through the worklist items and go to the **QC**, **Main** and **Data** screens.

This part of the screen will sometimes also display instructions, feedback, or error messages.

4.2 Touchscreen operation

You can operate the touchscreen with bare fingers, gloved fingers, ballpoint pens with retracted tips, or any stylus-like object. You need to tap the touchscreen gently but firmly in a touch-sensitive area to get a response. Generally, the screen areas that have frames around them respond to tapping: buttons, check boxes, radio buttons, and text boxes.

⚠ **The touchscreen display is made of glass. Do not touch the screen if the glass is cracked or shattered. Glass screens are sensitive to drops and mechanical shocks.**

ⓘ *A separate foil layer is attached to the screen to prevent liquids from leaking into the system.*

ⓘ *Sound effects are on by default and the system confirms successful tap events with a short clicking sound.*

4.2.1 Buttons and screen input areas

Buttons

You can use rectangular buttons to trigger actions and to navigate menus. Buttons come in several sizes. An indicator in the bottom left or the top right corner of a button indicates whether it has a menu navigation function.

Indicator in the bottom left corner: Tapping such a button closes a screen and moves you back up one level in the menu hierarchy.

Indicator in the top right corner: Tapping such a button opens a new screen and moves you one level down in the menu hierarchy.

Special buttons

 Apply	 Drop	 Left
 Up	 Down	 Right
 Inactive buttons are dimmed		

ⓘ *You can also use the 'Up' and 'Down' buttons to scroll through lists.*

ⓘ *You can also use the 'Left' and 'Right' buttons to cycle through values.*

Navigation buttons

	Back		Apply Modifications and Next (Apply & Next)
	Next		Drop modifications and Back (Drop & Back)
	Back (Return)		Forward (More)

Confirming changes

You can confirm any changes you made on **User options** or a **Settings** screens by tapping **Apply** and leaving the screen with the **Back** button.

  Drop &Back Apply	  Back
Changes are still not saved	No changes or changes are saved

To cancel the modifications simply tap the **Drop&Back** button before applying the changes.

Check boxes

Check boxes are displayed when you can decide to enable or disable an option (such as **Autostart**, see "9.4 User Options") or when you can select one or more options from a set of alternatives (for example the **QC options alternatives**: **Forced QC, L2, L3,** see "8.1 Quality control options")

Radio buttons

These buttons typically appear on screens that require a selection out of several items. Tap an empty button to select it. A dot in the middle of the button will indicate that it is now the selected option.

Text boxes

Text boxes are for alphanumeric data input. To edit a value in a text box, tap the input area. A cursor (|) appears in the input area when it is active.

4.2.2 Entering data via the touchscreen

When the screen prompts you to enter information, a numeric or alphabetical keyboard appears on the screen.

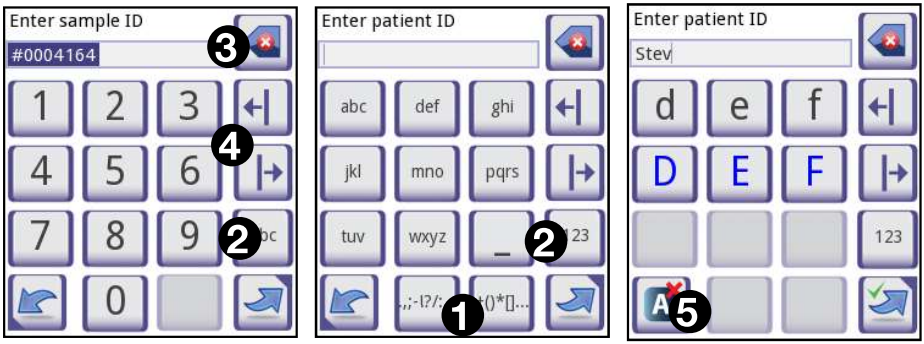


Figure 8: *Numerical, lowercase, and uppercase input*

Numbers can be entered easily. To enter an alphabetic character first tap the button representing the character group it belongs to, then select the specific lower case or upper case character you want. To enter special characters use the **.,;-:+*…** or the **()[]** buttons (❶)to go to the selection list. To switch between the numeric and alphabetic keyboard, use the **123** and the **abc** buttons respectively (❷).

You can erase data with the backspace (❸). You can move the cursor with the left and right buttons (❹). To cancel the entry of a character from the current selection, tap the button marked ❺. When you finish entering the information, tap **Apply** or **Apply&Next**.

4.2.3 Entering data via a barcode reader or a keyboard

Peripherals like a keyboard or a barcode reader can not only speed up the sample management workflow but improve data entry accuracy and reduce transcription errors.

Using a barcode reader:

Connect the barcode reader to the PS/2 or USB port at the rear of the device. Barcode readers can be used to enter the following information: sample ID, patient ID, QC LOT number, registration code, strip LOT number. No external power supply is necessary.

⚠ **Make sure that the barcode reader you use supports ALT mode, and select this mode of operation before using it with the DocUReader 2 PRO device.**

The following barcode reader models have been successfully tested with DocUReader 2 PRO:

- o CipherLab CL1000
- o DataLogic QuickScan I QD2100
- o Datalogic Touch 65 Pro
- o Intermec Scanplus 1800 SR

Using a standard PC keyboard:

Connect the keyboard to the PS/2 or USB port at the rear of the device.

When an input field (Sample ID, Patient ID, Operator ID, and so on) is active, no keyboard shortcut is needed to enter data in the system. Press 'Backspace' to delete characters and 'Esc' to cancel the input and move back to the previous screen. Press 'Enter' to accept the entered value and to move on to the next screen.

You can also use the keyboard to navigate between screens or to perform actions as an alternative to using the touchscreen.

Press 'Ctrl' to display the keyboard shortcuts on the screen. The relevant shortcuts will appear in the top left corner of the buttons.

Another option is to cycle through the onscreen buttons using the 'Tab' key. Every time you press 'Tab', a crosshairs pointer will move one button to the right, indicating the targeted button. Press 'Shift' and 'Tab' together to move the crosshairs to the left and 'Enter' to select the targeted button or text box.

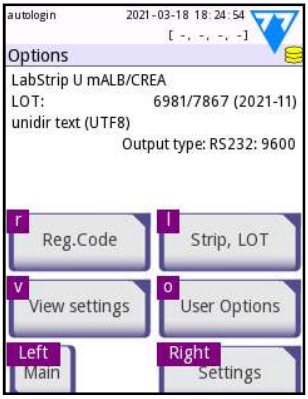


Figure 9:
The Options screen with keyboard shortcuts displayed above the onscreen buttons

5 START-UP WIZARD

The first time you switch on a DocUReader 2 PRO device, you will enter a quick setup procedure. Here you will be able to customize the basic options of the device to suit your needs.

The **Start-Up Wizard** will allow you to specify the following settings:

- Language
- Date and time (**"10.3 Date, time"**)
- System security (**"10.16.3 System security settings"**)
- Change the 'supervisor' operator's password

ⓘ *Optional: depends on the security level you selected.*

- Test workflow (**"10.6 Measurement"**)
- Printout (**"10.4 Printout"**)
- Quality control (**"8.1 Quality control options"**)
- Operators (**"10.16.2 Operator access levels overview"**)

ⓘ *Optional: depends on the security level you selected.*

ⓘ *If you wish to skip the wizard and walk through it at a later time, tap* **Skip** *on the second screen.*

ⓘ *If you require further information about the settings, see* **"1 Introduction"***.*

At the end of the setup procedure, tap **Start** to exit the wizard.

You can review all settings on the **Options » View** settings screen. All settings, including connectivity (See **"10.5 Output (Connectivity: Transfer/Export)"**) can be modified on the **Options » Settings** screens.

6 TESTING

The analyzer can be set up to be as simple or sophisticated as you prefer. You may simply insert a dipped urinalysis strip into the analyzer and the result will be reported. By modifying the user options the measurements can be started, printed and transferred automatically.

Alternatively, you have the option to enter the Sample ID, Patient ID, and color, clarity of the specimen manually (See **"6.2 Test features and customization"**). The walkthrough for full testing is found in **"6.3 Full Test".**

The analyzer can be operated in two different modes:

1. In normal mode, the system automatically waits for the strip to incubate for 1 minute before it reads the first test pad. This is the default mode and the throughput in this mode is approximately 50 strips per hour.
2. In fast mode, which can be selected at User Options, the test strip is measured directly after starting the test. In this case, it is up to the user to time the incubation period outside the analyzer (see **"6.2.1 Features: Autostart, -print, -transfer and fast mode"**).

ⓘ *If you require more information regarding use and storage of test strips, please refer to the strip's instructions of use.*

6.1 Quick Test

After switching on the instrument starts with the **Measurement** screen.

ⓘ *The Measurement screen can also be directly reached from the **Main** and **Database** screens.*

The test strip tray has to be correctly loaded into the reader. Have the test strip, urine sample and paper towel ready too.

1 Dip the reagent strip into the urine sample, wetting all pads. Immediately remove the strip from the urine.

2 Drag the edge of the strip against the side of the sample container as you remove it.

3 Blot by touching the edge of the strip to a paper towel to remove excess urine.

4 Place the reagent strip in the channel of the table with the test pads facing up.

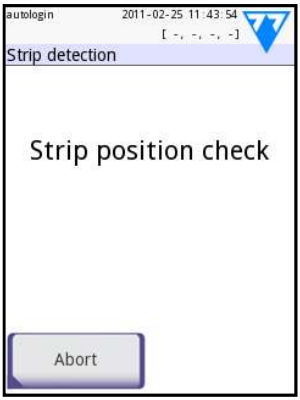
5 The instrument will automatically detect an applied strip. The measurement cycle will be started.

If the “Autostart” is deactivated, the measurement must be started using the **Start** button.

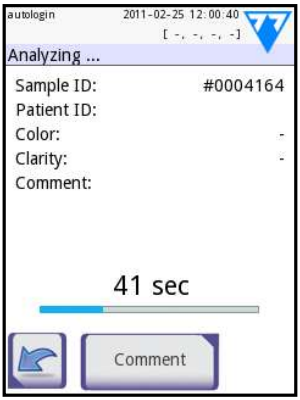
⚠ **Do not use damaged strips.**

⚠ **Do not push or pull the test strip tray.**

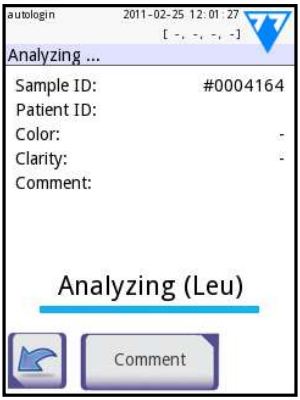
ⓘ *DocUReader 2 PRO will perform a sequence of checks (reference pad, strip detections (position of, slipped strip, dry strip, etc.) each time a test is run. See "6.2.3 Strip checking events" for more information.*



6 The strip position is checked before measurement.



7 A timer will count down the time remaining for analyzing the strip.



8 The analysis of the strip pads will begin.

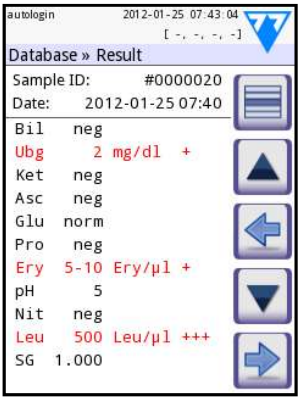
⚠ **To abort a measurement press the Back icon on the Analyzing screen and press Stop/Drop on the Measurement screen.**

⚠ **Comment can be also added during the countdown time.**

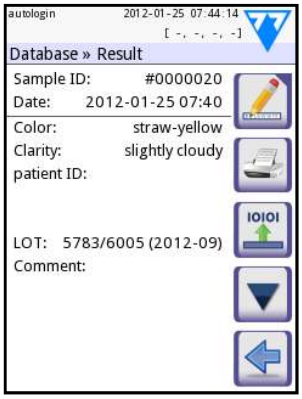
After approximately 60 seconds the pad results will be displayed on the screen and the test strip tray is automatically moved out of the analyzer.

⚠ **The buttons remain inactive until the tray is fully moved out.**

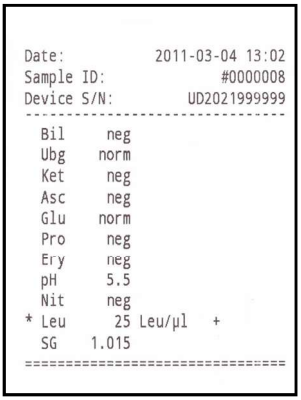
- **If Autostart is ON:** The result screen will be displayed until you remove the test strip from the tray. Once the strip is removed, the display automatically returns to the **Measurement** screen.
- **If Autostart is OFF:** The result screen will be displayed for approximately 5 seconds –while displaying a circle animation–, than the display will return to the **Measurement** screen (if no error occurred during the readout). If you touch the display while the circle animation is displayed, the system will not automatically return back.



9 Results Page 1/2



10 Results Page 2/2



11 Printed results

The pad results are displayed on the first page. Positive findings are clearly marked with red text on the display. To view the remaining test results, touch the **Right** icon on the screen.

The printout is light-sensitive and may turn yellow when exposed to light during storage. Test results which diverge from negative or normal values are flagged with an asterisk before the parameter concerned. The printout can be fully customized, see **"10.4 Printout"** for more details. For archiving purposes the printouts should be kept in a dark place (patient file) or as a photocopy.

Functions on the result screen

- By pressing the **Delete** button the result can be dropped.
- By pressing the **Printer** button the result can be printed.
- By pressing the **Transfer** button the result can be transferred.
- To go back to the **Measurement**, press the **Meas.** button.

How to modify the result?

Results can be modified by pressing the **Edit** button on the second result page, before the record is printed or sent.

All fields can be modified except date and pad results, even if the particular field was not available during the acquisition.

Before performing the next measurement

From the test table, remove the used urinalysis strip and dispose of it according to your standard laboratory procedures. Wipe the table insert, if necessary.

6.2 Test features and customization

The testing process can be customized to the need of the laboratory. The measurement feature settings define what activities related to testing process (start) are automatically performed by the instrument. The measurement settings define the activities performed by the analyzer and the collected information.

6.2.1 Features: Autostart, -print, -transfer and fast mode

The measurement features can be modified on the **Main»Options»User Options** screen.

- **Autostart**: if enabled, measurement is automatically started (without further user interaction) if a strip is placed on the test strip tray. By using this feature the instrument can operate “touch-free” (if all the additional data fields are disabled). Default value: enabled.
- **Auto print**: if enabled, the analyzer automatically prints the report of each measurement. Default value: enabled.
- **Auto transfer**: if enabled the analyzer automatically transfers the result to the defined output (i.e. through the serial port to an LIS). Default value: disabled.

ⓘ *These features can be modified by any operator and stored separately for each operator.*

- **Fast mode** (serial reading): if enabled, the test strip is measured directly after **Measure** is pressed on the **Measurement** screen (note: in fast mode the large start button is renamed to **Measure** and the background is changed to orange). In this case, it is up to the user to time the incubation period outside the analyzer. When working in **Fast Mode**, ensure that you have a foolproof system for matching sequence numbers to samples.

ⓘ *The status of fast mode cannot be saved. After logout or system restart the analyzer always starts in **Normal** mode.*

⚠ **When performing serial measurements in Fast Mode, allow the strips to react for approximately 60 seconds before inserting them in the analyzer and pressing MEASURE. False-low or false-negative results may be obtained for some parameters if the reaction time is too short. Likewise, false-high results may be obtained for some parameters if the incubation time outside the analyzer is too long.**

The option to enable **Fast mode** only appears on the **User options** screen, if this option is enabled on the **Settings»Measurement** screen.

6.2.2 Customization of testing

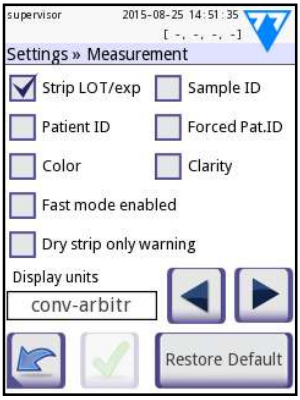


Figure 10:
Settings » Measurements

On the **Settings»Measurement** screen you can customize which fields are enabled during acquisition, to disable fast mode at the system level or to allow analysis of (partially) dry strips and modify the settings. You can set the display units here as well.

By default all extra fields are disabled and the display unit is set to conv-arbitr.

Strip LOT/exp: If you select this box, the system will prompt you to enter the strip LOT number you currently use with the expiry date at every single measurement. The system stores the information and at the next measurement it is enough to confirm the displayed data.

