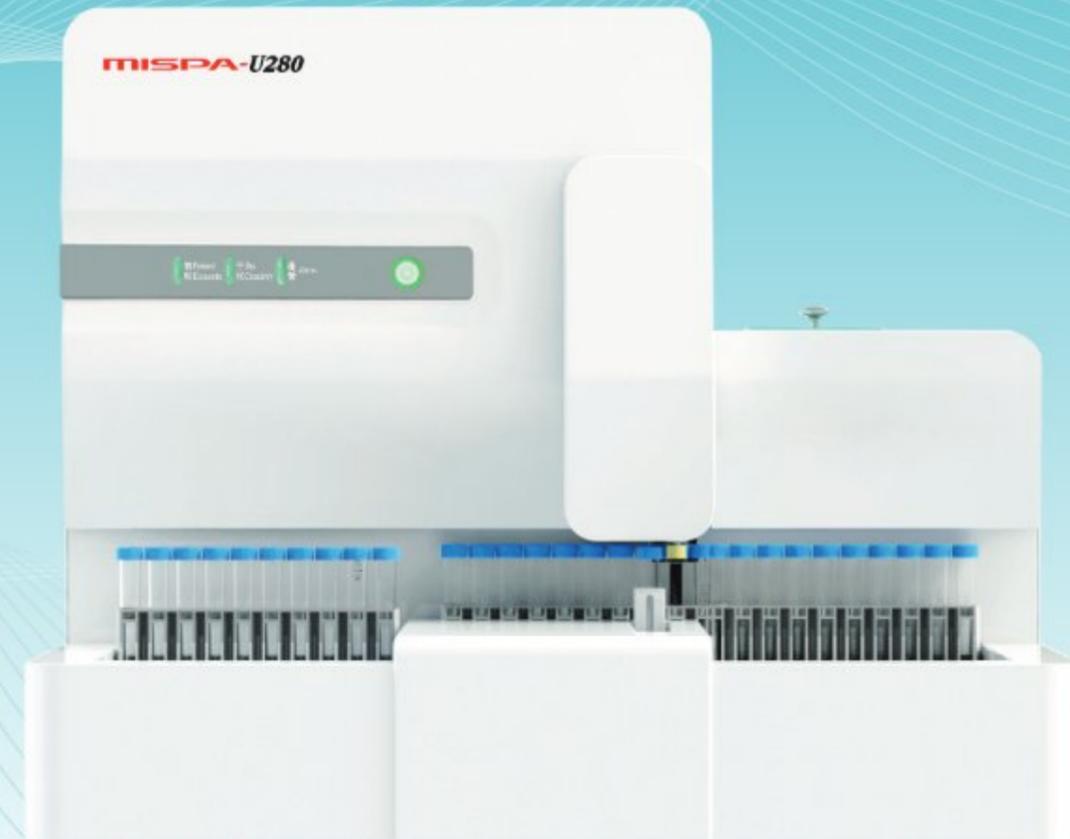


MISPA-U280

Automatic Urine Analysis System

Basic Parameters

Sample requirements	crude urine can be tested directly without centrifugation.
Sample volume	sample aspiration volume <3mL (for dry chemistry + formed elements).
Testing speed	dry chemistry: 220 samples/hour; formed element: 60~80samples/hour; dry chemistry + formed element: 60~80 samples/hour.
Result units	XX pcs/ μ l (international quantitative unit), or XX pcs/HP (quantitative report).
Sample loading	rail-mounted sample loading device; the sample loading compartment can hold 100 samples at one time.
Physical test items	color, turbidity, specific gravity, conductivity (standard).
Test strip	12 (12B) or 14 (14A) parameters available; you can select different test strips according to your needs.
Test strip compartment capacity	\geq 300 test strips.
STAT function	an STAT position is available for testing STAT samples at any time.
Test channel	flow counting cell; \geq 4 channels.
Accuracy	the difference between the dry chemical analysis results and label-value of corresponding reference solution is not more than 1 order of magnitude; detection accuracy for formed elements: \geq 95%.
Repeatability	CV \leq 7%.
Carry-over rate	\leq 0.02%.
Microscopic images	6 shooting modes; \geq 224 camera views (the number of camera views can be customized).
Shooting mode	scanning layer-by-layer in each field of view; \geq 5 shooting layers; the effect of reading image is similar to microscopy.
Scanner function	built-in barcode scanner, scanning sample tubes at 360° rotation.
Dimension	77.8cm(L)*71.3cm(W)*65.0cm(H).



