

# Marketing & Sales Guide

## HumaCombilyzer & HumaCombina urine dipsticks



**Executive  
Summary**

**Product  
Information**

**Objection  
Handling /  
Key Selling  
Arguments**

**Competition**

**Marketing  
Support**





# Executive Summary

## Introduction to Urinalysis

A urinalysis is one of the most common diagnostic tests worldwide which helps evaluate health problems, like urinary system infections, kidney issues, and diabetes. It does this by analyzing urine samples.

The analysis is based on parameters such as color, clarity, glucose and protein concentration, pH, and red/white blood cells and crystals. They are part of physical, chemical, and microscopic assessment.

Urinalysis is non-invasive and offers valuable health information. It has been recognized as basic diagnostic tool as it helps in making effective decisions for treatment and early disease evaluation.#



# Executive Summary

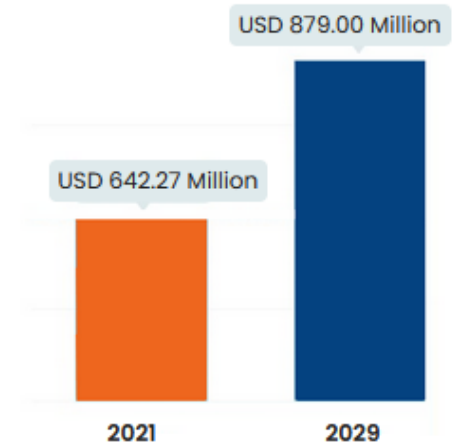
## Global Market

- The **global urinalysis market** attained a value of about USD 2.32 billion in 2024 driven by the rising cases urinary tract infection and geriatric population across the globe. The market is further expected to grow in the forecast period of 2025-2034 at a CAGR of 6.7% to reach nearly USD 4.15 billion by 2034.#
- The market of **urine dipstick** diagnostics is a growing market with an estimated CAGR of 4% until 2029\*. Global market data include dipsticks on top of HumaCombina analytes. These non-HumaCombina strips include pregnancy and fertility urine tests.
- In addition, urine dipsticks come with different **quantities of analyte** of between 2 and 14 analytes on a single strip.
- Furthermore, suppliers often offer their urine dipsticks for visual reading to the public, purchasable in **pharmacies**. A market HUMAN has not decided to cover, yet, but which has been positively influenced by Covid-19 diagnostics, in the western world.
- These factors make it difficult to estimate the specific market size of our newly launched products, in the field of professional use.

### Global Urine Test Strips Market

Marktgröße in Milliarden USD

**CAGR : 4.00%** 



# <https://www.expertmarketresearch.com/reports/urinalysis-market>

\* [https://www.databridgemarketresearch.com/de/reports/global-urine-test-strips-market?srsId=AfmBOoqJkiL2ElbXBtv3rf51q47tvNloZk\\_Pck7bkVsf8HrB3CNIGdH](https://www.databridgemarketresearch.com/de/reports/global-urine-test-strips-market?srsId=AfmBOoqJkiL2ElbXBtv3rf51q47tvNloZk_Pck7bkVsf8HrB3CNIGdH)

# K Executive Summary

## Market Trends

### On-the-Spot Testing (Point-of-Care Tests, POCT)

The adoption of point-of-care testing is increasing due to its ability to deliver rapid results. Healthcare providers frequently rely on this data with minimal delay, enhancing clinical decision-making.

### Growing awareness to Preventive Healthcare

There is a noticeable shift toward preventive healthcare, emphasizing early disease detection. This trend has significantly increased the demand for routine urinalysis and other early diagnostic measures.

### Rising Prevalence of Chronic Diseases

The increasing incidence of chronic conditions such as diabetes, kidney disorders, and liver disease is driving demand in the urinalysis market. Urinalysis plays a crucial role in monitoring these conditions and supporting effective disease management.

### Technological Advancements in Urinalysis Devices

Modern automated and digital urinalysis devices are transforming the market by enhancing diagnostic accuracy and speed. These advanced tools enable more precise urine analysis, aiding healthcare professionals in recommending effective treatment options.



# Executive Summary

## Product Introduction

- **HumaCombilyzer** is a semi-automated urine test strip (dipstick) reader for standardized incubation, automated strip reading, immediate result interpretation, optional printing, convenient data storage.
- **HumaCombilyzer** is HUMAN's next generation instrument replacing the current Combilyzer<sup>13</sup> instrument.
- **HumaCombina** urine test strips are multiparameter dipsticks that can be read visually or with an instrument.
  - **HumaCombina 10** offers 10 analytes and can be run on the new HumaCombilyzer, only.
  - **HumaCombina 13** offers 13 analytes and can be run both, on the new HumaCombilyzer and the current Combilyzer<sup>13</sup>. This strip replaces the current Combina<sup>13</sup> dipstick.
- **HumaCombina** multianalyte urine strips support the diagnostics of diseases like
  - Urogenital disorders
  - Renal insufficiency
  - Diabetes
  - Liver diseases
  - Tumour diagnostics
- Both product types, **HumaCombilyzer** and **HumaCombina** dipsticks are intended for professional use only.



HumaCombina 13	HumaCombina 10
Urobilinogen	Urobilinogen
Bilirubin	Bilirubin
Ketones	Ketones
Creatinine	--
Blood	Blood
Protein	Protein
Microalbumin	--
Nitrite	Nitrite
Leukocytes	Leukocytes
Glucose	Glucose
Specific gravity	Specific gravity
pH	pH
Ascorbic acid	--

# Executive Summary

## Product Compatibility



Visual reading

**HumaCombina 10 NEW** 100 tests 22100

- Urobilinogen
- Bilirubin
- Ketones
- ...
- Blood
- Protein
- ...
- Nitrite
- Leukocytes
- Glucose
- Specific gravity
- pH
- ...

**HumaCombina 13 NEW** 100 tests 22130

- Urobilinogen
- Bilirubin
- Ketones
- Creatinine
- Blood
- Protein
- Microalbumin
- Nitrite
- Leukocytes
- Glucose
- Specific gravity
- pH
- Ascorbic acid

**HumaCombilyzer NEW**



Installed base  
>500 units

**Sell of stock**  
**Combina 13** 100 tests 22132

**Discontinuation 04/2025**  
**Combina 11S** 150 tests 23111

**Sell of stock**  
**Combilyzer<sup>13</sup>** 17600



# Executive Summary

## Positioning and Target Customers



### Market Segment

- Hospital labs (private / public)
- Private labs
- Doctor's offices (urologists)
- General practitioners
- Health-posts (more rural)
- University labs

### Customer Segment

- Labs testing for urogenital, kidney, liver diseases.
- Labs already using urine dipsticks with visual reading.
- Labs already using urine dipsticks for urogenital diseases with semi-automated reading.
- Small labs, health posts or doctors' offices running at least about
  - 3 - 60 urine strips/day
  - 100 – 1.000 urine strips/month
  - 1200 – 12.000 urine strips/year

### Target Customer

1. Existing Combilyzer<sup>13</sup> end-users needing a Combina 13 alternative strip.\*
2. Existing Combina 13 end-users needing a replacement strip.\*
3. Labs running non-HUMAN urine dipsticks.
4. Labs running non-HUMAN urine instruments.
5. Growing labs requiring additional instruments.