Sample ID: By default the system assigns each reading with a consecutive sequence number of maximum seven (7) digits. If you select this box, the system will prompt you to enter an ID for the sample that you are analyzing.

Patient ID: If you select this box, the system will prompt you to enter an ID for the patient whose urine sample you are analyzing. The system does not assign a default patient ID.

Forced Patient ID: If you select this box, the system will require you to enter an ID for the patient whose urine sample you are analyzing. The measurement wil l not continue, if the Patient ID textbox is not filled in.

Color: If enabled, you can set the visually observed color of the sample during the test.

Clarity: If enabled, you can set the visually observed clarity of the sample during the test.

Fast mode enabled: If you select this box, the Fast mode button becomes available on the User Options screen (see **"9.4 User Options"**).

Dry strip only warning: If you select this box, the system will save the full analysis results of a dry strip or partially dry in the database with a warning message. If you leave it unchecked, the system will only save an error message (E261) and no results for dry or partially dry strips.

Display units: You can change the units the system displays the results in. Available options: conv-arbitr, SI-arbitr, conv, SI, and arbitr.

ⓘ *Use*  *to scroll between the options.*

6.2.3 Strip checking events

Errors in sample handling and testing procedure may lead to false results. In order to further improve the diagnostic decision making process advanced strip recognition features were introduced in DocUReader 2 PRO.

The outcome of these features is categorized into three groups:

- R1. Measurement is not started
- R2. Result is saved with a warning message
- R3. Result is saved with an error code

The analyzer automatically recognizes the following events during testing:

Feature	Outcome	Time of action
slipped test strip	R3	after third failed check
(partially) dry strip	R2/R3	after testing
upside-down strip	R3	before incubation period
background light too strong	R2/R3	during measurement

If the result is saved with a message, the pad values are listed and the code and the description of the warning is inserted into a new comment field of the result. To search for results with a warning, use the “with comment” extra filter in the database (see **“7.3 Setting up filters to find specific results”**).

ⓘ *Please note that this filter will also list results with comments inserted by the user.*

If the result is saved with an error, only the error code is visible. To search for results with an error code, use the “false meas.” extra filter in the database.

Slipped strip

The front of the test strip has to be at the leading edge of the test strip tray. Systems check for misposition:

1. Before the incubation time: warning window is displayed with two choices: 1. drop testing and restart with new strip; 2. reposition strip and repeat measurement. Choice is available during the incubation time.
2. Before the measurement: warning window is displayed with two choices, but repeating is limited for 10 seconds. In case of successful repositioning

the result will be flagged as 'Overincubate' (R2). After 10 seconds only 'cancel testing' option is available.

3. After the measurement (R3): result is stored with an error code ('Measurement error: strip position error')

Partially dry strip

The evaluation takes place after the measurement based on the reflectance data of the last pad. Based on the configuration settings (see "6.2.2 Customization of testing") the result is saved either with a flag (R2) or an error code (R3).

6.3 Full Test

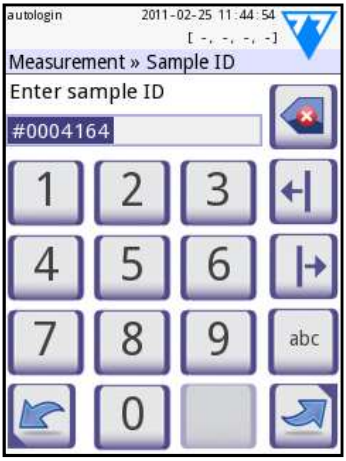
The description of the required preparations and the testing process can be found at **"6.1 Quick Test".**

This section only provides additional information on the data input process presuming that all additional fields (sample ID, patient ID, color and clarity) are enabled.

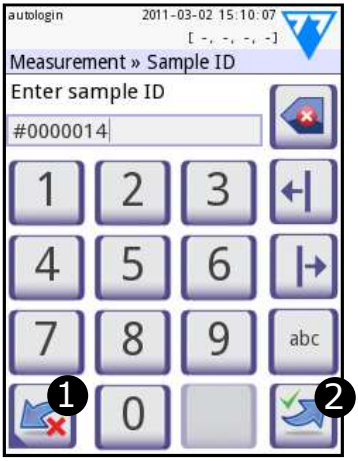
The data input is started after strip position check. The first screen appears when the test strip tray is moved back to the home position.

The sequence of the data input is Sample ID ⇨ Patient ID ⇨ Color ⇨ Clarity.

If a field is disabled at **`Settings` » `Measurement`**, the input screen won't appear for it



Sample ID: unique sampleID is assigned by default. To change it, use the onscreen keyboard, the attached keyboard or the barcode reader. Maximum 14 characters. Sample ID must not be empty.

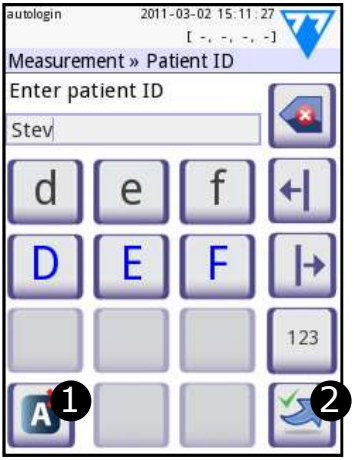


Sample ID: Automatic ID was changed, you can either ❶ cancel the change (press **Drop&Back**) or ❷ apply it and proceed to the next screen (press **Apply&Next**).

ⓘ *Reading a sample ID or patient ID with barcode will automatically take you to the next screen.*

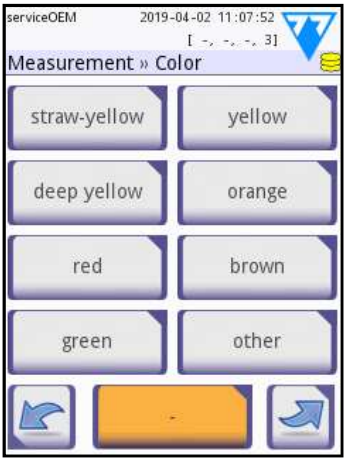
ⓘ *If you require further instruction regarding barcode reader or keyboard usage see* **"4.2.3 Entering data via a barcode reader or a keyboard"**.

Patient ID: Use the onscreen keyboard, the attached keyboard or the barcode reader to enter the patient ID. The Patient ID field can be left empty. In this case press Next button at the bottom right corner to move to next screen. Maximum 32 characters.

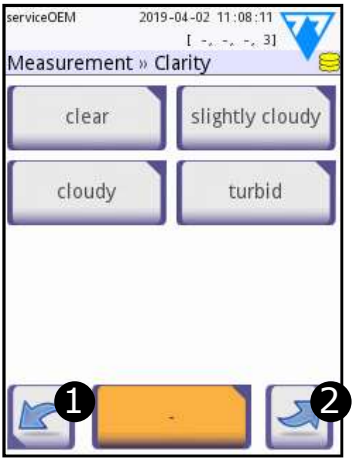


Patient ID: Touch ❷Apply&Next, when you have finished entering the patient ID and proceed to the next screen. To select a new character, press ❶. To abort and go back to the Sample ID screen, press Drop&Back[1].

[1]The Drop&Back icon does not appear on the sample screen because the character input is active.



Color: To select the visu-ally determined color of the urine sample press the appropriate button. This will also take you to the next screen.



Clarity: To select the vi-sually determined clarity of the urine sample press the appropriate button. This will also take you to the next screen.

ⓘ *You can select only one color and clarity type for a urine sample.*

After all data have been entered the next screen displayed will either be:

- Analyzing — if the strip is still being analyzed
- Result — if analyzing the strip has been completed

It is not required to input all data during the incubation time, the system will analyze the strip in the background and move out the test strip tray.

Once you have finished the data input, the **Result** screen will appear.

If Autostart is ON:

The result screen will be displayed until you remove the test strip from the tray. Once the strip is removed, the display automatically returns to the **Measurement** screen.

If Autostart is OFF:

The result screen will be displayed for approximately 5 seconds –while displaying a circle animation– then the display will return to the **Measurement** screen (if no error occurred during the readout). If you touch the display while the circle animation is displayed, the system will not automatically return back.

6.4 Worklist

The worklist is a predefined sequence of samples and contains the sample IDs and patient IDs in the sequence of planned evaluation. Tap the **Worklist** button on the **Measurement** screen to go to the worklist management. The worklist can be generated manually through the touchscreen, or a connected external keyboard or barcode reader, or automatically by downloading the worklist items from the LIS.

Figure 11:

The Worklist screen with the screen elements labelled

1 Worklist items
2 Delete active item
3 Delete all items
4 Download worklist from LIS
5 Search for sample ID
6 Move up by one record in the list
7 Modify item
8 Move down by one record in the list
9 Add new item
10 Action: select actual item
11 Print worklist
12 Return to Measurement menu

On the **Worklist** menu you can:

- Manually add, modify, delete the worklist items
- Download the worklist from the LIS
- Modify the sequence of the items
- Search for a sample ID in the worklist
- Print the worklist
- Delete the whole worklist

6.4.1 Creating worklist

ⓘ *If the worklist is empty, only the*  *and the*  *buttons are active. The other buttons are active if the worklist contains at least 2 items.*

1. Tap the **Main** button on the **Measurement** menu then **Worklist** button on the appearing **Main Menu** screen.
2. Use the **Add new item** button to add a new entry to the list.
3. Set the sample and patient ID and select the reagent strip:

- **Reagent strip**: It is possible to add multiple reagent strip types for the same sample and patient. They will be listed separately in the Worklist.
- **Sample ID:** The sample ID is a numeric string of up to 14 characters. A unique sample ID is assigned by default. To modify the default sample ID, use the touch screen keyboard, the connected keyboard or the barcode reader.

  Once you have modified the default Sample ID, you can either cancel the change by tapping **Drop&Back** or store the modified Sample ID with the record by tapping **Apply&Next**.

ⓘ *The system does not allow you to leave the Sample ID text box empty.*

- **Patient ID:** The patient ID is a string of up to 32 characters and can contain numeric, alphabetic, or special characters. Use the touch screen keyboard, the attached keyboard or the barcode reader to enter the patient ID. Tap **Next** to leave the **Patient ID** field empty. Tap **Apply&Next** when you have finished entering the patient ID and proceed to the next screen. To abort and go back to the **Sample ID** screen, tap **Drop&Back**.

ⓘ *By using external keyboard or barcode reader the editing process can be speeded up considerably. The new item will be added to the end of the list.*

4. When you return the **Measurement** screen with the **Back** button, the sample ID of the first worklist item will be shown in the list window.

6.4.2 Worklist from LIS

1. Tap the **Main** button on the **Measurement** menu then **Worklist** button on the appearing **Main Menu** screen.
2. Use the **Download worklist from LIS** button to download worklist from LIS.

6.4.3 Worklist management

6.4.3.1 Modifying and deleting worklist items

Worklist items can be modified by moving the cursor bar over them using the **Up** and **Down** arrow buttons and tapping **Modify item** button. The appearing input screens let operators making changes.

If a worklist item must be deleted, tap **Delete active item** button when the cursor bar is over it. Tapping **Delete all items** button erases every item on the worklist.

6.4.3.2 Changing the worklist order

New items always added to the end of the list notwithstanding the possible numeric order of the sample IDs. The sequence can be changed with one item at a time.

1. First go to worklist. Using the **Up** and **Down** arrow buttons place the cursor bar over the item you would like to move.
2. Select item by tapping **Select actual item** button. The button turns orange indicating that the selection has been made and you can move the item.
3. Using the **Up** and **Down** arrow buttons move the item on the list notwithstanding the possible numeric order.

ⓘ *If measurement is already started, change the sample ID during incubation time on the Measurement»in progress screen. To go through the sample IDs, use the Right and Left arrow buttons next to Sample textbox.*

6.4.3.3 Working outside worklist

When there are items on the worklist, the analyzer recording measurement results using the list, starting with the first sample ID and going down the list. If there is an urgently needed results and items are on the worklist, DocUReader 2 PRO still able to evaluate the new sample. Simply use the left or right arrow to cycle to the beginning or end of the list, so an automatically generated sample ID will appear in the window. In this case the (generated) text will appear under the sample ID.

7 RECALLING RESULTS

The DocUReader 2 PRO device can store up to 3000 measurement records. Every result is automatically saved after the analysis in an indexed database. Using the database, you can search, view, and print analysis records, or transfer them to an external device.

ⓘ *By default, the analyzer prompts you to free up memory (erase data) 30 records before reaching maximum database capacity. However, you can modify database settings and instruct the system to use a circular memory.*

ⓘ *For more information on database settings see* **"10.8 Database management"**.

You can access the database

- from the **Measurement** screen by tapping **Data**
- from the **Main** screen by tapping **Database.**

7.1 List view

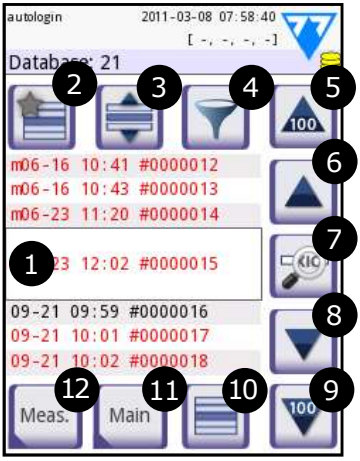


Figure 12: *Database - List view*

Key to the screen

1. Results list
2. Actions with selected records (**Database** » **Selected** screen)
3. Tap this button to make continuous selections using the up and down buttons on either side of a previously selected record. (This feature is similar to pressing down the 'Shift' key while clicking with the left mouse-key on a PC. See **"Multiple selection 219"**)
4. Set up filters to find specific records
5. Move the row cursor up by 100 records in the list
6. Move the row cursor up by 1 record in the list
7. View item (in the case of failed results, their relevant error message will be displayed)
8. Move the row cursor down by 1 record in the list
9. Move the row cursor down by 100 records in the list
10. Select current record
11. Go to the **Main** screen
12. Go to the **Measurement** screen

The records have the following color coding:

Black text:	Negative result
Red text:	Positive result
Ochre text:	Failed result

ⓘ *If you access the database from the **Measurement** screen, an automatic predefined filtering is applied and only the results measured on the current date are displayed. If you access the database from the **Main** screen, no automatic filtering is activated.*

ⓘ *The test results belong to LabStrip U mALB/CREA reagent strip is marked with 'm'.*

To view details of a urine test result, tap View (number 7 in the key). The first page of the patient's result will be displayed on the screen.

Tap  to see the second page of the selected record.

7.2 Result view

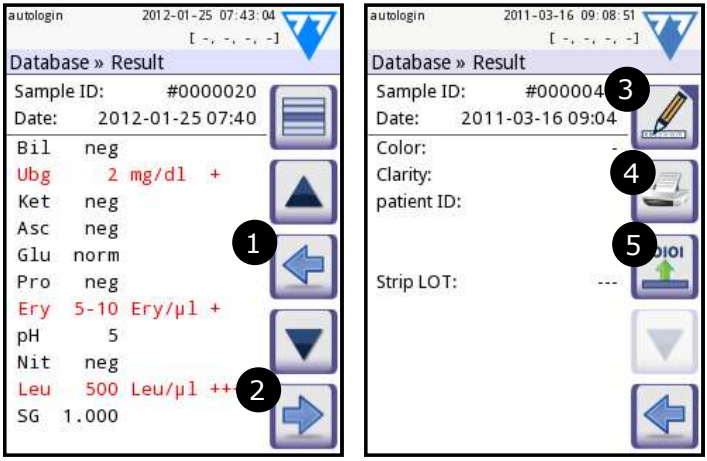
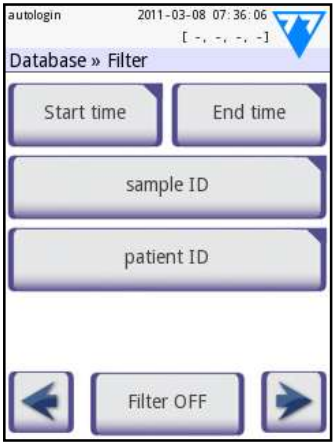


Figure 13: *The Results screen page 1 and 2*

The results for the reagent pads are listed on the first page. Use the up and down arrows to navigate the results. Tap ❶ **Return** to go back to list view. To view the second page of the results, tap the ❷ **More** button. On the second page the action buttons are displayed for the given record: ❸ **Edit**, ❹ **Print**, ❺ **Send for output**.

