

UriSed

Fully Automated Urine Sediment Analyzer

Short review



77 Elektronika

1116 Budapest,

Fehérvári út 98.

HUNGARY

Tel.: +36 1 206-1480

Fax: +36 1 206-1481

Email: sales@e77.hu

www.e77.hu



For professional use



Automating Urine Particle Analysis

Description of UriSed

Measurement Process

UriSed Images

UriSed Evaluation Module

Result Interpretation

Highlights of UriSed

The **UriSed** -developed and manufactured by 77 Elektronika- is a professional urine sediment analyzer, which is able to detect urine particles in urine sediment with high accuracy. This instrument performs sample preparation, takes several pictures of each sample through its built-in microscope and evaluates them using the **UriSed Evaluation Module** which is high quality image processing software.

The measurement technique of the instrument is a world novelty: it is the automatic centrifugation and microscopic measurement of native urine samples in special disposable cuvettes. This patented technology is actually the automation of the well-known traditional manual microscopy. Together with the automatic, real-time processing of the whole viewfield microscopic images, it is also a revolutionary new method for sedimentation, identification and classification of urine particles.

Automating Urine Particle Analysis

Urine analysis is part of the medical diagnostic methods frequently used by doctors in laboratories in order to reveal either disorders in the general state of health or diseases of the kidneys and the urinary tract. Review of recent literature on urine sediment examination shows that this test has important clinical implications with regard to a large spectrum of diseases. Microscopic urine analysis is diagnostically useful in symptomatic patients, in patients with chronic kidney and urinary tract disorders and as a follow-up examination. Presence or absence of urine particles are related to clinical decision-making, not only a routine measurement.¹ Indeed, a morphological analysis of the individual particles together with the general picture of the urinary sediment can provide valuable information that is as important as a careful clinical examination.

Although manual microscopy is the "Gold standard", even this traditional way of urine sediment analysis has some drawbacks:

Firstly, it is a very time consuming and tiring procedure and it needs significant human resources. On the one hand, proper preparation of urine samples has to be done before the microscopic investigation while on the other hand, the data handling is manual. So laboratories, which have to deal with hundreds of urine samples each day, are overwhelmed with the tasks related to sediment analysis.

Secondly, the sample preparation, as well as the evaluation (classification) depends on the operator. Therefore, even a standardized visual microscopy of urine sediment may be characterized by a very high dispersion of particle counts due to some possible sources of errors like losses during centrifugation, inaccurate transferring of sediment under the microscope and false classification.² As a result, manual microscopic urine analysis is often associated with poor reproducibility and accuracy.³

UriSed is a big help for laboratories as it does the sample preparation fully automatically and reproducibly, provides high resolution, whole viewfield microscopic images and also completes the analysis of the samples by reliably recognizing the particles in them. Another great advantage of **UriSed** is that it archives the obtained results of the analysis by storing the raw images of the microscope as well as the evaluated data. In this way, **UriSed** makes urine sediment analysis faster, easier, more reliable, more operator independent and independent of the manual microscopy.

^{1,2} Erzsébet Pintér M.D.: Evaluation of UriSed automated urine sediment analyzer (Presentation on The First International Symposium of Urinalysis Technology and New Progress in Hungary, on the 4th of September, 2009.)