\* Important: Combina 13 (REF 221322) will be discontinued in 2025

# Executive Summary



## Positioning statement HumaCombilyzer

*HumaCombilyzer is the ideal semi-automated one-channel urine test strip reader for lower volume sample labs and labs in more remote areas that require a higher degree of on-the spot user flexibility or lack consistent access of electricity, through its lightweight of only 600g and its capability of being optionally battery-powered.*



# K Executive Summary

## Competition



Competition in the diagnostic segment of urinalysis is very broad. Apart from the

- **corporate groups** offering semi-automated and/or fully-automated urine strip testing analyzers, like Abbott, Roche, Beckman Coulter, Sysmex or Siemens, there are a lot of
- **smaller or more specialized** companies offering urine dipsticks with reading instruments like ACON Laboratories, E77, NeoMedica, Clarity Diagnostics, Cormay, DFI Care, EKF, Germaine, YD Diagnostics, TECO or
- **without urine strip readers** like Nal-van-Minden, and of course
- **Chinese** companies are pushing more forcefully into the global markets, like DIRUI, AVE, Bioway, EMPSUN, Mejer, Qingdao, Rayto, Urit, Mindray, just like other
- **Asian** companies like Humasis, Arkray. Furthermore, manufacturers in
- **India** will become more present, globally. And of course, the many
- **OEM** partners like Analyticon, LifeAssay, probably some companies mentioned above as well as
- **Trade houses** like Henry Schein Medical and more.

The picture is far from being complete but should allow some insight into the dimension of competitive activities one can encounter in the field.

# Product Information HumaCombilyzer



Intended use



Product overview



# HumaCombilyzer & HumaCombina urine dipsticks



## Intended Purpose

### HumaCombilyzer (REF 17630)

HumaCombilyzer is a semi-automated urine test-strip reader for qualitative or semi-quantitative detection of urobilinogen, bilirubin, ketones, creatinine, blood, protein, microalbumin, nitrite, leukocytes, glucose, specific gravity, pH and ascorbic acid (vitamin C), calcium in human urine. In combination with HumaCombina urine test strips it may be used to screen for a range of medical conditions. For laboratory professional use only.

### HumaCombina (REF 22100 and REF 22130)

HumaCombina are urine testing strips for the semi-quantitative determination of urobilinogen (UBG), bilirubin (BIL), ketones (KET), creatinine (CRE), blood (ERY/Hb), protein (PRO), microalbumin (ALB), nitrite (NIT), leucocytes (LEU), glucose (GLU), specific gravity (SG), pH, ascorbic acid (VC). The strips are intended for screening patients for diseases like diabetes, liver diseases, hemolytic diseases, urogenital disorders, kidney disorders, and metabolic abnormalities. The urine strips are intended for evaluation by reflectometric reading or by visual reading. The strips are intended for professional use only.



# HumaCombilyzer system

## Components



### HumaCombilyzer instrument

Semi-automated urine strip reader



### HumaCombina 13 strips

100 strips/vial for testing of 13 analytes

Bilirubin, blood, glucose, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, **ascorbic acid, creatinine, microalbumin**



### HumaCombina 10 strips

100 strips/vial for testing of 10 analytes

Bilirubin, blood, glucose, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen

# HumaCombina 10 and HumaCombina 13

## General Information

### Test strips / bottle

100 strips

### Stability

Shelf-life 24 months  
In-use 30 days

### Storage temperature

2 - 30 °C  
Not in refrigerator.



### Analytes on strips

**10:** URO, BIL, KET, Blood, PRO, NIT, LEU, GLU, SG, pH

**13:** 10 + CREA + MALB + VC + MALB:CREA-ratio

### Testing temperature

20 - 30 °C

### Incubation time

60 seconds

Do not interpret coloration after > 2 min. after immersion.

### Instrument Applications

**10:** HumaCombilyzer

**13:** HumaCombilyzer  
**13:** Combilyzer<sup>13</sup>



# HumaCombilyzer

## Technical specifications



**Portable,  
handheld device**

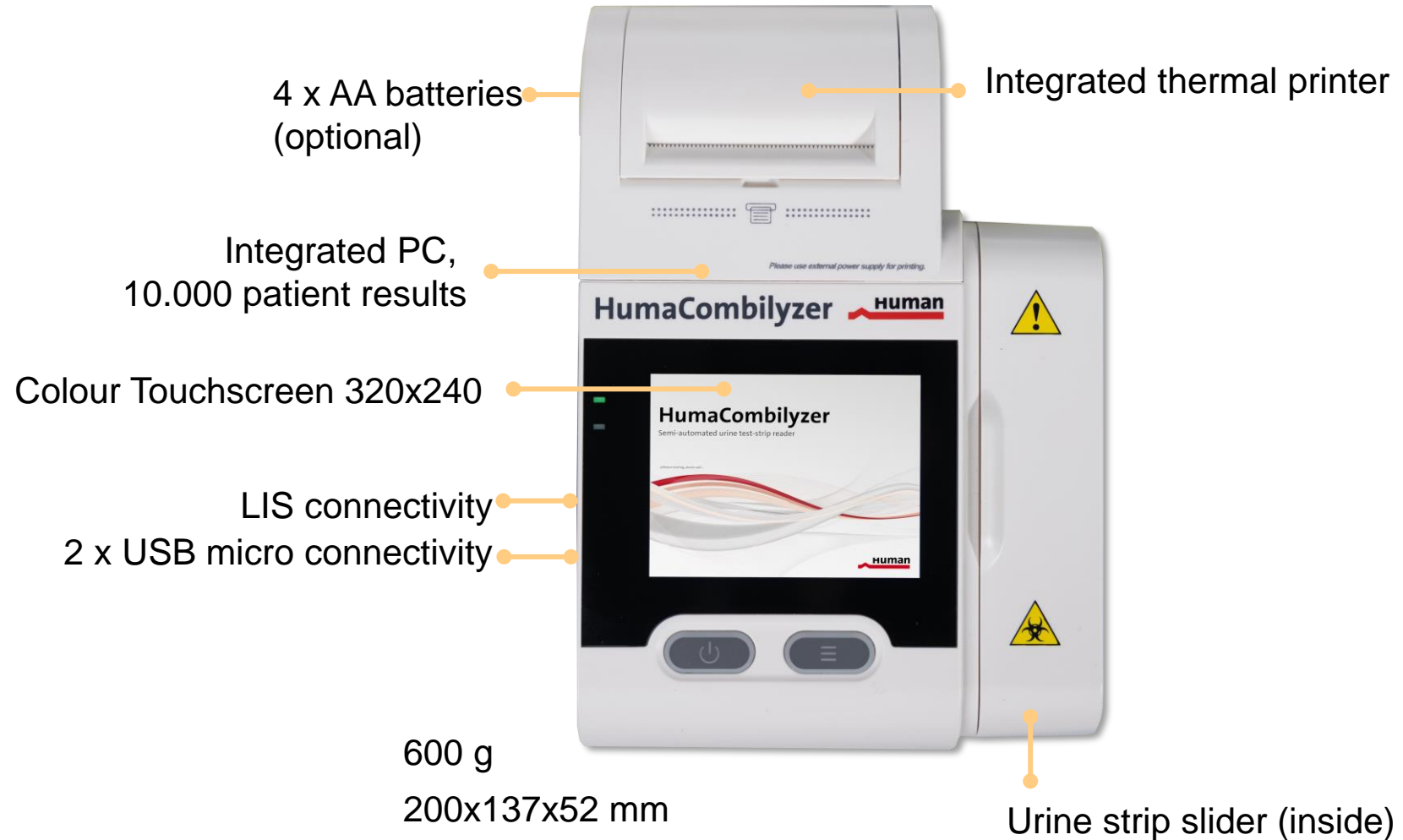


Aspect	Detail
Display	320x240 LED touchscreen
Languages	English, Spanish, Chinese. More to come.
Electrical requirements	AC 220V±22V 50Hz±1Hz DC 5.85V±0.45V (4xAA Batteries)
Incubation time	60 sec. / strip
Battery-driven	Optional
Sample type	Native urine
Printer	Built-in thermal printer
Storage	10,000 patient results
LED wavelengths	470nm, 525nm, 625nm