ⓘ *The* **Edit** *button is only active if the result has not yet been printed or transferred.*

7.3 Setting up filters to find specific results



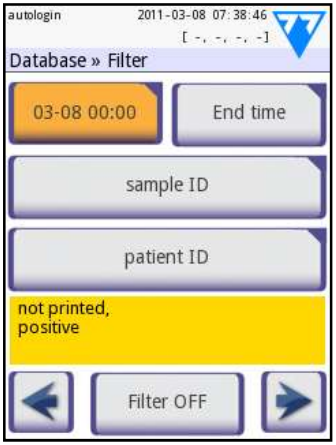


Figure 14: *The Database » Filter screens*

To narrow down the list of results DocUReader 2 PRO features a sophisticated filtering engine. You can set the following parameters as filtering criteria:

- Date and Time
- Sample ID
- Patient ID
- Status:
  - not printed
  - not transferred
- Additional information:
  - negative
  - positive
  - sediment recommendation
  - false (an error message is returned instead of measurement results)
  - with comment (including warning messages)
  - self measured (records that the operator setting up the filter created).

Tap the corresponding button to activate a filter.

Figure 15: *Examples of activated filters*

The background of active filter buttons changes to orange. Active filters from the second page appear above the navigation buttons on the first page of the **Filter** screen.

Tap **Filter OFF** to switch off filtering.

Tap **Return** to return to the list of results.

7.3.1 Filtering based on date or time

When setting up filters based on a time period, use the **Filter » Start time** and **Filter » End time** screens to define the start and the end of the time frame you want to filter, respectively.

By default, the **Day** field is active. Use  to modify the value of the selected field. Use  to move the row cursor.

Tap **Today** to set the beginning or end of the current day.

Tap **Switch** on to set the moment the device was last switched on as the start or end of the filtering period.

Tap **Cancel** to discard the changes and return to the filtering overview screen preserving previous filter settings.

Tap **Apply** to apply the changes and return to the filtering overview screen

Tap **Clear** to clear the start/end filter and return to the filters overview screen.

7.4 Selecting results

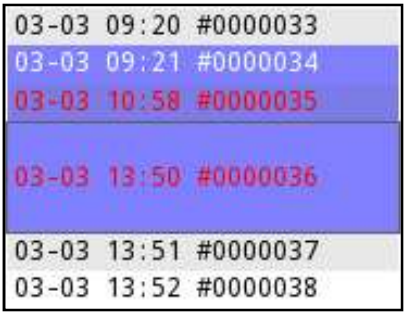


Figure 16: *Selected results in a cropped list view*

Selected records are indicated

- by a blue record entry background in list view
- by the blue Sample ID row background in result view.

In list view, the number of selected results is displayed in parentheses in the navigation bar.

7.4.1 Types of selection

Single selection

Tap  to select/deselect a single record in list view.

Multiple selection

Tap  to activate the 'single-tap continuous selection' feature. When this button is activated  (indicated by an orange background), you can select multiple records on either side (below or above) of a previously selected record. (This feature is similar to pressing down the 'Shift' key while clicking with the left mouse-key on a PC.)

Select all

Tap **Select all** on the **Database** » **Selected** screen to select every record.

Invert selection

Tap **Invert selection** on the **Database** » **Selected** screen to invert the current selection (deselect currently selected records and select currently deselected records).

Clear selection

Tap **Remove selection** on the **Database** » **Selected** screen to clear all previous selections.

7.5 Actions with selected items

ⓘ *If no record is selected, the action buttons are dimmed.*

Delete

Tap **Delete** on the **Database** » **Selected** screen to delete selected record or records. A dialog box will appear to confirm the action to prevent accidental loss of data.

Print

Tap **Print** on the **Database** » **Selected** screen to print the selected record or records.

Send for output

Tap Output on the **Database** » **Selected** screen to send the selected record or records.

8 QUALITY CONTROL TESTING

The performance of the system (analyzer and reagent test strips) should be monitored regularly to that ensure reliable results are obtained. To determine the frequency of quality control, consult your facility's quality control policy.
The following possibilities are offered to perform QC tests:

Type	Control
Check strip	Analyzer
L1, L2 or L3 (One-, two- or three-level) urine control solutions,	LabStrip U11 Plus test strips, LabStrip U mALB/CREA test strips

ⓘ *Several commercial controls are available. Control solutions may vary in the number of levels or components, the necessity for reconstitution or readiness for use, or the type and volume of container. 77 Elektronika Kft. recommends Quantimetrix Corporation Dipstick controls as these control solutions provide the necessary color development with LabStrip U11 Plus strips. For quality control of LabStrip U mALB/CREA 77 Elektronika recommends using the CombiScreen Dip Check (Analyticon Biotechnologies AG), the CombiScreen Drop Check (Analyticon Biotechnologies AG) and Microbumin Microalbumin Control / Level 1&2 (Quantimetrix Inc.) Other manufacturers' controls may provide abnormal results due to non-specific colorations of the test pads.*

⚠ **Verify the performance of the reader with the check strip after every accident (drops, spills, splashes), even if visible damage was not done.**

The supplied grey check strip can be used only as a mechanism to confirm the functionality of the analyzer.

The use of urine controls is highly recommended particularly in the following situations:

- monthly on each previously opened vial
- whenever a new vial of test strips is opened,
- whenever test results are in doubt,
- when new operators are trained on the system.

The urine control solutions are analyzed using a regular urine test strip as if it were a regular patient sample.

Proper quality control is a three-phase process:

1. Configuring the system: specifying urine control levels, setting upforced QC, and QC lockout on the **Options » Settings » QC Options** screen. See **"8.1 Quality control options"**.
2. Setting the urine control LOT number and the acceptance limits. See **"8.1.1 Editing QC LOT Information"**.
3. Performing QC testing at regular intervals. See **"8.2 QC Testing"**.

8.1 Quality control options

You can configure quality control settings for the device on the **Options** » **Settings** » **QC Options** screen

Figure 17: *The QC options screen*

The screen offers the following options:

- enabling/disabling QC lockout
- setting the QC lockout interval in days
- specifying the type of QC lockout (warning or forced)
- specifying the type of control solution used
- editing the QC solutions' LOT data
- deleting the LOT data and acceptance limits set for control solutions not in use (**Cleanup**).

Enabling QC Lockout will make sure that a quality check using the control solutions is performed regularly at the intervals you determine. If QC lockout is enabled, the device will become nonoperational after the time period that is set here is over, unless you perform a quality check.

To enable QC lockout and set the interval before the next QC in days, tap or tap inside the grey text box and use the numeric input screen.

ⓘ *When you apply changes to the QC lockout period, a pop-up window appears with the modified lockout time*

You can choose between two lockout modes by checking or unchecking the **Forced QC** check box.

Figure 18:
Forced L2 Quality control

- Warning  Forced QC

  When the QC lockout period is over, the status bar background changes orange and a warning message (**"W33"**) is displayed.

- Forced  Forced QC

  In this mode, when the QC lockout period is over, the status bar background changes to red and an error message (**"E89"**) is displayed. With forced QC lockout, the measurement function is disabled until a successful QC check is performed.

The QC check can be set for

- L1: negativ/normal
- L2: positive/abnormal,
- L3: high positive/abnormal

control solution checks, either individually or all together by ticking their checkbox.

ⓘ *If user security is set high on the system (See* **"10.16.5 Security settings overview"***), normal users will not be able to modify the QC settings, so the QC policy determined by the system administrator will be enforced. For example, only operators with Administrator or higher security level can override the QC lockout and perform a measurement without first doing a quality check.*

LOT expiry lockout: If **ON**, Expiry date must be entered. In case of entering LOT and a date after it in brakets, it is going to be the expiry date. It works with solution and strip LOT, too.

8.1.1 Editing QC LOT Information

⚠ **The QC evaluation relies on manually entered data. Double-check the values before activating them.**

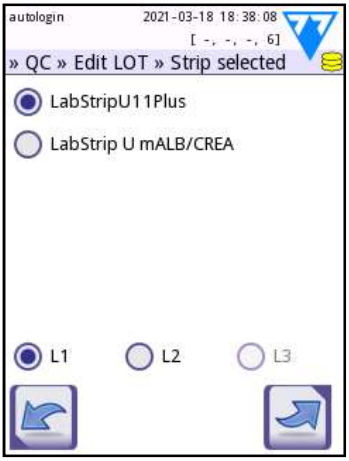


Figure 19: *Select QC level*

1. Tap **`Edit QC LOT`** on the **`QC options`** screen to enter the QC Urine Control solution LOT numbers and the acceptance limits for the solutions.
2. Select the type of control solution (L1, L2, L3) you will be using, and tap **`Next`**.
3. Enter the solution's LOT code then tap **`Next`**. If a LOT code is already stored for the current type of control solution, this will appear in the input field. The input field is otherwise empty.

   You can also enter the expiry date for the QC solution lot. Separate the expiry date from the lot number by putting it in parentheses. Use two digits for both the year and the month data, and separate the year and the month with a slash (/), a hyphen (-), a dot (.), or an underscore (_).
4. Consult your control solution's package insert and enter the acceptance limits for the type of control solution selected in step 2.

8.1.2 Setting QC solution acceptance limits

Figure 20: *The QC limits screen*

The columns of the table are, from left to right: parameter, lower limit, higher limit, unit.

A cursor box indicates which cell is selected (In Figure 20 this is the High pH limit cell.)

1. Use the arrows to navigate the cells and the plus and minus buttons to increase or decrease the values.
2. When you have finished, tap **`OK`** to store the values. You will be returned to the **`QC options`** screen.
3. Repeat the previous steps for each type of control solution.

ⓘ *QC limit definition is not possible for ACR and ACR interpretation.*

8.2 QC Testing

The QC measurement buttons are color coded:

- **If QC lockout is disabled**,

  - grey means no measurement is stored,

  - green means a valid measurement was made while in the **QC Measurement** menu, and

  - red means an invalid measurement was made while in the **QC Measurement** menu.

- **If QC lockout is enabled**,

  - grey means no measurement is stored,

  - green means a valid measurement was made within the time limit, and

  - red means an invalid measurement was made within the time limit.

ⓘ *The strip type of the given QC measurement is marked in the header.*

1. Go to the **Measurement » QC** or the **Main » QC Meas** screen.
2. Apply the negative (Low) or the positive (High) solution to the test strip following the instructions in the control solution and the test strip package inserts.

ⓘ *The solution button text is changed to „Stip LOT" and disabled on QC Measure screen when LOT expiry is enabled but no valid solution LOT is registered in the instrument.*

3. Place the strip on the tray and tap **...Solution 1** for a negative control solution, **…Solution 2** for a positive control solution, or **…Solution 3** for a 'High positive' control solution, if you are using a three-level control solution kit. If you have previously entered a LOT number and acceptance limits for the given solution type on the **QC Options** screen, the system will display this LOT number on the LOT input screen. If the LOT number is correct, tap Next  .

⚠ **If you enter a new LOT code on the numeric input screen, you will also have to set new acceptance levels after tapping Next.**

ⓘ *If the quality check is successful, the system displays 'PASSED' next to the QC result ID. The button background for passed QC tests changes to green. If the QC measurement has failed, red FAILED text is displayed after the QC result Id. The button background for failed QC tests changes to red.*

4. Repeat the previous steps for each control solution.
5. After all required solution levels have been successfully measured (that is, every

Start measure... button on the **QC Measurement** screen turned green), the analyzer is released for testing until the lockout time limit is reached once again. A pop-up window appears with the modified lockout time limit. The remaining lockout time and the date is displayed in the information windows of the **Main** screen.

ⓘ *The maximum negative value that can be displayed is -90. If you see this value, either more than 90 days have passed since reaching the limit, or a successful QC has never been performed.*

8.3 Recalling QC results

ⓘ *See "7 Recalling Results" for detailed information on how to recall and view results from system databases. Only information specific to the quality check database is discussed in this section.*

All quality check measurements are stored in the QC memory, a database separate from the memory used for urine test results. The DocUReader 2 device can store 1000 quality check results.

In list view, results that have passed the quality check appear in black; failed results appear in red.

On the **QC Result** screen 'PASSED' is displayed next to passed QC result IDs, while 'FAILED' in red is displayed next to failed ones.

In case of failed QC solution results, the out-of-range pad results also appear in red.

Tap **Forward**  to move to the second page of the QC Result screen, which lists the active QC limits for each parameter.

ⓘ *The QC results belong to LabStrip U mALB/CREA reagent strip is marked with 'm'.*

9 THE OPTIONS MENU

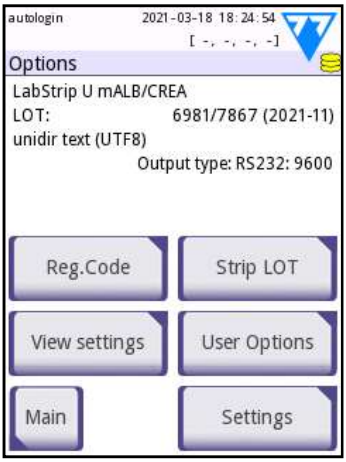


Figure 21: *The Options screen*

The **Options** screen displays the following information:

- strip type and LOT code information,
- output settings.

You can access the following options from this screen:

- Registration Code,
- Strip LOT,
- View Settings,
- User Options (auto features; fast mode; sound; LCD brightness),
- Instrument Settings (See **"10 Instrument Settings"**).

9.1 Registration Code

The system uses the registration code to precisely control the analysis process. The following strip-related information is incorporated in the registration code:

- the expiry date of the current LOT of test strips
- calibration information for the current test strip LOT

ⓘ *The strip manufacturer may or may not enable sensitivity adjustments for the individual test strip pads.*

- the number of test strip measurements still available with the currently registered LOT.

⚠ **Calibration is required for every test strip vial that you open to obtain correct results.**

When you open a new shipment or vial of test strips, find the registration/calibration card in the package. The unique registration code is attached to the registration card and it is valid for one (1), ten (10), or twenty (20) vials.

To enter the numeric registration code on the card tap the **New Registration Code** button. You can enter the 15-digit code manually via the touchscreen, via an external keyboard connected to the device, or automatically, using a barcode reader. After a successful registration the available tests counter is reset to the number defined by the new registration code.

ⓘ *If there are available test strip measurements remaining from the previous registration code when you enter a new one, these will not be lost. You can resume using a registration code that you entered previously by re-entering it.*

9.2 Strip LOT

Tap the **Strip LOT** button on the **Options** screen to set the LOT information of the test strips. You can also set the expiry date for the LOT that you enter.

You can use the following special characters together with numbers: hyphen '**-**', period (full stop) '**.**', forward slash '**/**', space '_' and parentheses '**(**' '**)**'.

The LOT code and the expiry date data are stored with every measurement until you manually change them.

ⓘ *The software does not check LOT code and expiry date entries. Because the registration code does not include the strip LOT code, the software cannot check whether the LOT code is correct. It is recommended that you double-check the code that you enter to prevent errors.*

9.3 View Settings

Tap **View settings** to review every currently active setting including user-specified options. Use the  buttons to scroll through the settings. You can print the list of active settings by tapping the  button.

9.4 User Options

Most of the settings on the **User Options** screen are related to the testing procedure except for **Sound** and **LCD brightness.**

- **Autostart:** If you check this box, measurement starts automatically whenever you place a test strip on the test strip tray. If automatic printing and automatic transfer is also enabled, this option allows 'touch-free' operation. The box is checked by default.
- **Auto print:** If you check this box, the device automatically prints the report for each measurement. The box is checked by default.
- **Auto transfer**: If you check this box, the device automatically transfers the result to the defined output (See **"10.5 Output (Connectivity: Transfer/Export)"** for output configuration). The box is unchecked by default.

Every operator can access the user options. The system stores the user options for each operator separately.

- **Fast mode** (serial reading)**:** If fast mode is enabled on the **Settings** » **Measurement** screen (See **"10.6 Measurement"**), the **Fast mode** button becomes available on this screen. If the box is checked, the test strip is measured directly after you tap **Measure** on the **Measurement** screen.

ⓘ *In fast mode the large* **Start** *button on the* **Measurement** *screen is renamed* **Measure**

and the background changes to orange.

⚠ **When performing serial measurements in Fast Mode, allow the strips to react for approximately 60 seconds before you insert them in the device and tap MEASURE. A too short reaction time can cause False-low or false-negative results. Similarly, a too long incubation time can cause false-high results.**

ⓘ *Enabling fast mode is valid for only a single measurement session. After you log out or when the system restarts, the device will start up in Normal mode.*

- **Sound:** If you check this box, the device confirms successful tapping events with a short clicking sound.
- **LCD brightness:** Use the left and right buttons to change the brightness of the LCD display or tap the text box to set the LCD brightness value with the numeric keyboard.
- **Change passw.**: The active operator can change the password by tapping the **Change passw.** button. The system prompts the user for the current password, and twice for the new password. The system will then confirm the new password.