³ Clinical Chemistry 1999; 45:6; 757-770

Description of UriSed



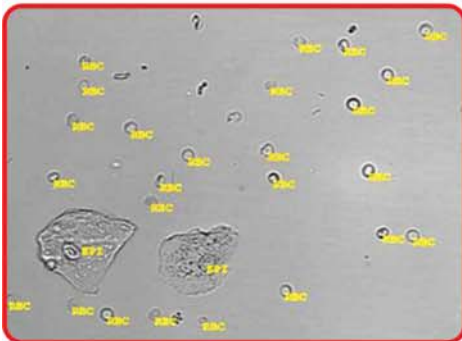
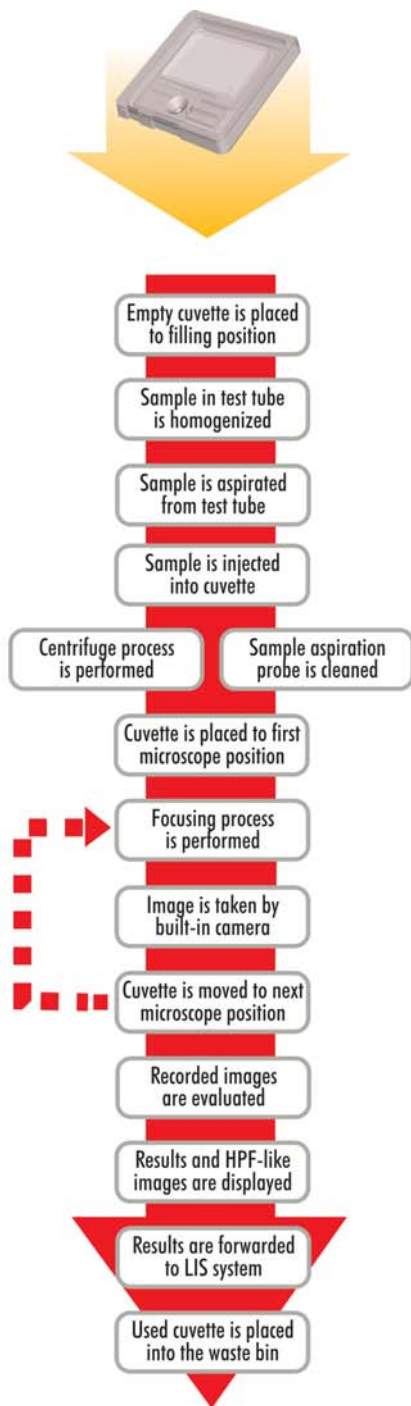
The UriSed system consists of four parts:

1. The Measuring Unit includes centrifuge, microscope, and other mechanical parts. This unit is responsible for performing sample preparation and taking the whole viewfield microscopic images.
2. The second part consists of wash and waste containers. For the proper cleaning of the instrument simple distilled water is enough, there is no need for special detergents.
3. The operating PC is responsible for the control of the main unit and evaluating the images by sophisticated image processing software.
4. The last part consists of different peripherals like monitor, keyboard, mouse and optional printer.

2.



Measurement Process



Preparation of the instrument for measurement only takes a few seconds. **UriSed** only needs standard distilled water for washing its pipette, and disposable plastic cuvettes for the observation of samples under its built-in microscope. 600 cuvettes can be inserted at once into the instrument, which should be enough for a day in most laboratories. After filling up the washing container and loading the cuvette holder, **UriSed** is ready for sediment analysis, no further preparation is needed.

To perform a measurement, the operator only has to pour urine sample into a standard test tube and install it on the rack mover part of the instrument in the supplied rack. The rest is performed automatically.

Firstly, the test tube is forwarded automatically to the sampling position. The urine sample is then mixed up by the pipette. (The pipette is the sample probe of **UriSed**.) This is to assure the homogeneity of the sample. In the next step, the urine sample is aspirated and transferred into a special disposable cuvette. For an accurate evaluation, **UriSed** needs only 2.0 mL urine sample in the test tube. However, in the course of the measurement only 0.2 mL is used.

After transferring the sample, the pipette is moved to the back of the instrument into a special washing unit. There both the inner and outer shell of the pipette is cleaned with distilled water in order to prevent carryover between different urine samples. This is a unique washing technique which does not require a special cleaning solution.

The cuvette with the urine sample inside is then forwarded into the built-in centrifuge. The time and speed of centrifugation is optimized to prevent particle destruction, while creating a sediment layer at the bottom of the cuvette.

Afterwards, the cuvette is forwarded to the microscope position, where 5-10-15 or 20 images are taken by the built-in camera, through the built-in microscope. The images are taken at different positions of the specimen after setting the focus plane automatically to the sediment layer at each position.

In the course of the measurement process, recorded whole viewfield images are evaluated automatically by the **UriSed Evaluation Module**, which is high quality image processing software.

At the end of the process, the used cuvette is placed into the waste bin. Meanwhile, the following sample is already being prepared for microscopic investigation.

UriSed Images

From the above written measuring procedure it can be seen that **UriSed** -unlike its competitors- automates the traditional process of urine sediment analysis, instead of trying to find an alternate solution, which has a similar result.

Therefore, **UriSed** has the very unique advantage, that it can provide not only images of individual particles, but also whole viewfield images of the microscope. This was one of the guiding principles during the development of this analyzer, to make it possible to automatically produce exactly the same kind of images the doctors got used to in their practice.

The **UriSed Images** are HPF-like images, the magnifications of which correspond to the standard 400x enlargement, which is usually used in laboratory practice. Based on different, widely accepted guidelines of urine sedimentation^{4,5,6}, and our calculations 15 **UriSed Images** as well as 10 regular HPF images of 20x concentrated urine sediment correspond to about 2.5 μ l native urine. That is why in the course of the measurement process, UriSed takes 15 images by default.