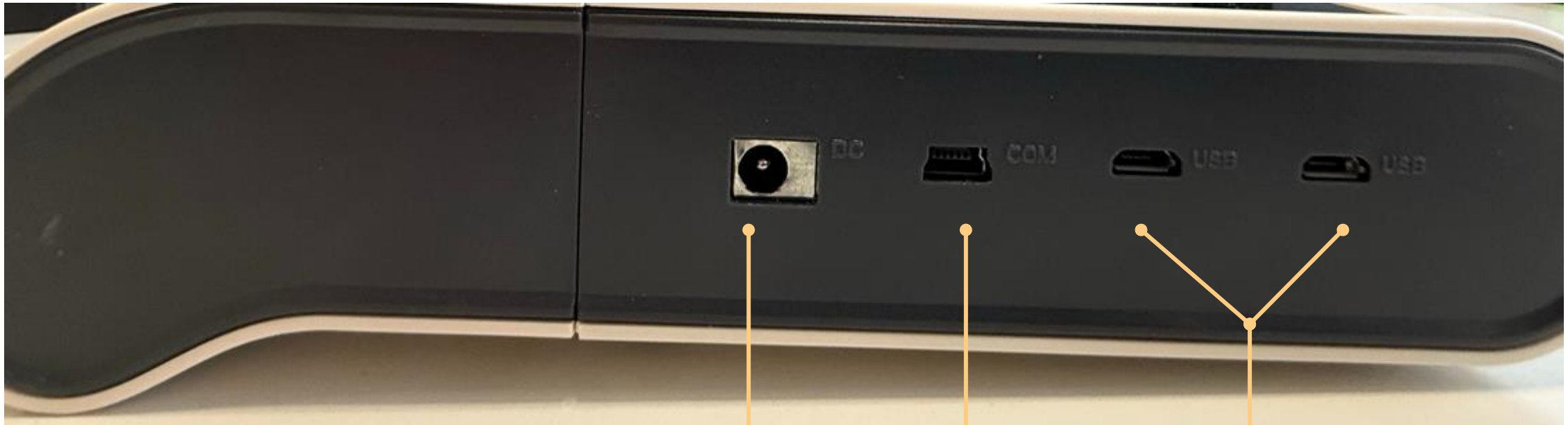
# HumaCombilyzer

## Technical Specifications



# K HumaCombilyzer

## External connectivities



**DC power connection**  
power supply

**COM port (USB mini)**  
Serial port for

- LIS connectivity
- Software upgrade

**2 x USB micro**  
To optionally connect

- barcode reader
- external printer





# HumaCombilyzer

## Packing list (REF 17630)



REF	Content	Quantity
17630	HumaCombilyzer	1
17630/1	User manual	1
17630/15	Calibration strip (in a protecting plastic tube)	1
17630/18	Power supply	1
15024/100	Printing paper (supported dimension max D30mm L57mm)	1
<b>Accessory not supplied with HumaCombilyzer. Item to be ordered separately</b>		
17630/50	Hand-held barcode reader (with adapter cable for USB micro to USB-A)	1
17630/51	Serial adapter cable (for COM USB Mini to RS232) for LIS and software update	1

# Key Selling Arguments HumaCombilyzer & HumaCombina



Key Selling Arguments



Feature – Benefit - Value



Comparison HumaCombilyzer and Combina<sup>13</sup>



# HumaCombilyzer & HumaCombina

## Main Features



### HumaCombilyzer (REF 17630)

- reflection photometer
- semi-automated urine test-strip reader
- Internal QC-module
- qualitative or semi-quantitative detection
- built-in thermal printer
- LIS capability
- detection of up to 14 analytes
- human urine specimen
- HumaCombina urine test-strips only (closed system)
- screening for a range of medical conditions.



### HumaCombina (REF 22100 and REF 22130)

- dipstick urine testing strips
- human urine specimen
- 10 or 13 analytes per strip
- visual or automated result reading on HumaCombilyzer.
- HumaCombina 13 reading on Combina<sup>13</sup>
- screening patients for diseases like
  - ❖ diabetes,
  - ❖ liver diseases,
  - ❖ hemolytic diseases,
  - ❖ urogenital disorders,
  - ❖ kidney disorders.

# Urine Strip Reader and Urine Strip Options

## Key Selling Arguments

### HumaCombilyzer

- Handheld, on-the-spot urine strip reader.
- Intuitive graphical user interface (GUI).
- Easy-to-use instrument.
- Saves distributor strip revenue through credit-system (barcode); closed system.
- Fast responding touchscreen.
- QC-module (internal).
- Light-weight handheld device.
- Battery-driven (optional).
- Optional direct printing.
- Large data storage capacity (10.000 patient results).
- LIS capability



### HumaCombina 10 and HumaCombina 13

- Portfolio with different strips to choose from.
- Strips can easily be read visually.
- Strips can be processed on HumaCombilyzer.

HumaCombina 13	HumaCombina 10
Urobilinogen	Urobilinogen
Bilirubin	Bilirubin
Ketones	Ketones
Creatinine	--
Blood	Blood
Protein	Protein
Microalbumin	--
Nitrite	Nitrite
Leukocytes	Leukocytes
Glucose	Glucose
Specific gravity	Specific gravity
pH	pH
Ascorbic acid	--

### HumaCombina 13

- Same analyte sequence like Combina 13 strips
- HumaCombina 13 can be run on current Combilyzer<sup>13</sup>.
- Microalbumin-to-creatinine ratio available.