MISPA-U280

Automatic Urine Analysis System

- Using the patented technology pioneered for multi-focal and multi-layer photographing of microscopic images of the urine, to obtain three-dimensional morphological images of cells.
- Dry chemistry in combination with analysis of formed elements.
- 5MP camera for high-definition images.
- Compact size, saving laboratory space.
- Computer analysis of physical indicators (color, turbidity), new testing technology for specific gravity and conductivity, ensuring more accurate results.
- Accurate dry chemistry results.

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ISO 9001:2015
EN ISO 13485:2016



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MISPA-U280

Automatic Urine Analysis System



Testing Principle

Dry chemistry analysis

The urine test strips are photographed, and the concentration gradient value of each item is obtained by a new optimization algorithm.

Working principle for formed elements

Based on the principle of microscopic image analysis of urine sediment, the formed elements of the urine are photographed by the camera and automatically interpreted. The interpretation results will be reported after manual review.

Test Items

Physical

Color, specific gravity, turbidity, conductivity (standard)

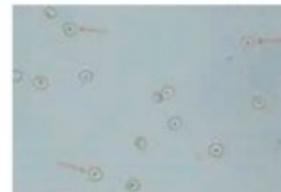
Dry Chemistry

12 items: specific gravity (SG), microalbumin (ALB), ketone bodies (KET), glucose (GLU), leukocytes (LEU), potential of hydrogen (PH), occult blood (BLD), protein (PRO), vitamin C (VC), bilirubin (BIL), urobilinogen (URO), nitrite (NIT).

14 items: urinary calcium (Ca), urinary creatinine (CRE) and the above 12 items.

Analysis of Formed Elements

Analysis and labeling of more than 30 formed elements in urine (red blood cells, white blood cells, calcium oxalate crystals, pathological casts, epithelial cells, bacteria, fungi, etc.)



Red blood cells



White blood cells



Calcium oxalate crystals

Morphological images of the formed elements of urine.