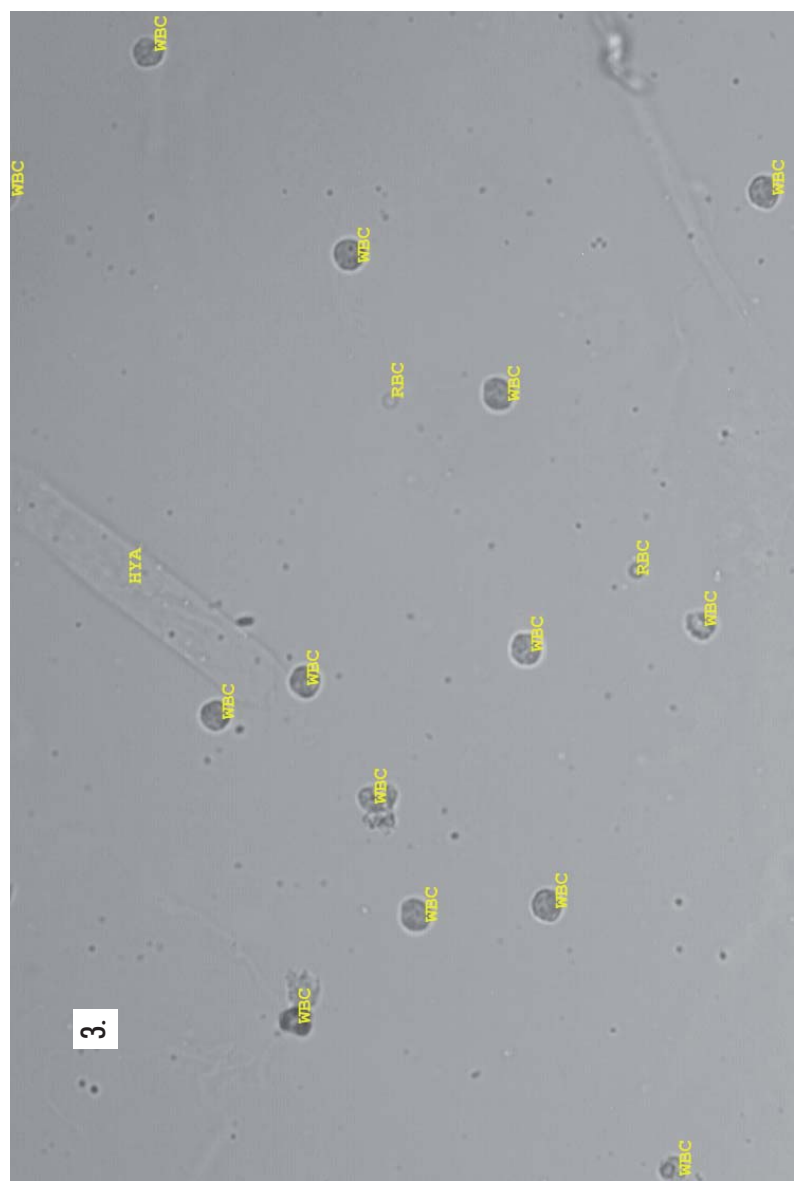
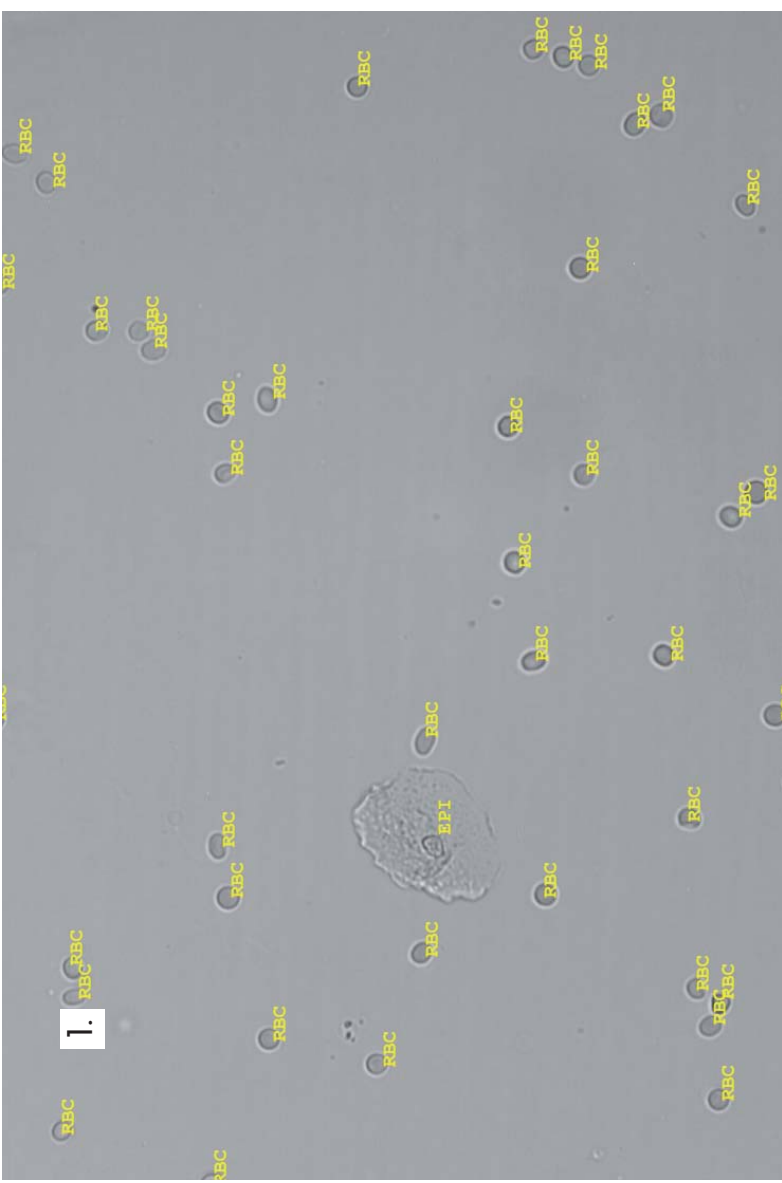