HumaCombina 13
Urobilinogen
Bilirubin
Ketones
Creatinine
Blood
Protein
Microalbumin
Nitrite
Leukocytes
Glucose
Specific gravity
pH
Ascorbic acid



# HumaCombilyzer



Main Menu



## Key Benefits and Values of main Features

Feature	Benefit	Value
<b>Automated</b> - incubation, - strip reading - result interpretation	Supporting patient result standardization.	<ul style="list-style-type: none"> <li>✓ <b>Increasing diagnostic accuracy</b> making results comparable and reducing variability.</li> <li>✓ <b>Improving patient safety</b> through the reduction of misinterpretation due to inconsistent visual reading and result interpretation.</li> <li>✓ <b>Increasing effectiveness of treatment decisions</b></li> </ul>
<b>Optional battery-powered lab device</b>	Allowing portability, increased flexibility and reliability.	<ul style="list-style-type: none"> <li>✓ <b>Ensuring diagnostic capability under various conditions</b> like the use in remote locations, field diagnostics, ambulances and mobile labs.</li> <li>✓ <b>Supporting diagnostics in rural or developing regions</b>, where power supply can be inconsistent.</li> </ul>
<b>QC-module onboard</b>	Allowing the continuous monitoring of test accuracy, reliability, and compliance with regulatory standards.	<ul style="list-style-type: none"> <li>✓ <b>Ensuring patient result reliability</b> by minimizing variability, thus ensuring consistency across multiple runs.</li> <li>✓ <b>Increasing patient safety</b> through real-time error detection identifying calibration drift, reagent degradation, or system malfunctions before they impact patient results.</li> </ul>
<b>Built-in thermal printer</b>	Allowing for immediate, reliable, and cost-effective printing of test results.	<ul style="list-style-type: none"> <li>✓ <b>Providing quick access to test results</b> without needing an external printer or network connection.</li> <li>✓ <b>Increasing patient safety</b> by eliminating potential transcription errors.</li> <li>✓ <b>Enhances workflow-efficiency</b> especially with decentralized testing like in field diagnostics, ambulances, and remote clinics enhancing patient record management (printed results can be attached to physical records)</li> </ul>
<b>Storage of 10,000 results</b>	Increasing traceability and immediate result retrieval.	<ul style="list-style-type: none"> <li>✓ <b>Increasing cost efficiency and operational effectiveness</b> by ensuring previously collected results to be easily available for further diagnostics.</li> <li>✓ <b>Enabling quick result retrieval</b> previous results can be reviewed directly on the device without needing external records.</li> <li>✓ <b>Increasing workflow-efficiency</b> through periodic export of batch release reports of stored data.</li> <li>✓ <b>Enhancing patient safety</b> through ensured QC-tracking (documentation of quality control).</li> </ul>
<b>LIS capability</b>	Allowing for real-time data transfer and eliminating risk of result error transcription	<ul style="list-style-type: none"> <li>✓ <b>Increasing workflow-efficiency</b> through instant result availability.</li> <li>✓ <b>Increasing patient safety</b> through result traceability by linking results directly to patient records, preventing misidentification or misplaced reports.</li> </ul>



# HumaCombilyzer

## More Key Benefits and Values



Feature	Benefit to END-USER	Benefit to DISTRIBUTOR
Open device for HumaCombina strips	Ensure quality results from	Saving distributor revenue.
Capability of running different strips presenting different analytes	Providing increased versatility, supporting multiple clinical applications on the same device.	Supporting additional potential revenue.
LIS capability	See previous slide	Allowing offers of state-of-the-art products
QC-module onboard	Built-in quality assurance; see previous slide	Enhancing the overall value proposition of HumaCombilyzer.



# HumaCombilyzer

## Comparison to Combina<sup>13</sup>



New



Feature	HumaCombilyzer (REF 17630)	Combilyzer <sup>13</sup> (REF 17600)
Format	Handheld	Benchtop
Weight	600 g	4 kg
Dimensions LxWxH	200 x 137 x 52 mm	400 x 330 x 185 mm
Detection technology	Reflection photometer	Reflection photometer
Reading	1 channel	1 channel
Operator interface	Large coloured touch-screen 320 x 240 pixel	18-button keypad Narrow LCD-screen
Battery-driven	4 x AA (optional)	-
Instrument design	Modern appearance	old-fashioned
Built-in thermal printer	available	available
GUI (Graphical User Interface)	Modern appearance, coloured	Difficult to read LCD-screen w/o icons
Languages (instrument)	English, Spanish, Chinese at launch. More to come.	EN, SP, IT, PL, PO, TK, DE
Data storage	10.000 results	5.000
LIS capability	RS-232 serial interface	RS-232 serial interface
Calibration strip	available	available
Handheld barcode scanner	optional (sample ID, credits)	comes with instrument
Fast mode	-	available
Information urine colour	-	user information possible

# Product Information

## HumaCombina



HumaCombina urine strip offer



Analyte Interpretation





# HumaComбина

## Urine strips offer



Aspects	HumaComбина 10	HumaComбина 13
Catalogue code	REF 22100	REF 22130
Analytes on strip; see picture	10 analytes	10 analytes + CREA, MALB, VC
Visual reading support	available	available
Instrument applications	HumaCombilyzer (REF 17630)	HumaCombilyzer (REF 17630) Combilyzer <sup>13</sup> (REF 17600)
Microalbumin-to-creatinine ratio (ACR)	-	ACR calculation available; and on printout
Incubation time	60 sec.	
BioRad Liquicheck Urinalysis controls	Target values & Target value Ranges from control lot 98050 onwards	

### HumaComбина 13



- Urobilinogen
- Bilirubin
- Ketones
- Creatinine
- Blood
- Protein
- Microalbumin
- Nitrite
- Leukocytes
- Glucose
- Specific gravity
- pH
- Ascorbic acid

### HumaComбина 10

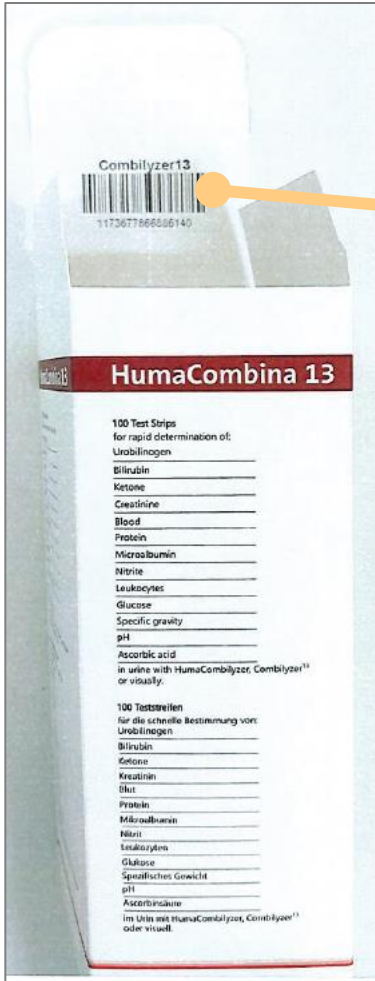


- Urobilinogen
- Bilirubin
- Ketones
- 
- Blood
- Protein
- 
- Nitrite
- Leukocytes
- Glucose
- Specific gravity
- pH
-



# HumaCombina

## Box & Bottle label



**Combilyzer<sup>13</sup>**  
100 HumaCombina 13 strip readings / barcode

**HumaCombilyzer**  
• 100 HumaCombina 13 strip readings / barcode  
• 100 HumaCombina 10 strip readings / barcode

### HumaCombina 13

for/für/para/pour HumaCombilyzer, Combilyzer<sup>13</sup>

Visual read at / visuelle Auswertung nach / lectura visual después de / lecture visuelle après: 60 sec.