Granular casts



Squamous epithelial cells



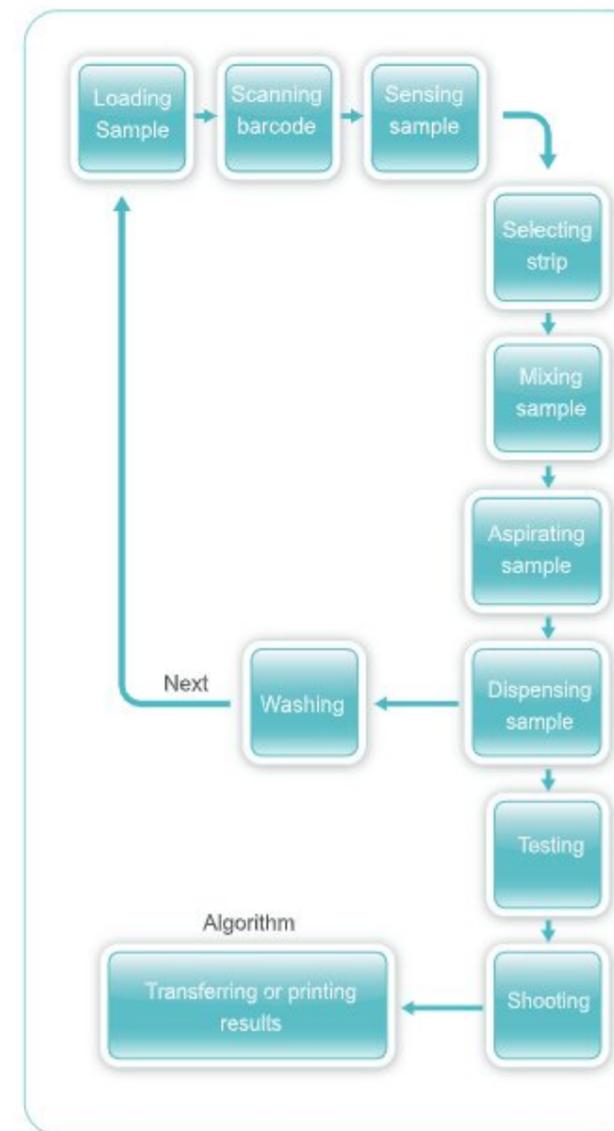
Bacteria



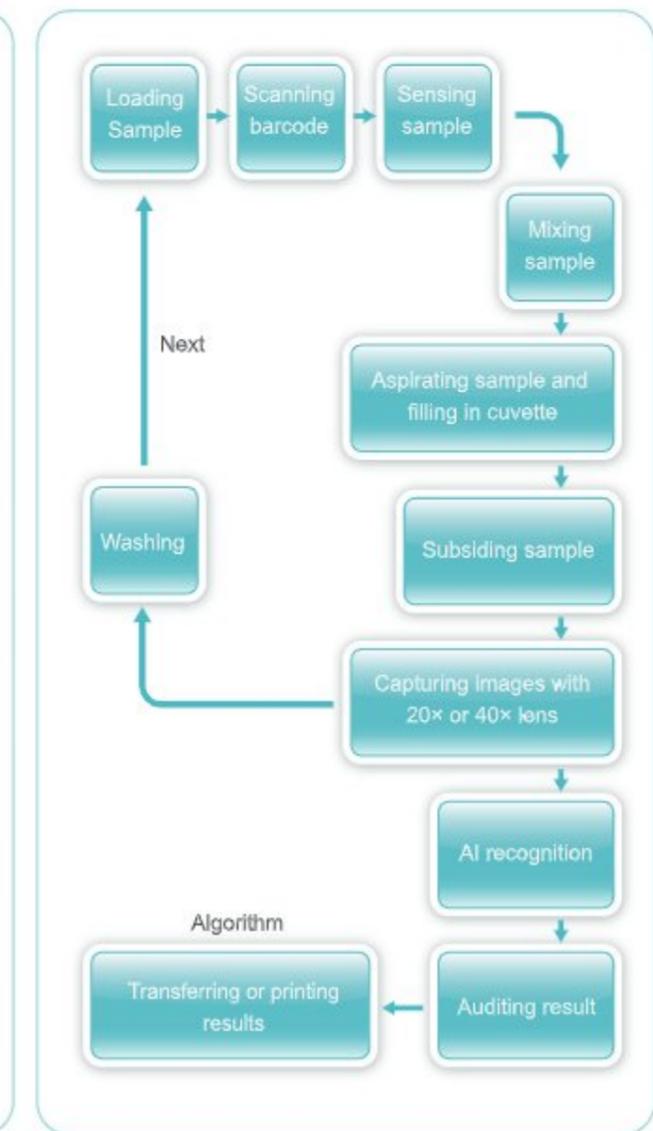
Fungi

Testing Process

Dry Chemistry



Formed elements Analysis





Accurate Testing

(to provide clinical evidence of disease diagnosis)

Through physical technology + new optimization algorithm + plane microscope camera technology, this machine can test the physical indicators and dry chemistry items of urine samples, and test the formed elements by microscopy. Combined with the AI-based image recognition technology based on deep learning, this machine can provide a basis for diagnosis of clinical urine-related diseases, so as to achieve early detection, early diagnosis and early treatment of diseases.

Concentration and dilution function of the kidney

◆Specific Gravity

The specific gravity of urine is quantitatively analyzed based on the principle of optical reflection, achieving a higher accuracy. The specific gravity of urine can roughly reflect the concentration and dilution function of the kidney. Isotonic urine can indicate serious impairment of the dilution and concentration function of the kidney, and can be detected in the polyuric phase of acute renal failure, chronic renal failure, tubulointerstitial nephritis, and acute tubular necrosis.

◆Conductivity

Conductivity is measured by resistivity method. It reflects the concentration and dilution function of the kidney, which is a process of maintaining and regulating the water balance in the body. Renal tubular reabsorption is usually accompanied by the absorption of sodium and chloride ions, so the conductivity of urine can reflect the concentration and dilution function of the kidney.

Turbidity

Turbidity is measured by scattered light method. This is an ancillary test used to determine the presence of urinary system disease. When the urinary system is infected with bacteria, the color or turbidity of the urine will change. This test can help determine the appropriate signs.