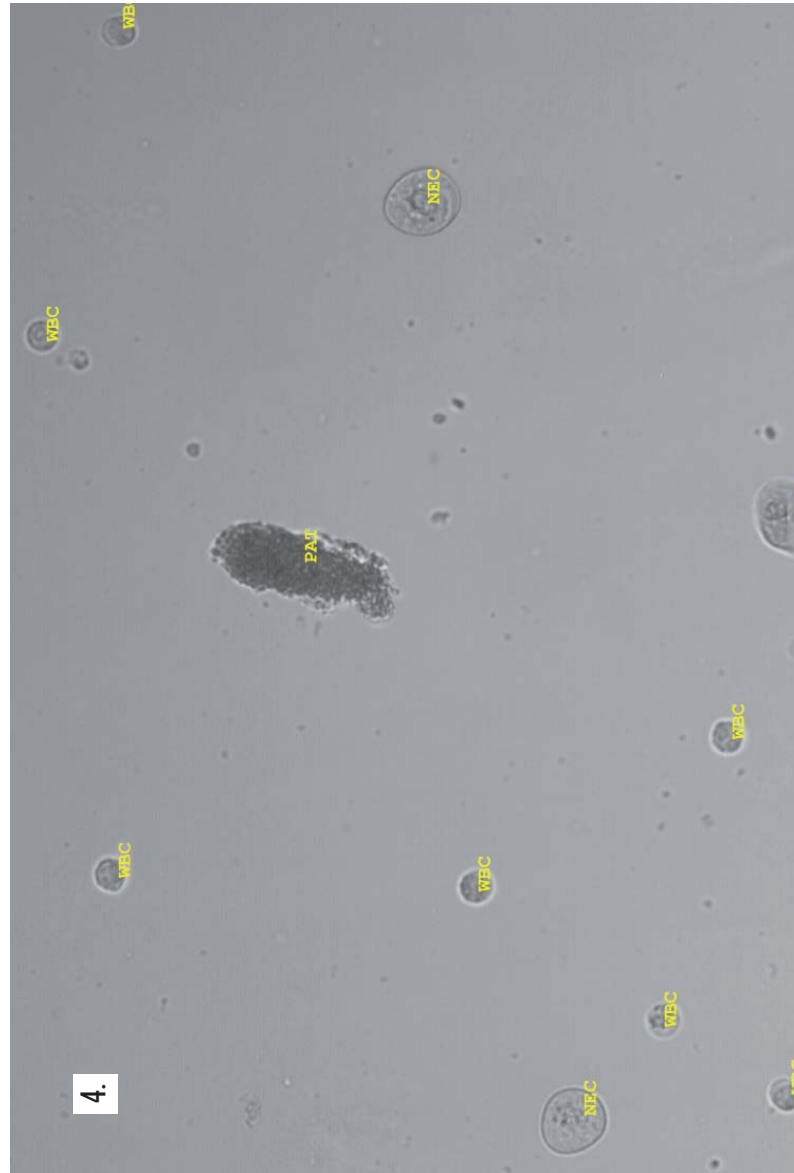
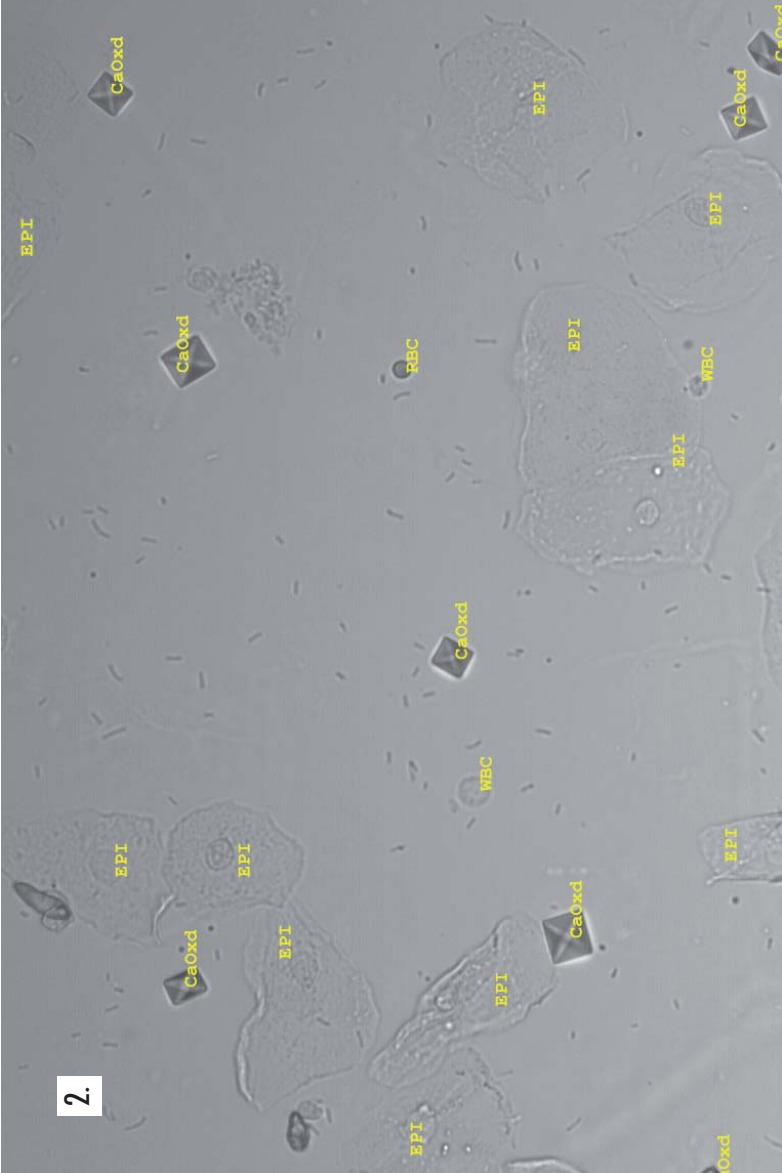
Some images of different samples can be seen on the following page
(displaying the captions of the recognized particles are optional)