IVD ⓘ CE

Σ 100 ⓘ

REF 22130

LOT

2...30°C

Beijing HumaDX Tech Co., Ltd  
Room 1309, 3rd Floor, 1st Block, No. 55 Jiachuang 2nd Road, BDA 101111, Beijing, China  
Tel: +86-10-80828658, E-Mail: service@humadx.com.cn

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Max-Planck-Ring 21, 65205 Wiesbaden, Germany  
Tel: +49-6122-99880, E-Mail: human@human.de

EC REP

**Human**  
Diagnostics Worldwide

UROBILINOGEN UROBILINOGENO UROBILINOGENE	0 (10)	1+ (25)	2+ (50)	3+ (100)	4+ (>150)
BILIRUBIN BILIRUBINA BILIRUBINE	Neg	1+ (17.1)	2+ (34.2)	3+ (51.3)	4+ (>102.6)
KETONES KETONE CETONAS CETONES	Neg	± (0.5 (5))	1+ (1.5 (15))	2+ (3.0 (30))	3+ (7.5 (75))
CREATININE KREATININ KREATININA KREATININE	0 (0.10)	4 (4.00)	8 (8.00)	12 (12.00)	20 (20.00)
BLOOD (ERY/Hb) BLUT (ERY/Hb) SANGRE (ERY/Hb) SANG (ERY/Hb)	Neg	± (0.10)	± (0.10)	1+ (0.25)	2+ (0.50)
PROTEIN PROTEÍNAS PROTEÏNES	Neg	± (Trace)	1+ (0.30)	2+ (0.60)	3+ (0.90)
MICROALBUMIN MIKROALBUMIN MICROALBUMINA MICROALBUMINE	±g	30	80	> 150	
NITRITE NITRIT NITRÍOS	Neg	Any degree of urinary pink colour			
LEUCOCYTES LEUCOCYTEN LEUCOCITOS	Neg	± (0.15)	± (0.15)	1+ (0.70)	2+ (1.20)
GLUCOSE GLUKOSE GLUCOSA	Neg	± (2.50)	1+ (5.00)	2+ (10.00)	3+ (20.00)
SPECIFIC GRAVITY SPEC. GRAVITY GRAVEDAD ESPECIFICA DENSIDAD URINARIA	< 1.000	1.025	1.010	1.015	1.020
pH	< 5.0	6.0	6.5	7.0	7.5
ASCORBIC ACID ASCORBINSÄURE ÁCIDO ASCÓRBICO ÁCIDO ASCORBÍQUE	0	0.6 (10)	1.4 (25)	3.8 (50)	7.5 (>100)

REV 01/25/003

- Visual reading
- Comparable look & feel to Combina strips

# HumaCombina dipsticks

## Analyte Interpretation

HumaCombina 13

Urobilinogen
Bilirubin
Ketones
Creatinine
Blood
Protein
Microalbumin
Nitrite
Leukocytes
Glucose
Specific gravity
pH
Ascorbic acid

HumaCombina 10

Urobilinogen
Bilirubin
Ketones
--
Blood
Protein
--
Nitrite
Leukocytes
Glucose
Specific gravity
pH
--

### Most important Analytes in Urine

- 1) Most important analyte is **blood** in urine due to e.g. infection or tumour.
- 2) If blood turns out positive, then check **leucocytes**. If both, blood and LEU pos, then most probably a bladder infection
- 3) 3<sup>rd</sup> most often is **protein** pos; protein deriving from the surface of bacteria.
  - Protein only pos. can be a sign of renal insufficiency
- 4) **Nitrite** is produced only by bacteria, like E.coli (bladder infection: blood, LEU, NIT pos.)
- 5) **Glucose** should be negative. If positive it can be a sign of diabetes.

### Further Analytes

- 6) **Sedimentation Gravity (SG)** 1000= water (1.005 – 1.030 is normal)
- 7) **pH** kidney stones
- 8) **Ketone** liver disease
- 9) **URO** liver disease
- 10) **BIL** liver disease

### Three more Analytes plus ALB-to-CREA-ratio

- 6) **Creatinine** normal
- 7) **Microalbumin** stones
- 8) **Albumin-to-creatinine-ratio** renal status
- 9) **Ascorbic acid** to support diagnosis of Vitamin C deficiency (food intake, medication)

# HumaCombina dipsticks

## Initial diagnostics

### Colour of Urine

- Normal urine: white/transparent/clear
- Alarming signal: Red/brownish => blood
  - w/ pain => bladder infection
  - w/o pain => bladder tumour?
  - Food intake: beetroot
- Pink / orange: medication  
e.g. Nitrofurantoin is urine soluble and colours the urine.
  - Brown: Insufficient drinking
  - Liver insufficiency
- Milky/turbid
  - Sign of inflammation
- Green
- Blue: Very ill



# Product Information

## HumaCombilyzer & HumaCombina



Testing of HumaCombina on HumaCombilyzer



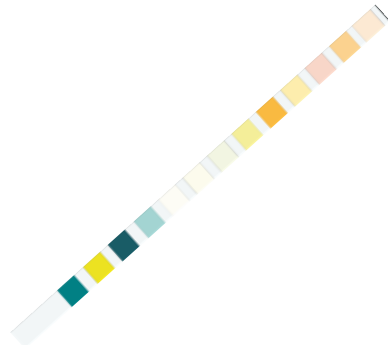
Method comparisons

# HumaCombina dipsticks

## Test procedure



Medium-jet urine



Transfer urine or control material into a tube and perform a dipstick test (10 or 13 parameter)

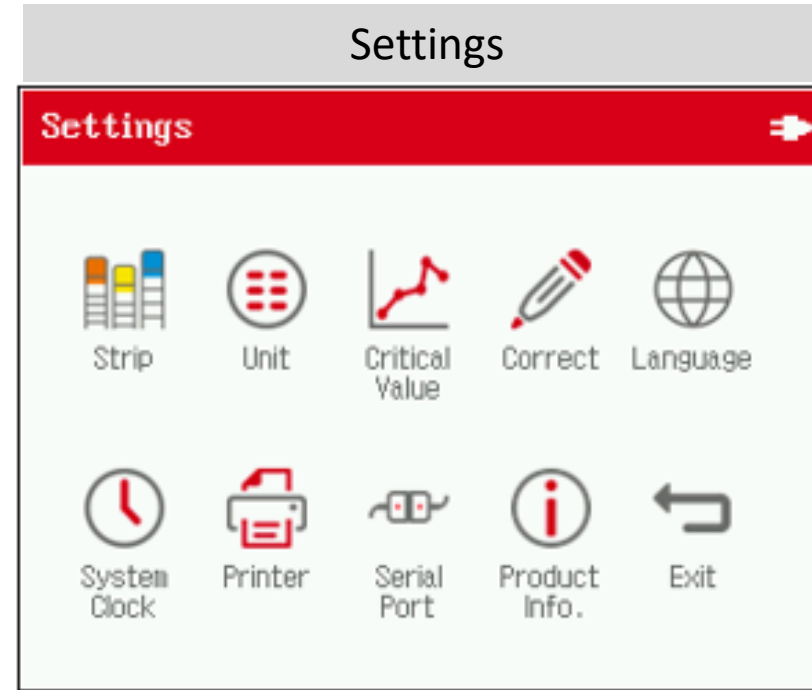
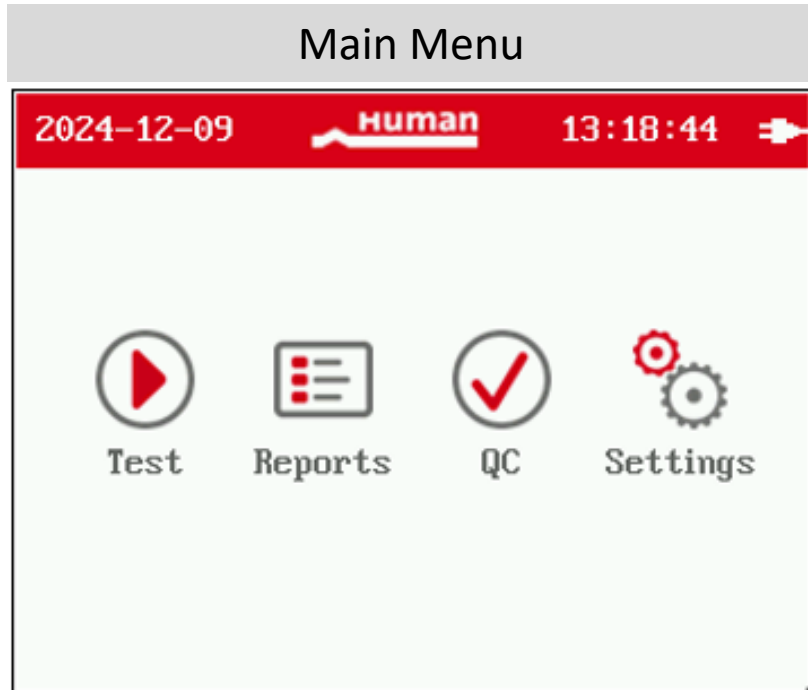