ⓘ *The* **Change passw.** *button appears only if an operator with a password is logged in to the system. An 'autologin' operator will not see this button.*

⚠ **The minimum password length is three (3) characters.**

10 INSTRUMENT SETTINGS

The DocUReader 2 PRO device allows you to change settings to suit the specific workplace requirements. You can modify the system settings on the **Main » Options » Settings** screen.

ⓘ *The list of available settings may vary according to operator access level.*

Figure 22:
The Settings screen page 1/2

Figure 23:
The Settings screen page 2/2

ⓘ *Use the back and forward arrows to navigate between the settings pages.*

Confirming changes

Tap **Apply**, then leave the screen with **Back** to confirm your changes on the **User options** or a **Settings** screen first.

No changes or changes are saved	
Changes not yet saved	

Tap **Drop & Back** before applying changes to cancel them.

Restoring default values

There is a button on every settings subscreen (named **Restore Default** or **DEF.**) which can be used to restore the default value or values for the given screen.

To restore all settings at system level, go to **Options » Settings » Manage Settings** screen and press the **Restore Default** button.

10.1 Manage settings

10.1.1 Default settings

Figure 24: *The Settings » Manage Settings screen*

If you check the **Default by "supervisor" settings** check box on the **Settings » Manage Settings** screen, the **Restore Default** button on the same screen reverts system-level settings to those specified by the 'Supervisor'-level user,

ⓘ *The settings cannot be restored at the system level while printing or data transfer is in progress.*

Exporting and importing settings Superviser level users can download settings to a flash drive and upload to one or multiple other analyzer/analyzers with this feature.

10.2 Language

To change the operating language select the desired language from the list and tap **Apply**.

ⓘ *If the translation of screen elements is only partially completed in the language you selected, the untranslated screen texts will appear in English.*

10.3 Date, time

Figure 25: *The Settings » Date/Time screen*

The date and time you set is displayed on the display header and is recorded with the test results. Use  to modify the value of the selected field.

Use  to move the row cursor.

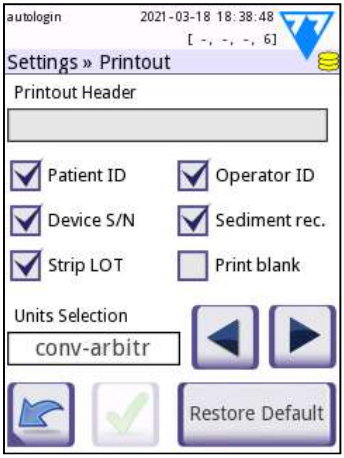
The format and delimiter settings determine how the system displays and prints date information.

Available date formats:

YYYY-MM-DD (ISO 8601 standard), MM-DD-YYYY, and DD-MM-YYYY Where 'Y' stands for the year, 'M' for the month, and 'D' for the day of the date.

Available delimiters: '**-**', '**/**', '**.**'

10.4 Printout



Printout Header: Custom string

Patient ID: If enabled, ~ appears on the printout

Operator ID: If enabled, ~ appears on the printout

Device S/N: If enabled, ~ appears on the printout

Sediment rec: If enabled, ~ appears on the printout

Strip LOT: If enabled, ~ appears on the printout

Print blank: If enabled, the fields that are checked will always be printed, even if they are empty

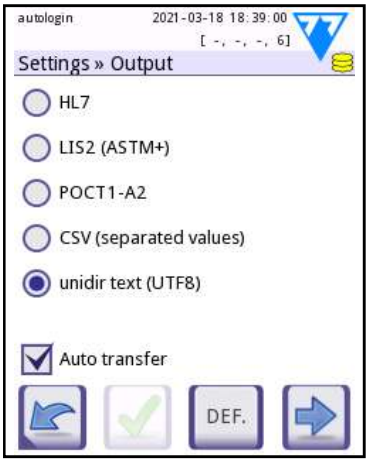
Units selection: You can change the default units that appear on the printout.

The options: conv-arbitr, SI-arbitr, conv, SI, arbitr. Use the left and right arrows to toggle between options.

Figure 26:

The Settings » Printout screen

10.5 Output (Connectivity: Transfer/Export)



You can configure how the DocUReader 2 PRO device connects to other systems or storage devices by defining the Output settings.

The system supports two protocols to transfer the analysis results through an interface:

- bidirectional (two-way) protocol based on the NCCLS LIS2-A2 standard protocol, the POTC1-A2 or the HL7 protocol
- unidirectional protocol, when the data are sent out as a one-way data flow, either formatted
  - as comma-separated values (CSV),
  - or as UTF8 text.

Figure 27:

The Settings » Output screen

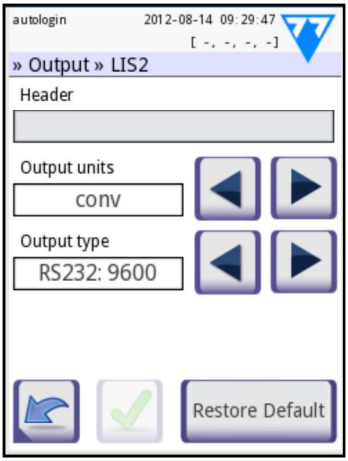
The **Output type** text box (available after you select any of the three output protocols and tap) is used to define the communication port (available options are based on the output protocol). Tap to scroll through the list.

	Serial (RS232)	TCP/IP Ethernet	File	USB B
Bidir:LIS2 (ASTM+)	⊕	⊕		⊕
Bidir: HL7		⊕		
Bidir: POCT1-A2		⊕		
Unidir: CSV	⊕		⊕	⊕
Unidir: UTF8 text	⊕		⊕	⊕

- For the serial port the selectable baud rates are 2400, 4800, 9600, 19200, 38400, 57600, and 115200 bits per second. The value defines the speed of the serial communication. The serial interface specification is 1 (one) stop-bit, no parity.
- If you select the **`Output: file`** option, the transferred data will be saved directly into a file on the root folder of a USB flash drive connected via a Type A USB port. The default file name is udr2(%Y%m%d-%H%M%S). (The placeholder string in parentheses indicates the time of measurement where %Y stands for the year, %m for the month, %d for the day, %H for the hour, %M for the minute, and %S for the second.) The file extension is either .csv or .txt, depending on the output protocol you selected.

ⓘ *You can specify a path for the saved file on the USB flash drive by entering your preferred folder name between double slashes (\\) as the first part of the file name. Make sure that you configure the communication ports properly, otherwise data transfer will not work.*

10.5.1 Bidirectional protocol (LIS2-A2)



`Figure 28:`
The Settings » Output » LIS2 screen

The two-way digital transmission protocol of the DocUReader 2 PRO device regarding remote requests and results between the analyzer and external information systems is based on the NCCLS LIS2A2 approved standard.
The standard enables DocUReader 2 PRO and any standard LIS system to establish a logical link for communicating text to send results and requests in a standardized and mutually interpretable form.
On this screen you can enter a custom header for the output, and, using the **`Output type`** text box, you can configure

- the output type (serial (RS232 or USB B), or TCP/IP (Ethernet))
- the speed of the serial communication in bits per second (in case you select the RS232 port).

If you select TCP/IP (Ethernet) as your output, you will need to enter the server's IP address and port number, separated with a colon (':').

10.5.2 HL7 bidirectional protocol

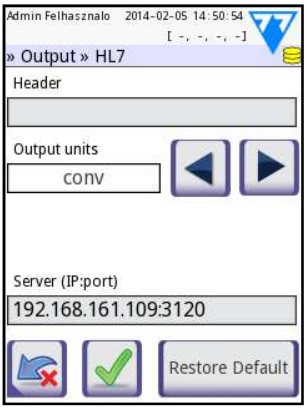


Figure 29:
The Settings»Output»HL7 screen

HL7 stands for Health Level Seven; it is a collective of healthcare informatics standards that allow exchange, intergration, sharing, and retrieval of the measurement data over the DocUReader 2 PRO device and a suitable network.

On this screen, you can set up a custom header and the preferred units for the output, and enter the IP and the port of the server that you are using.

ⓘ *Support for the HL7 protocol is in its introductory phase. Contact the manufacturer for the details of the specific HL7 standard or standards that the device supports.*

10.5.3 POCT1-A2 bidirectional protocol

The POCT1-A2 standard protocol allows bidirectional communication in Point-of Care environments with near-patient testing and is intended to be applied between the DocUReader 2 PRO and data managers (middleware). POCT features provided by the instrument are described in detail in the next sections. The POCT1-A2 protocol is specified in detail in the Interface description, which is available upon request and provides information to middleware developers or data manager developers to facilitate the attachment of DocUReader 2 PRO to a local laboratory information system (LIS).

10.5.3.1 Selecting POCT1-A2 protocol

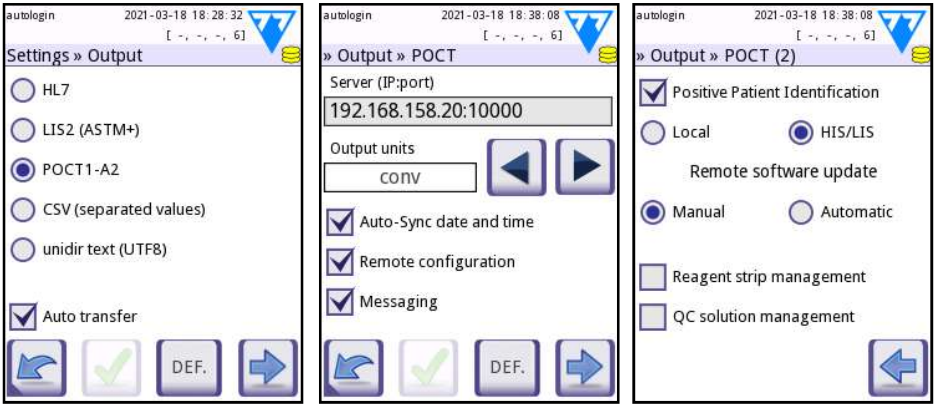


Figure 30: *Examples of POCT1-A2 output settings*

POCT1-A2 can be selected from the **Main»Options»Settings(1)»Output** menu and related settings are available as shown in Figure 30.

Type the server and port number in the Server (IP:port) field. Please separate the server IP and the port number with a ":", as shown in picture 2.

DocUReader 2 PRO supports POCT1-A2 communication protocol through TCP/IP network connection. Before activating POCT1-A2, it needs to be clarified and set from the ethernet menu if automatic (DHCP) or static IP address is used. An overview of POCT settings is given in table below.

POCT1-A2 settings		
Parameter	**Type of setting**	
Server (IP:port)	Editable field	
Output units	SI; arbitr; conv (default)	
Auto-sync date and time	Enabled; disabled (default)	
Remote configuration	Enabled (default); disabled	
Messaging	Enabled; disabled (default)	
Positive Patient Identification (PPID)	Disabled (default); Enabled then select	
	Local	HIS/LIS
Remote software update	Manual (default); automatic	
Reagent strip management	Enabled; disabled (default)	
QC solution management	Enabled; disabled (default)	

10.5.3.2 Auto-sync date and time

The data manager has the possibility to synchronize all devices, which are connected to the middleware, with the same date and time.

10.5.3.3 Remote configuration

Device settings can be set remotely by data manager through remote configuration directive. Device configuration is executed upon first start-up and/or during booting of the instrument. The possible configurations are shown in the table below. For details please refer to the interface description.

Setting	Remotely configurable parameters
Default	
Date & Time	Definition of date and time format as well as delimiter

Measurement	Strip LOT/exp.; Set Sample ID; Set Patient ID; Forced Patient ID; Color; Clarity; Dry Strip only warning; Fast mode; Display units; Patient ID length
Print	Operator ID; Patient ID; Device S/N; Sediment recommendation; Strip LOT; Print blank; Units; POCT1-A2 Server; Output unit; Automatic Sync. of Date and Time; Remote configuration; Messaging; Positive Patient Identification; Remote SW update; Strip reagent management; QC solution management
Output	Module (= protocol, e.g. HL7, POCT1-A2); Auto transfer of results
QC	Lockout period (days); Forced QC; Level of urine control solution (Mode L1, Mode L2, Mode L3); LOT expiry lockout
Power	LCD off time, Logout time; Power off time; After measurement logout
Database	Circular memory; Warning at circular memory limit; Prewarning
Ethernet	Automatic (DHCP); IP mask; IP gateway; IP DNS
Color	Definition of different color options
Clarity	Definition of different clarity options
AuthGen (Security level)	Auto login; Self add operators; Password not required; Operators on login screen; LIS operator list check; LIS operator list only; security setting mode (Open system, Anonymous usage, Self-add, Self-add with password, Secure, Custom)
CS5SYS Plus	(Settings referred to CS 5 SYS PLUS): Sensitivity of test pads; Displayed pad order; Sediment recommendation
CS7SYS Plus	(Settings referred to CS 7 SYS PLUS): Sensitivity of test pads; Displayed pad order; Sediment recommendation
CS11SYS Plus	(Settings referred to CS 11 SYS PLUS): Sensitivity of test pads; Displayed pad order; Sediment recommendation
CS11SYS	(Settings referred to CS 11 SYS): Sensitivity of test pads; Displayed pad order; Sediment recommendation
CS mALB/CREA	(Settings referred to CS mALB/CREA): Sensitivity of test pads; Displayed pad order; Sediment recommendation
Strip	Strip type selection

10.5.3.4 Messaging

The data manager can send free text messages only to logged in operators. To confirm or to exit the message, the operator has to type on the DocUReader 2 PRO screen. Remote messages can be addressed to the operator or the instrument.

10.5.3.5 Positive Patient Identification (PPID)

The device can receive information about the patient, including the patient ID, name, birthdate and gender. PPID function helps to avoid patient mismatch in the hospital environment since operators need to assure that the results are linked to the corresponding patient.

Two different PPID workflows are supported by the Urilyzer 100:

1. HIS/LIS PPID

start measurement >> ... >> enter patient ID >> PPID query to Data Manager >> PPID information or error message shows up >> message confirmed >> continue measurement

This workflow requires constant HIS/LIS connection since patient information is queried during the measurement from HIS/LIS. During the measurement, the patient ID is entered and the device receives the corresponding patient information from the HIS/LIS system that needs to be confirmed by entry of the patient birthdate (year).

2. Local PPID

start measurement >> ... >> enter patient ID >> PPID query to local patient database >> PPID information or error message shows up >> message confirmed >> continue measurement

Local PPID does not require a stable connection since the patient list is transferred to the instrument and the patient identification is performed on the instrument. The workflow itself is the same as described for HIS/LIS PPID but the PPID is sent to local database instead of the data manager.

In general, PPID function does not work on worklist testing.

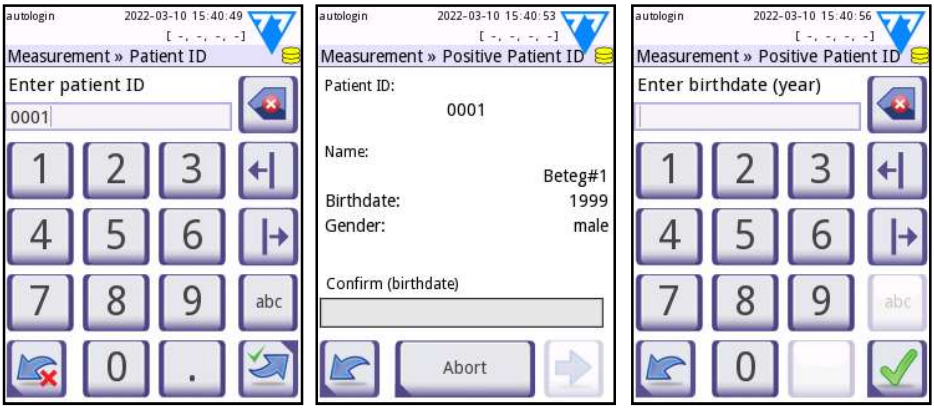


Figure 31: *Positive Patient ID function*

By asking to confirm the patient ID with the birthyear, please type in the following format: yyyy. For example: 2001.

Configurable length of patient ID string

The minimum and the maximum characters of the patient ID string can be set from the **Settings > Measurement (page 2)** menu. The maximum patient ID string length is 31 characters.