1. Sample with EPI, RBC
2. Sample with EPI, CaOxd
3. Sample with HYA, WBC
4. Sample with PAT, WBC, NEC

⁴ NCCLS: GP16-A2 Urinalysis and Collection, Transportation, and Preservation of Urine Specimens

⁵ ECLM: European Urinalysis Guidelines Clin Chem Lab Med 1999; 37:7; 753-764

⁶ Clinical Chemistry 1999; 45:6; 757-770



UriSed Evaluation Module

The **UriSed Evaluation Module** is a high quality image processing software which is able to detect the following urine particles: Red Blood Cells (RBC); White Blood Cells (WBC); Hyaline Casts (HYA); Pathological Casts (PAT); Squamous Epithelial Cells (EPI); Non-Squamous Epithelial Cells (NEC); Bacteria (BAC); Yeast (YEA); Crystals (CRY): Calcium-oxalate monohydrate (CaOxm), Calcium-oxalate dihydrate (CaOxd), Uric acid (URI), Triple phosphate (TRI); Mucus (MUC); Sperm (SPRM).

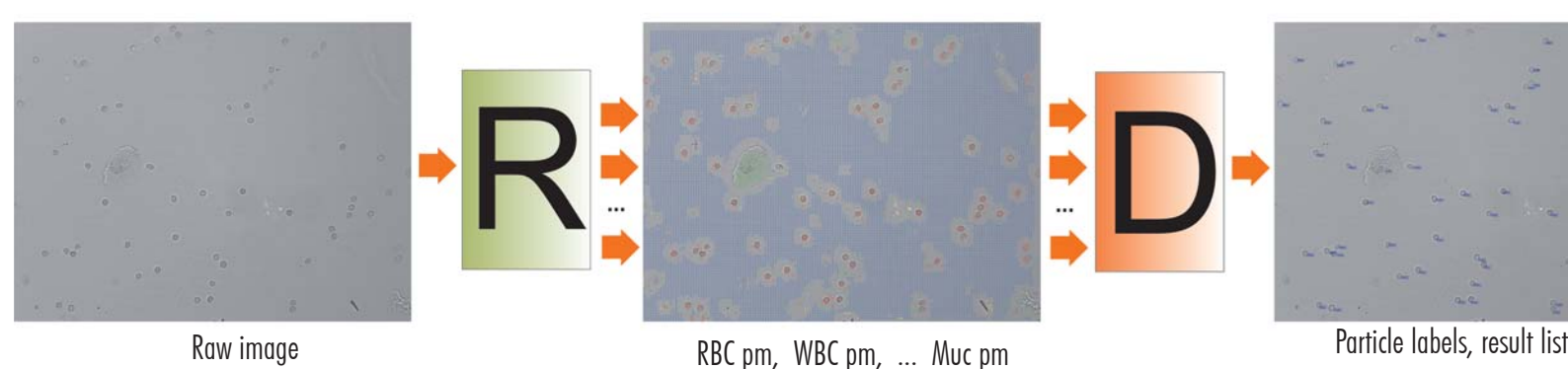
The evaluation is based on the good quality, high resolution digital images, which contain the essential information. Its unique evaluation method enables **UriSed** to recognize urine particles respectively on whole viewfield images containing hundreds of different particles.

The **UriSed Evaluation Module** combines elements of traditional image processing and advanced Neural Network structures. This software is trained to recognize particles according to several optimized parameters defined in the process of training.

Training is performed on manually marked images of a large representative database. This training database contains thousands of whole viewfield images and hundreds of thousands of particle images. As a result, a large number of different weight functions optimized on the training database (size, shape, contrast and texture are only a small part of them) are used for the particle recognition.

The evaluation process of UriSed is a complex system, which consists of two main levels:

- Firstly, in the Recognition Module "probability maps" (pm) are generated from the original image for each particle type respectively. These show the probability of different fields of the image belonging to a certain analyzed parameter (RBC, WBC, ...)
- Secondly, in the Decision Module the labels of certain particles and the final result list are defined through the special analysis of the probability maps.



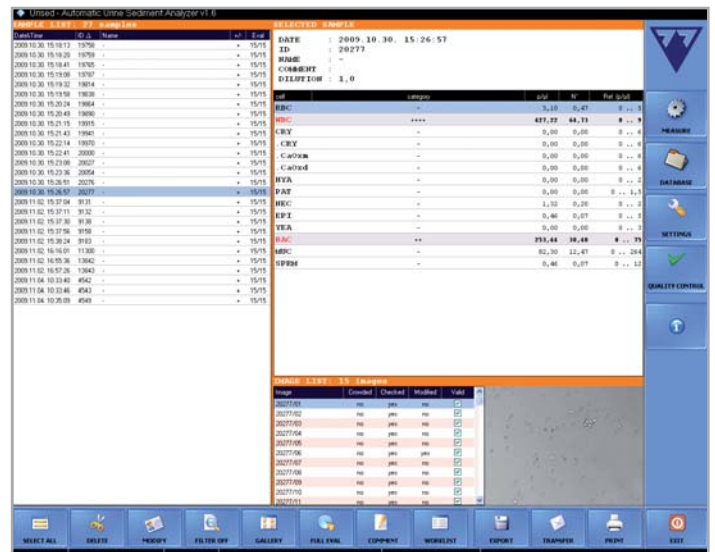
Result Interpretation

On the one hand the most significant advantage of **UriSed** is that it provides whole viewfield microscopic images. Since **UriSed Images** are direct results of the measurements, no information can be lost; not only the automatically detected particles, but all details can be seen on the stored images.