Insert sample strips into HumaCombilyzer for standardized incubation (60 sec.) and automated reading followed by result storage or direct printing.



# HumaCombilyzer

## User Interface main Touchscreens

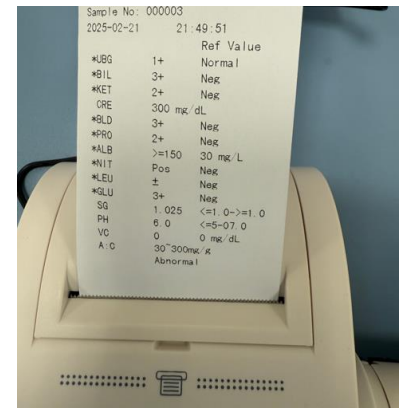


- Humanized “red”
- Modern look and feel
- Humanized icons with descriptive text



# HumaCombina

## Printout on HumaCombilyzer



### Arbitrary values

### Conventional values

### International (SI) values

Arbitrary values				Conventional values				International (SI) values			
Sample No: 08012007				Sample No: 08012007				Sample No: 08012007			
2025-03-05 11:04:07				2025-03-05 11:04:07				2025-03-05 11:04:07			
		Ref Value									
UBG	Normal	Normal		UBG	Normal	0.2 mg/dL		UBG	Normal	3.4 μmol/L	
BIL	Neg	Neg		BIL	Neg	Neg.		BIL	Neg	Neg.	
KET	Neg	Neg		KET	Neg	Neg.		KET	Neg	Neg.	
CRE	200 mg/dL			CRE		200 mg/dL		CRE		17.7 mmol/L	
*BLD	3+	Neg		*BLD	3+	>=200Ery/μL		*BLD	3+	>=200Ery/μL	
*PRO	1+	Neg		*PRO	1+	30 mg/dL		*PRO	1+	0.3 g/L	
*ALB	>=150	30 mg/L		*ALB		>=150 mg/L		*ALB		>=150 mg/L	
*NIT	Pos	Neg		*NIT		Pos		*NIT		Pos	
LEU	Neg	Neg		LEU	Neg	Neg.		LEU	Neg	Neg.	
*GLU	1+	Neg		*GLU	1+	100 mg/dL		*GLU	1+	5.6 mmol/L	
SG	1.020	<=1.0->=1.0		SG	1.020			SG	1.020		
PH	6.0	<=5-07.0		PH	6.0			PH	6.0		
VC	0	0 mg/dL		VC		0 mg/dL		VC		0 mmol/L	
A:C	30~300mg/g	Abnormal		A:C	30~300mg/g	Abnormal		A:C	3.4~33.9mg/mmol	Abnormal	

Note: Ref Value = Reference Value = Critical value (CV)



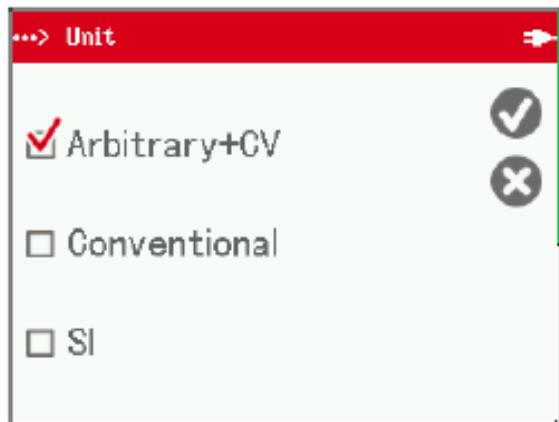


# HumaCombilyzer / HumaCombina

## U/M offers all Alternative Result Units

### Instrument Screen / Print out "Unit"

Select "Unit"  in the setting menu:



### User Manual

#### 11. GRADIENT TABLE

	Arbitrary	International (SI)	Conventional
UBG	Normal	3.4 $\mu\text{mol/L}$	0.2 mg/dL
	Normal	17 $\mu\text{mol/L}$	1 mg/dL
	1+	34 $\mu\text{mol/L}$	2 mg/dL
	2+	68 $\mu\text{mol/L}$	4 mg/dL
	3+	$\geq 135 \mu\text{mol/L}$	$\geq 8 \text{ mg/dL}$
BIL	Neg.	Neg.	Neg.
	1+	17 $\mu\text{mol/L}$	1 mg/dL
	2+	51 $\mu\text{mol/L}$	3 mg/dL
	3+	$\geq 103 \mu\text{mol/L}$	$\geq 6 \text{ mg/dL}$

Note: CV = Critical value = Reference Value = Ref Value

# Method Comparison to non-HUMAN devices

## HumaCombina 10 & 13

n = 340 samples each for every analyte distributed throughout the whole measuring range (concentrations).		HumaCombina 13/HumaCombilyzer vs. DIRUI R14Ca/Dirui N600		HumaCombina 10/HumaCombilyzer vs. DIRUI R14Ca/Dirui N600	
Analyte	Unit	% overall concentration levels exact match	%-agreement (± one colour pad)	% overall concentration levels exact match	%-agreement (± one colour pad)
Urobilinogen	µmol/L	95.59 %	100 %	96.76 %	100 %
Bilirubin	µmol/L	99.41 %	100 %	99.41 %	100 %
Ketone	mmol/L	95.29 %	100 %	97.06 %	100 %
Creatinine	mmol/L	95.00 %	100 %	-	-
Blood	Ery/µL	95.59 %	100 %	96.76 %	100 %
Protein	g/L	97.94 %	100 %	97.65 %	100 %
Microalbumin	mg/L	96.76 %	100 %	-	-
Nitrite	Neg. / Pos.	99.71 %	100 %	99.41 %	100 %
Leukocytes	Leu/µL	96.76 %	100 %	97.65 %	100 %
Glucose	mmol/L	98.24 %	100 %	98.82 %	100 %
Specific Gravity	-	80.00 %	99.12 %	85.00%	100 %
Ascorbic Acid	mmol/L	100.00 %	100 %	-	-
pH	-	95.00 %	100 %	97.35 %	100 %
Microalbumin-to-creatinine ratio	mg/g	89.12 %	na	-	-

# Method Comparison to HUMAN Combilyzer<sup>13</sup>

## HumaCombina 13

n = 100 samples each for every analyte distributed throughout the whole measuring range (concentrations).