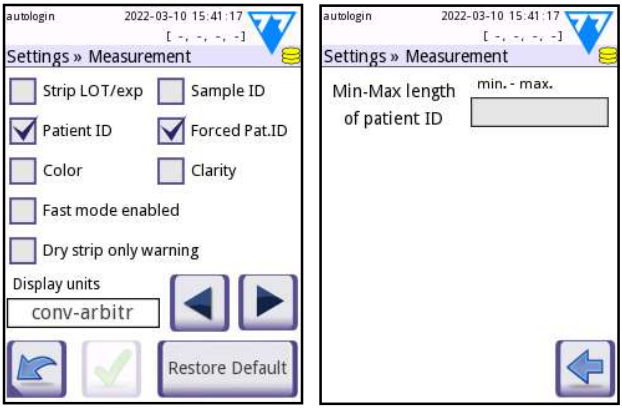


Figure 32: *Patient ID string length*

10.5.3.6 Remote software update

At institutions with multiple DocUReader 2 PRO devices, software updates may be processed remotely as they can be supervised by the data manager.

Download and installation of a software update are separated processes. If remote software update is enabled package is downloaded automatically. The update is split from the Data Manager and transferred in packages to the DocUReader 2 PRO Once all packages have been transferred successfully, the device assembles the whole package and the software update is installed according to settings (manually or automatically).

Installation of the remotely deployed software update can be executed according to the following setting:

1. Automatic

Software update is executed automatically during next boot-up of the instrument.

2. Manual (Default)

Operator needs to start and confirm the installation of the software update manually.

1. The Middleware will send the Update to the DocUReader 2 PRO.
2. A new window will appear on the device and ask the operator to manage to the **Settings >> Update** menu. Please confirm the window, by tapping on the window.

3. After that, the device will ask the operator to tap on the update button.
4. When the update installation is over, the device asks the operator to restart the device.

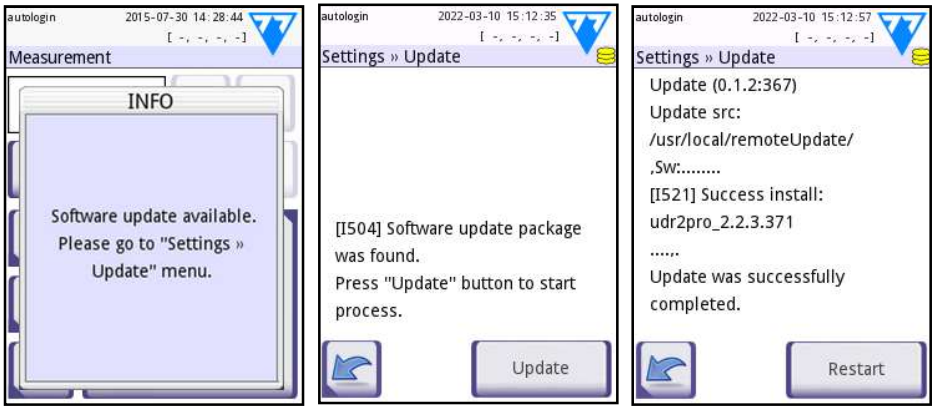


Figure 33: *Remote Software Update*

⚠ Remote software update is recommended to be used in case a stable network connection is available. When an update package is ready to be remotely deployed in an institution testing is recommended on a single dedicated instrument.

10.5.3.7 Reagent strip Management / QC solution Management

The device receives a list of permitted test strips / QC solution LOTs and expiry dates. A test strip / QC solution can only be used if it is accepted based on the list. Once the device receives a new list, it will overwrite the previous list. If the operator tries to use a LOT from the old list, which is unsupported by the new list, the operator receives a message to use another supported LOT.

The correct format of the test strip and QC solution LOT contains the LOT number, followed by the expiry date in round brackets. Please scan the LOT barcode or type in according to the following format: xxxx/xxxx(yyyy-mm)

For example:

Strip LOT: 8672/4578(2019-04)

QC LOT: A105(2018-01)

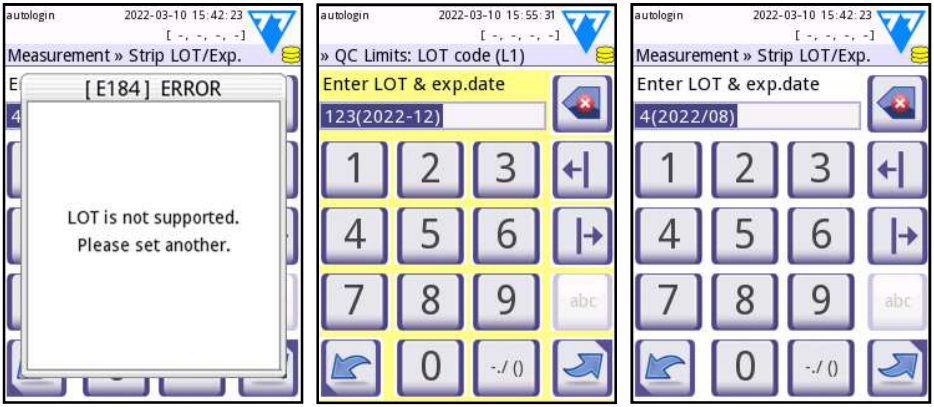


Figure 34: *LOT management*

10.5.3.8 Proficiency test feature

Proficiency testing (PT) is used to qualify expired operators for the use of the DocUReader 2 PRO according to a defined schedule of the institution. The proficiency test itself is not supported by the instrument, but the DocUReader 2 PRO is able to send a “Proficiency Test Result” message to the data manager after an approved proficiency test. This function helps higher level operators (administrator or above) in the examination process of the proficiency test. The flowchart below shows the workflow of a proficiency test.

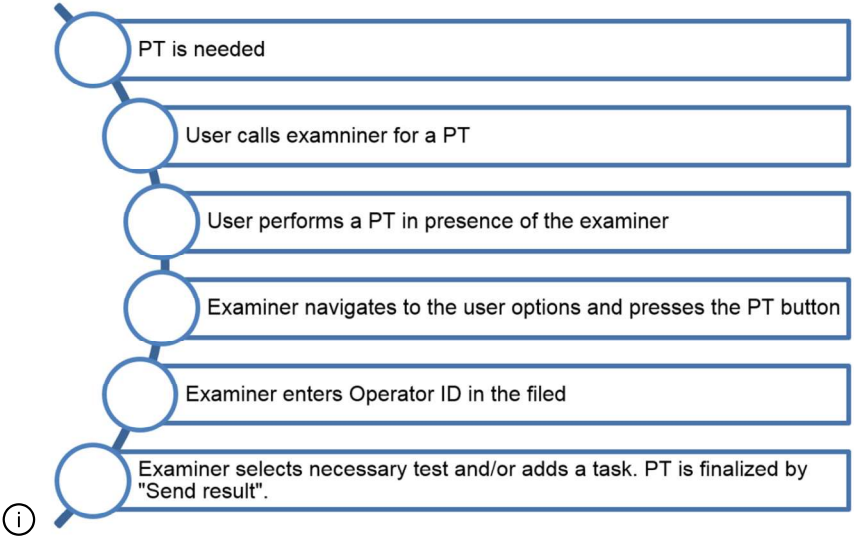


Figure 35: *Proficiency test workflow*

The proficiency test is executed by the operator in the presence of the examiner (administrator or higher level). To send the proficiency test result, the operator who has executed the proficiency test needs to enter the **Options > User Options** menu.

The examiner has to press the **Proficiency** button and type or scan in his/her operator ID and password if required. The examiner is responsible to approve that the test has been successfully executed by the operator. The following types of proficiency test are available for selection:

– successful patient test

– successful QC Test

– successful optional task, which can be described in the editable field below

Finally, the examiner can send the results to the data manger by pressing the **Send results** button.

Figure 36: *Proficiency test feature*

10.5.4 Comma-separated value output

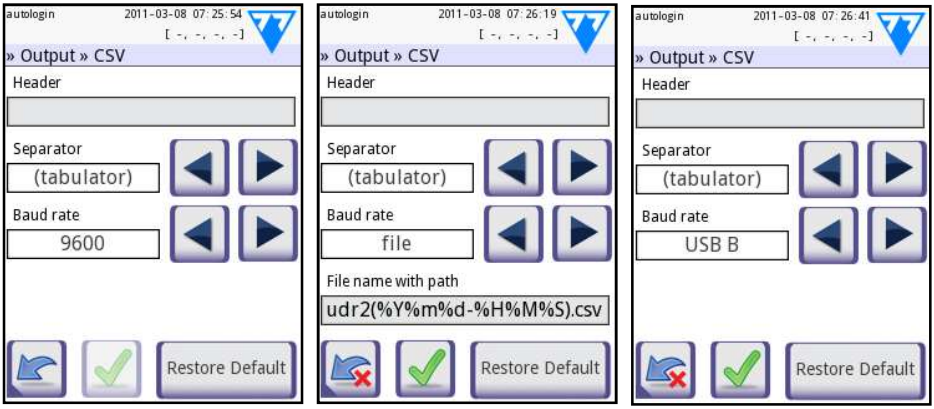


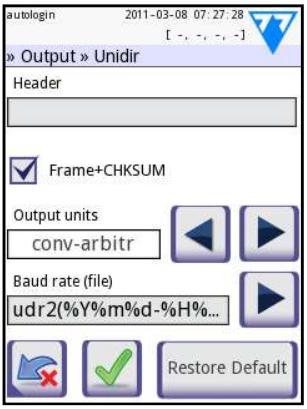
Figure 37: *Examples of Comma-separated output settings*

If you select this output protocol, the system will transfer the analysis results as plain text with a .csv file extension. In the text file, each result record is separated by a line break and each field in a record is separated by a predefined separator character. The resulting file can be opened by a spreadsheet editor such as Microsoft Excel.

Available separator characters: tabulator, semicolon (;), comma (,).

The options you can specify are almost identical to those in **Figure 73** with the exception of the TCP/IP (Ethernet) interface that is unavailable with CSV.

10.5.5 UTF8 unidir text



If you select this output protocol, the system will transfer the analysis results encoded as Unicode characters. The options you can specify are identical to those in **Figure 37**. However, the a **Frame+CHKSUM** check box is unique to this screen. If you leave it checked, the system will add a 'start text character' (STX) at the beginning, and an 'end text character' (ETX) at the end of the transferred string, as well as a two-digit checksum so that the transferred data can be verified.

Figure 38: *The Settings » Output » Unidir screen*

The following table is an example of UTF-8 output with every parameter set to visible and the with the frame and checksum option enabled.

[STX] Date:		2014-02-11 13:56	
Sample ID:		#0000020	
Patient:		Guaraldi, V.	
Device S/N:		6100074	
Operator ID:		Ed_02	
Strip LOT:		lot-13.06.2014	
	Bil	neg	
	Ubg	norm	
	Ket	neg	
	Asc	neg	
	Glu	norm	
	Pro	neg	
	Ery	neg	
	pH	6.5	
*	Nit	pos +	
	Leu	neg	
	SG	1.020	
	Color:		-
	Clarity:		-
[CR] [ETX]AC[CR]			

10.6 Measurement

The detailed description of the Measurement screen can be found in **"6.2.2 Customization of testing"**.

10.7 Strip options

Figure 39: *The Settings » Strip » Pads screen*

The main strip options screen shows the available strip types. To modify the strip settings select the strip type you are using and tap **order, sensitivity**.

The **Settings » Strip » Pads** screen will appear, that lists the pads on the strip corresponding to each analyte that is measured. (See **"1.3 Indications for use"** for a key to analyte abbreviations.) The selected pad is marked with a row cursor.

Tap  to change the selection. Tap  to increase or decrease the sensitivity of the selected test pad. You can modify the sensitivity between -2 and +2.

ⓘ ⓘ *For LabStrip U mALB/CREA reagent strip, setting sensitivity for ACR and ACR interpretation is not available.*

Tap **SED** to tag the selected test pad for additional sediment analysis. If the pad is tagged 'SED', all results of the selected pad with a positive value will get a "sediment examination is recommended" tag when stored in the database. The tag may also appear on the printout. Because the tag is stored in the database, you can create a filter to only return such tagged records (See **"7.3 Setting up filters to find specific results"**).

10.7.1 Reordering the test pads

Figure 40: *The Settings » Strip » Pads screen with an example of invisible analytes*

1. Select the pad with the row cursor.
2. Tap  **Move to 'grab' the selected pad**. Its background will change orange to indicate that it is active.
3. Use  to move the selected analyte pad. When it is in the position you want it, tap **Move** once again to release it.

You can exclude any analyte from the results view if you move it below the ---Invisible--- line. The analyte pads in this area will not appear on the printout or in the database.

ⓘ *The system will only measure and store results for invisible analytes after you have restored them above the ---Invisible--- line.*

10.8 Database management

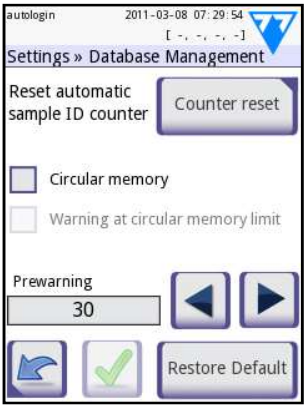


Figure 41: *The Settings » Database management screen*

On the **Database management** screen you can define how the DocUReader 2 PRO device manages the storage of the records.

The screen offers the following options:

- Resetting the automatic sample ID counter by tapping **Counter reset**. A confirmation screen will appear to prevent accidental data loss.
- Switching **Circular memory** on or off. When switched on, the system will start writing over older data when the memory is full. If this box is unchecked, the system will stop recording when memory gets full.
- Switching **Warning at…** on or off. When this option is on, the system will display a warning before old data is overwritten.
- Specifying the **Prewarning** limit. You can specify the number of records below the maximum database capacity at which the system should prompt you to free up space in the database. You will still be able to add new records past this point, but it is recommended that you erase some old data to free up database space.

10.9 QC Options

See **"8.1 Quality control options"** for a detailed description of the **QC Options** screen.

10.10 Power management

Figure 42: *The Settings » Power management screen*

On the **Power Management** screen you can enable and set the value in minutes for the following options:

- **LCD off time** (the screen saver starts)
- **Logout time** (the active operator is logged out)
- **Power off time** (the analyzer switches off)

The device will perform these actions if it has been idle for the specified time. Tap ◀ ▶ or tap inside the grey text box and use the numeric input screen to define the power management periods.

The screensaver mode and the automatic power-off feature help to reduce unnecessary power use and so reduce the ecological footprint of the device. The automatic logout feature offers an additional layer of security.

10.11 Log export

On this screen you can export log files, analyzer settings, and version information for diagnostic purposes. Complete the following steps.

1. Plug in the USB flash drive into one of the Type A USB ports on the back of the device. Wait until the disk icon appears in the status line. The icon indicates that the system recognized the USB flash drive.
2. Tap the **Log Export** button on the **Settings (2)** screen. An information message will appear (**"I111"**). When the information message disappears, the log export is finished.

ⓘ ⓘ *A warning message (**"W135"**) will appear if you try exporting a log file when no USB flash drive is connected. You will need to tap this warning screen to make it disappear.*

3. Remove the USB flash drive.

10.12 The color and clarity list

DocUReader 2 PRO analyzers offer you the option of customizing the urine color and clarity list values so that the device can conform to any medical facility's in-house standards.

You can edit the color list on the **Settings » Color list** screen. You can edit the clarity list on the **Settings » Clarity list** screen.

Complete the following steps to edit the list items.

1. Tap the item's button (for example **straw-yellow** or **clear**). A virtual keyboard will be displayed. Modify the text as necessary.
2. Tap the **Apply** button when you are done to move back to the **Color list** screen. The item you modified will be marked with an orange background.
3. Tap the **Apply** button to accept the changes. Tap the **Restore Default** button to cancel the changes and revert to the original list.

10.13 Ethernet interface configuration

To connect your DocUReader 2 PRO analyzer to the network via an Ethernet interface through TCP/IP, you have to configure the Ethernet interface.

Ask your IT system administrator for the necessary data.

The configuration can be performed:

- automatically (DHCP): select the **auto (DHCP)** checkbox. By using DHCP, TCP/IP configuration is done dynamically and automatically when the analyzer is started. Dynamic configuration requires a properly configured DHCP server on your network.

Figure 43: *The Ethernet screen*

- manually: uncheck the auto (DHCP) checkbox and manually assign
  1. the IP address / subnet mask
     (i.e. 192.168.1.5/24 or 192.168.1.5/255.255.255.0),
  2. the gateway
  3. the DNS server.
  4. Tap the **Apply** button after modification.