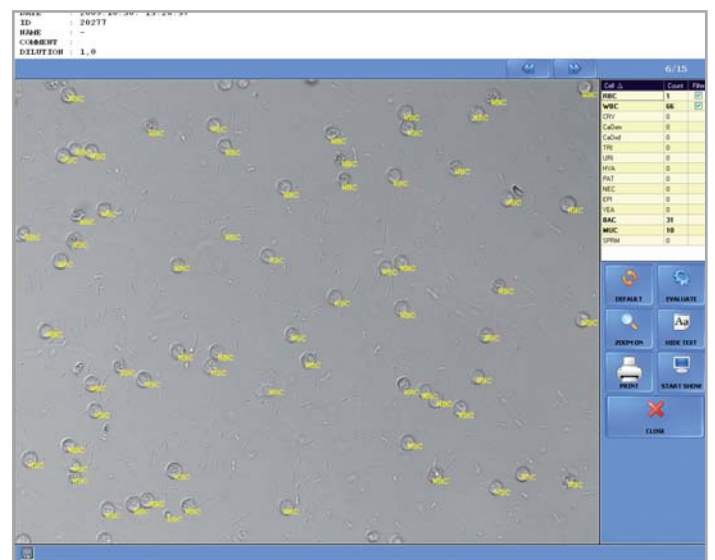
On the other hand the most significant added value of **UriSed** is the reliable automatic evaluation of the whole viewfield images in the course of which the final results, i.e. particle concentrations and categories are defined. The accuracy, sensitivity and specificity values of the automatic evaluation of different particles are in most cases over 80%, which fulfills the requirements of routine urine sedimentation.

Nevertheless, **UriSed** does not intend to substitute doctors, rather helps them to make their diagnosis in the most efficient way, while releasing them from the overwhelming laboratory work. That is why the results are interpreted in several different ways:

- For every sample general statistics (quantitative concentration values and semi-quantitative category ranges) are calculated, which include the average of all the images taken from the given sample.



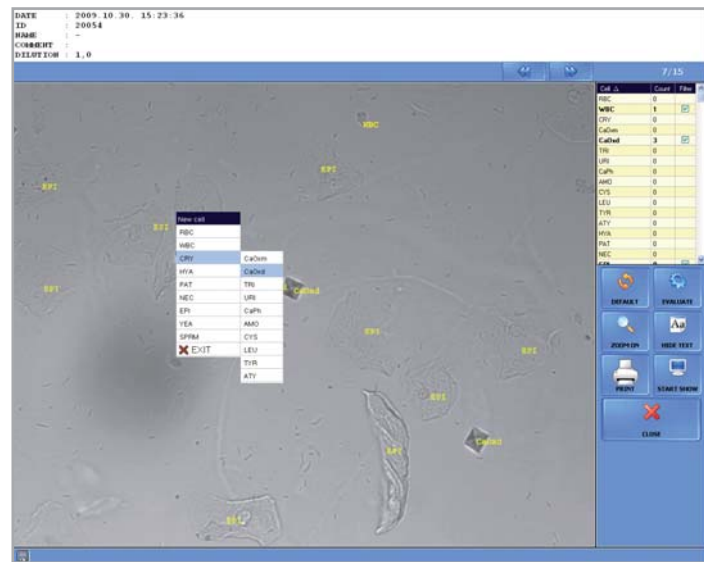
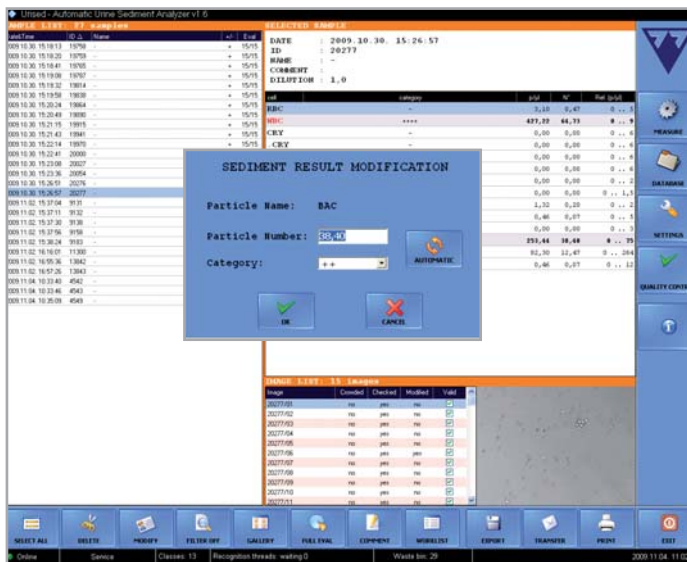
- All images can be accessed and displayed separately. On the images the recognized particles are identified and labeled by captions above them.