**HumaCombina 13/HumaCombilyzer vs.  
HumaCombina 13/Combilyzer<sup>13</sup>**

Analyte	Unit	% overall concentration levels exact match	%-agreement (± one colour pad)
Urobilinogen	µmol/L	94.00 %	100 %
Bilirubin	µmol/L	99.00 %	100 %
Ketone	mmol/L	94.00 %	100 %
Creatinine	mmol/L	93.00 %	100 %
Blood	Ery/µL	94.00 %	100 %
Protein	g/L	96.00 %	100 %
Microalbumin	mg/L	96.00 %	100 %
Nitrite	Neg. / Pos.	99.00 %	100 %
Leukocytes	Leu/µL	95.00 %	100 %
Glucose	mmol/L	97.00 %	100 %
Specific Gravity	-	80.00 %	99.12 %
Ascorbic Acid	mmol/L	100.00 %	100 %
pH	-	91.00 %	100 %

# SWOT & Competition



Is / Is Not



SWOT analysis and objection handling



HumaCombilyzer key selling points vs. competitors





# HumaCombilyzer

## Is / Is Not



Is	Is not
Replacing Combilyzer <sup>13</sup>	More than one reading channel
Semi-automated urine strip reader for small labs, health posts or doctors' offices running at least about <ul style="list-style-type: none"><li>• 3 – 60 urine strips/day</li><li>• 100 - 1.000 urine strips/month</li><li>• 1200 - 12.000 urine strips/year</li></ul>	Fully-automated urine strip reader
Intended for bundle business with HumaVision (REF 17660)	

# HumaCombilyzer & HumaCombina

## SWOT Analysis & Arguments

### STRENGTHS

- **Small handheld, optionally battery-powered device**  
=> versatile use even in rural or developing regions, where power supply is not available or can be inconsistent
- **HUMANized look & feel** => affordable products, German-quality-proven device
- **System closed for non-HumaCombina strips**  
=> easy opening for HumaCombina urine testing strips via barcode reading to safe revenue to distributors & HUMAN

### OPPORTUNITIES

- **Growing urinalysis market**  
=> serve the market demand with an attractive device
- **Brand new instrument with HumaVision bundle opportunity**  
=> door opener for new discussions & competitor lock-out
- **Existing urinalysis customer base**  
=> large customer base to offer HumaCombina 13 and 10

### WEAKNESSES

- **HUMAN is not widely known as strong urinalysis supplier**  
=> early adopters needed (reference labs)  
=> win tenders
- **Limited reagent portfolio at time of launch**  
=> identification of correct labs  
=> identify which further strip options should be introduced

### THREATS

- **Large number of competitors**  
=> Identify best pricing strategy in every country



# HumaCombilyzer



## Main Competitors' Technical Specifications



HumaCombilyzer (HUMAN)	CLINITEK Status <sup>®</sup> + Analyzer (Siemens Healthineers)	Urisys 1100 (Roche)	UC-1000 (Sysmex)
Stores 10,000 results	700 results	1,000 patient results	5,000 results
Coloured touchscreen	Grey, black interface.	White, blue	Grey, black, white, blue
Handheld (W x D x H; mm) 137 x 200 x 52	Benchtopy 171 x 272 x 158	Benchtopy 50 x 287 x 102	Benchtopy 315 x 215 x 135
Portable 600g	1.66 kg	1 kg	2,5 kg
10 or 13 parameter	13 parameter	10 parameter	10 or 12 parameter

# Sales Supporting Material



Control Material



Sales Tools



Sales Aspects





# HumaCombilyzer

## Third party control material

### BioRad Liquichek Urinalysis Control

- HUMAN Target values / Target value ranges
- Lot 98050 and higher
- On HUMAN website



HUMAN			
Target Values			
BioRad Liquichek™ Urinalysis Control			
435 435 (Level 1) 12x12 (5 per level) 435 435 (Level 2) 12x12 435 901 (Level 1) 12x12 (5 per level)		[LOT] 98050	Level 1 98051
		Level 2 98052	
		[IPI]	16 2024-07-31
		Link for latest version of target value sheet: <a href="https://www.human.de/urinalysis/target-value-sheet">https://www.human.de/urinalysis/target-value-sheet</a>	
REF			
HUMAN HumaCombis 13 TEST STRIP (REF 22130) / HUMAN (REF 22130)	Parameter / Analyte	Level 1 - 98031	Level 2 - 98032
	Bilirubin	Negative	01 - 103 µmol/L (2+ - 3+)
	Blood	Negative	ca. 80 - 200 Wbc/µL (2+ - 3+)
	Creatinine	50 - 200 mg/dL (4.4 - 17.7 mmol/L)	200 - 300 mg/dL (17.7 - 26.5 mmol/L)
	Glucose	Negative	200 - 300 mg/dL (14 - 28 mmol/L)
	Ketones	Negative	15 - 78 mg/dL (1.5 - 7.8 mmol/L)
	Leukocytes	Negative	70 - 125 Leuco/µL
	Microalbumin	10 mg/L	80 - 150 mg/L
	Nitrite	Negative	Positive
	pH	5.0 - 8.0	5.0 - 8.0
	Protein, Total	Negative	100 - 300mg/dL (1.0 - 3.0 g/L)
	Specific Gravity	1.000 - 1.020	Abnormal: 30 - 300 mg/g (3.4 - 33.9 mg/mmol) 1.000 - 1.030
	Urobilinogen	0.2 mg/dL (3.4 µmol/L)	2 - 8 mg/dL (34 - 132 µmol/L)
HUMAN HumaCombis 13 TEST STRIP (REF 22130) / Combilyzer 13 ANALYZER (REF 17360)	Parameter / Analyte	Level 1 - 98031	Level 2 - 98032
	Bilirubin	Negative	01 - 103 µmol/L (2+ - 3+)
	Blood	Negative	ca. 80 - 200 Wbc/µL (2+ - 3+)
	Creatinine	50 - 200 mg/dL (4.4 - 17.7 mmol/L)	200 - 300 mg/dL (17.7 - 26.5 mmol/L)
	Glucose	Negative	200 - 300 mg/dL (14 - 28 mmol/L)
	Ketones	Negative	15 - 78 mg/dL (1.5 - 7.8 mmol/L)
	Leukocytes	Negative	70 - 125 Leuco/µL
	Microalbumin	10 mg/L	80 - 150 mg/L
	Nitrite	Negative	Positive
	pH	5.0 - 8.0	5.0 - 8.0
	Protein, Total	Negative	100 - 300mg/dL (1.0 - 3.0 g/L)
	Protein-to-Creatinine Ratio	normal (30 mg/g) (3.4 mg/mmol)	Abnormal: 30 - 300 mg/g (3.4 - 33.9 mg/mmol)
	Specific Gravity	1.010 - 1.020	1.000 - 1.030
Urobilinogen	0.2 mg/dL (3.4 µmol/L) normal	2 - 8 mg/dL (34 - 132 µmol/L)	
HUMAN HumaCombis 13 TEST STRIP (REF 22130) / HumaCombilyzer ANALYZER (REF 17360)	Parameter / Analyte	Level 1 - 98031	Level 2 - 98032
	Bilirubin	Negative	01 - 103 µmol/L (2+ - 3+)
	Blood	Negative	ca. 80 - 200 Wbc/µL (2+ - 3+)
	Creatinine	50 - 200 mg/dL (4.4 - 17.7 mmol/L)	200 - 300 mg/dL (17.7 - 26.5 mmol/L)
	Glucose	Negative	200 - 300 mg/dL (14 - 28 mmol/L)
	Ketones	Negative	15 - 78 mg/dL (1.5 - 7.8 mmol/L)
	Leukocytes	Negative	70 - 125 Leuco/µL
	Microalbumin	10 mg/L	80 - 150 mg/L
	Nitrite	Negative	Positive
	pH	5.0 - 8.0	5.0 - 8.0
	Protein, Total	Negative	100 - 300mg/dL (1.0 - 3.0 g/L)
	Protein-to-Creatinine Ratio	normal (30 mg/g) (3.4 mg/mmol)	Abnormal: 30 - 300 mg/g (3.4 - 33.9 mg/mmol)
	Specific Gravity	1.010 - 1.020	1.000 - 1.030
Urobilinogen	0.2 mg/dL (3.4 µmol/L) normal	2 - 8 mg/dL (34 - 132 µmol/L)	
Rev. 011 valid 01.12.2024 <b>Human</b> Human Gesellschaft für Biochemie und Diagnostica mbH Max-Planck-Ring 21 · D-65205 Wiesbaden · Germany Tel.: +496122 99880 Fax: +496122 9988100 · e-mail: human@human.de			
<b>DEUTSCH</b> (1) Bei einigen Analyten kann eine atypische Farbe beobachtet werden. Ergebnisse basieren auf Reaktionsstärken. (2) Atypische Färbung beobachtet			
<b>ENGLISH</b> (1) Atypical color may be observed with some analytes. Results are based on reaction strengths. (2) Atypical coloration observed			
<b>FRANÇAIS</b> (1) Une couleur atypique peut être observée pour certains analytes. Les résultats sont basés sur les intensités de réaction. (2) Coloration atypique observée			
<b>ESPAÑOL</b>			