Improved automatic color recognition

Urine samples are photographed by a high-definition camera, based on which, the color of urine samples is recognized by special computer algorithms.

High detectability

The two-objective (high and low magnification) auto-focus microscope supports multi-layer photographing of formed elements in a single field of view, which can achieve comprehensive observation of formed elements at different focal lengths, improve the detectability of formed elements and reduce the risk of false negatives.

◆ **The morphological information of red blood cells (urine red blood cell phase) can indicate isomorphic red blood cell, dysmorphic red blood cell or mixed red blood cell, and classify and present the poikilocyte, helping diagnose the bleeding sites of renal diseases.**

◆ **The dry chemistry results can be saved as pictures, and thus can be traced.**

Instrument Features

Patented technology pioneered for multi-focal and multi-layer photographing

- Advanced microscope system with 5MP camera for high-definition images.
- The two-objective (40X and 20X magnification) microscope, scanning at different levels and focal lengths to generate
- images; each objective can take images at multiple levels and focal lengths in a single field of view, obtaining three-dimensional morphological images of cells.
- Image review: fine-tune the microscope to observe the form of cells at different focal lengths and to distinguish cells and casts of different clinical significance more effectively.

Highly accurate recognition

- For automatic recognition of formed elements by the machine through the AI-based image recognition technology based on deep learning, assisted by human judgment, the recognition rate is higher than 95%.

Accuracy

- The difference between the dry chemical analysis results and label-value of corresponding reference solution is not more than 1 order of magnitude.
- Detection accuracy for formed elements: >95%.

Repeatability

- Repeatability: CV<7%.

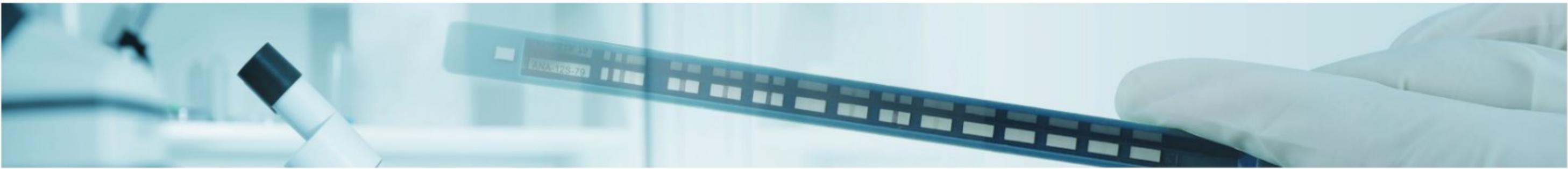
Precise loading of samples

- Minimum urine sample volume of 2mL.
- Rigorous sample loading volume.
- Precise measurement time.



Faster and more flexible

- 4-channel counting cell: four channels work independently to prepare the microscopic examination of the current sample and the processing of the next sample at the same time, greatly increasing the testing speed.
- Rail-mounted sample loading device: with large storage capacity, the sample loading compartment can hold 100 samples at one time; continuous sample loading during the testing process, improving efficiency.
- Testing speed:
dry chemistry: 220 samples/hour; formed element: 60-80 samples/hour;
dry chemistry + formed element: 60-80 samples/hour.
- The test strip compartment allows adding test strips at any time during the test, making it easy to operate.
- STAT function: STAT samples can be tested upon arrival.



Compact and All-In-One Analyzer

- The fully automated integrated analyzer has more powerful features, running physical analysis, dry chemistry analysis and formed element analysis at the same time to generate test results faster.
- Compact size, saving laboratory space; intended for clinical laboratory and outpatient/emergency laboratories of large and medium-sized hospitals, and laboratories of medical institutions at all levels.

Strengthen Informatization, More Accurate

- Built-in barcode scanner: sample tubes are scanned at 360° rotation to avoid the loss of sample data.
- Compatible with LIS, two-way communication function.

Complete QC system

- Original reagent, original test strips, original QC sets.
- New complete urine QC package; an individual QC module in the software; QC samples can be tested directly; one click can perform automatic QC testing; easy to operate.