10.14 Wi-Fi settings

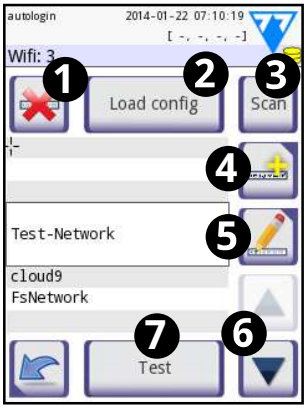


Figure 44: *Wifi screen*

10.14.1 Connect to an existing network

1. Insert a USB Wi-Fi adapter into one of the USB sockets at the back of the device. Access the **Main»Options»Settings(2)»Ethernet interface** screen. Tap the **WIFI** button.
2. Tap the **Scan** button. The system displays all the networks that are within range, listed by descending signal strength. Use the **Up** and **Down** arrow buttons (numbered 6 in Figure 81) to position the cursor over the network that you would like to connect to, and tap the **Add element** button (numbered 4 in Figure 81). On the keyboard screen that is displayed, enter the Password for the selected network, and tap **OK**.
3. Tap the **Scan** button once again to toggle it off. Use the **Up** and **Down** arrow buttons (numbered 6 in Figure 81) to position the cursor over the network that you are connecting to, and tap the **Test** button. A status text will be displayed below the name of the network. When the status text reads **COMPLETE**, the device is connected to the selected wireless network.

ⓘ *For functional bidirectional data transfer, you also need to have a receiving server set up.*

10.14.2 Add a new connection

1. Insert a USB Wi-Fi adapter into one of the USB sockets at the back of the device. Access the **Main»Options»Settings(2)»Ethernet interface** screen. Tap the **WIFI** button.
2. Tap the **Add element** button (numbered 4 in Figure 81). On the keyboard screen that is displayed, enter the ESSID (the name), and then the Password for the new wireless network.

ⓘ ⓘ *A valid password is between 8 and 63 characters long.*

3. Use the **Up** and **Down** arrow buttons (numbered 6 in Figure 81) to position the cursor over the network that you are connecting to, and tap the **Test** button (numbered 7 in Figure 81). A status text will be displayed below the name of the network. When the status text is **COMPLETE**, the device is connected to the selected wireless network.

10.14.3 Load pre-configured networks and advanced authentication protocols

The DocuRedear 2 system software includes a utility (the wpa_supplicant utility) that you can use to configure advanced wireless network options. To set up your preferred options, you need to supply the wpa_supplicant utility with the required configuration information in a text file.

1. Look up online **the documentation** on the proper format for wpa_supplicant configuration information. Create and bundle a 'wpa_supplicant.conf' file, and, if necessary, a 'certificate' and a 'key' file in a zip file that you name **wpa_supplicant.conf.zip**. Include the string **/usr/local/WIFI/** in the pathname for the files. Do not put the files inside folders before you zip them.

ⓘ *Examples of properly named certificate and key files:*

ca_cert="/usr/local/WIFI/ca.pem"
client_cert="/usr/local/WIFI/user.pem"
private_key="/usr/local/WIFI/user.prv"

2. Copy the zipped file to the root directory of a USB flash drive. Insert the USB flash drive into a USB socket at the back of the device.
3. Insert a working USB Wi-Fi adapter into a USB socket at the back of the device. Access the **Main»Options»Settings(2)»Ethernet interface** screen. Tap the **WIFI** button.
4. Tap the **Load config** button (numbered 2 in Figure 2) to load the zipped configuration files that you set up in step 1 above from the USB flash drive. The system unzips and saves the files on the USB flash drive in the **/usr/**

local/WIFI folder.

5. Exit and re-enter the **Wifi** screen to enable the modifications.

10.14.4 Edit or delete an existing wireless network

1. Insert a USB Wi-Fi adapter into one of the USB sockets at the back of the device. Access the **Main»Options»Settings(2)»Ethernet interface** screen. Tap the **WIFI** button.
2. Use the **Up** and **Down** arrow buttons (numbered 6 in Figure 2) to position the cursor over the network that you would like to modify or delete.
3. Tap the **Delete** or the **Edit** button (numbered 1 and 5, respectively, in **Figure 2**), as necessary. Follow the instructions and messages that are displayed.

10.15 Update

See **"3.5 Software updates"** for a detailed description of the system software updates.

10.16 Operators

You can manage the system security settings and the active operators on this screen.0

ⓘ *'User' refers to anyone using the device. 'Operator' is a user with an account (login name plus password) recognized by the device. Therefore, each user has at least one associated operator.*

ⓘ *You can modify the access levels separately for each operator. The system stores operator data in the database.*

Figure 45: *The Settings » Operators screen with its function buttons labelled*

1. The list of operators
2. Delete selected operator (requires confirmation to prevent accidental data loss)
3. Data Exchange
   You can: Clear, Import and Export Operators Lists here
   (available only to Supervisor and Service level operators)
4. Filter
5. Access system security settings
   (available only to Supervisor and Service level operators)
6. Move row cursor up one row
7. Edit the access level of the selected operator
8. Move row cursor down one row
9. Add new operator
10. Activate/deactivate operator reordering

ⓘ *You can reorder the operators that will be displayed on the* **Login** *screen with the* **Move** *button. The button will only become active if there is at least one operator listed that has the '***Display on login screen***' option checked (See "10.16.3 System security settings" and Figure 46). The button will only become functional if there are at least two (2) such items.*

11. Print operators list
12. Go back to the **Settings** screen

10.16.1 Navigating the Operators screen

The number of operators recognized by the system appears in the content navigation bar. A row cursor indicates the selected operators on the screen. The entries for administrator or higher level operators are displayed in red. The access level of selected operators is also displayed, followed by some additional information about them in parentheses:

- S indicates that the operator can only access the results for measurements that he or she performed
- L indicates that the operator can log in without a password
- D indicates that the operator's ID may be displayed on the **Login** screen

ⓘ *Like the other Operator settings options, the option to allow or disable operator IDs to appear on the Login screen has a security function. You may not want users of the device to know any of the other users' data, especially if no password is required and anybody can access the device with a valid operator ID.*

A blue entry background indicates operators that can be displayed on the **Login** screen. (If the **Operators on login screen** check box is checked. See 9.16.2). Tap the **Move** button to 'grab' the selected blue-background operator and move it higher or lower on the **Login** screen with the arrow buttons.

10.16.2 Operator access levels overview

Operator access level	User rights
Disabled	Disabled operators cannot log in or perform any tasks.
User	This is the default access level. User-level operators can perform the following routine tasks: worklist management testing quality control printing and exporting results editing user options.
Admin	Administrator-level operators can perform all user-level tasks, plus the following: editing settings managing operators installing software updates.
Supervisor	Supervisor-level operators can perform all of the above actions and modify the system security settings.
Service	Service operators can perform all of the above actions, and have access to the **Service** screen.

ⓘ *Users at a specific operator access level can only see other operators up to and including their own access level.*

10.16.3 System security settings

Supervisor- and service-level operators have access to the **Operators » Security** screens by tapping the  button on the **Operators** screen. On these screens, you can select any of the five (5) pre-programmed security schemes with the up and down arrows, or configure your own customized security policy.

The available security schemes, in order of increasing level of security, are the following:

- **Open system**

Logging in is automatic; no identification or password is required. Tests can be performed and settings can be freely modified by anyone using the 'autologin' operator that has an Administrator operator access level.

- **Anonymous usage**

Logging in is automatic; no identification or password is required. Tests can be performed but settings cannot be modified. Users can create operators for themselves; these operators will have a 'user' operator access level.

- **Self-add**

Logging in requires an Operator ID but no password. Tests can be performed but settings cannot be modified. Users can create operators for themselves; these operators will have a 'user' operator access level.

- **Self-add with password**

Logging in requires both an Operator ID and a password, however, users are free to create 'user'-level operators for themselves as long as they also set a password. The system keeps an audit trail of operator activities.

- **Secure**

Only registered operators can log in; operators can only be registered by operators with an operator access level of Administrator or higher. The system keeps an audit trail of operator activities.

- **Custom security settings**

Tap **Customize** on the sixth **Security** screen to access the **Operators » Security » Custom** screen. You can check or leave unchecked any or all of the check boxes on this screen to specify a customized device security scheme to fit your facility's needs or preferences.

10.16.3.1 Key to the custom security options check boxes

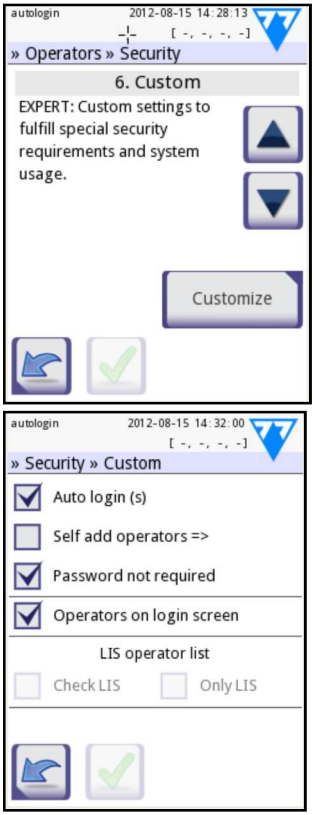


Figure 46: *The sixth Security screen and the Operators » Security » Custom screen*

- **Auto login**

  Checking this check box activates the preprogrammed 'autologin' operator. Users logging in as 'autologin' operators are never prompted for a password. As a Service level operator, you can assign any operator access level to the 'autologin' operator. The abbreviation of the current operator access level is indicated in parentheses next to the check box when it is checked.

  'autologin' operators do not need to enter an Operator name on the **Login** screen but can simply tap **Apply** to access the device at the operator access level granted to them.

- **Self add operators**

  Checking this check box allows users to create operators for themselves with any operator ID they choose. When you check this check box, you can specify what operator access level the operators that users create will automatically have. You can also decide whether they will need a password to log in, and whether they will be displayed on the **Login** screen. The current user access level and the relevant optional settings are indicated next to the check box when it is checked.

- **Password not required**

  Checking this check box makes sure that the system will not require a password from newly added operators. This is a global setting that applies to every operator—however, if a password has previously been set for an operator, the user will still have to enter the password to access the device.

- **Operators on login screen**

  Checking this check box has the effect that maximum four (4) operators' IDs are displayed on the **Login** screen. You can specify the order in which the operators that you allow to appear on the **Login** screen are displayed on the **Settings** » **Operators** screen (See "10.16.3.1 Key to the custom security options check boxes"). This is a global setting—if you uncheck it, the **Display on login screen** check box will not appear on any **Operators** » **Rights** screen (See "10.16.6 Managing operators").

- **`Check LIS`**

  Checking this check box has the effect that operators that are set up on the LIS2 connected to the device can also log in to the system.

- **`Only LIS`**

  Checking this check box will limit the number of operators that can log in to the system to the operators that are set up on the LIS2 connected to the device.

⚠ **When you check this check box, the following check boxes on this screen will automatically become unavailable: `Auto login`, `Self add operators`, and `Password not required`.**

ⓘ *The LIS options only become active when the device is connected to a LIS2.*

10.16.4 Preprogrammed operators

- 'autologin': See **"10.16.3 System security settings"**
- 'self add': See **"10.16.3 System security settings"**
- 'supervisor': Supervisor-level operators can modify system security settings. The operator name is 'supervisor' (all lower-case, without the inverted commas), and the default password is '1234'. Supervisor-level operators can never be displayed on the **`Login`** screen.
- 'service': Service-level operators can access the **`Service menu`** screen. See **3.6** for further details.
- 'Full database and config clear.': If you enter this string (as is, without the inverted commas, but with a capitalized first word and a period (full stop) at the end) as the Operator name on the **`Login`** screen, the system will perform a full database clear.

ⓘ *Full clear is a final, irrevocable command. Use it only when necessary. It is recommended that, for future reference, you perform a* **"Log export 255"** *before a Full clear.*

10.16.5 Security settings overview

	1 Open system	2 Anonymous usage	3 Self-add	4 Self-add with password	5 Secure
auto login	☑ On	☑ On	☐ Off	☐ Off	☐ Off
auto login rights	admin	user	N/A	N/A	N/A
self add	☐ Off	☑ On	☑ On	☑ On	☐ Off
self add rights	N/A	user	user	user	N/A
password not required	☑ On	☑ On	☑ On	☐ Off	☐ Off
perform test	anyone (anonymous)	anyone (anonymous)	anyone	anyone	registered users
modify settings	anyone	admins	admins	admins	admins
modify security	supervisor (def password)	supervisor (def password)	supervisor (def password)	supervisors	supervisors
add user	N/A	anyone	anyone	anyone	admins
login	autologin	autologin	self-registered users w/o password	self-registered users with password	admin-registered users with password
user management	N/A	admins	admins	admins	admins
identification	not forced	not forced	forced	forced	forced
password usage	not forced	not forced	not forced	yes	yes
real audit trail	no	no	no	yes	yes

10.16.6 Managing operators

10.16.6.1 Adding operators

1. Tap the  button on the **Operators** screen to access the **Settings » Operators » Add** screen.
2. Enter the Operator ID using the alphabetic character selection and tap **Apply** to move on to the **Settings » Operators » Rights** screen.
3. Use the left and right arrows to specify the new operator's access level.
4. Use the check boxes to specify additional security settings for the operator you are creating. See **"10.16.3.1 Key to the custom security options check boxes"** for an explanation of these check box options.

Figure 47: *The Operators » Add and the Operators » Rights screens*

ⓘ *Based on the global security settings, some or all of these check boxes can be disabled or unavailable.*

10.16.6.2 Data exchange

1. Tap Data exchange button on the Operators screen to access the **Settings » Operators » Data Exchange** screen.
2. **a,** If you want to delete the list of operators tap **Clear Operator List**.
   b, If you want to import a list of operators, insert a USB flash drive into to analyzer with the operators list on it, and tap **Import Operator List.**
   c, If you want to export the list of operators onto other analyzers, insert a USB memory stick and tap **Export Operator List.**

10.16.6.3 Editing operator settings

1. Select the operator whose settings you wish to edit with the row cursor on the **Settings** » **Operators** screen.
2. Tap the button marked '5' on the key to the **Settings** » **Operators** screen.
3. See **"10.16.6 Managing operators"** for further information about the **Operators** » **Rights** screen.

10.16.6.4 Passwords

ⓘ *The system encrypts all passwords and so not even Service-level users can recover lost passwords. It is recommended that you clear passwords that the user has lost and set a new one for the associated operator.*

- Setting passwords

When an operator is created and the security settings require a password, the system prompts the user for a password at the first login attempt. Valid passwords are at least three (3) characters long. The system will prompt the user to confirm the password. After the password is set up, the user is returned to the Login screen and has to enter the Operator name and the new password.

- Resetting passwords

You can reset operator passwords on the **Settings** » **Operators** » **Rights** screen. If there is an active password associated with the operator, the **Clear passw.** button is displayed on the screen.

1. Tap **Clear passw.** The button background will change to orange to indicate that is is active.
2. Tap **Apply** to confirm the password reset or tap **Clear passw.** again to cancel the action.

ⓘ *The system will prompt the operator with a cleared password to enter a new password at the next login attempt.*

11 MAINTENANCE

⚠ **It is recommended that you keep the DocUReader 2 PRO device clean and dust free.**

11.1 Cleaning the analyzer

⚠ **Always make sure that the analyzer is switched off before cleaning it.**

⚠ **Do not turn the analyzer on its side or upside down during cleaning as previously spilled urine or cleaning liquid could run inside the case and damage electrical parts.**

⚠ **Make sure that no liquid enters the device.**

⚠ **Do not use any type of solvent, oil, grease, silicone spray, or lubricant on the analyzer.**

⚠ **Don't use any sprayer/atomizer for cleaning the device! Use only wet towel dipped in a mild detergent.**

⚠ **Make sure that no liquid enters the printer compartment.**

Wipe the device and the touchscreen with a disposable towel dipped in a mild detergent. Recommended cleaning agents:

- Isorapid (a mixture of 20 g Ethanol, 28 g 1-Propanol, and 0.1 g quaternary ammonium compounds)
- Trigene Advance laboratory disinfectant (at a dilution of 1:100)
- Barrycidal-33 (at a dilution of 2:100)

11.2 Cleaning the test strip tray

Keep the test strip tray clean and free of obstructions. Pay particular attention to the reference pad (1) and the see-through LED window (2).