# Sales Tools



## Brochure, TechSpec-Flyer, Teaser video.....

Can be found in the **HUMAN [login area](#)**

Urinalysis Flyer

[English version](#) | [Spanish version](#) | [French version](#)

Specification Sheet HumaCombilyzer

[English version](#)

Customer Presentation HumaCombilyzer

[English version](#)

User Manual on HumaCombilyzer

[English version](#)

IFU HumaCombilyzer 10

[English version](#) | [Spanish version](#) | [French version](#)

IFU HumaCombilyzer 13

[English version](#) | [Spanish version](#) | [French version](#)

**HumaCombilyzer**  
SPECIFICATIONS

- System Specifications
- Scope of Supply
- Obligatory Items
- Optional Items

System Overview	REF	170
Analyzer type	REF	
Design system	CLM	
# of Parameters	13	
Throughput	100	
Barcode reader	REF	
Language available	Eng	
Display/Touch interface	REF	

**Urinalysis**  
On-the-spot urine strip analysis and microscopy

HUMAN provides advanced solutions for comprehensive urinalysis, including both chemical and sediment analysis.

Our cutting-edge HumaVision system leverages digital holographic microscopy and AI technology to accurately identify and count urine particles with precision.

For chemical analysis, the HumaCombilyzer and Combilyzer 13 urine test strip readers offer reliable results for 10 or 13 parameters, including microalbumin and creatinine testing.

Our Combina and HumaCombina test strips are designed for both visual assessment and automated analysis, ensuring flexibility and efficiency in every laboratory setting.

AI-based urine particle analysis | Urine test strip reader | Urine Test Strips

**URINALYSIS**

**human**  
Diagnostics Worldwide

## Videos

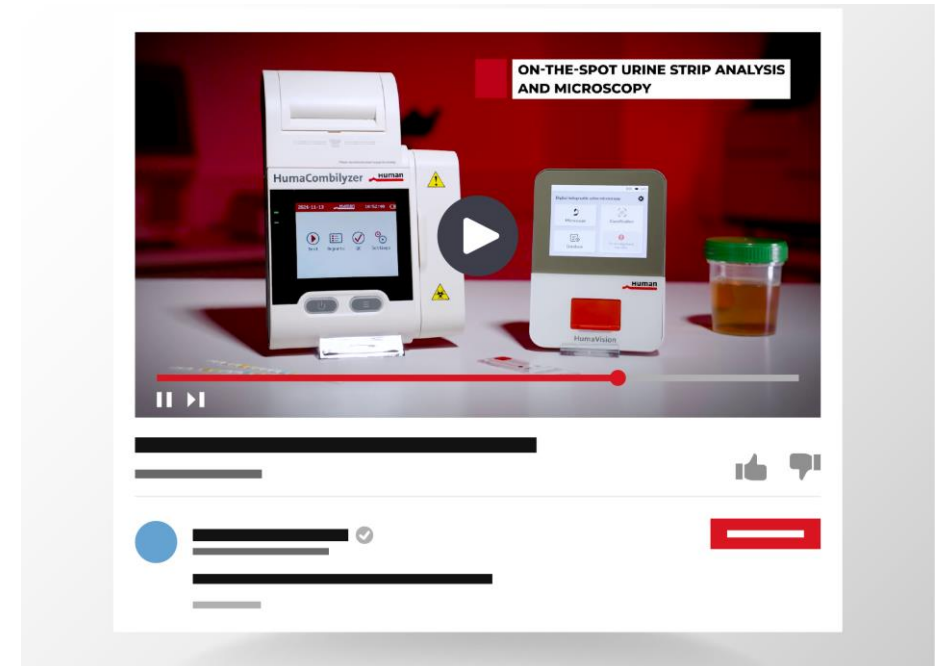
Engage and educate your audience with our selection of informative videos:

Urinalysis Video (EN)

[English version](#) | [Spanish version](#) | [French version](#)

Urinalysis Exhibition Totem Video  
(ideal for mobile phones, status advertisement)

[English version](#)





# Sales Aspects

## Product offers

### HumaCombilyzer & HumaCombina urine dipsticks

- The reagent prices will need to be adapted country by country.
- Pricing of the HumaCombilyzer can be lower, compared to the current Combilyzer<sup>13</sup>.
- Pricing of the HumaCombina 13 can be lower, compared to the current Combina 13 urine strips.
- Pricing of the HumaCombina 13 and HumaCombina 10 can be offered at staggered pricing depending on quantities needed by the end-users.
- Price bundling can be offered with HumaCombilyzer and HumaCombina urine dipsticks.
- Price bundling can be offered with HumaCombilyzer/HumaCombina urine dipsticks and HumaVision (REF 17660)