- Parts of the images (e.g. individual particles) can be zoomed out digitally and examined separately.
- Not only the automatically detected particles, but also other types of cells and other details can be seen on UriSed images.

- Final results as well as individual particle identifications can be easily verified and if necessary, modified by doctors.
- Besides the 15 automatically detected particle classes manual sub-classification is also available.



Both the images and particle concentrations are really important information for the doctors: while it is easier and faster to diagnose the automatically evaluated sample, in some cases it is also necessary to see the real appearance of the urinary sediment on microscopic images. Besides, it is very important that not only the individual particles, but also the general picture of the urinary sediment can be investigated on **UriSed Images**, as they are whole viewfield images.

In this way, the HPF-like images of **UriSed** can be used for verification of automatic results, for deeper analysis and understanding of certain samples, as well as for education of laboratory staff or medical students.

Since all images are stored together with the final results, review and human evaluation is also possible any time after the measurement on screen, without manual microscopy.

Highlights of UriSed

- With its performance and revolutionary new scientific approach to sediment analysis, **UriSed** has set the highest standard in its category.
- **UriSed** has a reproducible method for the preparation and evaluation of urine samples, which is based on the automation of the traditional manual process.
- **UriSed** does not need any special liquid reagent material for the operation: cuvette is the only consumable and as for the cleaning, only normal distilled water is required. Therefore, the operation of **UriSed** is really cost-effective.
- As each sample is observed in a separate chamber (cuvette), there is no carry over between different samples. Moreover in **UriSed** it is also impossible to have any kind of obstruction caused by big sediment particles, as during measurement, the samples do not have to go through any narrow channels inside the instrument.
- **UriSed** provides whole viewfield images -like HPF images in routine manual microscopy- in a fully automated way.
- **UriSed Images** are evaluated automatically and reliably by the **UriSed Evaluation Module**.
- The high quality clear and sharp images are stored in a database. In this way, human evaluation is also possible any time after the measurement on screen, without manual microscopy.
- Since **UriSed Images** are direct results of the measurements, no information can be lost; not only the automatically detected particles, but all details can be seen on the stored images.
- **UriSed** can be used to educate laboratory staff or medical students since images can be seen on full screen.
- **UriSed** can be easily connected to the **LabUMat** fully automated urine test strip reader. In this way, both the chemical and the microscopic part of the urinalysis can be performed as one process. Since both instruments are developed and manufactured by 77 Elektronika, there is a well designed hardware and software interface between them. Together, the two instruments make up a **Complete Urine Laboratory System**. Since both chemistry and sediment results are stored in a common database and reported as a common report, this system provides the most effective and reliable solution for complete and professional urinalysis.



Technical features

Measurement technique:	centrifugation and microscopic measurement of native urine samples in special disposable cuvettes
Detected particle classes:	RBC (red blood cells); WBC (white blood cells and wbc clumps); HYA (hyaline casts); PAT (pathological casts); EPI (squamous epithelial cells); NEC (non-squamous epithelial cells); BAC (bacteria); YEA (yeast); CRY (crystals): CaOxm (Calcium-oxalate monohydrate), CaOxd (Calcium-oxalate dihydrate), URI (Uric acid), TRI (Triple phosphate) MUC (mucus); SPRM (sperm); Further classes for manual sub-classification are also available!
Memory:	max 5,000 results (including all images)
Magnification:	standard, HPF-like images
Built-in centrifuge:	YES
Max. throughput:	up to 80 samples/hour
Batch size:	100 test tubes
Min. sample volume:	2.0 ml
Printer:	optional, external (connected to operating PC)
Interfaces:	USB, RS232 serial port
Size:	600x640x635 mm (LxDxH, without operating PC)
Weight:	63 kg (without operating PC)
Power (measuring unit):	100-250V AC / 50-60 Hz / max. 200 W
Power (operating PC):	100-127V AC / 47-63 Hz / max. 400 W 220-240V AC / 47-63 Hz / max. 400 W

77 Elektronika

77 Elektronika develops and manufactures in vitro medical diagnostic devices, mainly blood glucose monitoring systems and urine analyzers. The products are supplied all over the world under 77 Elektronika's own brand and also as OEM products for market-leading multinational companies.

77 Elektronika was established in 1986 with its headquarters in Hungary (EU). Since its establishment, the company has been developing dynamically to the complete satisfaction of its customers.