Safety and Eco-friendliness

- The new urine specimen collector allows sampling by puncturing with cap closed. In the testing process, the test tube is fully sealed and operators do not come into contact with urine sample, which reduces urine odor and the risk of infection.
- Totally-enclosed test strip compartment with desiccant, preventing test strips from moisture and oxidation so as not to affect the test results.
- The inner and outer walls of sampling probe are washed using unique patented cleaning technique. The flow counting cell is cleaned efficiently by automatic washing function to prevent cross contamination.

Test Report

An illustrated and comprehensive report will be generated to provide the results of formed elements (classification and quantitative counting), red blood cell morphological analysis (urine red blood cell phase), urinary dry-chemistry and physical indexes, as well as the morphological images of formed elements in urine.

Test Report for dry chemistry + formed elements

Report sheet of XXX hospital inspection

Name:	Patient type:	Hospitalization no:	Specimen no:
Gender:	Sending section:	Bar code no:	Specimen type:
Age:	Application by:	Medical card no:	Specimen status:

Test name	Results	Unit	Reference interval	Remarks
Urine color			Light yellow/yellow	
Transparency			Clear and transparent	
Cloudiness				

Physical method

Test name	Results	Unit	Reference interval	Remarks
LEU urine white fine suspension	neg	cell/L	Negative	
NET sub. Nitrite	neg	mmol/L	Negative	
URC Urinary RBC	neg	mmol/L	Negative	
URC Hemoglobin	neg	mmol/L	Negative	
URC Hematocrit	neg	mmol/L	Negative	
U-Creatinine/C	neg	mmol/L	Negative	
PRO Protein	g/L	g/L	4.5-8.0	
BLD urine waste blood	neg	cell/L	Negative	
PH Acidity and Alkalinity	/		Negative	
SG Specific Gravity	/		Negative	
GLU Glucose	mmol/L	mmol/L	1.00-1.000	
UA Uric Acid	mmol/L	mmol/L	Negative	
MA Microalbumin	g/L	g/L	Negative	
CA Calcium	mmol/L	mmol/L	4.4-17.7	
CA-urea calcium	mmol/L	mmol/L	2.2-7.3	

Microscopic examination results of formed elements

Test name	Results	Unit	Reference interval	Remarks
Leukocytes	pos	UL		
RBCs	pos	UL		
Erythrocyte	pos	UL		
Microcrystalline	pos	UL		
Squamous epithelial cells	pos	UL		
Transitional epithelial cells	pos	UL		
Microcrystalline	pos	UL		
Transitional tubule type	pos	UL		
Urinary crystals	pos	UL		
Urinary bacteria	pos	UL		
Fungi	pos	UL		
Other	pos	UL		

Microscopic view

Bythocyte histogram map	
Average diameter (UM): 8.1	
Average diameter (UM): 8.1	
Average diameter (UM): 8.1	

Sampling Time: Physician: Received by: Examiner: Reporting time: Reviewer:

This result is only responsible for the current test specimen and is for clinical reference.

Test Report for dry chemistry

Report sheet of XXX hospital inspection

Name:	Patient type:	Hospitalization no:	Specimen no:
Gender:	Sending section:	Bar code no:	Specimen type:
Age:	Application by:	Medical card no:	Specimen status:

Test name	Results	Unit	Reference interval	Remarks
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U-Creatinine/C	neg	mmol/L	Negative	
PRO Protein	g/L	g/L	4.5-8.0	
BLD urine waste blood	neg	cell/L	Negative	
PH Acidity and Alkalinity	/		Negative	
SG Specific Gravity	/		Negative	
GLU Glucose	mmol/L	mmol/L	1.00-1.000	
UA Uric Acid	mmol/L	mmol/L	Negative	
MA Microalbumin	g/L	g/L	Negative	
CA Calcium	mmol/L	mmol/L	4.4-17.7	
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Urinary bacteria	pos	UL		
Fungi	pos	UL		
Other	pos	UL		

Microscopic view

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Sampling Time: Physician: Received by: Examiner: Reporting time: Reviewer:

This result is only responsible for the current test specimen and is for clinical reference.

Test Report for formed elements

Report sheet of XXX hospital inspection

Name:	Patient type:	Hospitalization no:	Specimen no:
Gender:	Sending section:	Bar code no:	Specimen type:
Age:	Application by:	Medical card no:	Specimen status:

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Microscopic view

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