⚠ **Always wear protective gloves when handling the test strip tray. See "1.6 Safety information" for further details.**

Complete the following steps to clean the test strip tray at least once a day :

1. Switch off the device and remove the test strip tray by gently pulling it free from its slot.

Figure 48: *The test strip tray and its reference pad*

2. Rinse the parts that can come into contact with urine under running water. Wipe the tray with a disposable towel dipped in 70% (V/V) isopropyl alcohol.

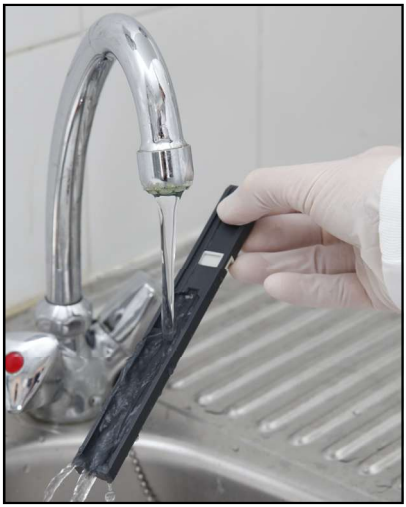


Figure 49: *Rinsing the test strip tray*

⚠ **Take care not to scratch the white reference pad.**

3. Dry the test strip tray with a lint-free wipe.

⚠ **Make sure that the test strip tray is completely dry before reinserting it.**

4. Reinsert the test strip tray. See **"3.4 Setup"**.

11.3 Cleaning the printer roller

The printer roller can pick up grease and dirt that can cause non-printing white spots or streaks on the printout. It is recommended that you clean the printer roller at least every six months of device operation.

1. Switch off the device and press the printer cover button to expose the printer roller.
2. Hold a lint-free wipe dipped in distilled water to the surface of the roller and use the roller's cog wheel on its left end to turn it. Make sure that you wipe every part of the roller surface.

11.4 The reference pad

The white reference pad on the test strip tray behind the test strip channel should not get soiled or discolored during normal operation. Nevertheless, it is recommended that you check that it is intact whenever you clean the test strip tray. If it is soiled or discolored, gently wipe it clean with a disposable towel dipped in distilled water. Replace the reference pad if there are irremovable marks or scratches on its surface.

12 TROUBLESHOOTING

To help you diagnose what is wrong with your DocUReader 2 PRO device, this section lists the most common problems and their suggested remedies.

12.1 Troubleshooting chart

When you encounter problems with the device, it is recommended that you first of all remove the casing (10.2). With the top casing panel off, check whether all the internal cables are properly plugged in and that they are not damaged. If the cables are all properly connected and intact, but the problem or problems persist, consult the Troubleshooting chart.

Problem	Cause	Corrective action
1/a The device does not respond to the On/Off switch.	1.1 The mains cable or the AC adapter is not plugged in correctly.	Check that the adapter is connected to the analyzer and that the mains cable is plugged into the wall socket. Make sure that the blue light on the AC adapter lights up when it is plugged in.
	1.2 The mains cable or the AC adapter is defective.	Check the mains cable and AC adapter for external signs of damage. If the cable or adapter is damaged, contact your certified service personnel.
	1.3 The On/Off switch is defective or it has lost its connection to the Interface board.	Contact your certified service personnel.
	1.4 The microSD memory card is defective.	
	1.5 The Mainboard is defective.	
1/b The device does not respond to the On/Off switch.	1.6 A bit of jagged solder fragment on the Mainboard punctured the touchscreen FFC, causing a short circuit.	Contact your certified service personnel.
2 The device switches on, but the touchscreen does not light up.	2.1 The touchscreen is not connected to the Mainboard, or it is not connected properly.	Contact your certified service personnel.
	2.2 The touchscreen is defective.	Contact your certified service personnel.

Problem	Cause	Corrective action
3 The touchscreen is very dim.	3.1 The LCD brightness is set too low.	Set the LCD brightness higher on the ***Main»Options»User Options*** screen.
	3.2 The touchscreen is defective.	Contact your certified service personnel.
4 The touchscreen does not respond to tapping, or the wrong area of the screen is activated.	4.1 The touchscreen is not calibrated correctly.	Contact your certified service personnel.
	4.2 The touchscreen is defective.	Contact your certified service personnel.
5 Measurement results are consistently below or above standard ranges.	The test strips used or the Optical module is defective.	
6 The test strip tray does not move.	6.1 The serrated edge of the test strip tray does not engage with the stepper motor cogs.	Carefully push the test strip tray farther inside the device until it locks firmly into the stepper motor cogs.
	6.2 The stepper motor is defective.	Contact your certified service personnel.
7 The movement of the test strip tray is slow or jerky.	7.1 A buildup of dried urine is obstructing the passage of the tray.	Clean the top casing panel underneath the test strip tray and the test strip tray itself. Pay close attention to the serrated edge on the bottom of the test strip tray. Clean the slot that the test strip tray slides into in the Optical module. (11.1)
	7.2 The stepper motor that moves the test strip tray is defective.	Contact your certified service personnel.

Problem	Cause	Corrective action
8 The system does not recognize one or more external connectors (USB, RS232, Ethernet, and so on).	8.1 The affected con-nector or connectors lost the connection with the Interface board.	Contact your certified service personnel.
	8.2 The Interface board is defective.	
9 The green LED under the test strip tray does not light up or it is very faint.	9.1 The LED's transparent plastic cover is blocked by dirt or dried urine build-up.	Clean the test strip tray and the top casing panel underneath the test strip tray. (11.1)
	9.2 The LED board is defective.	Contact your certified service personnel.
10 Results are not printed or the printout is very faint.	10.1 Autoprint is not enabled.	Check the **Autoprint** box on the ***Main»Options»User Options*** screen.
	10.2 The paper loaded is not compatible with the printer.	Make sure that thermal printer paper is loaded into the paper compartment.
	10.3 The thermal paper is too old; the heat-sensitive layer deteriorated.	Load the printer with a fresh roll of thermal paper.
	10.4 The printer is defective.	Contact your certified service personnel.
11 There are white spots or streaks on the printout where re-sults are not printed.	The grease and dirt accumulated on the printer roller prevents uniform printing.	Clean the printer roller (3.2.3). If the problem persists, contact your certified service personnel.
12 The date or time displayed in the display header is incorrect.	12.1 The Date/Time settings have been changed.	Go to ***Settings » Date/Time*** and tap **Restore Default** to reset the system to the current date and time.
	12.2 The real-time clock battery on the Mainboard is dead or lost its connection to the board.	Contact your certified service personnel.

12.2 System messages

This section lists all the messages the DocUReader 2 PRO system uses to communicate with the operator and the relevant corrective actions where necessary.

ⓘ *The status bar (the top part) of the display turns yellow to indicate that a warning message is active. The status bar will turn red to indicate that an error message is active. Tap the status bar when it is yellow or red to see the full text of the warning- or error message.*

12.2.1 General error-, warning-, and information messages

Key to the system messages table

The DocUReader 2 PRO system displays messages when the user's attention is required. In decreasing order of severity, the two categories are:

- Error messages (E), indicating that a malfunction occurred that prevents normal operation
- Warning messages (W), indicating that although normal operation is possible, some functionality of the system is lost
- Information messages (I) that provide feedback or additional information.

The system displays these messages in the following ways:

- Status line (S): the message appears in the status bar without a time limit
- Timed pop-up window (T): the message appears for a few seconds in a pop-up window.
- Pop-up window (A): the message appears in a pop-up window that disappears at the end of the process or event.
- Pop-up window (P): the message appears in a pop-up window that requires user confirmation to disappear.
- In-result message (R): the message is appears in the content area of the display.

ID	C	T	Short text	Full text	Corrective action
E99	E	S	Head HW	Head hardware error. Please call Service.	Contact your certified service personnel.
E98	E	S	Printer HW	Printer hardware error. Please call Service.	Contact your certified service personnel.
E97	E	S	Head voltage	Head voltage value is out of range. Please call Service.	Contact your certified service personnel.

ID	C	T	Short text	Full text	Corrective action
E96	E	S	Power voltage	Power voltage value is out of range. Please call Service.	See **point** "1" of the Troubleshooting chart.
E90	E	S	Reference	Failure of reference pad check. Reference pad value of the tray is out of range. See User's Manual for further instructions.	See **"12.2.2 Handling of failure of reference pad check (E90)".**
E89	E	S	QC lockout	Go to "QC measurement" to perform QC check.	Perform QC check measurements to lift the QC lockout.
E88	E	S	Memory limit	Database limit exceeded, please delete results to free up space.	Free up memory by erasing old data
W69	W	S	Output port	Output port not open. Please restart the system!	Restart the device
W68	W	S	Output internal	Output internal error. Please restart the system!	Restart the device
W67	W	S	Output init	Output not inited. Please restart the system!	Restart the device
W66	W	S	Output closed	Output closed. Please restart the system!	Restart the device
W65	W	S	Output memory	Not enough memory for output. Please restart the system!	Restart the device
W64	W	S	Output write	Cannot write output. Please change file name or (re)insert USB flash drive.	Use alphanumeric characters only and make sure that the USB flash drive is connected properly and is detected by the system. If necessary, re-initialize the USB port by tapping the 77E logo in the top right corner.

ID	C	T	Short text	Full text	Corrective action
W63	W	S	Output aborted	Output aborted. Please start again.	Restart transfer.
W62	W	S	Output limit	Output reached internal limit. Please check protocol.	Check and verify output settings.
W61	W	S	Output protocol	Protocol failure. Please check connection type.	Check and verify output settings.
W60	W	S	Output failure	Output failure. Please wait and try again in a minute. In case of repeated failure please check connection type.	The system continuously tries to deliver the output. When it can successfully display the output, the error message will automatically disappear. If the error persists, check and verify output settings.
W59	W	S	Output busy	Output line busy. Please wait and try again in a minute.	The system continuously tries to deliver the output. When it can successfully display the output, the error message will automatically disappear. If the error persists, check and verify output settings.
W58	W	S	Output file	Output file not open. Please change file name or insert flash drive.	Change the file name or its destination. Make sure the USB flash drive is connected properly and recognized by the system. If required, re-initialize the USB port by tapping the 77E logo in the top right corner.

ID	C	T	Short text	Full text	Corrective action
W57	W	S	Output link	Output link lost. Please wait a minute. In case of persistent failure please check connection and connection parameters.	The system continuously tries to deliver the output. When it can successfully display the output, the error message will automatically disappear. If the error persists, check and verify output settings.
W56	W	S	Output connect	Output port cannot connect to server. Please check Ethernet cable, Ethernet configuration in settings and server IP address and port number.	
W38	W	S	Head version	Measure head SW version is unknown. Please call Service.	Contact your certified service personnel.
W37	W	S	Temperature	Temperature out of allowed range.	Ensure the proper environmental conditions. See 3.3
W35	W	S	Data lost (limit)	Database limit exceeded. Earlier results will be dropped.	Free up memory by erasing old data (circular memory option is enabled, so old data will be overwritten by new data).
W34	W	S	Memory near full	Database counter is reaching its limit. Please delete some results.	Free up memory by erasing old data.
W33	W	S	QC lockout	Go to „QC measurement" to perform QC check.	Perform QC check measurements to remove the QC lockout. See "Quality control options".
W32	W	S	Strip-holder	Stripholder error. Can't go to home position. Please check it!	Check if the test strip tray is properly inserted and remove any obstacles from its path (See "Clearance limits")
W31	W	S	Door open	Printer door is open. Please close it!	Check if the paper roll is correctly loaded in the printer bay and close the printer door. (3.4.2)

ID	C	T	Short text	Full text	Corrective action
W30	W	S	Paper out	Paper out. Please replace the printer paper!	Open printer door and load a fresh paper roll in the printer. (3.4.2)
E199	E	P		DB failure: cannot write result. Please call Service!	Contact your certified service personnel.
E198	E	P		DB failure: cannot modify result. Please call Service!	
E197	E	P		DB failure: cannot delete result. Please call Service!	
E196	E	P		DB failure: configuration is corrupted. Please check the configuration settings.	
E195	E	P		Worklist DB failure: cannot write new item.	
E194	E	P		Worklist DB failure: cannot insert or modify item.	
E193	E	P		Worklist DB failure: cannot delete item.	
E181	E	P		Load config error: read details from \"wpa_supplicant.conf.err" file on PENDRIVE.	The system encountered a problem in the wpa_supplicant.con.zip file, and has saved an error report on the connected USB flash drive. Refer to the WPA Supplicant documentation to deal with the issue.
E180	E	P		Load config error: USB drive or "wpa_supplicant.con.zip" file not exists.	Make sure that the wpa_supplicant.con.zip file is properly saved on the connected USB flash drive.

ID	C	T	Short text	Full text	Corrective action
E177	E	T		Length of password must be between 8 and 63 characters	The password that you have entered is either too short or too long. Enter another password.
E174	E	T		Format of entered expiry is failed. Format of expiry is YEAR/ MONTH	Enter the QC LOT expiry date again. Do not use parentheses
E173	E	T		Format of entered LOT is failed. Format of expiry is (YEAR/MONTH)	Enter the QC LOT number and the expiry date again. Make sure that you separate the expiry date from the QC LOT number with parentheses.
E172	E	T		Time is expired	The expiry date of the QC solution lot that you are trying to register is already past. Register a lot of QC solution that is still valid.
E171	E	T		Cannot export log.	Make sure that the USB flash drive is connected properly and that the system detects it. If required, re-initialize the USB port by tapping the 77E logo in the top right corner of the touchscreen display.
E170	E	T		Sample ID already exists, please change it.	Verify and repeat the input or use another Sample ID.
E169	E	T		Registration Code is already used.	Verify and repeat the input or use another RegCode.
E168	E	T		Registration Code is not valid.	Verify and repeat the input or use another RegCode.
E167	E	T		Operator ID already exists, please change it.	Enter another Operator ID.
E166	E	T		Password check failed, please try again.	Enter the valid password.

ID	C	T	Short text	Full text	Corrective action
E165	E	T		Password is too short, please try again! (minimum length is 3 characters)	Enter a new password that is at least three (3) characters long.
E164	E	T		Password does not match, please try again.	Re-enter password.
E163	E	T		Operator does not exist, please try again.	The operator name that you entered is not on the operator list. Enter another Operator ID.
E162	E	T		Operator disabled, please try again.	The operator name that you entered has been disabled. Enter another Operator ID.
E161	E	T		Sample ID required. Please set it.	Enter Sample ID.
E160	E	T		LOT Code required. Please set it.	Enter LOT number from the test strip package.
W169	W	T		Cannot open serial port for output!	Check serial port connection. See **point** "8" of the Troubleshooting chart.
W158	W	T		Cannot open file for output!	Check the output port and presence of the output storage.
W156	W	T		Cannot connect to server for output.	Check output server settings.
W140	W	T		Due to changes the lockout time has been expired.	Perform a QC measurement to lift the lockout.
W139	W	T		Previous "strip pads" settings lost. Press "OK" (apply) before strip change.	Tap the Apply button to save changes, otherwise the special strip settings (pad order, sediment rec., and so on) will not be saved.
W138	W	P		Server IP address or mask format not right. (ex.: 192.168.1.12:4130)	Check and correct server IP address or mask input.

ID	C	T	Short text	Full text	Corrective action
W137	W	P		IP address or subnet mask format is not correct. (i.e. 192.168.1.5/24 or 92.168.1.5/ 255.255.255.0)	Check and correct server IP address or mask input.
W136	W	P		IP address format is not correct. (i.e. 192.168.1.12)	Check and correct server IP address or mask input.
W135	W	T		Cannot export log, because USB drive does not exists. Please insert it.	Make sure that the USB flash drive is connected properly and that the system detects it. If required, re-initialize the USB port by tapping the 77E logo in the top right corner of the touchscreen display.
W134	W	A		Worklist DB failure: possible data loss! Trying to repair. May take some minutes, please wait	Check the worklist to see if any data was lost. Clear the database (See 9.16.4). If problem persists, contact your certified service personnel.
W134	W	P		Worklist DB failure: possible data loss!	Database failure. The system is trying to repair the problem. This may take a few minutes.
W133	W	A		Config DB failure: possible data loss! Trying to repair. May take some minutes, please wait.	Data was probably lost. The system is trying to repair itself.
W133	W	P		Config DB failure: possible data loss!	Possible configuration loss, check database. Contact your certified service personnel.
W132	W	P		Config DB is recreated. Previous configuration is lost!	System settings are regenerated. Set the configuration options again. Contact your certified service personnel.

ID	C	T	Short text	Full text	Corrective action
W131	W	A		DB failure: possible data loss! Trying to repair. May take some minutes, please wait	Data was probably lost. The system is trying to repair itself.
W131	W	P		DB failure: possible data loss!	Check the worklist to see if data was lost. Contact your certified service personnel.
W130	W	P		DB is recreated. All previous data is lost!	All existing data was lost. Contact your certified service personnel.
I117	I	P		Due to changes lockout time was increased to X day(s).	You have successfully increased the active QC lockout time.
I117	I	P		Successful QC check. Lockout time was increased to X day(s).	The QC lockout time was restarted because of the successful QC measurement.
I116	I	T		Reminder: Last day before lockout.	There is only one day left to perform a successful QC measurement, before the QC lockout is activated.
I115	I	A		Measure head SW update in progress. May take some seconds, please wait.	N/A
I114	I	A		Connection is in progress. Please wait.	N/A
I113	I	T		Output is paused while in Settings » Ethernet screen.	N/A
I112	I	T		Log exported.	N/A
I111	I	T		Log export in progress. Please wait	N/A
I110	I	T		Output paused while navigating in settings menu.	N/A
I109	I	T		Unused QC LOTs and limits deleted.	N/A

ID	C	T	Short text	Full text	Corrective action
I107	I	T		No password set. Please set your password on login!	N/A
I106	I	T		Operator added.	N/A
I105	I	T	.	Selection was sent for printing	N/A
I104	I	T		Selection was sent for output.	N/A
I103	I	T		Selection is inverted.	N/A
I102	I	T		All samples are selected.	N/A
I101	I	T		Sample ID was not found, please try again or cancel the search	N/A

12.2.2 Handling of failure of reference pad check (E90)

1. Remove the test strip tray and clean it paying particular attention to the reference pad.

⚠ **Use one of the prescribed cleaning agents. See 11.1.**

2. After cleaning the reference pad make sure that there is not any apparent disorder on its grey surface.
3. Put back the test strip tray and check if E90 fixed.
4. If E90 remains, replace reference pad in case there is an available spare part. If you do not have spare reference pad, please call service.
5. If E90 remains after replacing the reference pad with a new one, please call service.

12.2.3 Testing- and Measurement error logs

The system displays the following error messages when a malfunction occurs during analysis. These are permanently stored in the database with the measurement results and will also be printed.

ID	C	T	Full text	Testing: Error Source & Corrective Action
E299	E	R	Head HW error: some LEDs may be defective. Please call Service.	Contact your certified service personnel.
E298	E	R	Head HW error: voltage out of range. Please call Service.	
E297	E	R	Head HW error: software check failed. Please call Service.	
E296	E	R	Head communication failed. Please restart the system.	Communication with the head failed after the measurement. Restart analyzer and repeat the test with a new test strip. If the problem persists, contact your certified service personnel.
E282	E	R	Database error. Stored item is corrupted. Please delete item from database.	Delete item from the database. If problem persists, contact your certified service personnel.
E281	E	R	Database error. Missing strip configuration data. Please delete item from database.	
E280	E	R	Configuration error. System configuration (or database) failed.	
E270	E	R	Strip tray reference pad error. Measured value out of acceptable range!	The reference pad is contaminated or damaged. Clean the test strip tray and the reference pad Replace the reference pad or the test strip tray if the problem persists contact your certified service personnel.
E269	E	R	Backlight is too strong. Measurement is not possible!	External light was too strong during testing. Reduce the intensity of the external light or do not expose the tray directly to a strong light source (for example to direct sunlight or a lamp).
E268	E	R	Mechanical error. Stripholder can't go to home position.	Check if the test strip tray is properly inserted and remove any obstacles from its path.
				Clean the test strip tray (11.2).

ID	C	T	Full text	Testing: Error Source & Corrective Action
E267	E	R	Home position error. Step failure detected after measurement.	Position count check failed after testing. Check if the test strip tray is properly inserted and remove any obstacles from its path (See "3.3.1") Make sure that you do not push or pull the tray during its movement.
E266	E	R	Strip type mismatch while calculating the results of measurement.	Make sure that only LabStrip U11 Plus or LabStrip U mALB/CREA test strips are used and that they are positioned correctly on the test strip tray.
E265	E	R	Measured value out of valid range for one or more pads.	Unrealistic data was collected. Make sure that the right test strips are used.
				Check the test strips' date of expiry. Discard expired strips and open a new lot of test strips.
E264	E	R	Strip position error. Strip position check failed after the measurement.	Strip moved from its initial position during testing. Make sure that the strip is correctly positioned on the test strip tray.
E263	E	R	Temperature was out of allowed range during measurement.	The ambient temperature was out of the operating range during the test. Maintain proper environmental conditions ("3.3 Setup considerations") and repeat the test with a fresh strip.
E262	E	R	Flipped strip error. Strip is put backside top on stripholder.	Test strip was placed downwards. Repeat the test ensuring the strip is correctly positioned on the test strip tray with the test pads facing up.
E261	E	R	Strip is (partially) dry.	Strip was (partially) dry. Repeat the test with a fresh strip. Make sure that every pad on the strip is immersed in the urine.
E260	E	R	No strip is present. Storing commented item without real values.	The system did not detect a strip during measurement. The result is saved only so you can add a comment.

12.2.4 Software update error- and information messages

SW Update ID	C	T	Full text	Corrective action
I502	I	U	The system is already up to date.	N/A
I503	I	U	SW update is not found. Please insert USB drive with SW package.	Follow the message text instructions.
I504	I	U	Software update package was found. Press “Update” button to start process.	Follow the message instructions.
E596	E	U	Update was failed.	Check and verify the software update sources on the media. Restart update.
E597	E	U	Internal configuration failure! (Please call Service)	Restart update.
E572	E	U	Failed install:....	Corrupted or missing files. Check and verify the software update sources on the media. Restart update.
E562	E	U	Failed backup:	Restart update.
E561	E	U	Missing: ...	Corrupted or missing files. Check and verify the software update sources on the media. Restart update.
E5XX	E	U	Package error:....	Corrupted or missing files. Check and verify the software update sources on the media. Restart update.
E5XX	E	U	Internal error:	Restart update.
E5XX	E	U	Missing source:	Check and verify the software update sources on the media. Restart update.
E5XX	E	U	Source check failure: ...	Corrupted or missing files. Check and verify the software update sources on the media. Restart update.
E5XX	E	U	Unpack failed: ...	Corrupted or missing files. Check and verify the software update sources on the media. Restart update.
I5XX	I	U	....	N/A
O5XX	I	U	....	N/A

13 APPENDICES

Appendix A Results table

The DocUReader 2 PRO analyzer prints the results in the following gradation of concentration using LabStrip U11 Plus:

Parameter	Conventional Units (Conv.)	SI Units (SI)	Arbitrary
BIL (Bilirubin)	neg 0.5 mg/dl 1 mg/dl 3 mg/dl 6 mg/dl	neg 8.5 µmol/l 17 µmol/l 50 µmol/l 100 µmol/l	neg (+) 1+ 2+ 3+
UBG (Uribilinogen)	norm 2 mg/dl 4 mg/dl 8 mg/dl 12 mg/dl	norm 35 µmol/l 70 µmol/l 140 µmol/l 200 µmol/l	neg 1+ 2+ 3+ 4+
KET (Ketone)	neg 5 mg/dl 15 mg/dl 50 mg/dl 150 mg/dl	neg 0.5 mmol/l 1.5 mmol/l 5 mmol/l 15 mmol/l	neg (+) 1+ 2+ 3+
ASC (Ascorbin)	neg 20 mg/dl 40 mg/dl 100 mg/dl	neg 20 mg/dl 40 mg/dl 100 mg/dl	neg 1+ 2+ 3+
GLU (Glucose)	norm 30 mg/dl 50 mg/dl 150 mg/dl 500 mg/dl 1000 mg/dl	norm 1.7 2.8 8 28 56	norm (+) 1+ 2+ 3+ 4+
PRO (Protein)	neg 15 mg/dl 30 mg/dl 100 mg/dl 500 mg/dl	neg 0.15 g/l 0.3 g/l 1 g/l 5 g/l	neg (+) 1+ 2+ 3+
ERY (Erythrocytes)	neg 5-10 Ery/µl 50 Ery/µl 300 Ery/µl	neg 5-10 Ery/µl 50 Ery/µl 300 Ery/µl	neg 1+ 2+ 3+
pH	5 / 5.5 / 6 / 6.5 / 7 / 7.5 / 8 / 8.5 / 9		

Parameter	Conventional Units (Conv.)	SI Units (SI)	Arbitrary
NIT (Nitrite)	neg pos	neg pos	neg +1
LEU (Leukocytes)	neg 25 Leu/µl 75 Leu/µl 500 Leu/µl	neg 25 Leu/µl 75 Leu/µl 500 Leu/µl	neg 1+ 2+ 3+
SG (Specific Gravity)	1.000 / 1.005 / 1.010 / 1.015 / 1.020 / 1.025 / 1.030 / 1.035		

The DocUReader 2 PRO analyzer prints the results in the following gradation of concentration using LabStrip U mALB/CREA:

Parameter	Conventional Units (Conv.)	SI Units (SI)	Arbitrary
mALB	10 mg/L 30 mg/L 80 mg/L 150 mg/L 500 mg/L	10 mg/L 30 mg/L 80 mg/L 150 mg/L 500 mg/L	norm + ++ +++ ++++
CREA	10 mg/dL 50 mg/dL 100 mg/dL 200 mg/dL 300 mg/dL	0.9 mmol/L 4.4 mmol/L 8.8 mmol/L 17.7 mmol/L 26.5 mmol/L	10 50 100 200 300

Appendix B Technical specifications

Type	reflectance photometer with 4 discrete wavelengths (505,530, 620, 660nm)		
Throughput	maximum 50 strips/hour (in normal mode)		
Display	3.5" QVGA touch-screen LCD (resolution: 240x320)		
Memory	3000 test results / 1000 QC results		
Printer	thermal line dot printer paper width: 58 millimeters		
Dimensions	Width 190 mm (7.4 inches)		
	Depth 236 mm (9.2 inches)		
	Height 77 mm (3 inches)		
Weight	1255 grams (2.767 pounds) including the AC adapter, the power cord, and a new roll of printer paper		
Power supply	100–240V AC ± +10% -15%, 50/60Hz ± 5% external mains adapter		
Environmental conditions	Temperature	Relative humidity	Altitude
Operating	+15˚C to +32˚C	30–80% (non-condensing)	3000 m (above sea level)
Storage	+5˚C to +40°C	10–85%	
Transportation	–25˚C to +60°C	75% at 30˚C (24h)	
Interfaces	PS2 (external keyboard, bar code scanner)		
	serial RS232 (with transmission speeds 1200–115200 bps)		
	USB Type B		
	USB Type A		
	Ethernet / Wi-fi		
	microSD card holder		
Expected lifetime	5 years or 50000 measurements		

Appendix C Default factory settings

User options:

Autostart:	ON
Auto print:	ON
Auto transfer:	OFF
Sound:	ON
LCD brightness (%):	100

Measurement:

color:	OFF
clarity:	OFF
Set Sample ID:	OFF
Set Patient ID:	OFF
Display units:	conv-arbitr

Strip: LabStripU11Plus

Bil:	0
Ubg:	0
Ket:	0
Asc:	0
Glu:	0
Pro:	0
Ery:	0
pH:	0
Nit:	0
Leu:	0
SG:	0

Printout:

Operator ID:	ON
Patient ID:	ON
Analyzer S/N:	ON
Sediment rec.:	ON
Strip LOT:	ON
Empty always:	OFF
Printout units:	conv-arbitr

Output: unidir text (UTF8)

Header:	empty
Frame+CHKSUM:	ON
Output units:	conv-arbitr
Baud rate:	9600

QC options:

QC Lockout (day):	0
L1:	ON
L2:	ON
L3:	OFF
LOT expiry lockout:	OFF

Power management options:

LCD off time (min):	5
Logout time (min):	10
Power off time (min):	60

Database management options:

Circular memory:	OFF
Warning at circ.mem. limit:	OFF
Prewarning:	30

Authent. general settings:

Auto login:	OFF
Self add operators at login:	OFF
Login without password:	OFF
Operators on login screen:	OFF
LIS operator list check:	OFF
LIS operator list only:	OFF

ⓘ *Authentication general settings do not change when you restore the default settings.*

Appendix D Support & ordering

D.1 Support

77 Elektronika offers full service support for its products. Feel free to contact us if you encounter any problem with the DocUReader 2 PRO device that consulting this manual does not or only partially solve. There are several channels of communication available, listed below.

By phone or e-mail

You can reach qualified 77 Elektronika service staff during office hours at the service hotline and the service staff e-mail address:

+36 1 371 0546

service@e77.hu

The number and the address are also listed on our website (www.e77.hu) in the 'For Distributors' section.

Through the Helpdesk

1. Sign in to the Helpdesk in the **For Distributors** section of our website (**www.e77.hu**) using your 77 Elektronika account user name and password.
2. Press the **New Issue** button in the top left corner.
3. In the **Description** text box, provide as much information about the problem as you can. You can also include photos or video clips that highlight the problem as attachments.
4. When you are done, press **Send** at the top of the screen. You will get status update notification e-mails as the reported issue is processed.

D.2 Ordering

You can order any replaceable part, accessories and consumables of the device directly from 77 Elektronika.

- Grey check strip (2 pcs) S-UD21150002
- Labstrip U 11 Plus ANA-9901-1
- LabStrip U mALB/CREA ACR-9902-1

ⓘ *Do not use the phone to place orders. Use the written forms of contact listed below and always include the article number of the part or parts you are requesting.*

Send your order by fax to **+36 1 206 1481**

or by e-mail to **service@e77.hu.**

Our service staff will get in touch with you to confirm your order as soon as possible.

Appendix E Disposal information

⚠ **You must not dispose of your used DocUReader 2 PRO device or any of its parts as municipal solid waste.**

⚠ **Without disinfection or sterilization, the device and any of its parts are considered infectious clinical waste (EWC code 180103*). Untreated infectious waste is typically incinerated, but you must follow local waste management guidelines and regulations.**

ⓘ *77 Elektronika will accept DocUReader 2 PRO devices that you no longer want to use, if you disinfect or sterilize the device before mailing it as written below. Before mailing the disinfected device to H-1116 Budapest, Fehérvári út 98., Hungary, make sure that you*

1. Sign in to the Helpdesk in the **For Distributors** section of our website (**www.e77.hu**) using your 77 Elektronika account user name and password.
2. Click the RMA button and follow the instructions.

Disinfect or sterilize all the disassembled parts:

- immerse the parts in a germicidal bath of chlorine bleach (5:100 Sodium hypochlorite solution) for two (2) minutes at room temperature (20°C or 68°F)

⚠ **Wear protective rubber gloves and protective goggles when handling chlorine bleach, and make sure that you work in a well-ventilated room.**

- sterilize the parts (according to DIN EN ISO 1764) in an autoclave for 7 minutes at 132 °C (270 °F) or for 20 minutes at 121 °C (250 °F).

Appendix F Safety and compliance information

Your DocUReader 2 PRO device was designed and manufactured to comply with the following international regulations, and left the factory in a safe condition. Follow the instructions and pay attention to the warnings in this manual to keep the analyzer in a safe condition.

The device complies with the protection requirements of IEC 61010-1:2001, IEC 61010-2-101:2002, IEC 61326-1:2005 and IEC 61326-2-6:2005.

CE Complies with the provisions of the applicable EU regulations.

According to EN 61326-2-6, it is the user's responsibility to ensure that a compatible electromagnetic environment for this instrument is provided and maintained in order that the device will perform as intended. Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these may interfere with the proper operation. The electromagnetic environment should be evaluated prior to operation of device.

This equipment has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case you may want to reduce the interference.

The analyzer must be operated only with the prescribed power supply unit (Class II protection).

Personal computers that you connect the device to must meet the EN 60950, UL 60950/CSA C22.2 No. 60950 requirements for data processing equipment.

Only connect the intended external devices with safety low voltages to the corresponding interfaces (serial, PS2, USB, Ethernet) to avoid the risk of electrical shock or the risk of damaging the devices or the analyzer.

Please note that the instrument may potentially be infectious. You must disinfect or sterilize all equipment before repair, maintenance, or removal from the laboratory (See **"Appendix E Disposal information"**).

F.1 Incident reporting

Inform your 77 Elektronika Kft. service representative and your local competent authority about any serious incidents which may occur when using this product.